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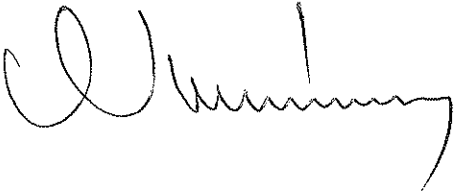

Dear Director General,

Please find attached, for your informal information, the intended positions of the European Union (EU) on the reports of the Terrestrial and Aquatic Animal Health Commissions to be proposed for adoption at the General Session in May 2011 in Paris.

Furthermore, please find attached the EU comments to the proposed new version of the OIE Organic and General Rules and related texts, as well as EU comments on the 2011-2013 OIE programme of work for the implementation of the 5th Strategic Plan.

I trust you will find this useful and I thank you for your continued cooperation.

Yours sincerely,

<p>Dr. Endre Kardeván Chief Veterinary Officer Hungary</p>	<p>Bernard Van Goethem Director, Veterinary and International Affairs DG Health and Consumers- European Commission</p>
	

Annexes: 3

Copy: All Directors / Chief Veterinary Officers of the EU 27 and Croatia, Iceland, Liechtenstein, Norway, Switzerland and Turkey.

Dr. B. Vallat
Directeur général OIE
12 rue de Prony
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ANNEX 1

EU position

The EU thanks the OIE Terrestrial Animal Health Standard Commission for its work.

The EU supports in general the adoption of the proposed changes to the Terrestrial Code.

However:

- in two cases, its comments are very important and the chapter does not seem to be ready for adoption;

- in four instances, minor though very important changes should be done before adoption is acceptable, so that the chapters are consistent and logical;

- in some others the EU wishes the OIE to take comments into account in a next revision of the chapters.

Concerning the three chapters proposed for comments, the EU has some important comments that will be sent in due time and should be taken into account by the TAHSC in its next meeting.

Concerning the chapters that were sent back to ad hoc groups, the EU is ready to propose its expertise to the OIE and wishes that its experts participate to the work.

The EU positions and comments are detailed below within the text of the OIE TAHSC report, as well as within its annexes.

Finally, the EU wishes to reiterate its former comment that the OIE should more clearly differentiate the standards that are binding as regards international trade, and the other ones. If the interpretation of the SPS Agreement would be "everything that is in the Codes and Manuals is binding for trade", then these Codes and Manuals would need restructuring.

Original: English
February 2011

REPORT OF THE MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 1–11 February 2011

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at the OIE Headquarters in Paris from 1 to 11 February 2011.

The members of the Code Commission are listed in [Annex I](#) and the agenda adopted is in [Annex II](#).

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Alex Thiermann, President of the Code Commission, welcomed members and thanked them for their ongoing work in support of the OIE.

The Code Commission thanked the following Members for providing written comments: Argentina, Australia, Canada, Chile, Chinese Taipei, the European Union (EU), Jamaica, Japan, Mexico, New Zealand, Norway, People's Republic of China, Republic of Korea, South Africa, Switzerland, Thailand and United States of America (USA). Comments were also received from the International Embryo Transfer Society (IETS), two regional organisations – the Comité Veterinario Permanente del CONOSUR (CVP) and the Organismo

Internacional Regional de Sanidad Agropecuaria (OIRSA), the International Coalition for Farm Animal Welfare (ICFAW) and an industry organisation.

The Code Commission examined various draft texts of the OIE *Terrestrial Animal Terrestrial Code (Terrestrial Code)* in the light of comments that Members had provided by the requested deadline of 7 January 2011, as well as comments outstanding from the September 2010 Code Commission meeting. It also reviewed the reports of several *ad hoc* Groups, the Animal Production Food Safety Working Group (APFSWG) and the Animal Welfare Working Group (AWWG).

The Code Commission's proposals for modification of the *Terrestrial Code* and related matters are presented as Annexes to this report. Amendments made to the *Terrestrial Code* Chapters at the September 2010 meeting, which were circulated to Members in November 2010, are shown as double underlined text and deleted text in ~~strike through~~. Amendments made at the February 2011 meeting, which are also shown in double underline/strikethrough, are highlighted with a coloured background to distinguish them.

All Member comments were considered by the Code Commission. However, because of the large volume of comments received, the Code Commission could not prepare a detailed explanation of the reasons for accepting or not accepting each individual comment. Members are reminded that if comments are resubmitted without modification or new justification, the Code Commission will not, as a rule, repeat previous explanations for decisions. The Code Commission encourages Members to refer to previous reports when preparing comments on longstanding issues.

The texts presented in Part A of this report are proposed for adoption at the 79th OIE General Session. Chapters provided for Member comment are presented in Part B, together with reports of meetings (Working Groups and *ad hoc* Groups) and related documents.

The Code Commission strongly encourages Members to participate in the development of the OIE's international standards by sending comments on this report. Comments should be submitted as specific proposed text changes, supported by a scientific rationale. Members should **not use the automatic 'track-change' function** provided by word processing software, because suggested text changes may be lost when preparing the working document prior to the Code Commission meeting. Rather, Members should show proposed new text with double underline and proposed text deletions with ~~strike through~~. Members should try to provide a scientific justification should for all proposed changes.

Submission of comments on this report for consideration by the Code Commission in September 2011

Comments should be sent to the International Trade Department at: trade.dept@oie.int by the deadline shown below. To facilitate the work of *ad hoc* Groups meeting in June-August 2011, the Commission set an earlier deadline for the submission of comments on Annexes 30, 31 and 34.

Text	Deadline for comment
Annex 30 (proposed new Chapter 3.3. on Veterinary Legislation)	31 May 2011
Annex 31 (revised Chapters 6.7. and 6.8. on Antimicrobial Resistance)	31 May 2011
Annex 34 (revised Chapters 8.4. and 8.13. on Zoonotic Parasites)	31 May 2011
All other annexes in Part B	6 August 2011

A. MEETING OF THE DIRECTOR GENERAL WITH THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION AND THE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Dr Vallat drew the attention of Commission members to the first OIE Global Wildlife Conference, which will be held in Paris in February 2011. This will be the first global forum between OIE and the agencies and public interested in both health and protection of wildlife and the environment.

Dr Vallat also commented on the forthcoming global Conference on Aquatic Animal Health Programmes and Food Security (Panama, 27-29 June 2011) and the OIE Global Conference on Rabies, to take place in Seoul, Korea on 7-9 September 2011.

Dr Vallat informed members of the decision to hold a global Conference on FMD in Bangkok, Thailand, in June 2012. This conference will also be a pledging conference. Based on the recommendations to be included in the *Terrestrial Code* on national FMD control programmes and following decisions from the Scientific Commission for Animal Diseases (SCAD) and the World Assembly of Delegates, donors will be encouraged to support long term activities of veterinary services in developing countries, where there is a priority to establish national strategic plans for FMD control and eradication. Dr Vallat noted that this work is being undertaken in close collaboration with the FAO, which has the role of supporting countries in the implementation of national FMD control programmes.

Dr Vallat reminded members that in 2011 the veterinary profession is celebrating its 250 years anniversary. The OIE is involved in several important initiatives relevant to the Vet2011 celebrations.

The second global Conference on Veterinary Education will take place in Lyon on 13-14 May 2011. This conference will feature presentations on the OIE's work on veterinary education. Dr Vallat stated his hope that in May 2011 the World Assembly will adopt a resolution supporting the OIE recommendations on veterinary education, specifically the day 1 competencies of graduates to enable future public and private sector veterinarians to ensure that Veterinary Services can fulfil key OIE objectives.

The final event of Vet 2011 celebrations will be during the World Veterinary Association Congress, which will be held in Capetown, South Africa, 10 – 14 October 2011. The OIE will organise a scientific seminar within that congress.

Dr Vallat indicated that he is looking forward to the declaration of World Freedom from Rinderpest at the OIE General Session in May 2011, which will be in principle attended by the FAO Director General. The FAO will also celebrate this important event at the annual meeting of the Committee of Agriculture Ministers in Rome, in June 2011. Dr Vallat indicated that the *Terrestrial Code* chapter on rinderpest would need to be revised to provide for the post-eradication era. In particular, new text would be needed on the management of virus infected samples and vaccine stocks and on contingency plans in the event of an outbreak of rinderpest in the post declaration period.

In terms of the ongoing work programme of the Specialist Commissions, Dr Vallat pointed to FMD and rabies as priority diseases for development of revised texts in the *Terrestrial Code*. On rabies, Dr Vallat noted that the draft revised chapter had been the subject of many Member comments. Although it might be difficult to resolve all the points raised by Members, Dr Vallat encouraged the two Commissions to work together to develop a consensus text for adoption, hopefully, in 2012. Dr Bonbon raised concerns about the timing of the revision of the rabies chapter in the *Terrestrial Code*, given that OIE Manual chapter on rabies is currently under revision. Dr Vallat indicated that the revision of the Manual chapter on rabies was a complex subject and that the work on the two chapters should be closely coordinated. Dr Vallat asked the two commissions to try to reach consensus as far as possible on recommendations for rabies before the conference in Seoul.

On the FMD national control programme, Drs Thiermann and Bruckner emphasised the need for explanation of the objectives of this initiative, as some Members have expressed serious concerns about the implications for international trade.

Dr Thiermann praised the greatly improved coordination of Members within regions, with particular reference to Africa and South America and the provision of comprehensive input to the work of the Code Commissions.

Disease reporting is a very important and sensitive topic. To improve the framework for updating and modernising texts, Dr Vallat stated that it would be important to improve communication and coordination on the issues of wildlife, disease reporting, food safety and potentially for health certification and labelling. On the definition and treatment of wildlife in the *Terrestrial Code*, Dr Vallat noted that the two Commissions should try to identify a consensus position in time for discussion at the OIE global wildlife conference in February 2011.

On African horse sickness, Dr Bruckner indicated that the revised chapter, with the disease freedom questionnaire, is now ready to be forwarded to the Code Commission, but noted that this text was not necessarily for adoption in 2011.

Dr Bruckner commented that, given its current work load, the SCAD would need to increase the number or duration of its meetings. Dr Vallat indicated that he could give this request positive consideration. He also indicated that the OIE could provide additional financial and logistical support, including the provision of secretaries or translators, to help the departments to achieve their work. Dr Vallat expressed his keenness for

new and revised standards to be adopted promptly, always providing that the established democratic procedures are respected.

Dr Thiermann indicated that several Members had commented on errors in and discrepancies between the Spanish and the English texts of the *Terrestrial Code* and the report of the Code Commission meeting. These Members also requested a more timely release of the Spanish text of the *Terrestrial Code* to facilitate the participation of hispanophone countries. Dr Vallat explained that a professional translator had recently been recruited with the financial support of Spain to examine all Spanish texts and develop a glossary of terms used in the *Terrestrial Code*.

B. ADOPTION OF THE AGENDA

Annex 1 contains the adopted agenda and the list of Code Commission members.

C. JOINT MEETING OF WITH THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION AND THE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

1. Rinderpest

The two Commissions held an extensive discussion on the expected declaration in 2011 of the global eradication of rinderpest and the need that would arise for amendment of Chapter 8.12. Bearing in mind that a major modification of the current chapter, and the inclusion of new text would be required to formulate recommendations for the post freedom declaration period, the two Commissions agreed that this should be carefully considered before proposing text for examination by Members. It was agreed that the Code Commission would review the text provided by the SCAD and would develop a proposal for an amended chapter on rinderpest after the May 2011 General Session and for distribution to Members after the Code Commission meeting in September 2011.

2. Foot and mouth disease

Dr Bruckner identified a need for care in the development of new text on the 'OIE endorsed official control programme for FMD'. Dr Thiermann agreed and noted that Members had submitted extensive comments on the proposed amendment of Article 8.5.7 bis. 'OIE endorsed official control programme for FMD'. Mindful of the voluntary nature of the undertaking, Members questioned whether the implementation of an OIE endorsed official control programme for FMD was considered mandatory for a Member to comply with the provisions of the *Terrestrial Code*. Members also highlighted the fact that the official control programme is meant to be progressive (ie that Members should continue pursuing the pathway towards eradication).

Dr Thiermann pointed out that some Members had proposed that the OIE endorsed official control programme for FMD be addressed in a new, horizontal chapter in the *Terrestrial Code* rather than being incorporated in Chapter 8.5. (FMD).

Dr Bonbon supported the view of Members that countries should not be disadvantaged as a result of not seeking OIE endorsement of an official control programme for FMD as this was a sovereign decision. The provisions in the *Terrestrial Code* (Article 8.5.25.) already distinguish, for trade purposes, between countries that adopt an official control programme and those that do not.

Dr Bruckner suggested that the new text be placed in Chapter 8.5. because, for the time being, the text specifically refers to FMD. There was general agreement that the Code Commission would include the text on the OIE recognised official control programme towards the end of the chapter and next to the articles on OIE recognition.

3. Trade in animal products ('commodities')

The two Commissions agreed that the concept of the official control programme for FMD would contribute positively towards the strengthening of the competencies of Veterinary Services, thereby facilitating safe trade in animal products (commodities). In addition, the clarification of what is needed to achieve effective immunisation when vaccinating a population could help to promote commodity trade.

The two Commissions agreed that there was no need to undertake new work on trade in commodities pending adoption of new text with provisions on the official control programme for FMD.

4. Compartmentalisation

The Code Commission noted the generic, user-friendly checklist for the practical implementation of compartments, which had been provided by the Epidemiology *ad hoc* Group. Noting that SCAD supported this text, the Code Commission undertook to circulate it to Members for information and comment. Dr Thiermann noted that this document was destined to be placed on the OIE internet site rather than for incorporation into the *Terrestrial Code*, as had been done with the Checklist on the Application of Compartmentalisation for avian influenza and Newcastle disease.

On the use of compartmentalisation for the control of bovine tuberculosis, it was agreed to proceed with both concepts, i.e. compartmentalisation and herd freedom.

Dr Thiermann provided a brief progress report on a Member's compartmentalisation project.

5. Wildlife

Dr Thiermann noted that the Code Commission had decided to withdraw the proposed definition of 'wildlife' as this had raised some confusion and concern on the part of Members. Both Commissions agreed that the terms introduced by the OIE Wildlife Working Group (i.e. captive wild animal, feral animal and wild animal) being proposed for adoption should be introduced into the Glossary.

6. Rabies

Dr Bruckner and Dr Thiermann agreed that, in light of the volume and diversity of Member comments, the draft revision of Chapter 8.10 would be sent to a new *ad hoc* Group on Rabies for review. Dr Erlacher Vindel informed the meeting that an additional new *ad hoc* Group on rabies would be convened under the Biological Standards Commission to review the Manual chapter.

7. Zoonotic parasitic diseases

Dr Bruckner asked that the report of the *ad hoc* Group on Zoonotic Parasitic Diseases be shared with the SCAD as soon as the Code Commission has reviewed it. Dr Thiermann agreed to this request and further noted that both the OIE and the Codex Alimentarius Commission (CAC) are working on trichinellosis and *Cysticercus bovis*. Dr Thiermann expressed the view that this area of work was appropriate and could serve as model for joint development of common standards by the OIE and CAC.

8. Scrapie

The position of the two Commissions has not changed in regard to an agreement not to include in the *Terrestrial Code* information on pathogen/host genotype interactions and on maintaining the title of Chapter 14.9. as 'scrapie' (i.e. not changing it to 'classical scrapie', as per the request of the International Embryo Transfer Society).

9. Request for new chapters in the *Terrestrial Code*

The two Commissions were in agreement that no new diseases be considered for inclusion in the list of diseases, and that no work be launched to draft new chapters pending the finalisation of the revised approach to disease listing criteria.

10. Antimicrobial resistance

Dr Erlacher Vindel advised that an *ad hoc* Group had reviewed and proposed revisions to Chapters 6.8. and 6.9. and that this Group would hold a second meeting after the General Session. Noting that the report of the Group had been endorsed by the SCAD, Dr Thiermann confirmed that the Code Commission would distribute the report to Members with a request for comment.

D. EXAMINATION OF MEMBER COMMENTS AND WORK OF RELEVANT EXPERT GROUPS

1. Update on reports of other commissions; harmonisation with the OIE *Aquatic Animal Health Code*; other relevant activities of the OIE.

The Code Commission noted the work of the Codex Committee on Food Inspection and Certification Systems (CCFICS), which is developing a standard on national food safety systems, and urged OIE Members to strive for better coordination with their CAC counterparts at the national level to ensure that the OIE role in setting standards for animal diseases and zoonoses is appropriately recognised in this standard.

2. Revision of the *Terrestrial Code*

Agenda item 1. Categorisation of Part A and B

The Code Commission discussed and agreed on the inclusion of items in Part A and B of the report.

Agenda item 2. Foreword of the *Terrestrial Code*

The Code Commission noted the revised foreword, which clarifies the aim of the *Terrestrial Code* as being the improvement of animal health and welfare and veterinary public health worldwide, including by describing health measures to be used by veterinary authorities to detect, report and control pathogenic agents, and to prevent their transfer via international trade. Members of the Code Commission undertook to send comments to the OIE subsequent to the meeting.

Agenda item 3. Spanish translation of the *Terrestrial Code*

See discussion under Point A.

Agenda item 4. General comments

The Code Commission agreed with Members who requested that supporting documents (including reports of *ad hoc* Groups) be placed in the public domain before or at the same time as amendments are proposed to the *Terrestrial Code*.

The Code Commission noted a Member's comment opposing the proposal for adoption of chapters that are circulated for the first time in the February report, and agreed with the principle stated by the Member. However, emergency situations could occur in the future.

A Member called for the OIE to provide more information in advance of the consultation process and for the criteria for the establishment of a new chapter to be explained. Such criteria should include the feasibility of implementing the proposed chapter. The Code Commission agreed to pay more attention to this point in future but reminded Members that this information was generally provided in the meeting reports of the Code and the Scientific Commission.

Agenda item 5. *Terrestrial Code* Glossary

Comments were received from Argentina, Australia, Chile, the EU, Norway, Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA) and the International Scientific Working Group of the International Natural Sausage Casings Association (INSCA).

The Code Commission discussed Member comments on the definition of 'wildlife' and decided to remove this definition from the Glossary, based on the consideration that the categories (eg 'feral animal, captive wild animal') should be specified whenever they are mentioned in the Code.

Following Members' recommendations, the definition of 'captive wild animal' and 'feral animal' were modified for clarity.

A request to develop a new definition for ‘natural casings’ was not accepted because this term is not currently used in the *Terrestrial Code*.

The revised Glossary, proposed for adoption, is at annex 2.

EU position

The EU thanks the OIE TAHSC and supports the adoption of the modified Glossary.

Agenda item 6. Notification and criteria for listing diseases (Chapters 1.1. and 1.2.)

a) Notification of diseases and epidemiological information (Chapter 1.1.)

Comments were received from Canada, the EU, New Zealand and the USA.

The Code Commission accepted Member comments and modified the text of Articles 1.1.1. and 1.1.3. to improve clarity and to heighten awareness of the importance of notification, using WAHIS for reporting.

The revised Chapter 1.1., for adoption, is in annex 3.

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter.

b) Criteria for listing diseases (Chapter 1.2.)

Comments were received from Canada, the EU, Norway and the USA.

The Code Commission noted a Member’s support for the proposal to reorganise the *Terrestrial Code* according to the scientific name of pathogens.

The Code Commission noted that some Members had objected to the proposed modification of Article 1.2.1. with respect to the proposed inclusion of the text ‘potential for international spread’. Dr MacDiarmid noted that definitions and interpretations of ‘potential’ are at the source of many disputes on sanitary measures. The inclusion of text in a footnote: ‘..it may be decided, in limited cases, not to list a disease’ was considered to be inappropriate. The Code Commission also considered that the proposed new text in Article 1.2.1. point 1 (v) referring to ‘wild animal populations that are an asset *worth protecting* for economic or ecological reasons’ and in point 2 : ‘possible significant economical (*sic*) impact’ was not sufficiently clear.

In a joint meeting with Dr Ben Jebara, the Code Commission proposed modifications to Chapter 1.2., with the exception of the decision tree, which would be modified only after the proposed new text had been adopted.

In response to Member comments, the Code Commission agreed that no new diseases (including chronic wasting disease) should be listed until such time as the revised listing criteria have been considered by Members. However, the decision to delist diseases, where Members generally support delisting of a disease, should not be delayed.

A member’s request to retain leptospirosis as a listed disease was not supported but the Code Commission agreed that the OIE consider providing advice on leptospirosis via other routes (e.g. via a document on the OIE website or a technical disease card.)

The revised Chapter 1.2. with modification only to Article 1.2.3., proposed for adoption, is at Annex 3.

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter. The EU

commends the Code Commission for agreeing that the OIE keep the chapter on Leptospirosis in the Manual and consider providing advice via other routes (e.g. via a document on the OIE website or a technical disease card). The EU would like this fact expressed during the General Session, and also reiterates that in the light of the reasoning of the ad hoc group on listing diseases, the deletions of some diseases, such as Swine Vesicular Disease should be re-considered by the OIE, as this disease appears not to fulfil all criteria, especially not the morbidity/mortality rate.

The EU will provide further comments on the draft modifications of Article 1.2.1 before the 6th of August.

The revised Article 1.2.1. is at Annex 29 for Member comments.

Agenda item 7. Veterinary Services

a) Quality and Evaluation of Veterinary Services (Chapters 3.1. and 3.2.)

Comments were received on both chapters from the EU, Switzerland and South Africa.

In response to Members' comments, the Code Commission deleted point 11 of Article 3.2.14.

A Member's concern about the inclusion of animal welfare in the responsibilities of Veterinary Services was not accepted, given that the OIE World Assembly of Delegates has, since 2005, adopted in the *Terrestrial Code* seven animal welfare standards and that the Veterinary Authority is in most countries the main governmental authority responsible for implementation of these standards.

As discussed under Agenda item 37, the Code Commission endorsed the report of the *ad hoc* Group on Veterinary Education. In view of the general support of Members for the work of the OIE in strengthening the quality of Veterinary Services, including through specifying the minimum competencies of day 1 graduate veterinarians, the Code Commission proposed to include new text in Article 3.2.14, sub-point 2 a (vi) as follows: 'curriculum addressing the minimum competencies of day 1 veterinary graduates to assure the delivery of quality Veterinary Services, as described by the OIE'

The revised Chapter 3.1., as presented for Member comments after the September 2010 meeting of the Code Commission and the revised Chapter 3.2., proposed for adoption, are in Annex 4.

EU position

The EU supports the adoption of these modified chapters but has a comment that should be taken into account before adoption.

b) Veterinary Legislation (proposed Chapter 3.3.)

Comments were received from Australia, the EU, Japan, New Zealand, Switzerland, Thailand, the USA and an expert.

The Code Commission recalled the resolution adopted by Members at the OIE Global Conference on Veterinary Legislation (December 2010): 'that the OIE propose the adoption and publication of the current Veterinary Legislation Guidelines as standards in the *Terrestrial Code*' and the comments of Members regarding the timing of such adoption. Dr Kahn informed the Code Commission that the OIE would convene an *ad hoc* Group on Veterinary Legislation for a first meeting after the General Session in May 2011.

Noting that the numbering of the text was rather complicated, that some text appeared repeatedly (eg: 'veterinary legislation should address the following elements'), and that there was an imbalance in the level of detail provided on some subjects (eg regulation of veterinary products) and others (eg disease control), the Code Commission considered that the draft text was not ready for adoption in May 2011.

The Code Commission encouraged the *ad hoc* Group to take whatever steps are possible to simplify and clarify the text so that it is easier for Members to use.

In light of Member comments the Code Commission made some amendments to the draft Chapter 3.3.

The Code Commission strongly encouraged Members to provide comment on the draft text, in order for the *ad hoc* Group to take this into account in producing a revised text that could be proposed for adoption in 2012.

The new draft Chapter 3.3., for Member comment, is at Annex 30.

The EU has numerous general and specific comments on the new draft chapter 3.3, which should be taken into account by the TAHSC in its next meeting.

Agenda item 8. New chapter on communication (Chapter 3.4.)

Comments were received from the EU and Japan.

The Code Commission reviewed Members' comments and made some modifications to the draft text, to provide clarification on the objectives and recommendations in the proposed text.

The new Chapter 3.4., proposed for adoption, is at Annex 5.

EU position

The EU thanks the OIE TAHSC and would support in general the adoption of guidelines on general principles of communication systems and examples of application, but has some important comments that should be taken into account.

In general, there is need for flexibility with respect to different organisational structures in OIE Members; this should be better taken into account in the wording. There is also a need to highlight in the General Consideration that the scope of this chapter does not relate to trade. As stated above in the general comments, the EU, in the framework of the Fifth Strategic Plan already highlighted the importance of better differentiation in the Codes and Manuals between standards relating or not to international trade.

The adoption of this chapter as is during the 2011 General Session is not an emergency and discussions should continue until next General Session of 2012.

Agenda Item 9. Design and implementation of identification systems to achieve animal traceability (Chapter 4.2.)

Comments were received from Chile, the EU and Switzerland. Changes proposed by a Member were not accepted because, as previously stated, the OIE convention is to use the term 'should' rather than 'must' throughout the Code.

The revised Chapter 4.2., proposed for adoption, is at Annex 6.

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Agenda item 10. Compartmentalisation (Chapters 4.3. and 4.4.)

a) Zoning and compartmentalisation (Chapter 4.3.)

Comments were received from Chinese Taipei, the EU and Thailand

Dr MacDiarmid noted, in response to an enquiry about the status of compartmentalisation projects, that an article on the experiences of Thailand would be published in the OIE Scientific and Technical Review, Volume 30 No.2., August 2011.

b) Application of compartmentalisation (Chapter 4.4.)

A comment was received from the EU supporting the proposed amendment.

c) Generic checklist on the application of compartmentalisation

The Code Commission received a new document ‘‘User- friendly, generic checklist on the practical application of Compartmentalisation’’ and a recommendation from the Epidemiology *ad hoc* Group to modify Article 4.4.7. regarding the procedures for notification of importing countries in the event that the status of the compartment is lost.

The Code Commission modified Article 4.4.7 by replacing the reference to Chapter 1.1. with a reference to Article 5.3.7.

The Code Commission also added sub-point (i) to point 2 of Article 5.3.7. in order to clearly situate the recognition of a compartment as being based on a bilateral agreement between Members.

In the event of detection of the disease for which the compartment was defined, the status of the compartment should be revoked and importing countries that had recognised the compartment informed.

The International Trade Department undertook to review the new checklist in liaison with the two OIE Members that are currently implementing compartments for avian influenza and Newcastle disease.

The revised Chapters 4.3. and 4.4. and the revised Chapter 5.3., proposed for adoption, are at Annex 7.

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of these modified chapters, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Agenda item 11. Semen and embryos (Chapter 4.5., 4.6. and 4.7.)**a) General hygiene in semen collection and processing centres (Chapter 4.5.)**

Comments were received from Australia.

For the purpose of harmonisation with other articles and following a Member’s comment, the audit interval in Article 4.5.2. point 8, was changed from 6 months to 12 months on the basis that an annual audit would provide a suitable level of oversight and would be consistent with ‘at least once a year’ audits for embryo collection teams (in Articles 4.7.2.7 and 4.8.2.7).

b) Collection and processing of bovine, small ruminant and porcine semen (Chapter 4.6.)

Comments were received from Australia, the EU and Switzerland.

A Member raised concerns about the handling of bluetongue in Chapter 4.6. and some modifications were made to Article 4.6.3. accordingly.

A Member commented on the articles dealing with BVD-MD and ovine epididymitis but the Code Commission made no modifications because it considered that no valid justification was given to support the proposed modification and that the current text was correct.

Article 4.6.3.2. (b) was modified as testing of semen is not, typically, performed before rams enter a semen collection centre and especially not in a pre-entry isolation facility.

c) Collection and processing of *in vivo* derived embryos from livestock and horses (Chapter 4.7.)

Comments were received from the International Embryo Transfer Society (IETS).

Following the recommendation of the International Embryo Transfer Society (IETS) the Commission modified Article 4.7.14. to include a reference to equine coital exanthema as a pathogen in category 4.

The revised Chapters 4.5., 4.6. and 4.7., proposed for adoption, are at Annex 8.

EU position

The EU supports in general the adoption of these modified chapters. However, the EU questions the fact that diseases that are not OIE listed be added to article 4.7.14 as it could be confusing in relation to trade. The list in this article should only include OIE listed diseases and the complete list including non-listed diseases should be published elsewhere.

Furthermore, the title only refers to "horses", and not to "equids": the EU would like to know if this is justified, as embryo transfer of equids other than horses might happen. In addition, the use of the word "equine(s)" is to be banned as a noun, throughout the Code, as it can lead to confusion. "Equine" should only be used as an adjective that refers to equids.

Agenda item 12. Certification procedures (Chapter 5.2.)

The revised Chapter 5.2., proposed for adoption, is at Annex 9.

EU position

The EU supports in general the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Agenda item 13. Control of OIE listed diseases in heat treated, shelf stable pet food (draft new chapter 5.X.)

Comments were received from Australia, Canada, Chile, China (P.R. of), Chinese Taipei, the EU, Japan, New Zealand, Norway and the USA.

The Code Commission noted the many divergent and incompatible comments received. Some Members objected to the creation of provisions seemingly 'in parallel' to the existing recommendations in the *Terrestrial Code*. Others commented on the complexity of the issue if addressed as a Code chapter, given the wide range of ingredients and time/temperature processes used by the global pet food industry. Some noted that the pet food industries themselves have divergent views on the nature of recommendations to be made by the OIE, and the fact that OIE Members in general have not called for this work to be done.

The Code Commission recalled that the rationale for undertaking this work was a request from two pet food industry associations as a result of impediments to global trade in pet food arising from non-scientific and non risk-based trade measures that have been imposed by some countries. Notwithstanding the concerns raised by Members, the Code Commission considered that it might be possible to make specific recommendations on the certification of heat treated pet food for international trade. Chapter 5.10. covers model veterinary certificates for international trade, including model certificates for products of animal origin. The Code Commission requested that the Director General convene a new *ad hoc* Group with the following terms of reference: to review Chapter 5.10. and to make recommendations on new text that should be added, if needed, to provide a predictable and scientific basis for certification of heat treated shelf stable pet food.

EU comment

The EU agrees with the TAHSC approach and is ready to provide expertise to the ad hoc group so that this issue has a favourable outcome.

Agenda item 14. Control of hazards of animal health and public health importance in animal feed (Chapter 6.3.)

Comments were received from Chile, the EU and the USA.

A Member's recommendation to define the term 'undesirable substances' rather than 'contamination' was not accepted because the former term is not used in Chapter 6.3., whereas the latter is. In reply to a Member's comment about feed for bees, the Code Commission invited the Member to provide information that could be relevant for inclusion in the chapter.

The revised Chapter 6.3., proposed for adoption, is at Annex 11.

EU position

The EU thanks the OIE TAHSC and supports the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Agenda item 15. Salmonellosis (Chapters 6.4. and 6.5.)

a) Biosecurity procedures in poultry production (Chapter 6.4.)

Comments were received from Chinese Taipei, Costa Rica, the EU, New Zealand, Panama, Switzerland, the USA and the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA).

The Code Commission made several text amendments to improve clarity and completeness.

b) Prevention, Detection and Control of Salmonella in Poultry (Chapter 6.5.)

Comments were received from Chile, China (P.R. of), the EU, New Zealand, Switzerland and the USA.

The Code Commission made some minor amendments to the text.

The revised Chapters 6.4. and 6.5., proposed for adoption, are presented at Annex 12.

EU position

The EU supports in general the adoption of these modified chapters but has a comment.

Agenda item 16. Animal welfare (Chapters 7.1.–7.8.)

a) Transport of animals by land (Chapter 7.3.)

Comments were received from Canada, the EU, Switzerland and the USA.

In response to a Member's comment, the preamble was amended for clarity.

As regards point 7.a) of Article 7.3.5., the Code Commission noted Members' comments on the need to make effort to observe animals during transport, including in the case of poultry, and the text was amended accordingly.

b) Transport of animals by air (Chapter 7.4.)

Comments were received from the EU and the USA.

In response to a Member's comment, it was agreed to add a preamble to this chapter for consistency with other chapters. The preamble will reflect the amendments proposed by the Code Commission, if adopted by OIE Members.

A Member's comment on pallet size was not accepted as the size of pallet is variable.

Several texts were further amended in response to Members' comments.

c) Slaughter of animals (Chapter 7.5.)

Comments were received from Canada, the EU, Switzerland, Thailand, the USA and the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA).

Article 7.5.4. was reviewed, taking into account the number of comments received from Members. It was agreed to move point 14 into point 6 in order to clearly state that waiting time should be minimised and should not exceed 12 hours.

One Member commented that all slaughterhouses, whether high throughput or not, should have a waiting pen to ensure good animal welfare. The Code Commission did not agree. In some cases small slaughterhouses with a low throughput may not need a waiting pen.

Several requests from Members were not accepted as they were already addressed in the current text or did not significantly improve the text.

A Member's comment on Article 7.5.6 was not accepted as the objective of this table is to summarise the methods and their associated animal welfare concerns, not to rate or recommend individual methods.

d) Killing of animals for disease control purposes (Chapter 7.6.)

Comments were received from Australia, Chinese Taipei, the EU and Switzerland.

A Member's comments in regard to the cervical dislocation and decapitation for poultry of Article 7.6.5. were accepted and the table amended accordingly.

Members' comments on Article 7.6.12 and Article 7.6.13 were discussed extensively. The Code Commission decided to maintain the current text except for minor changes to increase clarity as the text has already been reviewed by the Animal Welfare Working Group. However, the Commission undertook to send the scientific references provided by Members to the AWWG for further review. The suggestion of Members to add text in Article 7.6.13., after (2) (c) (ii) the sentence "However cessation of vocalisation and convulsing wing flapping sounds can be used to determine the onset of unconsciousness that will in due time lead to death" was not accepted, as point 2c contains a list of the disadvantages of methods and the proposed amendment is not relevant.

The Code Commission accepted a Member's comment on cervical dislocation in Article 7.6.17. as it was considered to be relevant.

e) Stray dog population control (Chapter 7.7.)

Comments were received from the EU and the USA.

Members' comments were generally accepted where these increased clarity. However, a Member's comment on Article 7.7.4., (which had been previously submitted and denied) was not accepted as the Code Commission considers the existing text already addresses the issue raised.

f) Use of animals in research and education (Chapter 7.8.)

Comments were received from the EU, Norway, Switzerland and the USA, and advice was provided by the *ad hoc* group on Laboratory Animal Welfare.

Members' comments on Article 7.8.4. point 1 were noted and it was agreed to add the word 'minimum' to point c) to ensure that reasonable analysis can be taken into consideration upon review of a project proposal.

The *ad hoc* Group's comment on animal procurement under Article 7.8.7. was accepted to address a Member's concerns about the use of nonhuman primates.

Revised Chapters 7.3., 7.4., 7.5., 7.6., 7.7. and 7.8., proposed for adoption, are at Annex 13.

EU position

The EU supports in general the adoption of these modified chapters but have some comments.

g) New chapter on broiler chicken production (new Chapter 7.X.)

Comments were received from Chile, the EU, Jamaica, Japan, Korea (Rep. of), New Zealand, Switzerland, USA and the International Council for Animal Welfare (ICFAW).

The Code Commission clarified that the term ‘backyard flocks’ was used in the sense defined by the FAO, under sector 4 production, i.e. ‘village and backyard production with minimal biosecurity and birds or products consumed locally’ (for more information, see:

<http://www.fao.org/docs/eims/upload/214190/ProductionSystemsCharacteristics.pdf>)

The first three sentences of Article 4 (from ‘It would be impractical at this time’ to ‘and genetic selection’) were removed from the draft chapter because this is an explanation of the use of criteria or measurables and it is not appropriate to include such explanatory text in the *Terrestrial Code*.

Some Members’ comments on Article 7.X.4 paragraph 1 were accepted because these improved the description of mortality.

In Article 7.X.4 Paragraph 2 ‘Gait’, a Member’s request to delete the entire paragraph was not accepted because the Code Commission found the explanation to be useful and relevant.

The Code Commission noted a request from a welfare organisation for the inclusion of guidelines of scoring systems (e.g. for gait and for feather condition) in the *Terrestrial Code*. While this type of guidance was not considered to be appropriate for inclusion in the *Terrestrial Code*, the Commission encouraged the OIE to consider making a list of useful references available to Members, via a document on the OIE internet site.

In response to comments of Members and an animal welfare organisation, the Code Commission made a number of amendments to the text.

A Member’s proposal to include a measurable relating to the percentage of broilers that is *not* sent to the slaughterhouse was not accepted as such but the Code Commission made an appropriate modification to the text of point 10 in Article 7.X.4. ‘Injury rate’, to clarify that injuries can occur during production and also during the catching operation.

The Code Commission accepted a recommendation of a Member to add a new point 12 ‘Animal vocalisation’ in Article 7.X.4., based on the scientific reference provided [Jeon, J.H., Yeon, S.C., Ha, J.K., Lee, S. J., and Chang, H.H., 2005. Acoustic analysis for thermal environment-related vocalizations in laying hens. *J. Anim. Sci. & Technol.* 47 (4): 697–702.]

In Article 7.X.5., the Code Commission advised that term ‘thermal heat index’ (THI) can be described as an index that integrates air temperature and relative humidity, which provides an indication of how an animal feels the ambient conditions. The THI is higher when high air temperatures occur with high humidity and lower when they occur with low humidity.

A Member’s proposal to include a table with specific optimal temperature ranges was not accepted because OIE policy does not favour the inclusion of quantitative measurables at this time.

Regarding the frequency of checking of the management of the thermal environment, the Code Commission modified Article 7.X.5. point 2.1. to read ‘The management system of the thermal environment should be checked at least twice a day’, to address a Member’s concern about unnecessary entry of farmers into poultry houses.

At the request of an animal welfare organisation, the Code Commission added ‘eye condition’ to the list of measurables in Article 7.X.5. point 2.2.

In Article 7.X.5. point 2.6., at a Member's request, 'rice husks' was added to the list of appropriate bedding materials. The Code Commission also modified the order of points so that the two points dealing with day old broilers were grouped together.

The Code Commission modified Article 7.X.5. points 2.7., 2.12. and 2.13. as requested by Members.

The Code Commission noted that an animal welfare organisation and some Members had made several recommendations to put more information and recommendations into the draft text and thanked the organisation for its input. However, in many cases the Code Commission did not agree to include the additional details proposed, because it considered that the comments represented excessive detail and were based on experience drawn mainly from Europe. For example, the organisation proposed to delete the reference to 'performance' from the list of measurables, on the basis that high growth rates can lead to leg problems (etc). This may be correct but it does not change the fact that performance is a useful measure of welfare.

The Code Commission was generally not prepared to quantify measurables because the OIE Members did not generally support the adoption of quantitative measurables in the new chapter at this time.

The Commission noted that Members' positions on the need to specify and quantify measurables vary, with some in favour and some opposed to the inclusion of numeric values. Members have seen the text of the proposed chapter and have had the opportunity to comment on it on two occasions. The policy regarding the inclusion of animal based criteria rather than design criteria, and the arguments for and against the inclusion of quantitative parameters was set out in the report of the Animal Welfare Working Group's June 2010 meeting. The Code Commission considered that the draft text was ready to be proposed for adoption.

The revised Chapter 7.X., proposed for adoption, is at Annex 14.

EU position

The EU would support in general the adoption of this new chapter but have major comments. The text is still perfectible and should not be adopted in 2011. This is the first time that the TAHSC officially proposes this very important chapter for Members' comments and Members' comments should be looked at in detail in order to get a revised draft aiming at a consensus in 2012.

h) Report of the Animal Welfare Working Group (AWWG) June 2010, including guidance from the AWWG to *ad hoc* Groups on the development of animal welfare standards

Comments were received from Canada, Jamaica, Japan and the USA.

The Code Commission noted the report of the OIE Animal Welfare Working Group (AWWG), including the work programme, and endorsed it.

The Code Commission did not accept the comments of a Member who referred to the AWWG Discussion paper on the Development of Animal Welfare Guidelines for Production Systems and called for the inclusion of additional points and restructuring of the guidance document. The Code Commission considered that the guidance document was complementary to but separate from the Discussion paper. Both documents are considered to provide valuable guidance to *ad hoc* Groups.

The Code Commission accepted a recommendation from a Member to modify a phrase in the guidance document to read: 'In some cases, input-based or resource-based criteria are also acceptable and can supplement outcome-based criteria where there is a good scientific basis for doing so'.

The Code Commission also accepted a Member's recommendation to reorder items for internal consistency.

The revised Guidance document is provided at Annex 32 for Members' information.

Agenda item 17. Anthrax (Chapter 8.1.)

Comments were received from Australia, Canada, China (P.R. of), the EU, Korea (Rep. of), New Zealand and the USA.

The Code Commission made some amendments following Members comments.

Following Members' comments, the procedures for inactivation of *B. anthracis* spores in animal products were amended in Articles 8.1.10. and 8.1.11. The scientific references supporting these amendments are as follows:

GARCIA R.A. *ET AL.* (2006). Characteristics of North American meat and bone meal relevant to the development of non-feed applications. *Applied Engineering in Agriculture*. 22: 729–736

JUNEJA V. K. *ET AL.* (2010). Thermal inactivation of *Bacillus anthracis* Sterne in irradiated ground beef heated in a water bath or cooked on commercial grills. *Innovative Food Science & Emerging Technologies*. 11: 123–129.

MONTVILLE *ET AL.* (2005). Thermal resistance of Spores from Virulent Strains of *Bacillus anthracis* and Potential Surrogates. *Journal of Food Protection*. 68, 11, 2362–2366.

MURRAY T.J. (1931). Thermal death point: II. Spores of *Bacillus anthracis* *Journal of Infectious Diseases*, 48 (5): 457–467.

SETLOW P. (2006). Spores of *Bacillus subtilis*: their resistance to and killing by radiation, heat and chemicals. *Journal of Applied Microbiology*, 101: 514–525.

Spotts Whitney E.A., Beatty M.E., Taylor T.H., Weyant R., Sobel J., Arduino M.J. & Ashford D.A. (2003). Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases*, 9(6): 623–627.

In response to a Member's inquiry on the qualifier of articles with subparagraphs, the Code Commission confirmed that "and" is implicit but use of "or" must be made explicit.

After request of a Member, the Code Commission reviewed and updated Chapter 4.13 and transferred the articles on anthrax disinfection procedures from Chapter 8.1., to a new article at the end of Chapter 4.13.

The revised Chapters 4.13. and 8.1., proposed for adoption, are at Annex 15.

EU position

The EU thanks the OIE TAHSC and supports the adoption of this modified chapter.

Agenda item 18. Aujeszky's disease (Chapter 8.2.)

Comments were received from the EU, Mexico, Thailand and Switzerland.

The Code Commission accepted a Member's comment regarding the necessity to update Article 8.2.1 to make it consistent with the structure of other chapters (e.g. CSF) and better define the disease, the populations concerned and the determination of status.

The Code Commission did not accept a Member's recommendations to specify the radius of the surveillance zone in various articles on the basis that it is the prerogative of the Veterinary Authority to establish the surveillance zone based on knowledge and understanding of the disease epidemiology in the national situation.

The Code Commission agreed with the reasoning of Members and deleted point 3 (b) iii in Article 8.2.3.

The Code Commission rejected a Member's proposal to replace 'Provisionally free country or zone' with 'Country or zone with low prevalence' because the concept of provisional freedom has been adopted by Members. The Member's comment on the phrase 'at a level of confidence not sufficient to meet requirements for freedom' (point (b) in Article 8.2.4. point) was accepted and a modification made to this point and to point (b) iii in Article 8.2.3. to address the Member's comment.

As noted by the Member, what constitutes an ‘acceptable level of confidence’ is not quantified in Chapter 1.4. However, the Code Commission considered that it would not be feasible to provide a quantitative recommendation on a general basis, as the design of surveillance programmes, including the level of confidence sought, varies according to many factors, including disease epidemiology and the objectives of the surveillance programme.

The Code Commission did not accept a Member’s recommendation on Article 8.2.12., that pigs in free countries or zones be serologically tested for Aujeszky’s disease before donating semen, on the basis that the freedom of the country or zone provided sufficient safeguard.

The revised Chapter 8.2., proposed for adoption, is at Annex 16.

EU position

The EU thanks the OIE TAHSC for these important changes and supports in general the adoption of this modified chapter. However, in light of the new definitions of captive wild and feral animals in the Glossary, two minor but important changes should be done before adoption or taken into account by the TAHSC in its next meeting.

Agenda item 19. Bluetongue (Chapter 8.3.)

Comments were received from Australia, the EU, New Zealand, Norway and the USA.

The Code Commission discussed a Member’s proposal to modify Article 8.3.3. point 3 (c), as follows:

‘(imported) animals are not vaccinated and a surveillance programme in accordance with Articles 8.3.16. to 8.3.21., has been in place in the source population for a period of at least 60 days immediately prior to dispatch and no evidence of BTV transmission has been detected’.

Although a Member provided a rationale for considering the provisions in point 3 (c) as a valid risk management option, SCAD and the Code Commission did not agree to the proposal because they considered that the Member had not presented a scientific rationale to justify the safety of moving animals of unknown status from an infected country or zone into a free country/zone where *Culicoides* is present. Furthermore, this text was considered to contradict the introductory paragraph of the Article that referred to: “importation of vaccinated or seropositive animals from infected countries or zones”.

On the same grounds, the Code Commission and the SCAD also rejected the request to maintain a similar text in Article 8.3.8. paragraph 6.

With respect to Chapter 8.3., the Code Commission acknowledged that a Member had repeatedly asserted that not all *Culicoides* species are competent vectors. However, to date, it has not been possible to make a positive response due to the lack of evidence showing that the arguments advanced would be applicable to all countries. The Commission encouraged the Member to provide a supporting document to SCAD for detailed evaluation.

A Member’s proposal to modify Article 8.3.5. was accepted because the Code Commission considered that this improved clarity.

Members’ comments on Article 8.3.15. were reviewed and some modifications made to the text. The Code Commission recalled that the term ‘vector protected’ had been adopted rather than ‘vector proof’ in recognition of the fact that absolute prevention of *Culicoides* entry is unlikely to be achievable. However, systematic use of appropriate gauge mesh and insecticide represents an effective approach to risk management.

The revised Chapter 8.3., for adoption, is at Annex 17.

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter.

However, there are still some uncertainties as regards the efficiency of vector-protected establishments. It would be valuable to collect and assess data from practical experience when applying such management procedures. Furthermore, the vector protected establishments used should be approved by the competent authority.

Agenda item 20. Foot and mouth disease (Chapters 8.5. and Article 1.6.3. – Questionnaire for Official status recognition; new Article 1.6.5. *bis* Questionnaire on endorsement of official control programme for FMD)

Comments on Chapter 8.5. were received from Argentina, Australia, Canada, Chile, Chinese Taipei, the EU, Japan, Korea (Rep. of), Mexico, New Zealand, South Africa, Thailand, USA, the Permanent Veterinary Committee of MERCOSUR (CVP) and the International Scientific Working Group of the International Natural Sausage Casings Association (INSCA).

The Code Commission noted the support of some Members for the proposal to include in the *Terrestrial Code* the concept of an OIE endorsed official control programme for FMD as a voluntary process. Many comments were received on the draft Article 8.5.7.*bis*. The Code Commission decided that the new article would better be co-located with the articles on FMD surveillance. Accordingly, the Code Commission proposed a new draft Article 8.5.47 *bis*.

Noting that the Manual Chapter 2.1.5. (adopted in May 2009) provided extensive detail on the choice of vaccine and use of serological tests in surveillance programmes, the Code Commission did not accept a Member's proposals to add details on FMD vaccines in Articles 8.5.3. and 8.5.5.

In response to a Member's proposal to modify Article 8.5.6., the Code Commission noted that the term 'official control programme' is already defined in the Glossary and put the term in italics (where this had not already been done).

On Article 8.5.8., the Code Commission did not accept a Member's objection to the proposed modification of point 1 (e) as it felt that the need to quickly establish that the outbreak had been contained was addressed in the proposed text. The comment of a Member and a regional organization to add 'modified stamping out policy' in point 2 was not accepted because, as defined in the Glossary, *stamping out policy* already includes 'modified stamping out policy'.

The Code Commission noted the proposal of a Member to redraft Chapter 8.5. with the objective of improving clarity (correcting the English grammar and simplifying the writing style) and considered that this proposal had merit. However, the Commission considered that the OIE should wait for the adoption of the important new text on the official control programme for FMD before undertaking a large editorial exercise. In addition, the SCAD proposes to review the scientific provisions of Chapter 8.5. Accordingly, the Code Commission decided to revert to the 2010 text for Articles 8.5.22., 8.5.23. and 8.5.24.

At a Member's recommendation, the Code Commission reverted to the 2010 version of the title of Article 8.5.25., to clarify that the reference to 'official control programme' is in the context of the definition of this term in the Glossary. The Code Commission noted that, at the present time, this title does not imply that the control programme has been endorsed by the OIE, as this step remains voluntary. The same rationale applied in relation to Members' comments (which were not accepted) on the title of Article 8.5.28.

Members' comments on Article 8.5.27. were not accepted by the Code Commission on the basis that they should be addressed when the SCAD undertakes a review of the entire chapter.

The Code Commission referred a Member's comment on point 3 of Article 8.5.31. to SCAD for review.

The recommendation of the International Scientific Working Group of the International Natural Sausage Casings Association (INSCA) on Article 8.5.41. was supported by SCAD and the Code Commission, which cited the scientific article which is 'in press' and will soon be published in a peer-reviewed journal. The text was amended accordingly.

In response to Members' comments on Article 8.5.46., the Code Commission noted the advice of SCAD

and modified the text accordingly.

The Code Commission drafted a new Article 8.5.47. *bis*, taking into account input from SCAD and the comments provided by Members on the proposed Article 8.5.7. *bis*.

The revised Chapter 8.5., proposed for adoption, is at Annex 18.

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter.

However, the EU wishes to reiterate its comment about the recommendations for importation of milk and milk products intended for use in animal feeding, which is not covered by Article 8.5.27: in a future revision of the chapter, this should be addressed. EU comment is inserted in the text below.

Chapter 1.6. Status for OIE Listed diseases: Procedures for self-declaration and for official recognition by the OIE

Comments were received from Argentina, Australia, Canada, the EU, Japan, Korea (Rep. of), Mexico, New Zealand, Thailand and the Permanent Veterinary Committee of MERCOSUR (CVP). The Code Commission addressed the comments on the basis of advice from the SCAD and in light of the joint discussion between the two Commissions.

In response to a Member's comment on Article 1.6.3.1. point 6., the Code Commission added references to swill feeding in relation to all country classification categories.

The Code Commission noted that Members raised concerns about the fact that OIE endorsement of an official control programme for FMD is not the same as official recognition of disease free status. To address this concern the Code Commission added a new draft Article 1.6.1. *bis* as follows:

OIE Members may request OIE endorsement of their national official control programme for FMD. When requesting this endorsement, the Member should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate).

The Code Commission relocated the questionnaire on OIE endorsement of an official control programme for FMD to a new Article 1.6.5. *bis*.

Proposals of Members to modify various points were adopted or disregarded on the basis of SCAD advice.

The Code Commission recommended that, once Chapter 8.5. had been revised to clarify and simplify the text, attention be given to Chapter 1.6., because the structure of the current text (e.g., the coverage of an entire questionnaire in single articles) contributes to difficulty in reading and understanding the recommendations.

The revised text of Article 1.6.3. (Questionnaire on FMD), Article 1.6.5. (Questionnaire on CBPP) and new Article 1.6.5. *bis* (Questionnaire for OIE endorsed official control programme for FMD), proposed for adoption, are at Annex 19.

EU position

The EU supports in general the adoption of this modified chapter.

The revised text of new Article 1.6.6. (new Questionnaire on African horse sickness), for Member comment, is at Annex 33.

The EU will provide further comments on the draft modifications of Article 1.6.6 before the 6th of August.

Agenda item 21. Rabies (Chapters 5.11. and 8.10.)

Comments were received from Australia, Canada, the EU, Japan, Mexico, New Zealand, Switzerland and

the USA on Chapter 8.10.

Comments were received from Canada, the EU and the USA on Chapter 5.11.

The Code Commission and the SCAD agreed with Members that it would be premature to adopt the revised text. The Code Commission therefore proposed that Members' comments be reviewed and new text proposed by a new *ad hoc* expert group, preferably before September (i.e. prior to the Global Rabies Conference in Seoul). The review of the Manual chapter on rabies should be taken into account by the *ad hoc* Group when it undertakes this work.

The review should focus in particular on rabies as defined in the *Terrestrial Code*, including canine rabies and livestock rabies transmitted by vampire bats. The *Terrestrial Code* chapter should also address the risks associated with the rabies reservoir in wildlife.

The EU is willing to participate in the work of the new ad hoc group.

Agenda item 22. Vesicular stomatitis (Chapter 8.15.)

Comments were received from the EU and the USA.

At the recommendation of a Member and in consultation with SCAD, the Code Commission added 'Safe Commodities' to the title of Article 8.15.1. and listed several commodities under this article.

The Code Commission modified Article 8.15.6 in accordance with Members' comments as the modification was considered appropriate.

The revised Chapter 8.15., for adoption, is at Annex 20.

EU position

The EU supports in general the adoption of this modified chapter and has one comment.

Agenda item 23. Diseases of bees

a) Hygiene and disease security procedures in apiaries (Chapter 4.14.)

Comments were received from Argentina, Canada, the EU, Jamaica, New Zealand, Switzerland and the Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA).

b) Diseases of Apidae (Chapters 9.1.–9.6.)

Comments were received from Argentina, Canada, the EU, Jamaica and New Zealand and Switzerland on Chapter 9.1.

In view of the extensive and diverse comments provided by Members, the Code Commission asked the Director General to convene an *ad hoc* expert group to address comments submitted on all of the bee disease chapters.

The EU is willing to participate in the work of the new ad hoc group.

Agenda item 24. Avian influenza (Chapter 10.4.)

Comments were received from Canada, the EU, South Africa and the USA.

Members' recommendations to change the text of point 9 in Article 10.4.1. and to modify Article 10.4.33.2 were not accepted, because the text already covered the issue and the proposed modification did not present a significant improvement.

The Code Commission made some minor amendments following Members' recommendations.

The revised Chapter 10.4., proposed for adoption, is at Annex 21.

EU position

The EU supports the adoption of this modified chapter, which now should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Agenda item 25. Newcastle Disease (Chapter 10.13.)

Comments were received from the EU, Switzerland and the USA and advice was received from an expert.

The Code Commission decided to modify Article 10.13.1., as recommended by a Member, noting that the revised values for thermal inactivation of Newcastle disease virus reflect the up to date scientific evidence, derived from studies that were specifically designed to address sources of uncertainty in earlier studies on thermal inactivation. The scientific evidence is shown in the study by Thomas, King and Swayne, Journal of Food Protection, Vol.71, N°6 2008, page 1214 "Thermal inactivation of avian influenza and Newcastle disease viruses in chicken meat".

The revised Chapter 10.13., proposed for adoption, is at Annex 22.

EU position

The EU supports the adoption of this modified chapter, which now should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Agenda item 26. Bovine tuberculosis (Chapter 11.6.)

Comments were received from the EU, Mexico and Switzerland.

On the advice of the SCAD, the Code Commission did not include *M.caprae* in Chapter 11.6.

In response to a Member's recommendation that Article 11.6.2. be modified to make reference to a risk analysis of wildlife, the Code Commission asked SCAD to refer this matter to the OIE Wildlife Working Group.

The Code Commission proposed no modification to Chapter 11.6.

Agenda item 27. Contagious bovine pleuropneumonia (Chapter 11.8. and Article 1.6.5.) (Questionnaire on CBPP)

A comment received from the EU on Article 1.6.5. was accepted and the article modified accordingly (see Agenda item 19).

At the request of the SCAD, the yak (*Bos grunniens*) was added to the list of susceptible animals in Article 11.8.1.

The revised Chapter 11.8., proposed for adoption, is at Annex 23.

EU position

The EU supports the adoption of this modified chapter, which now should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Agenda item 28. Lumpy skin disease (Chapter 11.12.)

Comments were received from Australia and the EU.

In response to Members' comments, the Code Commission withdrew the draft article on safe commodities and will forward it to SCAD to request the preparation of articles on milk and meat products.

A Member comment on Article 11.12.2 was not taken into account as point 1 of this Article is not subjected to time; however, for point 4 it was agreed to modify the text for consistency.

Regarding a Member's comment on Article 11.12.4, the Code Commission decided to specify the susceptible species listed in Article 11.12.1. and to modify the chapter accordingly.

The revised Chapter 11.12., proposed for adoption, is at Annex 24.

EU position

The EU thanks the OIE TAHSC and supports the adoption of this modified chapter.

Agenda item 29. Equine diseases

a) African horse sickness (Chapter 12.1. and revised new Article 1.6.6.)

Comments were received from Canada, China (P.R. of), the EU, New Zealand, Norway and the USA.

The Code Commission did not accept the recommendation of Members who called for deletion of certain text, including point 4 in Article 12.1.2. and the whole of Article 12.1.3., on the basis that this text had been adopted by the World Assembly of Delegates. Indeed, although the establishment of a seasonally free zone, or a containment zone, for African horse sickness is not a simple undertaking, Members have previously adopted this text on the basis that the establishment of such zones are technically feasible.

Several text modifications were made to improve grammar and clarity.

Comments on Chapter 12.1. were received from Canada, New Zealand and the USA.

The Code Commission made some amendments based on SCAD advice and Members' recommendations to improve clarity or grammar, but based on advice from SCAD, rejected some Members' recommendations .

The revised Chapter 12.1 and the new Article 1.6.6., for Member comments, are at Annex 33.

The EU will provide further comments on the draft modifications of Chapter 12.1 and Article 1.6.6 before the 6th of August.

b) Equine influenza (Chapter 12.6.)

Comments were received from the EU and the USA.

The Code Commission made one amendment based on SCAD advice and Members' recommendations to improve clarity.

c) Equine viral arteritis (Chapter 12.9.)

Comments were received from the EU and the USA.

The Code Commission made some amendments to improve clarity taking into account SCAD advice and Members' recommendations.

The revised Chapters 12.6. and 12.9., proposed for adoption, are at Annex 25.

EU position

The EU supports in general the adoption of these modified chapters.

However, in this chapter and throughout the *Terrestrial Code*, by convention and for the sake of clarity, the use of the word "equine(s)" should not be used as a noun, as it can lead to confusion: "equine" should

only be used as an adjective that refers to "equids", word that should be used to refer to members of the family Equidae.

Item 30. Enzootic abortion of ewes (ovine chlamydiosis) (Chapter 14.5.)

Comments were received from the EU and Switzerland

Based on SCAD advice and Members' recommendations, the Code Commission made one amendment to improve clarity.

The revised Chapter 14.5., proposed for adoption, is at Annex 26.

EU position

The EU supports the adoption of this modified chapter.

Agenda item 31. Scrapie (Chapter 14.9.)

Comments were received from Australia, the EU, New Zealand, Switzerland and the International Embryo Transfer Society (IETS).

The Code Commission did not agree to modify the title of the chapter to 'Classical scrapie' because it considered that a convincing rationale had not been presented to justify this modification and that the current text was clear as to the exclusion of atypical scrapie.

The Code Commission did not accept the arguments of a Member against accepting *in vivo* derived sheep embryos as safe because the IETS had established the safety of *in vivo* derived embryos on the basis of current world wide scientific research on the issue. The Code Commission's position was supported by the conclusions of a recent, peer reviewed risk analysis, which may be viewed at <http://www.biosecurity.govt.nz/files/biosec/consult/import-risk-analysis-scrapie-sheep-goat.pdf>.

No further modifications were made to the draft text proposed in September 2010.

The revised Chapter 14.9., proposed for adoption, is at Annex 27.

EU position

The EU supports the adoption of this modified chapter, which now should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Agenda item 32. Classical swine fever (Chapter 15.2.)

Comments were received from Chinese Taipei, the EU, Mexico, New Zealand and the USA. The Code Commission followed SCAD advice relevant to Members' comments on scientific issues.

In response to Members' comments, the Code Commission modified the text of Article 15.2.1. to read 'For the purposes of this chapter, a distinction is made between domestic pig populations on the one hand, and wild pig, including captive wild, and feral pig populations on the other'.

Having made this modification, the Code Commission did not accept Members' recommendations to modify the text of several articles to clarify the treatment of domestic pigs and pigs in captivity in comparison with the treatment of wild pigs, nor did it accept a Member's recommendation to change 'domestic pigs' to 'susceptible animals' in Article 15.2.3. Dr Thiermann noted that the objective of Chapter 15.2. is to recognise and protect the status of domestic pig populations with respect to classical swine fever. With this goal in mind, the recommendations in the *Terrestrial Code* are based on the definition of classical swine fever as an infection in domestic pigs. The risks associated with wild pig populations are equally associated with free-ranging and captive wild pig populations.

Noting that there was a risk of producing recommendations that would make the task of certifying pigs and pig meat exports complicated and difficult, the Code Commission tried to keep the text as simple and clear

as possible.

The Code Commission deleted ‘and according to Article 15.2.26.’ from point 7 of Article 15.2.2. because it considered that this cross reference was redundant.

The Code Commission did not accept a Member’s recommendation to add ‘since birth or for at least 3 months prior to slaughter’ to Article 15.2.12. because the requirement is already covered in the definition of a free country, zone or compartment (Articles 15.2.5. and 6).

The Code Commission did not accept Members’ proposals to modify the text of Article 15.2.13. (‘the entire consignment of meat’) because the consignment may be made up of meat from multiple origins and this text is consistent with that found in other disease chapters. The Commission also noted that the conduct of ante mortem inspection is not feasible in wild pigs.

The Code Commission modified Article 15.2.21 *bis* to include text on the inactivation of CSF virus present in natural casings of pigs, consistent with the modification to Article 8.5.41 (FMD), based on a publication showing that these procedures are sufficient to inactivate CSF virus. [See Wijnker JJ, Depner KR, Berends BR (2008). Inactivation of classical swine fever virus in porcine casing preserved in salt. *International Journal of Food Microbiology* 128: 411-413.]

In considering Members’ comments on Chapter 15.2. overall, the Code Commission agreed with the recommendation of the SCAD that the OIE should continue to develop the OIE policy on the wildlife/livestock interface to clarify the implications of infection in wild animals for disease status and trade, as well as the appropriate recommendations for surveillance and reporting of OIE listed diseases in wildlife. A number of issues raised by Members (e.g. comments on surveillance provisions, in Article 15.2.25.) should be addressed by the SCAD when it reviews the chapter to provide a basis for OIE official recognition of CSF status.

The revised Chapter 15.2., proposed for adoption, is at Annex 28.

EU position

The EU thanks the OIE TAHSC and would support in general the adoption of this modified chapter except the way that the new terms for wild pigs in the Glossary have been inserted, which cannot be accepted as proposed.

Indeed, in the framework of the OIE policy on wildlife/livestock interface, the EU asks the OIE to take into account the EU previous comment regarding the populations of captive wild pigs, which might be kept in zoos but also used for the production of meat, and thus play a significant epidemiological role equivalent to that of free range domestic pigs: the distinction then should be made between domestic pigs and captive wild pigs on the one hand, and wild and feral pigs on the other hand. This is the policy adopted for the draft modified chapter on Aujeszky's disease, with which consistency should be sought. Proposals are inserted in the Article 15.2.1, which cannot be adopted as such.

Agenda item 33. Swine vesicular disease (Chapter 15.4.)

Comments were received from Canada, China (P.R. of), Chinese Taipei, the EU, Japan, New Zealand and the USA.

The Code Commission did not accept a Member’s request to modify point 3 in Article 15.4.1. *bis* (authority over all pigs) because this text has already been adopted by Members elsewhere in the *Terrestrial Code* (e.g. for classical swine fever). A Member's request to include wild pigs in the surveillance of SVD in Article 15.4.1. *bis* was not accepted because it was not considered to be epidemiologically relevant.

The Code Commission did not accept a Member’s request to reinstate the text proposed for deletion in Article 15.4.2. because the proposed text accurately reflects the epidemiology of SVD.

On Article 15.4.4., the Code Commission did not accept any modifications proposed by Members because

the text was consistent with articles on containment zones found elsewhere in the *Terrestrial Code*.

The Code Commission accepted a Member's proposal to modify the text of Article 15.4.5. for improved grammar and clarity.

The Code Commission accepted Members' recommendations to modify the text of Article 15.4.7. and 15.4.8. to reflect that the articles cover the importation of domestic, not wild, pigs. The requirements in point 2 of Article 15.4.8. were also modified to reflect the epidemiology of swine vesicular disease.

The Code Commission referred a Member's request for modification of the conditions for testing boars in Article 14.4.9. and 10., on the grounds that semen should be considered safe, to SCAD for review.

Noting the large number of comments received from Members on remaining articles and the fact that SCAD had not yet provide advice on these, the Code Commission referred the comments on Articles 8.4.11.–19. to SCAD for review. The Code Commission asked the SCAD to specifically focus its further review on Articles 8.4.11.–19. and not to revisit the proposed modifications to Articles 8.4.1.–10.

EU position

The EU thanks the OIE TAHSC for this approach, though it is now important to adopt new standards on SVD. The EU hopes that the exchanges between the SCAD and the TAHSC will allow the proposal of a good proposal in September.

Agenda item 34. Report of the *ad hoc* Group on Zoonotic Parasites

Dr Mylrea recalled the background to this work. Under the auspices of the Animal Production Food Safety Working Group, the OIE had developed a discussion paper 'Animal production food safety: priority pathogens for standard setting by the OIE'. The zoonotic parasites *Taenia solium*, *T. saginata*, *Echinococcus granulosus* and *Trichinella spiralis* were identified as pathogens with a very significant impact on human health, particularly in Africa, South America and the Middle East. Echinococcus/hydatidosis, trichinellosis and porcine cysticercosis are OIE listed diseases. The *Terrestrial Code* 2010 contains some recommendations relevant to trade measures in the current Chapters 8.4. Echinococcus/hydatidosis and 8.13. Trichinellosis, but no recommendations on measures at the animal/farm level to avoid human infection with these zoonotic pathogens. The *Terrestrial Code* does not contain any recommendations on porcine cysticercosis.

The OIE *ad hoc* Group on Zoonotic Parasites met for the first time on 5–7 October 2010 and revised the text of *Terrestrial Code* Chapters 8.4. Echinococcus/hydatidosis and 8.13. Trichinellosis to include recommendations on the management of these pathogens in animals in order to avoid risks to human health.

The *ad hoc* Group was also requested to discuss the feasibility of developing guidelines for good on-farm practices to prevent and control important non OIE-listed parasites, such as *T. saginata*, as these parasites, although not always a significant public health concern can result in significant economic losses due to condemnation of affected tissues.

The Code Commission reviewed the report of the first meeting of the *ad hoc* Group on Zoonotic Parasites.

The Code Commission noted the *ad hoc* Group's opinion that it was not feasible to establish a trichinella free country or zone and the rationale for this view, as set out in the report of its meeting. The Code Commission considered that, depending on the way the disease was defined in the *Terrestrial Code*, it could be feasible to make provisions for recognition of country or zone freedom.

The Code Commission discussed the location of the revised chapter on trichinellosis and considered that there were arguments for placement of this text in Volume 1 Section 6 'Veterinary Public Health' rather than in Volume 2, primarily based on the fact that the text provides recommendations for control of a pathogen that does not cause disease in animals, in relation to which the primary focus of disease control measures is to assure the safety of products for human consumption

It is clear that a complete freedom of a country or zone might not be achievable if wild species are

included. However, a specific definition of the disease focusing on the main species at risk (e.g. domestic pigs) would help in defining at least zones and populations of lower risk, as has been addressed in other chapters (e.g. on classical swine fever). In combination with risk reduction measures adapted to each situation, this would allow the use in the revised chapter of both risk prevention and reduction (consistent with the philosophy of the *Terrestrial Code* Section 6) to define the trichinella status of defined populations and the measures to be applied to trade. The key consideration is to link the level of biosecurity measures to the status of a population and relevant risk mitigation measures. This should be addressed by the *ad hoc* group at its next meeting, together with Members' comments. The Code Commission noted that the Codex Alimentarius Commission is undertaking new work on trichinellosis and *Cysticercus bovis* and discussed what steps could be taken to ensure that the two international standard setting organisations closely coordinate this work.

The Code Commission recommended that the OIE work closely with the CAC, specifically with the Codex Committee on Food Hygiene, to support the elaboration of parallel complementary standards that address the risk from farm to fork.

Revised Chapters 8.4. and 8.13., for Member comment, are at Annex 34.

The EU has numerous and important comments on the draft modifications of chapters 8.4 and 8.14, which should be taken into account by the ad hoc group and by the TAHSC in its next meeting.

Agenda item 35. Report of the Animal Production Food Safety Working Group

The Code Commission noted the report of the APFSWG and endorsed the proposed terms of reference for the review of linkages between food safety and animal welfare.

The report of the APFSWG is at Annex 35 for information of Members.

Agenda item 36. Report of the *ad hoc* Group on Laboratory Animal Welfare

The report was noted and endorsed. The Code Commission encouraged the *ad hoc* Group to continue working on the proposed new Article 7.8.10 ‘transport of laboratory animals between institutes’ with a view to circulating a draft text to Members after the next General Session.

The Code Commission noted and supported the proposed priorities identified by the *ad hoc* Group, i.e. recommendations on the training of laboratory animal veterinarians and means to encourage the adoption of scientifically validated, non animal-based methods in regulatory testing.

The report of the *ad hoc* Group, for Member information, is at Annex 36.

Agenda item 37. Report of the *ad hoc* Group on Veterinary Education

The Code Commission endorsed the report of the *ad hoc* Group. In view of the strong support of Members for the work of the OIE in strengthening the quality of Veterinary Services by establishing the PVS Pathway, and the direct relevance of veterinary education to the performance of Veterinary Services, the Code Commission proposed to make direct reference to the recommendations of the *ad hoc* Group by including new text in Article 3.2.14, sub-point 2 a (vi), as follows:

‘curriculum addressing the minimum competencies of day 1 veterinary graduates to assure the delivery of quality Veterinary Services, as described by the OIE’

The report of the *ad hoc* Group, for Member information, is at Annex 37.

As shown under Agenda item 7, the revised Chapter 3.2., proposed for adoption, is in Annex 4.

EU position

The EU supports the adoption of this modified chapter but has a comment that should be taken into account before adoption.

The EU will provide further comments on the report of the ad hoc group on veterinary education.

3. OTHER ISSUES

Agenda item 38. Antimicrobial resistance – review of Chapters 6.7. and 6.8.

The Code Commission reviewed the revised text provided by an *ad hoc* Group and supported by SCAD and made minor modifications. The Code Commission endorsed the removal of reference to farmed fish in Chapter 6.7. and noted that the Aquatic Animal Health Standards Commission is in the process of developing new text on the topic of antimicrobial resistance in aquatic animals.

The Code Commission strongly encouraged Members to provide timely comment on these revised chapters in view of the importance of this area of work to human and animal health.

The revised Chapters 6.7. and 6.8., for Member comment, are provided at Annex 31.

The EU has comments on the draft modifications of chapters 6.7 and 6.8, which should be taken into account by the ad hoc group and by the TAHSC in its next meeting.

Agenda item 39. Future work programme of the Code Commission

The revised work program is at Annex 38.

Agenda item 40. Other issues

a) Proposed draft policy on the wildlife-domestic animal interface as a guideline for future standard setting by the OIE (proposal submitted by the SCAD September 2010)

The Code Commission generally endorsed the proposed draft policy and made the following observations. Members should continuously be reminded of the importance of the obligation to notify disease occurrence in wildlife in accordance with the *Terrestrial Code*, not only because of trade. The specific obligations of Members to report disease occurrence in wildlife will vary according to the provisions of each disease chapter. The relevant provisions will need to be spelled out – and this is a task to be addressed by disease specific *ad hoc* Groups reporting to SCAD, with input, as appropriate, from the Wildlife Working Group.

Members should be encouraged to report the presence in wildlife of listed diseases, even if it is not required by the Code. The fact that wildlife may harbour pathogens without obvious signs of disease and act as a reservoir of infection should be highlighted.

In the situation where notification of a disease in wildlife has no impact on trade, this should serve as an incentive to reporting.

The Commission considered that the future work plan of the Wildlife Working Group, as with all OIE working groups, should be prioritised on the basis of requests from Members, OIE headquarters and Specialist Commissions.

b) Review of quarantine measures applicable to non-human primates (Chapters 5.9. and 5.10.)

The Code Commission agreed with text modifications proposed by the Wildlife Working Group and supported by the SCAD.

The revised Chapters 5.9. and 5.10., proposed for adoption, are in Annex 10.

EU position

The EU strongly supports the adoption of this modified chapter.

c) Questions from Members on BSE

The Code Commission received advice from the *ad hoc* Group on BSE and from SCAD in response to a question from Members about the BSE risk associated with bovine intestines. The Commission was informed that, on the basis of current scientific knowledge, no modification to the current provisions on bovine intestine in Chapter 11.5. was warranted. A request submitted by a Member on the BSE questionnaire was not supported by SCAD. Accordingly, the Code Commission proposed no amendments to Chapter 11.5.

d) Date of next meeting

The next meeting of the Code Commission is scheduled for 13-22 September 2011.

.../Annexes

GLOSSARY

EU position

The EU thanks the OIE TAHSC and supports the adoption of the modified Glossary.

For the purposes of the *Terrestrial Code*:

Antimicrobial agent

means a naturally occurring, semi-synthetic or synthetic substance that ~~at *in vivo* concentrations~~ exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms) at concentrations attainable *in vivo*. Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Captive wild animal

means an *animal* that has a phenotype not significantly affected by human selection but that are captive or otherwise lives under direct human supervision or control by humans, including zoo animals and pets.

Euthanasia

means the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to the *animal*.

Feral animal

means an previously domestic *animal* of a domesticated species that now lives without direct human supervision, or control by or dependence on humans.

Veterinary legislation

means laws, regulations and all associated legal instruments that pertain to the veterinary domain.

Wild animal

means an *animal* that has a phenotype unaffected by human selection and lives independent of direct human supervision or control.

Wildlife

means any combination of *feral animals, captive wild animals and wild animals.*

 — text deleted

CHAPTER 1.1.

NOTIFICATION OF DISEASES AND
EPIDEMIOLOGICAL INFORMATION**EU position****The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter.**

Article 1.1.1.

For the purposes of the *Terrestrial Code* and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, every OIE Members of the organisation shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its territory or territories.

All *notifications* and all information sent by the OIE to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Authority* shall be regarded as having been sent by the country concerned.

Article 1.1.2.

1. Members shall make available to other Members, through the OIE, whatever information is necessary to minimise the spread of important animal *diseases* and to assist in achieving better worldwide control of these *diseases*.
2. To achieve this, Members shall comply with the *notification* requirements specified in Article 1.1.3.
3. To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE *disease* reporting format.
4. Recognising that scientific knowledge concerning the relationship between disease agents and *diseases* is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of a *disease*, Members shall ensure through their reports that they comply with the spirit and intention of point 1 above.
5. In addition to notifying new findings in accordance with Article 1.1.3., Members shall also provide information on the measures taken to prevent the spread of *diseases*; including quarantine measures and restrictions on the movement of *animals*, animal products and biological products and other miscellaneous objects which could by their nature be responsible for transmission of *disease*. In the case of *diseases* transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the national Delegate, send to the *Headquarters*:

1. in accordance with relevant provisions in the disease specific chapters, ~~notification from the national Delegate to the OIE~~ through WAHIS or by telegram, fax or e-mail, within 24 hours, of any of the following events:
 - a. first occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment*;
 - b. re-occurrence of a *listed disease* and/or *infection* in a country, a *zone* or a *compartment* following a report declared the *outbreak* ended;
 - c. first occurrence of a new strain of a pathogen of an OIE *listed disease* in a country, a *zone* or a *compartment*;
 - d. a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a *listed disease* prevalent within a country, a *zone* or a *compartment*;
 - e. an *emerging disease* with significant morbidity or mortality, or zoonotic potential;
 - f. evidence of change in the epidemiology of a *listed disease* (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;
2. weekly reports by telegram, fax or e-mail subsequent to a *notification* under point 1 above, to provide further information on the evolution of an incident which justified urgent *notification*; these reports should continue until the situation has been resolved through either the *disease* being eradicated or it becoming endemic so that six-monthly reporting under point 3 will satisfy the obligation of the Member to the OIE; in any case, a final report on the incident should be submitted;
3. a six-monthly report on the absence or presence, and evolution of *listed diseases listed by the OIE* and information of epidemiological significance to other Members;
4. an annual report concerning any other information of significance to other Members.

Article 1.1.4.

1. The *Veterinary Authority* of a territory in which an *infected zone* was located shall inform the *Headquarters* when this zone is free from the *disease*.
2. An *infected zone* for a particular *disease* shall be considered as such until a period exceeding the *infective period* specified in the *Terrestrial Code* has elapsed after the last reported *case*, and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the *disease*. These measures will be found in detail in the various chapters of Volume 2 of the *Terrestrial Code*.

3. A Member may be considered to regain freedom from a specific *disease* when all conditions given in the relevant chapters of the *Terrestrial Code* have been fulfilled.
4. The *Veterinary Authority* of a Member which sets up one or several *free zones* shall inform the OIE giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the *zones* on a map of the territory of the Member.

Article 1.1.5.

1. The *Headquarters* shall send by telegram, fax, e-mail or *Disease Information* to the *Veterinary Authorities* concerned, all *notifications* received as provided in Articles 1.1.2. to 1.1.4.
2. The *Headquarters* shall dispatch to the Delegates information on new *outbreaks* of *listed diseases*.
3. The *Headquarters*, on the basis of information received and of any official communication, shall prepare an annual report concerning the application of the *Terrestrial Code* and its effects on *international trade*.

Article 1.1.6.

~~All~~ Telegrams or faxes sent by *Veterinary Authorities* in pursuance of Articles 1.1.3. and 1.1.5. shall receive priority in accordance with the circumstances. Communications by telephone, telegram or fax, sent in the case of exceptional urgency when there is danger of spread of a notifiable epizootic *disease*, shall be given the highest priority accorded to these communications by the International Arrangements of Telecommunications.

— text deleted

CHAPTER 1.2.

CRITERIA FOR LISTING DISEASES

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter. The EU commends the Code Commission for agreeing that the OIE keep the chapter on Leptospirosis in the Manual and consider providing advice via other routes (e.g. via a document on the OIE website or a technical disease card). The EU would like this fact expressed during the General Session, and also reiterates that in the light of the reasoning of the ad hoc group on listing diseases, the deletions of some diseases, such as Swine Vesicular Disease should be re-considered by the OIE, as this disease appears not to fulfil all criteria, especially not the morbidity/mortality rate.

The EU will provide further comments on the draft modifications of the criteria of article 1.2.1 that were sent in a separate annex.

Article 1.2.1.

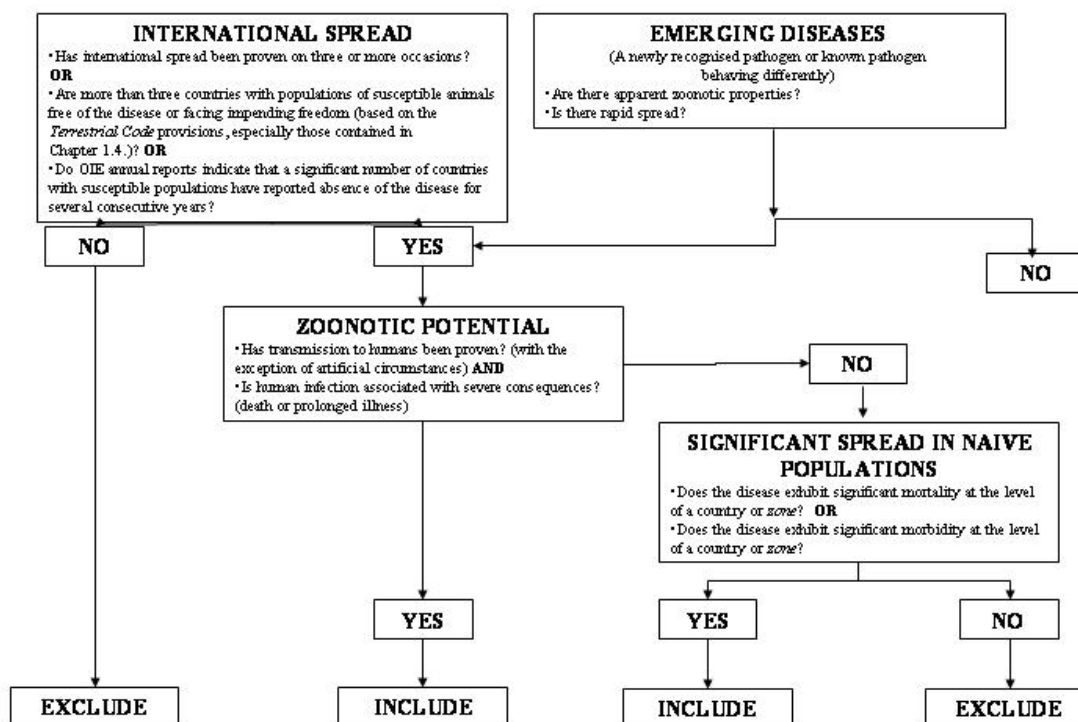
The criteria for the inclusion of a *disease* in the OIE List are as follows:

Basic criteria	Parameters (at least one 'yes' answer means that the criterion has been met)
International Spread	Has international spread been proven on three or more occasions? OR Are more than three countries with populations of susceptible animals free of the <i>disease</i> or facing impending freedom (based on the relevant provisions of the <i>Terrestrial Code</i> , and in particular those contained in Chapter 1.4.)? OR Do OIE annual reports indicate that a significant number of countries with susceptible populations have reported absence of the <i>disease</i> for several consecutive years?
Zoonotic Potential	Has transmission to humans been proven? (with the exception of artificial circumstances) AND Is human infection associated with severe consequences? (death or prolonged illness)
Significant Spread within Naïve Populations	Does the <i>disease</i> exhibit significant mortality at the level of a country or a <i>zone</i> ? OR Does the <i>disease</i> exhibit significant morbidity at the level of a country or a <i>zone</i> ?

Emerging Diseases	Are there apparent zoonotic properties or is there a rapid spread?
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Article 1.2.2.

The criteria in Article 1.2.1. above are applied according to the decision-making model shown below:



Article 1.2.3.

The following *diseases* are included in the OIE List.

In case of modifications of this list of animal *diseases* adopted by the General Assembly, the new list comes into force on 1 January of the following year.

1. The following *diseases* are included within the category of multiple species *diseases*:

- Anthrax
- Aujeszky's disease
- Bluetongue
- Brucellosis (*Brucella abortus*)

- Brucellosis (*Brucella melitensis*)
 - Brucellosis (*Brucella suis*)
 - Crimean Congo haemorrhagic fever
 - Echinococcosis/hydatidosis
 - Epizootic haemorrhagic disease
 - Equine encephalomyelitis (Eastern)
 - Foot and mouth disease
 - Heartwater
 - Japanese encephalitis
 - ~~Leptospirosis~~
 - New world screwworm (*Cochliomyia hominivorax*)
 - Old world screwworm (*Chrysomya bezziana*)
 - Paratuberculosis
 - Q fever
 - Rabies
 - Rift Valley fever
 - Rinderpest
 - Surra (*Trypanosoma evansi*)
 - Trichinellosis
 - Tularemia
 - Vesicular stomatitis
 - West Nile fever.
2. The following *diseases* are included within the category of cattle *diseases*:
- Bovine anaplasmosis
 - Bovine babesiosis
 - Bovine genital campylobacteriosis
 - Bovine spongiform encephalopathy
 - Bovine tuberculosis
 - Bovine viral diarrhoea

- Contagious bovine pleuropneumonia
 - Enzootic bovine leukosis
 - Haemorrhagic septicaemia
 - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
 - Lumpy skin disease
 - Theileriosis
 - Trichomonosis
 - Trypanosomosis (tsetse-transmitted).
3. The following *diseases* are included within the category of sheep and goat *diseases*:
- Caprine arthritis/encephalitis
 - Contagious agalactia
 - Contagious caprine pleuropneumonia
 - Enzootic abortion of ewes (ovine chlamydiosis)
 - Maedi–visna
 - Nairobi sheep disease
 - Ovine epididymitis (*Brucella ovis*)
 - Peste des petits ruminants
 - Salmonellosis (*S. abortusovis*)
 - Scrapie
 - Sheep pox and goat pox.
4. The following *diseases* are included within the category of equine *diseases*:
- African horse sickness
 - Contagious equine metritis
 - Dourine
 - Equine encephalomyelitis (Western)
 - Equine infecti-us anaemia
 - Equine influenza
 - Equine piroplasmosis
 - Equine rhinopneumonitis

- Equine viral arteritis
 - Glanders
 - Venezuelan equine encephalomyelitis.
5. The following *diseases* are included within the category of swine *diseases*:
- African swine fever
 - Classical swine fever
 - Nipah virus encephalitis
 - Porcine cysticercosis
 - Porcine reproductive and respiratory syndrome
 - Swine vesicular disease
 - ~~Teschevirus encephalomyelitis (under study)~~
 - Transmissible gastroenteritis.
6. The following *diseases* are included within the category of avian *diseases*:
- Avian chlamydiosis
 - Avian infectious bronchitis
 - Avian infectious laryngotracheitis
 - Avian mycoplasmosis (*Mycoplasma gallisepticum*)
 - Avian mycoplasmosis (*Mycoplasma synoviae*)
 - Duck virus hepatitis
 - ~~Fowl cholera~~
 - Fowl typhoid
 - Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 10.4.
 - Infectious bursal disease (Gumboro disease)
 - ~~Marek's disease~~
 - Newcastle disease
 - Pullorum disease
 - Turkey rhinotracheitis.
7. The following *diseases* are included within the category of lagomorph *diseases*:

- Myxomatosis
 - Rabbit haemorrhagic disease.
8. The following *diseases* are included within the category of bee *diseases*:
- Acarapisosis of honey bees
 - American foulbrood of honey bees
 - European foulbrood of honey bees
 - Small hive beetle infestation (*Aethina tumida*)
 - *Tropilaelaps* infestation of honey bees
 - Varroosis of honey bees.
9. The following *diseases* are included within the category of other *diseases*:
- Camel pox
 - ≡ Chronic wasting disease
 - Leishmaniosis.
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— text deleted

Annex 3 (contd)

~~CHAPTER 10.6.~~~~AVIAN TUBERCULOSIS~~~~Article 10.6.1.~~**General provisions**

~~Standards for diagnostic tests are described in the *Terrestrial Manual*.~~

~~Article 10.6.2.~~**Recommendations for the importation of birds for breeding or rearing**

~~*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:~~

- ~~1. showed no clinical sign of avian tuberculosis on the day of shipment;~~
- ~~2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and which are recognised as being free from avian tuberculosis;~~

~~Article 10.6.3.~~**Recommendations for the importation of birds for slaughter**

~~*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:~~

- ~~1. showed no clinical sign of avian tuberculosis on the day of shipment;~~
- ~~2. come from *establishments* which are regularly inspected by the *Veterinary Authority* and are recognised as being free from avian tuberculosis; or~~
- ~~3. come from *establishments* in which no *case* of avian tuberculosis has been reported;~~
- ~~4. are not being eliminated as part of an eradication programme against avian tuberculosis.~~

~~Article 10.6.4.~~**Recommendations for the importation of wild avian species destined for zoological gardens**

Annex 3 (contd)

~~Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that prior to shipment, the birds showed no clinical sign of avian tuberculosis and, as far as can be determined, had not been exposed to avian tuberculosis.~~

~~Article 10.6.5.~~**Recommendations for the importation of hatching eggs**

~~Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the hatching eggs:~~

- ~~1. come from establishments and/or hatcheries which are regularly inspected by the Veterinary Authority;~~
- ~~2. come from establishments and/or hatcheries which are recognised as being free from avian tuberculosis;~~
- ~~3. were shipped in clean and unused packages.~~

— text deleted

Annex 3 (contd)

~~CHAPTER 10.7.~~~~DUCK VIRUS ENTERITIS~~~~Article 10.7.1.~~**General provisions**

~~For the purposes of the *Terrestrial Code*, the *incubation period* for duck virus enteritis (DVE) shall be 7 days (chronic carriers occur).~~

~~Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.~~

~~Article 10.7.2.~~**Recommendations for the importation of ducks**

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:~~

- ~~1. showed no clinical sign of DVE on the day of shipment;~~
- ~~2. come from *establishments* which are regularly inspected by the *Veterinary Authority*;~~
- ~~3. come from *establishments* which are recognised as being free from DVE;~~
- ~~4. have not been vaccinated against DVE; or~~
- ~~5. were vaccinated against DVE (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*).~~

~~Article 10.7.3.~~**Recommendations for the importation of day-old ducks**

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *day-old birds*:~~

- ~~1. come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;~~
- ~~2. have not been vaccinated against DVE; or~~

Annex 3 (contd)

3. ~~were vaccinated against DVE (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*);~~
4. are the progeny of parent *flocks* which:
 - a. ~~come from *establishments* and/or hatcheries which are recognised as being free from DVE;~~
 - b. ~~come from *establishments* and/or hatcheries in which vaccination against DVE is not practised on the parent stock; or~~
 - c. ~~come from *establishments* and/or hatcheries in which vaccination against DVE is practised on the parent stock;~~
5. ~~were shipped in clean and unused packages.~~

~~Article 10.7.4.~~

~~Recommendations for the importation of hatching eggs of ducks~~

~~*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:~~

1. ~~have been disinfected in conformity with the standards referred to in Chapter 6.4.;~~
2. ~~come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;~~
3. ~~were shipped in clean and unused packages.~~

— text deleted

Annex 3 (contd)

~~CHAPTER 10.9.~~~~FOWL CHOLERA~~~~Article 10.9.1.~~**General provisions**

For the purposes of the *Terrestrial Code*, the *incubation period* for fowl cholera (FC) shall be 14 days (chronic carriers occur).

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

~~Article 10.9.2.~~**Recommendations for the importation of domestic birds**

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the birds:

- ~~1. showed no clinical sign of FC on the day of shipment;~~
- ~~2. come from establishments which are regularly inspected by the *Veterinary Authority*;~~
- ~~3. come from establishments which are recognised as being free from FC;~~
- ~~4. have not been vaccinated against FC; or~~
- ~~5. were vaccinated against FC (the nature of the vaccine used and the date of vaccination should also be stated in the certificate).~~

~~Article 10.9.3.~~**Recommendations for the importation of day-old birds**

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *day-old birds*:

- ~~1. come from establishments and/or hatcheries which are regularly inspected by the *Veterinary Authority*;~~
- ~~2. have not been vaccinated against FC; or~~

Annex 3 (contd)

3. ~~were vaccinated against FC (the nature of the vaccine used and the date of vaccination shall also be stated in the *certificate*);~~
4. ~~are the progeny of parent *flocks* which:~~
 - a. ~~come from *establishments* and/or hatcheries which are recognised as being free from FC;~~
 - b. ~~come from *establishments* and/or hatcheries in which vaccination against FC is not practised on the parent stock; or~~
 - c. ~~come from *establishments* and/or hatcheries in which vaccination against FC is practised on the parent stock;~~
5. ~~were shipped in clean and unused packages.~~

~~Article 10.9.4.~~

Recommendations for the importation of hatching eggs of domestic birds

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *hatching eggs*:~~

1. ~~have been disinfected in conformity with the standards referred to in Chapter 6.4.;~~
2. ~~come from *establishments* and/or hatcheries which are regularly inspected by the *Veterinary Authority*;~~
3. ~~were shipped in clean and unused packages.~~

— text deleted

Annex 3 (contd)

~~CHAPTER 10.12.~~~~MAREK'S DISEASE~~~~Article 10.12.1.~~**General provisions**

For the purposes of the *Terrestrial Code*, the *incubation period* for Marek's disease (MD) shall be 4 months.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

~~Article 10.12.2.~~**Recommendations for the importation of chickens**

~~Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the birds:~~

- ~~1. showed no clinical sign of Marek's disease on the day of shipment;~~
- ~~2. come from an *establishment* which is regularly inspected by the *Veterinary Authority*;~~
- ~~3. have not been vaccinated against MD and come from an *establishment* which has been free from MD for at least the past 2 years; or~~
- ~~4. were vaccinated against MD (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*).~~

~~Article 10.12.3.~~**Recommendations for the importation of day-old birds**

~~Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *day-old birds*:~~

- ~~1. come from *establishments* which are regularly inspected by the *Veterinary Authority* and from hatcheries which comply with the standards referred to in Chapter 6.4;~~
- ~~2. were vaccinated against MD (the nature of the vaccine used and the date of vaccination should also be stated in the *certificate*);~~
- ~~3. were shipped in clean and unused packages.~~

~~Article 10.12.4.~~**Recommendations for the importation of hatching eggs of chickens**

~~Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the hatching eggs:~~

- ~~1. have been disinfected in conformity with the standards referred to in Chapter 6.4.;~~
- ~~2. come from establishments which are regularly inspected by the Veterinary Authority and from hatcheries which comply with the standards referred to in Chapter 6.4.;~~
- ~~3. come from establishments in which vaccination against MD is practised (the nature of the vaccine used and the date of vaccination should also be stated in the certificate);~~
- ~~4. were shipped in clean and unused packages.~~

~~Article 10.12.5.~~**Recommendations for the importation of meat-meals and feather-meals**

~~Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that these products have been processed using heat treatment to ensure the destruction of the MD virus.~~

~~Article 10.12.6.~~**Recommendations for the importation of feathers and down**

~~Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that these products have been processed to ensure the destruction of the MD virus.~~

 — text deleted

Annex 3 (contd)

~~CHAPTER 15.5.~~~~TESCHOVIRUS ENCEPHALOMYELITIS
(PREVIOUSLY ENTEROVIRUS
ENCEPHALOMYELITIS, TESCHEN
DISEASE, TOLFAN DISEASE) (UNDER STUDY)~~~~Article 15.5.1.~~**General provisions**

~~For the purposes of the *Terrestrial Code*, the *incubation period* for teschovirus encephalomyelitis shall be 40 days.~~

~~Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.~~

~~Article 15.5.2.~~**Teschovirus encephalomyelitis free country**

~~A country may be considered free from teschovirus encephalomyelitis when it has been shown that teschovirus encephalomyelitis has not been present for at least the past 3 years.~~

~~This period shall be 6 months after the *slaughter* of the last affected *animal* for countries in which a *stamping out policy* is practised with or without vaccination against teschovirus encephalomyelitis.~~

~~Article 15.5.3.~~**Teschovirus encephalomyelitis infected zone**

~~A zone shall be considered as infected with teschovirus encephalomyelitis until:~~

- ~~1. at least 40 days have elapsed after the confirmation of the last *case* and the completion of a *stamping out policy* and *disinfection* procedures, or~~
- ~~2. 6 months have elapsed after the clinical recovery or *death* of the last affected *animal* if a *stamping out policy* was not practised.~~

~~Article 15.5.4.~~**Recommendations for importation from teschovirus encephalomyelitis free countries**

Annex 3 (contd)for domestic pigs

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:~~

- ~~1. showed no clinical sign of teschovirus encephalomyelitis on the day of shipment;~~
- ~~2. were kept in a country free from teschovirus encephalomyelitis since birth or for at least the past 40 days.~~

~~Article 15.5.5.~~**Recommendations for importation from teschovirus encephalomyelitis free countries**for wild pigs

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:~~

- ~~1. showed no clinical sign of teschovirus encephalomyelitis on the day of shipment;~~
- ~~2. come from a country free from teschovirus encephalomyelitis;~~

~~if the country of origin has a common border with a country considered infected with teschovirus encephalomyelitis:~~

- ~~3. were kept in a quarantine station for the 40 days prior to shipment.~~

~~Article 15.5.6.~~**Recommendations for importation from countries considered infected with teschovirus encephalomyelitis**for domestic pigs

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:~~

- ~~1. showed no clinical sign of teschovirus encephalomyelitis on the day of shipment;~~

Annex 3 (contd)

- ~~2. were kept since birth, or for the past 40 days, in an *establishment* where no *case* of teschovirus encephalomyelitis was officially reported during that period, and that the *establishment* of origin was not situated in a teschovirus encephalomyelitis *infected zone*; or~~
- ~~3. were kept in a *quarantine station* for the 40 days prior to shipment;~~
- ~~4. have not been vaccinated against teschovirus encephalomyelitis; or~~
- ~~5. were vaccinated against teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).~~

~~Article 15.5.7.~~~~**Recommendations for importation from countries considered infected with teschovirus encephalomyelitis**~~~~for wild pigs~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals*:~~

- ~~1. showed no clinical sign of teschovirus encephalomyelitis on the day of shipment;~~
- ~~2. were kept in a *quarantine station* for the 40 days prior to shipment;~~
- ~~3. have not been vaccinated against teschovirus encephalomyelitis; or~~
- ~~4. were vaccinated against teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).~~

~~Article 15.5.8.~~~~**Recommendations for importation from teschovirus encephalomyelitis free countries**~~~~for semen of pigs~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *donor animals*:~~

- ~~1. showed no clinical sign of teschovirus encephalomyelitis on the day of collection of the semen;~~

Annex 3 (contd)

2. were kept in a country free from teschovirus encephalomyelitis for not less than 40 days prior to collection.

~~Article 15.5.9.~~**~~Recommendations for importation from countries considered infected with teschovirus encephalomyelitis~~**~~for semen of pigs~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the donor animals:~~

1. showed no clinical sign of teschovirus encephalomyelitis on the day of collection of the semen;
2. were kept in the ~~exporting country~~, for the 40 days prior to collection, in an ~~establishment or artificial insemination centre~~ where no case of teschovirus encephalomyelitis was officially reported during that period, and that the ~~establishment or artificial insemination centre~~ was not situated in a teschovirus encephalomyelitis ~~infected zone~~.

~~Article 15.5.10.~~**~~Recommendations for importation from teschovirus encephalomyelitis free countries~~**~~for fresh meat of pigs~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat comes from animals:~~

1. which have been kept in a country free from teschovirus encephalomyelitis since birth or for at least the past 40 days;
2. which have been slaughtered in an approved ~~abattoir~~ and have been subjected to ante mortem and post mortem inspections for teschovirus encephalomyelitis with favourable results.

~~Article 15.5.11.~~**~~Recommendations for importation from countries considered infected with teschovirus encephalomyelitis~~**~~for fresh meat of pigs~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat comes from animals:~~

1. which have not been kept in a teschovirus encephalomyelitis ~~infected zone~~;

Annex 3 (contd)

2. which have been slaughtered in an approved *abattoir* not situated in a teschovirus encephalomyelitis *infected zone* and have been subjected to ante-mortem and post-mortem inspections for teschovirus encephalomyelitis with favourable results.

~~Article 15.5.12.~~

~~Recommendations for importation from countries considered infected with teschovirus encephalomyelitis~~

~~for meat products of pigs~~

~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:~~

- ~~1. the entire consignment of *meat products* comes from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for teschovirus encephalomyelitis with favourable results;~~
- ~~2. the *meat products* have been processed to ensure the destruction of the teschovirus encephalomyelitis virus;~~
- ~~3. the necessary precautions were taken after processing to avoid contact of the *meat* with any source of teschovirus encephalomyelitis virus.~~

~~Article 15.5.13.~~

~~Recommendations for importation from teschovirus encephalomyelitis free countries~~

~~for products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use~~

~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a country free from teschovirus encephalomyelitis since birth or for at least the past 40 days.~~

~~Article 15.5.14.~~

~~Recommendations for importation from countries considered infected with teschovirus encephalomyelitis~~

~~for meal and flour from blood, meat, defatted bones, hooves and claws (from pigs)~~

~~Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of teschovirus encephalomyelitis virus.~~

~~Article 15.5.15.~~

~~Recommendations for importation from countries considered infected with teschovirus encephalomyelitis~~

Annex 3 (contd)

for bristles

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products have been processed to ensure the destruction of teschovirus-encephalomyelitis virus, in premises controlled and approved by the Veterinary Authority of the exporting country.~~

— text deleted

CHAPTER 3.1.

VETERINARY SERVICES

EU position

The EU supports the adoption of this modified chapter.

Article 3.1.1.

The quality of the *Veterinary Services* depends on a set of factors, which include fundamental principles of an ethical, organisational, legislative, regulatory and technical nature. The *Veterinary Services* shall conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by the *Veterinary Services* of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members.

The same fundamental principles should apply in countries where the responsibility for establishing or applying certain animal health or welfare measures, or issuing some *international veterinary certificates* is exercised by an organisation other than the *Veterinary Services*, or by an authority or agency on behalf of the *Veterinary Services*. In all cases, the *Veterinary Services* retain ultimate responsibility for the application of these principles.

These fundamental principles are presented in Article 3.1.2. Other factors affecting quality are described in Volume 1 of the *Terrestrial Code* (notification, principles of certification, etc.).

The quality of *Veterinary Services*, including veterinary legislation ~~and regulations~~, can be measured through an evaluation, whose general principles are described in Article 3.1.3. and in Article 3.1.4.

Recommendations on the evaluation of *Veterinary Services*, including veterinary legislation, are described in Chapter 3.2.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

Article 3.1.2.

Fundamental principles of quality

The *Veterinary Services* shall comply with the following principles to ensure the quality of their activities:

1. Professional judgement

The personnel of *Veterinary Services* should have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

Care should be taken to ensure that *Veterinary Services'* personnel are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

Annex 4 (contd)3. Impartiality

The *Veterinary Services* should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

4. Integrity

The *Veterinary Services* should guarantee that the work of each of their personnel is of a consistently high level of integrity. Any fraud, corruption or falsification should be identified and corrected.

5. Objectivity

The *Veterinary Services* should at all times act in an objective, transparent and non-discriminatory manner.

6. Veterinary legislation

Veterinary legislation is prerequisite to support good governance and provide the legal framework for all key activities of the *Veterinary Services*.

Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, it should define and document the responsibilities and structure of the organisations in charge of the *animal identification system*, control of animal movements, animal disease control and reporting systems, epidemiological *surveillance* and communication of epidemiological information.

A similar demonstration should be made by *Veterinary Services* when they are in charge of veterinary public health activities.

7. General organisation

The *Veterinary Services* should be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of animal health and *animal welfare* measures, and of international veterinary certification activities.

The *Veterinary Services* should have at their disposal effective systems for animal disease *surveillance* and for *notification* of disease problems wherever they occur, in accordance with the provisions of the *Terrestrial Code*. Adequate coverage of animal populations should also be demonstrated. They should at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* should define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international veterinary certificates*.

Each position within the *Veterinary Services* which has an impact on their quality should be described. These job descriptions should include the requirements for education, training, technical knowledge and experience.

8. Quality policy

The *Veterinary Services* should define and document their policy and objectives for, and commitment to, quality, and should ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The recommendations for the quality and evaluation of *Veterinary Services* propose a suitable reference system, which should be used if a Member choose to adopt a quality system.

9. Procedures and standards

The *Veterinary Services* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

- a) programming and management of activities, including international veterinary certification activities;
- b) prevention, control and notification of disease *outbreaks*;
- c) *risk analysis*, epidemiological *surveillance* and zoning;
- d) inspection and sampling techniques;
- e) diagnostic tests for animal *diseases*;
- f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of *diseases*;
- g) border controls and import regulations;
- h) *disinfection* and *disinfestation*;
- i) treatments intended to destroy, if appropriate, pathogens in animal products.

Inasmuch as the OIE has adopted standards on these matters, the *Veterinary Services* should comply with these standards when applying animal health measures and when issuing *international veterinary certificates*.

10. Information, complaints and appeals

The *Veterinary Authority* should undertake to reply to legitimate requests from *Veterinary Authorities* of other Members or any other authority, in particular ensuring that any requests for information, complaints or appeals that they may present are dealt with in a timely manner.

A record should be maintained of all complaints and appeals and of the relevant action taken by the *Veterinary Services*.

11. Documentation

The *Veterinary Services* should have at their disposal a reliable and up-to-date documentation system suited to their activities.

Annex 4 (contd)12. Self-evaluation

The *Veterinary Services* should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the efficiency of their organisational components and resource adequacy.

A procedure for evaluating *Veterinary Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

13. Communication

Veterinary Services should have effective internal and external systems of communication covering administrative and technical staff and parties affected by their activities.

14. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 3.1.3.

For the purposes of the *Terrestrial Code*, every Member should recognise the right of another Member to undertake, or request it to undertake, an evaluation of its *Veterinary Services* where the initiating Member is an actual or a prospective importer or exporter of *commodities* and where the evaluation is to be a component of a *risk analysis* process which is to be used to determine or review sanitary measures which apply to such trade.

Any evaluation of *Veterinary Services* should be conducted having regard to the OIE recommendations on the evaluation of *Veterinary Services* presented in Chapter 3.2.

A Member has the right to expect that the evaluation of its *Veterinary Services* will be conducted in an objective manner. A Member undertaking evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 3.1.4.

A Member which intends to conduct an evaluation of another Member's *Veterinary Services* should give them notice in writing. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its *Veterinary Services* by another Member, and following bilateral agreement of the evaluation process and criteria, a Member should expeditiously provide the other country with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 3.1.1. and in Article 3.1.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 3.1.1., prevailing in the countries concerned.

The outcome of the evaluation conducted by a Member should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Members over the conduct or the conclusions of the evaluation of the *Veterinary Services*, the matter should be dealt with having regard to the procedures set out in Article 5.3.8.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of the *Veterinary Services* of a Member, upon request by the Member.

The World Assembly of OIE Delegates endorses a list of approved experts to facilitate the evaluation process.

Under these procedures, the Director General of the OIE recommends an expert(s) from that list.

The expert(s) facilitate(s) the evaluation of the *Veterinary Services* of the Member based on the provisions in Chapter 3.2., using the OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE *PVS Tool*).

The expert(s) produce(s) a report in consultation with the *Veterinary Services* of the Member.

The report is submitted to the Director General of the OIE and, with the consent of the Member, published by the OIE.

— text deleted

CHAPTER 3.2.

EVALUATION OF
VETERINARY SERVICES**EU position**

The EU would support the adoption of this modified chapter but has a comment that should be taken into account before adoption.

Article 3.2.1.

General considerations

1. Evaluation of *Veterinary Services* is an important element in the *risk analysis* process which countries may legitimately use in their policy formulations directly applying to animal health and sanitary controls of *international trade in animals*, animal-derived products, animal genetic material and animal feedstuffs.

Any evaluation should be carried out with due regard for Chapter 3.1.

2. In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these recommendations which can be practically applied to the evaluation of *Veterinary Services*. These are relevant for evaluation of the *Veterinary Services* of one country by those of another country for the purposes of *risk analysis* in *international trade*. The recommendations are also applicable for evaluation by a country of its own *Veterinary Services* – the process known as self-evaluation – and for periodic re-evaluation. These recommendations should be used by OIE experts when facilitating an evaluation under the auspices of the OIE, following a request of a Member. In applying these recommendations on the evaluation, the OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE *PVS Tool*) should be used.

In carrying out a *risk analysis* prior to deciding the sanitary/zoosanitary conditions for the importation of a *commodity*, an *importing country* is justified in regarding its evaluation of the *Veterinary Services* of the *exporting country* as critical.

3. The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of *risk analysis* in *international trade in animals* and animal-derived products to which official sanitary and/or zoosanitary controls apply.
4. In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include adequacy of resources, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and history of performance, including *disease* reporting.
5. Good governance is the key to competence, integrity and confidence in organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade in animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.

6. Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.
7. An *importing country* has a right of assurance that information on sanitary/zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.
8. An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.
9. As the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration/licensing of *veterinarians* and authorisation of *veterinary para-professionals* is included.

Article 3.2.2.

Scope

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:
 - organisation, structure and authority of the *Veterinary Services*;
 - human resources;
 - material (including financial) resources;
 - veterinary legislation, regulatory frameworks and functional capabilities;
 - animal health, *animal welfare* and veterinary public health controls;
 - formal quality systems including quality policy;
 - performance assessment and audit programmes;
 - participation in OIE activities and compliance with OIE Members' obligations.
2. To complement the evaluation of *Veterinary Services*, the legislative and regulatory framework, the organisational structure and functioning of the *veterinary statutory body* should also be considered.
3. Article 3.2.14. outlines appropriate information requirements for:
 - self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
 - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
 - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
 - evaluation by third parties such as OIE PVS experts or regional organisations.

Annex 4 (contd)

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

1. A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.
2. The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.
3. Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological *surveillance*, *disease* control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.
4. To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.
5. The *Veterinary Authority* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and compartmentalisation are being applied. The responsibilities of the *Veterinary Authority* should be made clear in the process of evaluation of *Veterinary Services*.
6. The *Veterinary Authority* is defined in the Glossary of the *Terrestrial Code*. As some countries have some relevant roles of the *Veterinary Authority* vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the *Veterinary Authority* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.
7. Similarly, where the *Veterinary Authority* has arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the organisational and functional standards that apply to the *Veterinary Authority* should also apply to the service providers.

Article 3.2.4.

Evaluation criteria for quality systems

1. The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.
2. Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Article 3.2.5.

Evaluation criteria for human resources

1. The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core should always include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.
2. In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that *disease* monitoring is being conducted by a sufficient number of qualified, experienced field *veterinarians* who are directly involved in farm visits; there should not be an over-reliance on *veterinary para-professionals* for this task.
3. Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private *veterinarians* would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of *notifiable diseases*) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.
4. These data should be assessed in close conjunction with the other information described in this chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Annex 4 (contd)

Article 3.2.6.

Evaluation criteria for material resources1. Financial

Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 3.2.14. Information is required on conditions of service for veterinary staff (including salaries and incentives), and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to *veterinarians* in their official responsibilities.

2. Administrative

a. Accommodation

The *Veterinary Services* should be accommodated in premises suitable for efficient performance of their functions. The component parts of the *Veterinary Services* should be located as closely as possible to each other at the central level, and in the regions where they are represented, in order to facilitate efficient internal communication and function.

b. Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes. Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between laboratories and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

Examples of types of communications which should be routinely available on an adequate country-wide basis are national postal, freight and telephone networks. Rapid courier services, facsimile and electronic data interchange systems (e.g. e-mail and Internet services) are examples of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the *Veterinary Authority*, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart *Veterinary Authorities* in trading-partner countries.

c. Transport systems

The availability of sufficient reliable transport facilities is essential for the performance of many functions of *Veterinary Services*. This applies particularly to the field services components of animal health activities (e.g. emergency response visits). Otherwise, the *Veterinary Services* cannot assure counterpart services in other countries that they are in control of the animal health situation within the country.

Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary laboratories, for inspection of imports and exports, and for the performance of *animals* and animal product inspection in outlying production or processing establishments.

3. Technical

Details available on laboratories should include resources data, programmes under way as well as those recently completed and review reports on the role or functions of the laboratory. Information as described in the model questionnaire should be used in the evaluation of laboratory services.

a. Cold chain for laboratory samples and veterinary medicines

Adequate refrigeration and freezing systems should be available and should be used throughout the country to provide suitable low temperature protection for laboratory samples in transit or awaiting analysis, as well as veterinary medical products (e.g. vaccines) when these are required for use in animal disease control programmes. If these assurances cannot be given, it may be valid to discount many types of test results, as well as the effectiveness of certain disease control programmes and the export inspection system in the country undergoing evaluation.

b. Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic laboratories of a country underpins the whole control and certification processes of the zoosanitary/sanitary status of exported *animals* and animal products, and therefore these laboratories should be subject to rigid quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic laboratories include those which are concerned with either animal health or veterinary public health activities. The *Veterinary Services* should approve and designate these laboratories for such purposes and have them audited regularly.

c. Research

The scope of animal disease and veterinary public health problems in the country concerned, the stages reached in the controls which address those problems and their relative importance can be measured to some degree by analysis of information on government priorities and programmes for research in animal health. This information should be accessible for evaluation purposes.

Annex 4 (contd)

Article 3.2.7.

Legislation and functional capabilities1. Animal health, animal welfare and veterinary public health

The *Veterinary Authority* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise control over all animal health matters. These controls should include, where appropriate, compulsory notification of prescribed animal diseases, inspection, movement controls through systems which provide adequate traceability, registration of facilities, quarantine of infected premises/areas, testing, treatment, destruction of infected *animals* or contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic *animals* and their reproductive material, animal products, wildlife as it relates to the transmission of *diseases* to humans and domestic *animals*, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the *Veterinary Authorities* of the neighbouring countries for the control of animal *diseases* in border areas and for establishing linkages to recognise and regulate transboundary activities. Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities include *animal welfare*. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export/import inspection

The *Veterinary Authority* should have appropriate legislation and adequate capabilities to prescribe the methods for control and to exercise systematic control over the import and export processes of *animals* and animal products in so far as this control relates to sanitary and zoosanitary matters. The evaluation should also involve the consideration of administrative instructions to ensure the enforcement of *importing country* requirements during the pre-export period.

In the context of production for export of foodstuffs of animal origin, the *Veterinary Authority* should demonstrate that comprehensive legislative provisions are available for the oversight by the relevant authorities of the hygienic process and to support official inspection systems of these *commodities* which function to standards consistent with or equivalent to relevant Codex Alimentarius and OIE standards.

Control systems should be in place which permit the exporting *Veterinary Authority* to approve export premises. The *Veterinary Services* should also be able to conduct testing and treatment as well as to exercise controls over the movement, handling and storage of exports and to make inspections at any stage of the export process. The product scope of this export legislation should include, *inter alia*, *animals* and animal products (including animal semen, ova and embryos), and animal feedstuffs.

The *Veterinary Authority* should be able to demonstrate that they have adequate capabilities and legislative support for zoosanitary control of imports and transit of *animals*, animal products and other materials which may introduce animal *diseases*. This could be necessary to support claims by the *Veterinary Services* that the animal health status of the country is suitably stable, and that cross-contamination of exports from imports of unknown or less favourable zoosanitary status is unlikely. The same considerations should apply in respect of veterinary control of public health. The *Veterinary Services* should be able to demonstrate that there is no conflict of interest when certifying veterinarians are performing official duties.

Legislation should also provide the right to deny and/or withdraw official certification. Penalty provisions applying to malpractice on the part of certifying officials should be included.

Annex 4 (contd)

The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on Chapters 5.1. and 5.2. of the *Terrestrial Code*. They should have appropriately organised procedures which ensure that sanitary/animal health certificates are issued by efficient and secure methods. The documentation control system should be able to correlate reliably the certification details with the relevant export consignments and with any inspections to which the consignments were subjected.

Security in the export certification process, including electronic documentation transfer, is important. A system of independent compliance review is desirable, to safeguard against fraud in certification by officials and by private individuals or corporations. The certifying veterinarian should have no conflict of interest in the commercial aspects of the *animals* or animal product being certified and be independent from the commercial parties.

Article 3.2.8.

Animal health controls1. Animal health status

An updated assessment of the present animal disease status of a country is an important and necessary procedure. For this undertaking, studies of the OIE publications such as *World Animal Health*, the *Bulletin* and *Disease Information* should be fundamental reference points. The evaluation should consider the recent history of the compliance of the country with its obligations regarding international notification of animal *diseases*. In the case of an OIE Member, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

An *exporting country* should be able to provide further, detailed elaboration of any elements of its animal disease status as reported to the OIE. This additional information will have particular importance in the case of animal *diseases* which are foreign to or strictly controlled in the *importing country* or region. The ability of the *Veterinary Services* to substantiate elements of their animal disease status reports with surveillance data, results of monitoring programmes and details of disease history is highly relevant to the evaluation. In the case of evaluation of the *Veterinary Services* of an *exporting country* for *international trade* purposes, an *importing country* should be able to demonstrate the reasonableness of its request and expectations in this process.

2. Animal health control

Details of current animal disease control programmes should be considered in the evaluation. These programmes would include epidemiological surveillance, official government-administered or officially-endorsed, industry-administered control or eradication programmes for specific *diseases* or *disease* complexes, and animal disease emergency preparedness. Details should include enabling legislation, programme plans for epidemiological surveillance and animal disease emergency responses, quarantine arrangements for infected and exposed animals or *herds*, compensation provisions for animal owners affected by disease control measures, training programmes, physical and other barriers between the free country or zone and those infected, incidence and prevalence data, resource commitments, interim results and programme review reports.

3. National animal disease reporting systems

The presence of a functional animal disease reporting system which covers all agricultural regions of the country and all veterinary administrative control areas should be demonstrated.

Annex 4 (contd)

An acceptable variation would be the application of this principle to specific zones of the country. In this case also, the animal disease reporting system should cover each of these zones. Other factors should come to bear on this situation, e.g. the ability to satisfy trading partners that sound animal health controls exist to prevent the introduction of *disease* or export products from regions of lesser veterinary control.

Article 3.2.9.

Veterinary public health controls1. Food hygiene

The *Veterinary Authority* should be able to demonstrate effective responsibility for the veterinary public health programmes relating to the production and processing of animal products. If the *Veterinary Authority* does not exercise responsibility over these programmes, the evaluation should include a comprehensive review of the role and relationship of the organisations (national, state/provincial, and municipal) which are involved. In such a case, the evaluation should consider whether the *Veterinary Authority* can provide guarantees of responsibility for an effective control of the sanitary status of animal products throughout the *slaughter*, processing, transport and storage periods.

2. Zoonoses

Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities include the monitoring and control of zoonotic diseases and, where appropriate, liaison with medical authorities.

3. Chemical residue testing programmes

Adequacy of controls over chemical residues in exported *animals*, animal products and feedstuffs should be demonstrated. Statistically-based *surveillance* and monitoring programmes for environmental and other chemical contaminants in *animals*, in animal-derived foodstuffs and in animal feedstuffs should be favourably noted. These programmes should be coordinated nationwide. Correlated results should be freely available on request to existing and prospective trading partner countries. Analytical methods and result reporting should be consistent with internationally recognised standards. If official responsibility for these programmes does not rest with the *Veterinary Services*, there should be appropriate provision to ensure that the results of such programmes are made available to the *Veterinary Services* for assessment. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

4. Veterinary medicines

It should be acknowledged that primary control over veterinary medicinal products may not rest with the *Veterinary Authority* in some countries, owing to differences between governments in the division of legislative responsibilities. However, for the purpose of evaluation, the *Veterinary Authority* should be able to demonstrate the existence of effective controls (including nationwide consistency of application) over the manufacture, importation, export, registration, supply, sale and use of veterinary medicines, biologicals and diagnostic reagents, whatever their origin. The control of veterinary medicines has direct relevance to the areas of animal health and public health.

Annex 4 (contd)

In the animal health sphere, this has particular application to biological products. Inadequate controls on the registration and use of biological products leave the *Veterinary Services* open to challenge over the quality of animal disease control programmes and over safeguards against *animal disease* introduction in imported veterinary biological products.

It is valid, for evaluation purposes, to seek assurances of effective government controls over veterinary medicines in so far as these relate to the public health risks associated with residues of these chemicals in *animals* and animal-derived foodstuffs. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

5. Integration between animal health controls and veterinary public health

The existence of any organised programme which incorporates a structured system of information feedback from inspection in establishments producing products of animal origin, in particular *meat* or dairy products, and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national disease surveillance scheme.

Veterinary Services which direct a significant element of their animal health programmes specifically towards minimising microbial and chemical contamination of animal-derived products in the human food chain should receive favourable recognition in the evaluation. There should be evident linkage between these programmes and the official control of veterinary medicines and relevant agricultural chemicals.

Article 3.2.10.

Performance assessment and audit programmes

1. Strategic plans

The objectives and priorities of the *Veterinary Services* can be well evaluated if there is a published official strategic plan which is regularly updated. Understanding of functional activities is enhanced if an operational plan is maintained within the context of the strategic plan. The strategic and operational plans, if these exist, should be included in the evaluation.

Veterinary Services which use strategic and operational plans may be better able to demonstrate effective management than countries without such plans.

2. Performance assessment

If a strategic plan is used, it is desirable to have a process which allows the organisation to assess its own performance against its objectives. Performance indicators and the outcomes of any review to measure achievements against pre-determined performance indicators should be available for evaluation. The results should be considered in the evaluation process.

3. Compliance

Matters which can compromise compliance and adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or interference by higher political levels in international veterinary certification, and lack of resources and poor infrastructure.

It is desirable that the *Veterinary Services* contain (or have a formal linkage with) an independent internal unit/section/commission the function of which is to critically scrutinise their operations.

Annex 4 (contd)

The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

An important feature when demonstrating the integrity of the *Veterinary Services* is their ability to take corrective action when miscertification, fraud or corruption has occurred.

A supplementary or an alternative process for setting performance standards and application of monitoring and audit is the implementation of formal quality systems to some or all activities for which the *Veterinary Services* are responsible. Formal accreditation to international quality system standards should be utilised if recognition in the evaluation process is to be sought.

4. Veterinary Services administration

a. Annual reports

Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary Services*. Current and retrospective copies of such reports should be available to counterpart Services in other countries, especially trade partners.

b. Reports of government review bodies

The reports of any periodic or ad hoc government reviews of *Veterinary Services* or of particular functions or roles of the *Veterinary Services* should be considered in the evaluation process. Details of action taken as a consequence of the review should also be accessible.

c. Reports of special committees of enquiry or independent review bodies

Recent reports on the *Veterinary Services* or elements of their role or function, and details of any subsequent implementation of recommendations contained in these reports should be available. The *Veterinary Services* concerned should recognise that the provision of such information need not be detrimental to the evaluation outcome; in fact, it may demonstrate evidence of an effective audit and response programme. The supplying of such information can reinforce a commitment to transparency.

d. In-service training and development programme for staff

In order to maintain a progressive approach to meeting the needs and challenges of the changing domestic and international role of *Veterinary Services*, the national administration should have in place an organised programme which provides appropriate training across a range of subjects for relevant staff. This programme should include participation in scientific meetings of animal health organisations. Such a programme should be used in assessing the effectiveness of the Services.

e. Publications

Veterinary Services can augment their reputation by demonstrating that their staff publish scientific articles in refereed veterinary journals or other publications.

f. Formal linkages with sources of independent scientific expertise

Details of formal consultation or advisory mechanisms in place and operating between the *Veterinary Services* and local and international universities, scientific institutions or recognised veterinary organisations should be taken into consideration. These could serve to enhance the international recognition of the *Veterinary Services*.

g. Trade performance history

In the evaluation of the *Veterinary Services* of a country, it is pertinent to examine the recent history of their performance and integrity in trade dealings with other countries. Sources of such historical data may include Customs Services.

Article 3.2.11.

Participation in OIE activities

Questions on a country's adherence to its obligations as a member of the OIE are relevant to an evaluation of the *Veterinary Services* of the country. Self-acknowledged inability or repeated failure of a Member to fulfil reporting obligations to the OIE will detract from the overall outcome of the evaluation. Such countries, as well as non-member countries, will need to provide extensive information regarding their *Veterinary Services* and sanitary/zoosanitary status for evaluation purposes.

Article 3.2.12.

Evaluation of veterinary statutory body

1. Scope

In the evaluation of the *veterinary statutory body*, the following items may be considered, depending on the purpose of the evaluation:

- a. objectives and functions;
- b. legislative basis, autonomy and functional capacity;
- c. the composition and representation of the body's membership;
- d. accountability and transparency of decision-making;
- e. sources and management of funding;
- f. administration of training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

2. Evaluation of objectives and functions

The *veterinary statutory body* should define its policy and objectives, including detailed descriptions of its powers and functions such as:

- a. to regulate *veterinarians* and *veterinary para-professionals* through licensing and/or registration of such persons;

Annex 4 (contd)

- b. to determine the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;
 - c. to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.
3. Evaluation of legislative basis, autonomy and functional capacity

The *veterinary statutory body* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all *veterinarians* and *veterinary para-professionals*. These controls should include, where appropriate, compulsory licensing and registration, minimum standards of education (initial and continuing) for the recognition of degrees, diplomas and certificates, setting standards of professional conduct and exercising control and the application of disciplinary procedures.

The *veterinary statutory body* should be able to demonstrate autonomy from undue political and commercial interests.

Where applicable, regional agreements for the recognition of degrees, diplomas and certificates for *veterinarians* and *veterinary para-professionals* should be demonstrated.

4. Evaluation of membership representation

Detailed descriptions should be available in respect of the membership of the *veterinary statutory body* and the method and duration of appointment of members. Such information includes:

- a. *veterinarians* designated by the *Veterinary Authority*, such as the Chief Veterinary Officer;
 - b. *veterinarians* elected by members registered by the *veterinary statutory body*;
 - c. *veterinarians* designated or nominated by the veterinary association(s);
 - d. representative(s) of veterinary para-professions;
 - e. representative(s) of veterinary academia;
 - f. representative(s) of other stakeholders from the private sector;
 - g. election procedures and duration of appointment;
 - h. qualification requirements for members.
5. Evaluation of accountability and transparency of decision-making

Detailed information should be available on disciplinary procedures regarding the conducting of enquiries into professional misconduct, transparency of decision-making, publication of findings, sentences and mechanisms for appeal.

Additional information regarding the publication at regular intervals of activity reports, lists of registered or licensed persons including deletions and additions should also be taken into consideration.

Annex 4 (contd)6. Evaluation of financial sources and financial management

Information regarding income and expenditure, including fee structure(s) for the licensing/registration of persons should be available.

7. Evaluation of training programmes and programmes for continuing professional development, for veterinarians and veterinary para-professionals

Descriptive summary of continuing professional development, training and education programmes should be provided, including descriptions of content, duration and participants; documented details of quality manuals and standards relating to Good Veterinary Practice should be provided.

Article 3.2.13.

1. The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.
2. A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a *risk analysis* process, which is necessary to determine the sanitary or zoonosanitary measures which the country will use to protect human or animal life or health from *disease* or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.
3. In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 3.2.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study should be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country should be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 3.2.14.

This article outlines appropriate information requirements for the self-evaluation or evaluation of the *Veterinary Services* of a country.

1. Organisation and structure of Veterinary Services

a. National Veterinary Authority

Organisational chart including numbers, positions and numbers of vacancies.

b. Sub-national components of the Veterinary Authority

Organisational charts including numbers, positions and number of vacancies.

c. Other providers of veterinary services

Description of any linkage with other providers of veterinary services.

Annex 4 (contd)2. National information on human resources

a. Veterinarians

i. Total numbers of *veterinarians* registered/licensed by the *Veterinary statutory body* of the country.

ii. Numbers of:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions [*Describe accreditation standards, responsibilities and/or limitations applying to these private veterinarians.*];
- other *veterinarians*.

iii. Animal health:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area [*Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import/export and other functions, as applicable.*]:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

iv. Veterinary public health:

Numbers employed in food inspection on a majority time basis, by commodity [*Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable.*]:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

v. Numbers of veterinarians relative to certain national indices:

- per total human population;
- per farm livestock population, by geographical area;
- per livestock farming unit, by geographical area.

vi. Veterinary education:

- number of veterinary schools;

- length of veterinary course (years);
- curriculum addressing the minimum competencies of day 1 veterinary graduates to assure the delivery of quality Veterinary Services, as described by the OIE;

EU position

This additional point can only be adopted if the words ", as described by the OIE" are deleted, since there is no such description in the Code or the Manual, which are the only possible documents for cross reference in the Code.

The EU will provide further comments to the OIE on the report of the ad hoc group on veterinary education.

- international recognition of veterinary degree.
- vii. Veterinary professional associations.
- b. Graduate personnel (non-veterinary)
- Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within the *Veterinary Authority* and available to the *Veterinary Authority*.
- c. *Veterinary para-professionals* employed by the *Veterinary Services*
- i. Animal health:
- Categories and numbers involved with farm livestock on a majority time basis:
 - by geographical area;
 - proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
 - Education/training details.
- ii. Veterinary public health:
- Categories and numbers involved in food inspection on a majority time basis:
 - *meat* inspection: export *meat* establishments with an export function and domestic *meat* establishments (no export function);
 - dairy inspection;
 - other foods.
 - Numbers in import/export inspection.
 - Education/training details.
- d. Support personnel

Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).

- e. Descriptive summary of the functions of the various categories of staff mentioned above
- f. Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations
- g. Additional information and/or comments.

3. Financial management information

- a. Total budgetary allocations to the *Veterinary Authority* for the current and past two fiscal years:
 - i. for the national *Veterinary Authority*;
 - ii. for each of any sub-national components of the *Veterinary Authority*;
 - iii. for other relevant government-funded institutions.
- b. Sources of the budgetary allocations and amount:
 - i. government budget;
 - ii. sub-national authorities;
 - iii. taxes and fines;
 - iv. grants;
 - v. private services.
- c. Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.
- d. Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*
- e. Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

a. Accommodation

Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.

b. Communications

Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.

c. Transport

- i. Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.

- ii. Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

- a. Diagnostic laboratories (laboratories engaged primarily in diagnosis)
 - i. Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.
 - ii. Numbers of veterinary diagnostic laboratories operating in the country:
 - government operated laboratories;
 - private laboratories accredited by government for the purposes of supporting official or officially-endorsed animal health control or public health testing and monitoring programmes and import/export testing.
 - iii. Descriptive summary of accreditation procedures and standards for private *laboratories*.
 - iv. Human and financial resources allocated to the government veterinary *laboratories*, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.
 - v. List of diagnostic methodologies available against major *diseases* of farm livestock (including *poultry*).
 - vi. Details of collaboration with external *laboratories* including international reference laboratories and details on numbers of samples submitted.
 - vii. Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
 - viii. Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
 - ix. Details of procedures for storage and retrieval of information on specimen submission and results.
 - x. Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - xi. Strategic and operational plans for the official veterinary laboratory service (if available).
- b. Research laboratories (laboratories engaged primarily in research)
 - i. Numbers of veterinary research *laboratories* operating in the country:
 - government operated *laboratories*;
 - private *laboratories* involved in full time research directly related to animal health and veterinary public health matters involving production animal species.
 - ii. Summary of human and financial resources allocated by government to veterinary research.
 - iii. Published programmes of future government sponsored veterinary research.
 - iv. Annual reports of the government research *laboratories*.

6. Veterinary legislation, ~~regulations~~ and functional capabilities

- a. Animal health and veterinary public health
 - i. Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:
 - animal and veterinary public health controls at national frontiers;
 - control of endemic animal diseases, including zoonoses;
 - emergency powers for control of exotic disease outbreaks, including zoonoses;
 - inspection and registration of facilities;
 - animal feeding;
 - veterinary public health controls of the production, processing, storage and marketing of meat for domestic consumption;
 - veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;
 - registration and use of veterinary pharmaceutical products including vaccines;
 - animal welfare.
 - ii. Assessment of ability of *Veterinary Services* to enforce legislation.
- b. Export/import inspection
 - i. Assessment of the adequacy and implementation of relevant national legislation concerning:
 - veterinary public health controls of the production, processing, storage and transportation of meat for export;
 - veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;
 - animal health and veterinary public health controls of the export and import of animals, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
 - animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
 - animal health controls of importation of veterinary biological products including vaccines;
 - administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
 - documentation and compliance.
 - ii. Assessment of ability of *Veterinary Services* to enforce legislation.

7. Animal health and veterinary public health controls

- a. Animal health

- i. Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.
 - ii. Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.
 - iii. Description and relevant data of current official control programmes including:
 - epidemiological surveillance or monitoring programmes;
 - officially approved industry administered control or eradication programmes for specific *diseases*.
 - iv. Description and relevant details of animal disease emergency preparedness and response plans.
 - v. Recent history of animal disease status:
 - animal *diseases* eradicated nationally or from defined sub-national zones in the last ten years;
 - animal *diseases* of which the prevalence has been controlled to a low level in the last ten years;
 - animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;
 - *emerging diseases* in the last ten years;
 - animal *diseases* of which the prevalence has increased in the last ten years.
- b. Veterinary public health
- i. Food hygiene
 - Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).
 - Estimate of total annual slaughterings which occur but are not recorded under official statistics.
 - Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.
 - Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.
 - Numbers of commercial *fresh meat* establishments in the country which are registered for export by the *Veterinary Authority*:
 - *slaughterhouses* (indicate species of *animals*);
 - cutting/packing plants (indicate *meat* type);
 - *meat* processing establishments (indicate *meat* type);

- cold stores.
 - Numbers of commercial *fresh meat* establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.
 - Numbers of commercial *fresh meat* establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).
 - Description of the veterinary public health programme related to production and processing of animal products for human consumption (including *fresh meat, poultry meat, meat products, game meat, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin*) especially including details applying to exports of these *commodities*.
 - Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption and/or exports of the *commodities* concerned.
- ii. Zoonoses
- Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.
 - Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of *zoonoses* to be provided if the *Veterinary Authority* does not have these responsibilities.
- iii. Chemical residue testing programmes
- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
 - Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.
 - Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

Annex 4 (contd)

iv. Veterinary medicines

- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing *animals*.
- Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

8. Quality systems

a. Accreditation

Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of any components thereof.

b. Quality manuals

Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

c. Audit

Details of independent (and internal) audit reports which have been undertaken of the *Veterinary Services* of components thereof.

9. Performance assessment and audit programmes

a. Strategic plans and review

- i. Descriptive summary and copies of strategic and operational plans of the *Veterinary Services* organisation.
- ii. Descriptive summary of corporate performance assessment programmes which relate to the strategic and operational plans - copies of recent review reports.

b. Compliance

Descriptive summary of any compliance unit which monitors the work of the *Veterinary Services* (or elements thereof).

c. Annual reports of the Veterinary Authority

Copies of official annual reports of the national (sub-national) *Veterinary Authority*.

d. Other reports

- i. Copies of reports of official reviews into the function or role of the *Veterinary Services* which have been conducted within the past three years.
- ii. Descriptive summary (and copy of reports if available) of subsequent action taken on recommendations made in these reviews.

Annex 4 (contd)

e. Training

- i. Descriptive summary of in-service and development programmes provided by the *Veterinary Services* (or their parent Ministries) for relevant staff.
- ii. Summary descriptions of training courses and duration.
- iii. Details of staff numbers (and their function) who participated in these training courses in the last three years.

f. Publications

Bibliographical list of scientific publications by staff members of *Veterinary Services* in the past three years.

g. Sources of independent scientific expertise

List of local and international universities, scientific institutions and recognised veterinary organisations with which the *Veterinary Services* have consultation or advisory mechanisms in place.

10. Membership of the OIE

State if country is a member of the OIE and period of membership.

11. Other assessment criteria

— text deleted

CHAPTER 3.4.

COMMUNICATION

EU position

The EU thanks the OIE TAHSC and would support in general the adoption of guidelines on general principles of communication systems and examples of application, but has some important comments that should be taken into account.

In general, there is need for flexibility with respect to different organisational structures in OIE Members; this should be better taken into account in the wording. There is also a need to highlight in the General Consideration that the scope of this chapter does not relate to trade. The EU, in the framework of the Fifth Strategic Plan already highlighted the importance of better differentiation in the Codes and Manuals between standards relating or not to international trade.

Further specific comments are inserted in the text.

The adoption of this chapter during the 2011 General Session is not an emergency and discussions should continue until next General Session of 2012.

Article 3.4.1.

General considerations

In general communication entails the exchange of information between various individual, institutional and public audiences for purposes of informing, guiding and motivating action. The application of the science and technique of communication involves modulating messages according to situations, objectives and target audiences.

EU comment

In general, it should be considered to use the well accepted term “target groups” instead of “target audiences”.

The recognition of communication as a discipline of the *Veterinary Services* and its incorporation within it is critical for their operations. The integration of veterinary and communication expertises is essential for effective communication.

Communication should be an integral part of all the activities of the *Veterinary Services* including animal health (surveillance, early detection and rapid response, prevention and control), animal welfare and veterinary public health (food safety, zoonoses) and veterinary medicine.

Objectives of this chapter on communication for the *Veterinary Services* are to provide guidance for the development of a communication system, strategic and operational communication plans and elements to assess their quality.

Article 3.4.2.

Principles of communication

1. *Veterinary Services* should have the authority and capability to communicate on matters within their mandate.
2. Veterinary and communication expertises should be combined.

3. Communication should be targeted and follow the fundamental criteria of transparency, consistency, timeliness, balance, accuracy, honesty and empathy and respect the fundamental principles of quality of *Veterinary Services* (article 3.1.2.).
4. Communication should be a continuous process.
5. *Veterinary Services* should be responsible for planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.4.3.

Definitions

Communication

means the discipline of informing, ~~influencing~~ guiding and motivating individual, institutional and public audiences, ~~preferably ideally~~ on the basis of interactive exchanges, about any issue ~~falling under the mandate of the OIE and~~ under the competence of the *Veterinary Services*.

Crisis

means a ~~time situation~~ of great ~~danger~~ threat, difficulty or uncertainty when ~~problems related to any issues falling under the mandate of the OIE and~~ the competence of the *Veterinary Services* require immediate action.

Crisis Communication

means the process of ~~providing~~ communicating information of potentially incomplete nature within time constraints in the event of a crisis, that allows an individual, affected and/or interested parties, an entire community or the general public to make best possible decisions and be informed of and/or accept policy decisions and rationale behind policy decisions during a crisis.

EU comment

The following, slightly modified wording is proposed for reasons of clarity:

"means the process of communicating information as quickly and accurately as possible, even of potentially incomplete nature within time constraints in the event of a crisis, including, where applicable, actions necessary within the meaning of outbreak communication."

(NB: the word "crisis" should not be italicised as the definition stands only for this chapter.)

Outbreak communication

means the process of communicating in the event of an *outbreak*. Outbreak communication includes *notification*.

Article 3.4.4.

Communication system

In addition to the Principles for Communication the following **critical** elements should be used in conjunction with Chapter 3.1., when planning, implementing and assessing a communication system:

Critical elements

1. Authority and organizational structure

- a) Legislation providing authority to *Veterinary Services* under the responsibility of the CVO to communicate on matters within their mandate

~~b) Identified and accessible official contact points for communication~~

~~e)1. Organisational chart indicating a direct link between the communication personnel and to the Veterinary Authority, CVO through the chain of command (e.g. dedicated communication unit, communication officer)~~

2. Human resources

~~a) Identified and accessible official communication focal point~~

~~ab) Job descriptions of communication personnel identifying roles and responsibilities~~

~~bc) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication~~

~~ed) Continuous training and education on communication provided to communication personnel~~

3. Financial and ~~material-physical~~ resources

a) Clearly identified budget for communication that provides adequate funding

b) Provision and/or access to appropriate material resources in order to carry out roles and responsibilities: suitable premise/accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet

4. Management of the communication system

a) Roles and responsibilities of the communication unit

i) Report to the ~~CVO-Veterinary Authority~~

ii) Engaged in decision-making process

EU comment

The points ii and v should be merged, since the engagement of the communication unit is in order to provide guidance.

iii) ~~Be R~~ responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures

iv) Function as contact point on communication issues for the *Veterinary Services*

v) Provide guidance and expertise on communication issues to the *Veterinary Services*

vi) Provide and coordinate continuous education on communication for the *Veterinary Services*

EU comment

The words "communication unit" should be replaced by "communication personnel" and "contact point" by "focal point", to be in line with the modified wording proposed in No 1 and 2 of the present Article.

b) Strategic plan for communication

A well-designed strategic plan for communication should support the *Veterinary Services* strategic plan and have management support and commitment. The strategic plan for communication should address all high level organization-wide communication objectives. The plan should be a long-term plan.

A strategic plan for communication should be monitored, periodically reviewed and should identify measurable performance objectives and techniques to assess.

EU comment

The words "the success of communication activities" should be added at the end of the sentence (after "to assess").

The strategic plan for communication should consider the different types of communication: routine communication, risk communication, outbreak communication and crisis communication, to allow individuals, affected and/or interested parties, an entire community or the general public to make best possible decisions and be informed of and/or accept policy decisions and their rationale.

EU comment

The words "risk communication" should be italicised in the above paragraph as there is a definition in the Glossary.

The key outcomes in effectively implementing a strategic plan for communication are increased knowledge and awareness of issues by the public and stakeholders, higher understanding of the role of the Veterinary Services, higher visibility of and improved trust and credibility in the Veterinary Services. These will enhance understanding and/or acceptance of policy decisions and subsequent change of perception, attitude and/or behaviour.

EU comment

The words "Veterinary Services" should be italicised (twice) in the above paragraph.

c) Operational plans for communication

Operational plans for communication should be based on the assessment of specific issues and should identify specific objectives and target audiences such as staff, partners, stakeholders, media and the general public.

Each operational plan for communication should consist of a well-planned series of activities using different techniques, tools, messages and channels to achieve intended objectives and utilizing available resources within a specific timeframe.

— text deleted

CHAPTER 4.2.

**DESIGN AND IMPLEMENTATION OF
IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL
TRACEABILITY**

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 4.2.1.

Introduction and objectives

These recommendations are based on the general principles presented in Article 4.1.1. The recommendations outline for Members the basic elements that need to be taken into account in the design and implementation of an *animal identification system* to achieve *animal traceability*. Whatever *animal identification system* the country adopts, it should comply with relevant OIE standards, including Chapters 5.10. to 5.12. for *animals* and animal products intended for export. Each country should design a programme in accordance with the scope and relevant performance criteria to ensure that the desired *animal traceability* outcomes can be achieved.

Article 4.2.2.

Definitions

For the purpose of this chapter:

Desired outcomes: describe the overall goals of a programme and are usually expressed in qualitative terms, e.g. ‘to help ensure that *animals* and/or animal products are safe and suitable for use’. Safety and suitability for use could be defined in terms such as animal health, food safety, trade and aspects of animal husbandry.

Performance criteria: are specifications for performance of a programme and are usually expressed in quantitative terms, such as ‘all *animals* can be traced to the *establishment* of birth within 48 hours of an enquiry’.

Reporting: means advising the *Veterinary Authority* and other partner organisations as appropriate in accordance with the procedures listed in the programme.

Scope: specifies the targeted species, population and/or production/trade sector within a defined area (country, *zone*) or *compartment* that is the subject of the *identification* and *traceability* programme.

Transhumance: periodic/seasonal movements of *animals* between different pastures within or between countries.

Article 4.2.3.

Key elements of the animal identification system1. Desired outcomes

Desired outcomes should be defined through consultation between the *Veterinary Authority* and interested other parties, which should include (depending on scope) those in the animal production and processing chain, producers and food processors, private sector veterinarians, scientific research

organisations and other public and private organisations ~~government agencies~~. Desired outcomes may be defined in terms of any or all of the following:

- a) animal health (e.g. *disease surveillance* and notification; detection and control of *disease*; vaccination programmes);
- b) public health (e.g. *surveillance* and control of zoonotic diseases and food safety);
- c) management of emergencies e.g. natural catastrophies or man-made events;
- d) trade (support for inspection and certification activities of *Veterinary Services*, as described in Chapters 5.10. to 5.12. which reproduce model international veterinary certificates);
- e) aspects of animal husbandry such as animal performance, and genetic data.

2. Scope

Scope should also be defined through consultation between the *Veterinary Authority* and other parties, as discussed above. The scope of *animal identification systems* is often based on the definition of a species and sector, to take account of particular characteristics of the farming systems e.g. pigs in pork export production; poultry in a defined *compartment*; cattle within a defined FMD free *zone*. Different systems will be appropriate according to the production systems used in countries and the nature of their industries and trade.

3. Performance criteria

Performance criteria are also designed in consultation with other parties, as discussed above. The performance criteria depend on the desired outcomes and scope of the programme. They are usually described in quantitative terms according to the epidemiology of the *disease*. For example, some countries consider it necessary to trace susceptible *animals* within 24-48 hours when dealing with highly contagious *diseases* such as FMD and avian influenza. For food safety, animal tracing to support investigation of incidents may also be urgent. For chronic animal *diseases* that are not *zoonoses*, it may be considered appropriate that *animals* can be traced over a longer period.

4. Preliminary studies

In designing *animal identification systems* it is useful to conduct preliminary studies, which should take into account:

- a) animal populations, species, distribution, *herd* management,
- b) farming and industry structures, production and location,
- c) animal health,
- d) public health,
- e) trade issues,
- f) aspects of animal husbandry,
- g) zoning and compartmentalisation,
- h) animal movement patterns (including transhumance),
- i) information management and communication,

- j) availability of resources (human and financial),
- k) social and cultural aspects,
- l) stakeholder knowledge of the issues and expectations,
- m) gaps between current enabling legislation and what is needed long term,
- n) international experience,
- o) national experience,
- p) available technology options,
- q) existing identification system(s),
- r) expected benefits from the *animal identification systems* and *animal traceability* and to whom they accrue,
- s) issues pertaining to data ownership and access rights,
- t) reporting requirements.

Pilot projects may form part of the preliminary study to test the *animal identification system* and *animal traceability* and to gather information for the design and the implementation of the programme.

Economic analysis may consider costs, benefits, funding mechanisms and sustainability.

5. Design of the programme

a) General provisions

The programme should be designed in consultation with the stakeholders to facilitate the implementation of the *animal identification system* and *animal traceability*. It should take into account the scope, performance criteria and desired outcomes as well as the results of any preliminary study.

All the specified documentation should be standardised as to format, content and context.

To protect and enhance the integrity of the system, procedures should be incorporated into the design of the programme to prevent, detect and correct errors e.g. use of algorithms to prevent duplication of identification numbers and to ensure plausibility of data.

b) Means of animal identification

The choice of a physical animal or group identifier should consider elements such as the durability, human resources, species and age of the *animals* to be identified, required period of identification, cultural aspects, *animal welfare*, technology, compatibility and relevant standards, farming practices, production systems, animal population, climatic conditions, resistance to tampering, trade considerations, cost, and retention and readability of the identification method.

Annex 6 (contd)

The *Veterinary Authority* is responsible for approving the materials and equipment chosen, to ensure that these means of animal identification comply with technical and field performance specifications, and for the supervision of their distribution. The *Veterinary Authority* is also responsible for ensuring that identifiers are unique and are used in accordance with the requirements of the *animal identification system*.

The *Veterinary Authority* should establish procedures for *animal identification* and *animal traceability* including:

- i) the *establishment* of birth, and time period within which an *animal* is born;
- ii) when *animals* are introduced into an *establishment*;
- iii) when an *animal* loses its identification or the identifier becomes unusable;
- iv) arrangements and rules for the destruction and/or reuse of identifiers;
- v) penalties for the tampering and/or removal of official animal identification devices.

Where group identification without a physical identifier is adequate, documentation should be created specifying at least the number of *animals* in the group, the species, the date of identification, the person legally responsible for the *animals* and/or *establishment*. This documentation constitutes a unique group identifier and it should be updated to be traceable if there are any changes.

Where all *animals* in the group are physically identified with a group identifier, documentation should also specify the unique group identifier.

c) Registration

Procedures need to be incorporated into the design of the programme in order to ensure that relevant events and information are registered in a timely and accurate manner.

Depending on the scope, performance criteria and desired outcomes, records as described below should specify, at least, the species, the unique animal or group identifier, the date of the event, the identifier of the *establishment* where the event took place, and the code for the event itself.

i) Establishments/owners or responsible keepers

Establishments where *animals* are kept should be identified and registered, including at least their physical location (such as geographical coordinates or street address), the type of establishment and the species kept. The register should include the name of the person legally responsible for the *animals* at the establishment.

The types of establishments that may need to be registered include holdings (farms), assembly centres (e.g. agriculture shows and fairs, sporting events, transit centres, breeding centres), *markets*, *abattoirs*, rendering plants, dead stock collection points, transhumance areas, centres for necropsy and diagnosis, research centres, zoos, *border posts*, *quarantine stations*.

In cases where the registration of establishments is not applicable e.g. some transhumance systems, the animal owner, the owner's place of residence and the species kept should be recorded.

Annex 6 (contd)

ii) Animals

Animal identification and species should be registered for each establishment/owner. Other relevant information about the *animals* at each establishment/owner may also be recorded (e.g. date of birth, production category, sex, breed, number of *animals* of each species, *animal identification* of the parents).

iii) Other events

The *registration* of animal movements is necessary to achieve *animal traceability*. When an *animal* is introduced into or leaves an establishment, these events constitute a movement.

Some countries classify birth, *slaughter* and *death* of the *animal* as movements. When establishments are not registered as part of the *animal identification system*, ownership and location changes constitute a movement record.

The information registered should include the date of the movement, the establishment from which the *animal* or group of *animals* was dispatched, the number of *animals* moved, the destination establishment, and any establishment used in transit. ~~The Movement recording~~ may also include a description of the means of transport and the identification of the vehicle/vessel/identifier.

Procedures should be in place to maintain *animal traceability* during *transport* and when *animals* arrive at and leave an establishment.

The following events may also be registered:

- birth, *slaughter* and *death* of the *animal* (when not classified as a movement),
- attachment of the unique identifier to an *animal*,
- change of owner or keeper regardless of change of establishment,
- observation of an *animal* on an establishment (testing, health investigation, health certification, etc.),
- animal imported: a record of the *animal identification* from the *exporting country* should be kept and linked with the *animal identification* assigned in the *importing country*,
- animal exported: a record of the *animal identification* from the *exporting country* should be provided to the *Veterinary Authority* in the *importing country*,
- animal identifier lost or replaced,
- animal missing (lost, stolen, etc.),
- animal identifier retired (at *slaughter*, following loss of the identifier or *death* of the *animal* on a farm, at diagnostic *laboratories*, etc.).

d) Documentation

Documentation requirements should be clearly defined and standardised, according to the scope, performance criteria and desired outcomes and supported by the legal framework.

Annex 6 (contd)

e) Reporting

Depending on the scope, performance criteria and desired outcomes, relevant information (such as *animal identification*, movement, events, changes in numbers of livestock, *establishments*) should be reported to the *Veterinary Authority* by the person responsible for the *animals*.

f) Information system

An information system should be designed according to the scope, performance criteria and desired outcomes. This may be paper based or electronic. The system should provide for the collection, compilation, storage and retrieval of information on matters relevant to *registration*. The following considerations are important:

- have the potential for linkage to traceability in the other parts of the food chain;
- minimize duplication;
- relevant components, including databases, should be compatible;
- confidentiality of data;
- appropriate safeguards to prevent the loss of data, including a system for backing up the data.

The *Veterinary Authority* should have access to this information system as appropriate to meet the scope, performance criteria and desired outcomes.

g) Laboratories

The results of diagnostic tests should record the animal identifier or the group identifier, the date of sample was taken from the *animal* and the establishment where the sample was collected.

h) Abattoirs, rendering plants, dead stock collection points, markets and assembly centres

Abattoirs, rendering plants, dead stock collection points, *markets* and assembly centres should document arrangements for the maintenance of *animal identification* and *animal traceability* in compliance with the legal framework.

These establishments are critical points for control of animal health and food safety.

Animal identification should be recorded on documents accompanying samples collected for analysis.

The components of the *animal identification system* operating within *abattoirs* should complement and be compatible with arrangements for tracking animal products throughout the food chain. At an *abattoir*, *animal identification* should be maintained during the processing of the *animal's* carcass until the carcass is deemed fit for human consumption.

The *animal identification* and the establishment from which the *animal* was dispatched should be registered by the *abattoir*, rendering plant and dead stock collection points.

Annex 6 (contd)

Abattoirs, rendering plants and dead stock collection points should ensure that identifiers are collected and disposed of according to the procedures established and regulated within the legal framework. These procedures should minimize the risk of unauthorized reuse and, if appropriate, should establish arrangements and rules for the reuse of identifiers.

Reporting of movement by *abattoirs*, rendering plants and dead stock collection points should occur according to the scope, performance criteria and desired outcomes and the legal framework.

i) Penalties

Different levels and types of penalties should be defined in the programme and supported by the legal framework.

6. Legal framework

The *Veterinary Authority*, with other relevant governmental agencies and in consultation with stakeholders, should establish a legal framework for the implementation and enforcement of *animal identification system* and *animal traceability* in the country. The structure of this framework will vary from country to country.

Animal identification, *animal traceability* and animal movement should be under the responsibility of the *Veterinary Authority*.

This legal framework should address:

- i) desired outcomes and scope;
- ii) obligations of the *Veterinary Authority* and other parties;
- iii) organisational arrangements, including the choice of technologies and methods used for the *animal identification system* and *animal traceability*;
- iv) management of animal movement;
- v) confidentiality of data;
- vi) data access / accessibility;
- vii) checking, verification, inspection and penalties;
- viii) where relevant, funding mechanisms;
- ix) where relevant, arrangements to support a pilot project.

7. Implementation

a) Action plan

For implementing the *animal identification system*, an action plan should be prepared specifying the timetable and including the milestones and performance indicators, the human and financial resources, and checking, enforcement and verification arrangements.

Annex 6 (contd)

The following activities should be addressed in the action plan:

i) Communication

The scope, performance criteria, desired outcomes, responsibilities, movement and registration requirements and sanctions need to be communicated to all parties.

Communication strategies need to be targeted to the audience, taking into account elements such as the level of literacy (including technology literacy) and spoken languages.

ii) Training programmes

It is desirable to implement training programmes to assist the *Veterinary Services* and other parties.

iii) Technical support

Technical support should be provided to address practical problems.

b) Checking and verification

Checking activities should start at the beginning of the implementation to detect, prevent and correct errors and to provide feedback on programme design.

Verification should begin after a preliminary period as determined by the *Veterinary Authority* in order to determine compliance with the legal framework and operational requirements.

c) Auditing

Auditing should be carried out under the authority of the *Veterinary Authority* to detect any problems with the *animal identification system* and *animal traceability* and to identify possible improvements.

d) Review

The programme should be subject to periodic review, taking into account the results of checking, verification and auditing activities.

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CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

EU position

The EU thanks the OIE TAHSC and supports the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 4.3.1.

Introduction

For the purposes of the *Terrestrial Code*, ‘zoning’ and ‘regionalisation’ have the same meaning.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, given the difficulty of establishing and maintaining a *disease* free status for an entire territory, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a Member under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*. While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management including *biosecurity plans* play important roles in the application of both concepts.

A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of limited *outbreaks* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

This chapter is to assist OIE Members wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of *disease*.

Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.

As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within a Member's territory. Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, the use of compartmentalisation may allow a Member to take advantage of epidemiological links among *subpopulations* or common practices

relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the continuation of trade.

Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain free status following a *disease outbreak* in a *zone* or *compartment*, Members should follow the recommendations in the relevant *disease* chapter in the *Terrestrial Code*.

Article 4.3.2.

General considerations

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Terrestrial Code*, including those on *surveillance*, and the *identification* and *traceability* of live *animals*. The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* ~~should be appropriate to the particular circumstances, and~~ will depend on the epidemiology of the *disease*, in particular, the presence and importance role of susceptible wildlife species ~~species, and~~ environmental factors, ~~and appropriate~~ on the application of biosecurity measures.

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*.

In the context of maintaining the health status of a *population*, references to ‘import’, ‘importation’ and ‘imported animals/products’ found in the *Terrestrial Code* apply both to importation into a country and to the movement of *animals* and their products into *zones* and *compartments*. Such movements should be the subject of appropriate measures to preserve the *animal health status* of the *zone/compartment*.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry and production system, in the case of a *compartment*) including *disease surveillance* and diagnosis.

Biosecurity and *surveillance* are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.

Industry’s responsibilities include the application of biosecurity measures, documenting and recording movements of *animals* and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

Annex 7 (contd)

The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, biosecurity measures, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting and *laboratory* diagnostic examinations.

Article 4.3.3.

Principles for defining and establishing a zone or compartment, including protection and containment zones

In conjunction with the above considerations, the following principles should apply when Members define a *zone* or a *compartment*.

1. The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.
2. A *protection zone* may be established to preserve the health status of *animals* in a free country or *zone*, from adjacent countries or *zones* of different *animal health status*. Measures should be implemented based on the epidemiology of the *disease* under consideration to prevent introduction of the pathogenic agent and to ensure early detection.

These measures should include intensified movement control and *surveillance* and may include:

- a) *animal identification* and *animal traceability* to ensure that animals in the protection zone are clearly distinguishable from other populations;
- b) vaccination of all or at risk susceptible *animals*;
- c) testing and/or vaccination of *animals* moved;
- d) specific procedures for sample handling, sending and testing;
- e) enhanced biosecurity including cleansing – *disinfection* procedures for transport means, and possible compulsory routes;
- f) specific *surveillance* of susceptible wildlife species and relevant vectors;
- g) awareness campaigns to the public or targeted at breeders, traders, hunters, *veterinarians*.

The application of these measures can be in the entire free *zone* or in a defined area within and/or outside the free *zone*.

3. In the event of limited *outbreaks* in a country or *zone* previously free of a *disease*, a *containment zone* may be established for the purposes of trade. Establishment of a *containment zone* should be based on a rapid response including:
 - a) appropriate standstill of movement of *animals* and other commodities upon notification of suspicion of the specified *disease* and the demonstration that the *outbreaks* are contained within this zone through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* has been identified and investigations on the likely source of the outbreak have been carried out ~~should be identified~~ and all *cases* shown to be epidemiologically linked.

Annex 7 (contd)

- b) A *stamping-out policy* or another effective control strategy aimed at eradicating the *disease* should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*.
 - c) Measures consistent with the disease specific chapter should be in place to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing *surveillance* in the *containment zone*.
 - d) For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.
 - e) The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated, once the *containment zone* is clearly established, irrespective of the provisions of the disease specific chapter.
 - f) The *containment zone* should be managed in such a way that it can be demonstrated that *commodities for international trade* can be shown to have originated outside the *containment zone*.
 - g) The recovery of the free status of the *containment zone* should follow the provisions of the disease specific chapter.
4. The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.
5. *Animals* and *herds* belonging to such *subpopulations* need to be recognisable as such through a clear epidemiological separation from other animals and all things presenting a *disease risk*. For a *zone* or *compartment*, the *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its health status through a *biosecurity plan*. The measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, the health status of *animals* in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *animals*, and commercial management and husbandry practices), and *surveillance*.
6. Relevant *animals* within the *zone* or *compartment* should be identified in such a way that their ~~history can be audited~~ movements are traceable. Depending on the system of production, identification may be done at the *herd, flock* lot or individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented, and controlled ~~and supervised~~. The existence of a valid *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.

Annex 7 (contd)

7. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted, the live *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on animal movement controls, the plan should include *herd* or *flock* production records, feed sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk* mitigation. The information required may vary according to the species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.

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CHAPTER 4.4.

APPLICATION OF COMPARTMENTALISATION

EU position

The EU supports the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 4.4.1.

Introduction and objectives

The recommendations in this chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.3. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, establishing and maintaining a *disease-free* status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based on management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease-free herds/flocks*.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease-specific* separation between *subpopulations*.

In *disease-free* countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* should be under the responsibility of the *Veterinary Authority* in the country. For the purposes of this chapter, compliance by the Members with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.4.2.

Principles for defining a compartment

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* should be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the *animals* in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and *surveillance*.

Article 4.4.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* should provide to the *Veterinary Authority* documented evidence on the following:

1. Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and *surveillance* measures:

- a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;
- b) location, disease status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
 - i) *flocks* or *herds* with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;
 - ii) *slaughterhouses*, rendering plants or feed mills;
 - iii) *markets*, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

2. Infrastructural factors

Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

- a) fencing or other effective means of physical separation;
- b) facilities for people entry including access control, changing area and showers;
- c) *vehicle* access including washing and *disinfection* procedures;
- d) *unloading* and *loading* facilities;
- e) isolation facilities for introduced *animals*;

Annex 7 (contd)

- f) facilities for the introduction of material and equipment;
- g) infrastructure to store feed and veterinary products;
- h) disposal of carcasses, manure and waste;
- i) water supply;
- j) measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;
- k) air supply;
- l) feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 4 and 6 of the *Terrestrial Code*.

3. Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

- a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- b) the critical control points for each pathway;
- c) measures to mitigate exposure for each critical control point;
- d) standard operating procedures including:
 - i) implementation, maintenance, monitoring of the measures,
 - ii) application of corrective actions,
 - iii) verification of the process,
 - iv) record keeping;
- e) contingency plan in the event of a change in the level of exposure;
- f) reporting procedures to the *Veterinary Authority*;
- g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;
- h) the *surveillance* programme in place.

Annex 7 (contd)

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the *compartment*.

4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid *traceability* system. All *animals* within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary Authority* should provide sufficient assurance of *traceability*.

All animal movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Article 4.4.4.

Documentation

Documentation should provide clear evidence that the biosecurity, *surveillance*, *traceability* and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include *herd* or *flock* production records, feed sources, *laboratory* tests, birth and *death* records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* a baseline animal health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration should be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information should be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Authority*.

Article 4.4.5.

Surveillance for the agent or disease

The *surveillance* system should comply with Chapter 1.4. on surveillance and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

Annex 7 (contd)

If there is an increased *risk* of exposure to the agent for which the *compartment* has been defined, the sensitivity of the internal and external *surveillance* system should be reviewed and, where necessary, increased. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

2. External surveillance

The biosecurity measures applied in a *compartment* should be appropriate to the level of exposure of the *compartment*. External *surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted *surveillance* based on an assessment of *risk* factors may be the most efficient *surveillance* approach. Targeted *surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.4.6.

Diagnostic capabilities and procedures

Officially-designated *laboratory* facilities complying with the OIE standards for quality assurance, as defined in Chapter 1.1.3. of the *Terrestrial Manual*, should be available for sample testing. All *laboratory* tests and procedures should comply with the recommendations of the *laboratory* for the specific *disease*. Each *laboratory* that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.4.7.

Emergency response and notification

Early detection, diagnosis and notification of *disease* are critical to minimize the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, the free status of the *compartment* should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified **following the provisions of Article 5.3.7. Chapter 1.1.**

In case of an occurrence of any infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in Article 4.4.4., the management of the *compartment* should notify the *Veterinary Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in biosecurity, even in the absence of *outbreak*, is detected, export certification as a free *compartment* should be suspended. Disease free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original biosecurity level and the *Veterinary Authority* re-approves the status of the *compartment*.

Annex 7 (contd)

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and consider whether any additional biosecurity measures are needed to ensure that the integrity of the *compartment* is maintained.

Article 4.4.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

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CHAPTER 5.3.

**OIE PROCEDURES RELEVANT TO THE AGREEMENT
ON THE APPLICATION OF SANITARY AND
PHYTOSANITARY MEASURES OF
THE WORLD TRADE ORGANIZATION**

EU position

The EU supports the adoption of this modified chapter.

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) encourages the Members of the World Trade Organization to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to *risk assessment* and to a consistent approach of *risk management*. The SPS Agreement encourages Governments to make a wider use of *risk analysis*: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual *risk* involved.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live *animals* and animal products.

Article 5.3.2.

Introduction on the judgement of the equivalence of sanitary measures

The importation of *animals* and animal products involves a degree of *risk* to the animal health status of an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made more difficult by differences among the animal health and production systems in OIE Members. It is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purpose of *international trade*, with benefits to both the *importing country* and the *exporting country*.

These recommendations are to assist OIE Members to determine whether *sanitary measures* arising from different animal health and production systems may provide the same level of animal and human health protection. They discuss principles which might be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in facilitating a judgement of equivalence. These provisions are applicable whether equivalence applies at the level of specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or generally.

Article 5.3.3.

General considerations on the judgement of the equivalence of sanitary measures

Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its *animal health status* will be appropriately protected. In most cases, the *risk management* measures drawn up will rely in part on judgements made about the animal health and production system(s) in the *exporting country* and the effectiveness of sanitary procedures undertaken there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be with respect to infrastructure, policies and/or operating procedures, *laboratory* systems, approaches to the pests and *diseases* present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the *importing country's appropriate level of protection* (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.

Benefits of applying equivalence may include:

1. minimising costs associated with *international trade* by tailoring animal health measures to local circumstances;
2. maximising animal health outcomes for a given level of resource input;
3. facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and
4. decreased reliance on relatively costly *commodity* testing and isolation procedures in bilateral or multilateral agreements.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases* and pathogenic agents. Equivalence may be gained, for example, by enhanced *surveillance* and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the judgement of equivalence, Members should base their *sanitary measures* on OIE standards, guidelines and recommendations.

It is essential to apply a scientific *risk analysis* to the extent practicable in establishing the basis for a judgement of equivalence.

Article 5.3.4.

Prerequisite considerations in a judgement of equivalence1. Application of risk assessment

Application of the discipline of *risk assessment* provides a structured basis for judging equivalence among different *sanitary measures* as it allows a close examination to be made of the effect of a measure(s) on a particular step(s) in the importation pathway, and the relative effects of proposed alternative measure(s) on the same or related steps.

Annex 7 (contd)

A judgement of equivalence needs to assess the *sanitary measure* in terms of its effectiveness regarding the particular *risk* or group of *risks* against which the measure is designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the *importing country*.

2. Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising a single component of a measure (e.g. an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for *commodity*), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

Sanitary measures are those described in each chapter of the *Terrestrial Code* which are used for *risk* reduction and are appropriate for particular *diseases*. *Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of judging equivalence, *sanitary measures* can be broadly categorised as:

- a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of national and regional animal health authorities, emergency response organisations);
- b) programme design/implementation: including documentation of systems, performance and decision criteria, *laboratory* capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

A *sanitary measure (s)* proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's* animal health and production system. For example, a judgement of equivalence for a specific *sanitary measure* at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.

Article 5.3.5.

Principles for judgement of equivalence

In conjunction with the above considerations, judgement of the equivalence of *sanitary measures* should be based on application of the following principles:

1. an *importing country* has the right to set the level of protection it deems appropriate (its ALOP) in relation to human and animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;

Annex 7 (contd)

2. the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a *hazard*;
3. an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of providing the same level of protection;
4. the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a judgement of equivalence;
5. any *sanitary measure* or combination of *sanitary measures* can be proposed for judgement of equivalence;
6. an interactive process should be followed that applies a defined sequence of steps, and utilizes an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;
7. the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure (s)* proposed as equivalent will provide the same level of protection;
8. the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;
9. the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and according to appropriate *risk assessment* principles;
10. the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
11. the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;
12. the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
13. to facilitate a judgement of equivalence, OIE Members should base their *sanitary measures* on relevant OIE standards;
14. to allow the judgement of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and
15. an *importing country* should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of a judgement of equivalence.

Article 5.3.6.

Sequence of steps to be taken in judgement of equivalence

There is no single sequence of steps which must be followed in all judgements of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. The interactive sequence of steps described below may be useful for all *sanitary measures* irrespective of their categorisation as infrastructure, programme design/implementation or specific technical requirement components of an animal health and production system.

Annex 7 (contd)

This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Recommended steps are:

1. the *exporting country* identifies the measure(s) for which it wishes to propose an alternative measure(s), and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a *hazard(s)*;
2. the *importing country* explains the reason for the measure(s), in terms which would facilitate comparison with an alternative *sanitary measure (s)* and consistent with the principles set out in these provisions;
3. the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure (s)* in a form which facilitates analysis by an *importing country*;
4. the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
5. judgement of equivalence by the *importing country* takes into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative *sanitary measure(s)* on all relevant *hazards*;
 - c) OIE standards;
 - d) application of solely qualitative frameworks where it is not possible or reasonable to conduct *quantitative risk assessment*;
6. the *importing country* notifies the *exporting country* of its judgement and the underlying reasons within a reasonable period of time:
 - a) recognition of the equivalence of the *exporting country*'s alternative *sanitary measure (s)*;
 - b) request for further information; or
 - c) rejection of the case for equivalence of the alternative *sanitary measure(s)*;
7. an attempt should be made to resolve any differences of opinion over judgement of a case, either interim or final, by using an agreed mechanism to reach consensus (e.g. the OIE informal procedure for dispute mediation), or by referral to an agreed expert;
8. depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal equivalence agreement giving effect to the judgement or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.

An *importing country* recognising the equivalence of an *exporting country*'s alternative *sanitary measure(s)* needs to ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.

Annex 7 (contd)

Article 5.3.7.

Sequence of steps to be taken in establishing a zone/compartment and having it recognized for international trade purposes

There is no single sequence of steps which should be followed in establishing a *zone* or a *compartment*. The steps that the *Veterinary Services* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended steps are:

1. For zoning

- a) The *exporting country* identifies a geographical area within its territory, which it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific *disease* /specific *diseases*, based on *surveillance*.
- b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.
- c) The *exporting country* provides:
 - i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;
 - ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.
- d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals* and animal products, taking into account:
 - i) an evaluation of the *exporting country*'s *Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the *disease (s)* concerned; and
 - iv) other relevant OIE standards.
- e) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
 - i) recognition of the *zone*; or
 - ii) request for further information; or
 - iii) rejection of the area as a *zone* for *international trade* purposes.
- f) An attempt should be made to resolve any differences over recognition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

Annex 7 (contd)

- g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognizing the *zone*.

2. For compartmentalisation

- a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* comprising an animal *subpopulation* contained in one or more *establishments* or other premises operating under common management practices related to biosecurity. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to specific *disease (s)*. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
- i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
 - ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to such *disease(s)*.
- c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Terrestrial Code*.
- d) The *exporting country* provides:
- i) the above information to the *importing country*, with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
 - ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.
- e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *animals* and animal products, taking into account:
- i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the *disease (s)* concerned; and
 - iv) other relevant OIE standards.
- f) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
- i) recognition of the *compartment*; or
 - ii) request for further information; or
 - iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.

Annex 7 (contd)

- g) An attempt should be made to resolve any differences over recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8).
- h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognising the *compartment*.
- i) The *Veterinary Authority* of the *exporting country* should promptly inform *importing countries* of any occurrence of a *disease* in respect of which the *compartment* was defined.

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE shall maintain its existing voluntary in-house mechanisms for assisting OIE Members to resolve differences. In-house procedures which will apply are that:

1. Both parties agree to give the OIE a mandate to assist them in resolving their differences.
2. If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
3. Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.
4. The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
5. The expert or experts shall submit a confidential report to the Director General of the OIE, who will transmit it to both parties.

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CHAPTER 4.5.

GENERAL HYGIENE IN SEMEN COLLECTION AND
PROCESSING CENTRES**EU position**

The EU supports the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 4.5.1.

General considerations

Observation of the recommendations described in the articles below will very significantly reduce the likelihood of the semen being contaminated with common micro-organisms some of which are potentially pathogenic.

Article 4.5.2.

Conditions applicable to artificial insemination centres

1. The artificial insemination centre is comprised of:
 - a) animal accommodation areas (including one isolation facility for sick *animals*) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;
 - b) a semen laboratory and semen storage areas;
 - c) administration offices;
 - d) apre-entry isolation facility which is not compulsory in case of horses.
2. The centre should be under the direct supervision and control of a centre *veterinarian*.
3. Only *animals* associated with semen production should be permitted to enter the centre. Other species of livestock may exceptionally be resident on the centre, provided that they are kept physically apart from these *animals*.
4. Donors and teasers on the centre should be adequately isolated from farm livestock on adjacent land or buildings for instance by natural or artificial means.
5. The entry of visitors should be strictly controlled. Personnel at a centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Protective clothing and footwear for use only on the centre should be provided.
6. Individual semen containers and storage rooms should be capable of being disinfected.
7. The centre should be officially approved by the *Veterinary Authority*.
8. The centre should be under the supervision and control of the *Veterinary Services* which will be responsible for regular audits, at an interval of no more than **6 12** months, of protocols, procedures and records on the health and welfare of the *animals* in the centre and on the hygienic production, storage and dispatch of semen.

Annex 8 (contd)

Article 4.5.3.

Conditions applicable to semen collection facilities

1. The semen collection facilities should include separate and distinct areas for accommodating resident *animals*, for semen collection, for feed storage, for manure storage, and for the isolation of *animals* suspected of being infected.
2. Only *animals* associated with semen production should be permitted to enter the semen collection facilities. Other species of *animals* may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All *animals* resident at the semen collection facilities should meet the minimum health requirements for donors.
3. The donors and teasers should be adequately isolated to prevent the transmission of *diseases* from farm livestock and other *animals*. Measures should be in place to prevent the entry of wild *animals* susceptible to ruminant and swine *diseases* transmissible via semen.
4. Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.
5. Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises should be examined and treated if necessary to ensure that they cannot introduce *disease*.
6. *Vehicles* used for transport of *animals* to and from the semen collection facilities should not be allowed to enter the facilities.
7. The semen collection area should be cleaned daily after collection. The *animals'* accommodation should be kept clean.
8. Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

Article 4.5.4.

Conditions applicable to semen laboratories

1. The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.
2. The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.
3. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.
4. The laboratory should be constructed with materials that permit effective cleaning and *disinfection*.
5. The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.

Annex 8 (contd)

6. The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.
7. The storage rooms and individual semen containers should be easy to clean and disinfect.
8. Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

Article 4.5.5.

Conditions applicable to the management of bulls, rams, bucks and boars

The objective is to keep the *animals* in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1. Whether on pasture or housed, the *animal* should be kept under hygienic conditions. If housed, the litter should be kept clean and renewed as often as necessary.
2. The coat of the *animal* should be kept clean.
3. For bulls, the tuft of hairs at the preputial orifice, which is often soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.
4. The *animal* should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.
5. In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.
6. When the *animal* is brought into the collection area, the technician should make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves.

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CHAPTER 4.6.

COLLECTION AND PROCESSING OF BOVINE,
SMALL RUMINANT AND PORCINE SEMEN**EU position**

The EU supports the adoption of this modified chapter.

Article 4.6.1.

General considerations

The purposes of official sanitary control of semen production are to:

1. maintain the health of *animals* on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible risk of infecting other *animals* or humans with pathogens transmissible by semen;
2. ensure that semen is hygienically collected, processed and stored.

Artificial insemination centres should comply with recommendations in Chapter 4.5.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 4.6.2.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals should enter an *artificial insemination centre* only when they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The *animals* should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

- a) Bovine brucellosis – Point 3 or 4 of Article 11.3.5.
- b) Bovine tuberculosis – Point 3 or 4 of Article 11.6.5.
- c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

The *animals* should be subjected to:

- i) a virus isolation test or a test for virus antigen, with negative results; and
 - ii) a serological test to determine the serological status of every *animal*.
- d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis

If the *artificial insemination centre* is to be considered as infectious bovine rhinotracheitis-infectious pustular vulvovaginitis free (IBR/IPV), the *animals* should either:

- i) come from an IBR/IPV free *herd* as defined in Article 11.11.3.; or
 - ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.
- e) Bluetongue

The *animals* should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the *animals*.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, bulls and teaser animals should be kept in a pre-entry isolation facility for at least 28 days. The *animals* should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, except for *Campylobacter fetus* subsp. *venerealis* and *Tritrichomonas foetus*, for which testing may commence after 7 days in pre-entry isolation. All the results should be negative except in the case of BVD-MD antibody serological testing (see point 2b)i) below).

- a) Bovine brucellosis

The *animals* should be subjected to a serological test with negative results.

- b) BVD-MD

- i) All *animals* should be tested for viraemia as described in point 1c) above.

Only when all the *animals* in pre-entry isolation test negative for viraemia, may the *animals* enter the semen collection facilities upon completion of the 28-day pre-entry isolation period.

- ii) After 21 days in pre-entry isolation, all *animals* should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.
- iii) Only if no sero-conversion occurs in the *animals* which tested seronegative before entry into the pre-entry isolation facility, may any *animal* (seronegative or seropositive) be allowed entry into the semen collection facilities.
- iv) If sero-conversion occurs, all the *animals* that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of 3 weeks. Serologically positive *animals* may be allowed entry into the semen collection facilities.

- c) *campylobacter fetus* subsp. *venerealis*

- i) *Animals* less than 6 months old or kept since that age only in a single sex group prior to pre-entry isolation should be tested once on a preputial specimen, with a negative result.
- ii) *Animals* aged 6 months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

- d) *Tritrichomonas foetus*

- i) *Animals* less than 6 months old or kept since that age only in a single sex group prior to pre-entry isolation, should be tested once on a preputial specimen, with a negative result.

- ii) *Animals* aged 6 months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

e) IBR-IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any *animal* tests positive, the *animal* should be removed immediately from the pre-entry isolation facility and the other *animals* of the same group should remain in pre-entry isolation and be retested, with negative results, not less than 21 days after removal of the positive *animal*.

f) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

a) Bovine brucellosis

b) Bovine tuberculosis

c) BVD-MD

Animals negative to previous serological tests should be retested to confirm absence of antibodies.

Should an *animal* become serologically positive, every ejaculate of that *animal* collected since the last negative test should be either discarded or tested for virus with negative results.

d) *campylobacter fetus* subsp. *venerealis*

- i) A preputial specimen should be tested.

- ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

e) Bluetongue

The *animals* should comply with the provisions referred to in Article [8.3.10](#) or 8.3.11.

f) *Tritrichomonas foetus*

- i) A preputial specimen should be cultured.

- ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

Annex 8 (contd)

g) IBR-IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should comply with the provisions in point 2)c) of Article 11.11.3.

4. Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD-MD serologically positive bulls, a semen sample from each *animal* should be subjected to a virus isolation or virus antigen test for BVD-MD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

5. Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 11.11.7.

Article 4.6.3.

Conditions applicable to testing of rams/bucks and teaser animals

Rams/bucks and teaser animals should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The *animals* should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

- a) Caprine and ovine brucellosis – Article 14.1.6.
- b) Ovine epididymitis – Article 14.7.3.
- c) Contagious agalactia – Points 1 and 2 of Article 14.3.1.
- d) Peste des petits ruminants – Points 1, 2, and 4 or 5 of Article 14.8.7.
- e) Contagious caprine pleuropneumonia – Article 14.4.7., depending on the CCPP status of the country or *zone* of origin of the *animals*.
- f) Paratuberculosis – Free from clinical signs for the past 2 years.
- g) Scrapie – Comply with Article 14.9.8. if the *animals* do not originate from a scrapie free country or *zone* as defined in Article 14.9.3.
- h) Maedi-visna – Article 14.6.2.
- i) Caprine arthritis/encephalitis – Article 14.2.2. in the case of goats.
- j) Bluetongue

The *animals* should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the *animals*.

- k) Tuberculosis — In the case of goats, a single or comparative tuberculin test, with negative results.

Annex 8 (contd)2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, rams/bucks and teasers should be kept in a pre-entry isolation facility for at least 28 days. The *animals* should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

- a) Caprine and ovine brucellosis – Point 1c) of Article 14.1.8.
- b) Ovine epididymitis – Points 1d) and 2) of Article 14.7.4.
- c) Maedi-visna and caprine arthritis/encephalitis – Test on *animals* and semen.
- d) Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. Testing programme for rams/bucks and teasers resident in the semen collection facilities

All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

- a) caprine and ovine brucellosis;
- b) ovine epididymitis;
- c) Maedi-visna and caprine arthritis/encephalitis;
- d) tuberculosis (for goats only);
- e) bluetongue.

The *animals* should comply with the provisions referred to in Article 8.3.10. or 8.3.11.

Article 4.6.4.

Conditions applicable to testing of boars

Boars should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The *animals* should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the *diseases* in question.

- a) Porcine brucellosis – Article 15.3.3.
- b) Foot and mouth disease – Articles 8.5.12., 8.5.13. or 8.5.14.
- c) Aujeszky's disease – Article 8.2.8. or Article 8.2.9.
- d. ~~Teschevirus encephalomyelitis – Article 15.5.4. or Article 15.5.6.~~

Annex 8 (contd)

- ed) Transmissible gastroenteritis – Article 15.6.2.
- fe) Swine vesicular disease – Article 15.4.5. or Article 15.4.7.
- ef) African swine fever – Article 15.1.5. or Article 15.1.6.
- fg) Classical swine fever – Article 15.2.5. or Article 15.2.6.
- fh) Porcine reproductive and respiratory syndrome – Test complying with the standards in the *Terrestrial Manual*.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, boars should be kept in a pre-entry isolation facility for at least 28 days. The *animals* should be subjected to diagnostic tests as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

- a) Porcine brucellosis – Article 15.3.5.
- b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.
- c) Aujeszky's disease – Articles 8.2.12., 8.2.13. or 8.2.14.
- ~~d. Teschovirus encephalomyelitis – Article 15.5.8. or Article 15.5.9.~~
- ed) Transmissible gastroenteritis – Article 15.6.4.
- fe) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.
- ef) African swine fever – Article 15.1.8. or Article 15.1.9.
- fg) Classical swine fever – Article 15.2.8. or Article 15.2.9.
- fh) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

3. Testing programme for boars resident in the semen collection facilities

All boars resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

- a) Porcine brucellosis – Article 15.3.5.
- b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.
- c) Aujeszky's disease – Articles 8.2.12., 8.2.13. or 8.2.14.
- ~~d. Teschovirus encephalomyelitis – Article 15.5.8. or Article 15.5.9.~~
- ed) Transmissible gastroenteritis – Article 15.6.4.
- fe) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.
- ef) African swine fever – Article 15.1.8. or Article 15.1.9.

Annex 8 (contd)

hg) Classical swine fever – Article 15.2.8. or Article 15.2.9.

ih) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

Article 4.6.5.

General considerations for hygienic collection and handling of semen

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 4.6.6.

Conditions applicable to the collection of semen

1. The floor of the mounting area should be clean and provide safe footing. A dusty floor should be avoided.
2. The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animals should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.
3. The hand of the person collecting the semen should not come into contact with the *animal's* penis. Disposable gloves should be worn by the collector and changed for each collection.
4. The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.
5. The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.
6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.
7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the *animal* has inserted its penis without ejaculating.
8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.
9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Article 4.6.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory1. Diluents

- a) All receptacles used should have been sterilised.
- b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
- c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
- d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free of pathogens or sterilised; milk heat-treated at 92°C for 3-5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilized before use.
- e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.
- f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75µg), divexacin (25µg).

The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

2. Procedure for dilution and packing

- a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
- b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.
- c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.
- d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage of semen

Semen for export should be stored separately from other genetic material not meeting the requirements of this chapter with fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Annex 8 (contd)

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR)¹.

Prior to export, semen straws or pellets should clearly and permanently be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an *Official Veterinarian*. The contents of the container or flask should be verified by the *Official Veterinarian* prior to sealing with an official numbered seal before export and accompanied by an *international veterinary certificate* listing the contents and the number of the official seal.

4. Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between *animals* according to the recommendations of the licencer of the system.

Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from *animals* of same or better health status.

— text deleted

1. The ICAR international standards on straws are contained in Recording Guidelines - Appendices to the international agreement of recording practices. The text of this document is available at the following web site: www.icar.org

CHAPTER 4.7.

**COLLECTION AND PROCESSING OF *IN VIVO*
DERIVED EMBRYOS FROM LIVESTOCK AND
HORSES**

EU position

The EU supports in general the adoption of this modified chapter.

However, the EU questions the fact that diseases that are not OIE listed be added to article 4.7.14 as it could be confusing in relation to trade. The list in this article should only include OIE listed diseases and the complete list including non-listed diseases should be published elsewhere.

Furthermore, the title only refers to "horses", and not to "equids": the EU would like to know if this is justified, as embryo transfer of equids other than horses might happen. In addition, the use of the word "equine(s)" is to be banned as a noun, throughout the Code, as it can lead to confusion. "Equine" should only be used as an adjective that refers to equids.

Article 4.7.1.

Aims of control

The purpose of official sanitary control of *in vivo* derived embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with embryos, are controlled and transmission of *infection* to recipient *animals* and progeny is avoided.

Article 4.7.2.

Conditions applicable to the embryo collection team

The embryo collection team is a group of competent technicians, including at least one *veterinarian*, to perform the collection, processing and storage of embryos. The following conditions should apply:

1. The team should be approved by the *Competent Authority*.
2. The team should be supervised by a team *veterinarian*.
3. The team *veterinarian* is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and *disinfection* and hygienic procedures.
4. Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practiced to preclude the introduction of *infection*.
5. The collection team should have adequate facilities and equipment for:
 - a) collecting embryos;
 - b) processing and treatment of embryos at a permanent site or mobile laboratory;
 - c) storing embryos.

These facilities need not necessarily be at the same location.

6. The embryo collection team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority* for a period of at least 2 years after the embryos have been

exported.

7. The embryo collection team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

Article 4.7.3.

Conditions applicable to processing laboratories

A processing laboratory used by the embryo collection team may be mobile or permanent. It is a facility in which embryos are recovered from collection media, examined and subjected to any required treatments such as washing and being examined and prepared for freezing and storage. A permanent laboratory may be part of a specifically designed collection and processing unit, or a suitably adapted part of an existing building. It may be on the premises where the donor *animals* are kept. In either case, the laboratory should be physically separated from *animals*. Both mobile and permanent laboratories should have a clear separation between dirty areas (animal handling) and the clean processing area.

Additionally:

1. The processing laboratory should be under the direct supervision of the team *veterinarian* and be regularly inspected by an *Official Veterinarian*.
2. While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of a lesser health status should be processed.
3. The processing laboratory should be protected against rodents and insects.
4. The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently, and always before and after each occasion on which embryos for export are processed.

Article 4.7.4.

Conditions applicable to the introduction of donor animals

1. Donor animals

- a) The *Veterinary Authority* should have knowledge of, and authority over, the *herd/flock* from which the donor *animals* have been sourced.
- b) The donor *animals* should not be situated in a *herd/flock* subject to veterinary restrictions for OIE *listed disease* or pathogens for relevant species (see Chapter 1.2. of the *Terrestrial Code*), other than those that are in IETS Category 1 for the species of embryos being collected (see Article 4.7.14. and footnote¹).
- c) At the time of collection, the donor *animals* should be clinically inspected by the team *veterinarian*, or by a *veterinarian* responsible to the team *veterinarian* and certified to be free of clinical signs of *diseases*.

2. Semen donors

- a) Semen used to inseminate donor *animal s* artificially should have been produced and processed in accordance with the provisions of Chapter 4.6.
- b) When the donor of the semen used to inseminate donor females for embryo production is dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests may be required of the inseminated donor female after embryo collection to verify that these infectious

diseases were not transmitted. An alternative may be to test an aliquot of semen from the same collection date.

- c) Where natural service or fresh semen is used, donor sires should meet the health conditions set out in Chapter 4.6. as appropriate to the species.

Article 4.7.5.

Risk management

With regard to *disease* transmission, transfer of *in vivo* derived embryos is a very low risk method for moving animal genetic material. Irrespective of animal species, there are three phases in the embryo transfer process that determine the final level of risk:

1. The first phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation 1 (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:
 - a) the disease situation in the *exporting country* and/or *zone* ;
 - b) the health status of the *herds/flocks* and the donors from which the embryos are collected;
 - c) the pathogenic characteristics of the specified disease agents that are of concern to the *Veterinary Authority* of the *importing country* .
2. The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual². These include the following:
 - a) The embryos should be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash.
 - b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.
 - c) Sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, and Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual².
 - d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.

[NOTE: All shipments of embryos should be accompanied by a statement signed by the team veterinarian certifying that these embryo processing procedures have been completed.]
3. The third phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation 1 (Article 4.7.14.) and which are of concern to the *Veterinary Authority* of the *importing country*, encompasses the risk reductions resulting from:
 - a) post-collection *surveillance* of the donors and donor *herd/flock* based on the recognized *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*;
 - b) testing of embryo-collection (flushing) fluids and non-viable embryos, or other samples such as blood, in a laboratory for presence of specified disease agents.

Annex 8 (contd)

Article 4.7.6.

Conditions applicable to the collection and storage of embryos1. Media

Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos should be free of pathogenic micro-organisms.

Media and solutions used in the collection and storage of embryos should be sterilized by approved methods according to the IETS Manual² and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to collection, processing, washing and storage media as recommended in the IETS Manual².

2. Equipment

- a) All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilised prior to use as recommended in the IETS Manual².
- b) Used equipment should not be transferred between countries for re-use by the embryo collection team.

Article 4.7.7.

Optional tests and treatments

1. The testing of samples can be requested by an *importing country* to confirm the absence of pathogenic organisms that may be transmitted via *in vivo* derived embryos, or to help assess whether the degree of quality control of the collection team (with regard to adherence to procedures as described in the IETS Manual²) is at an acceptable level. Samples may include:

- a) Non-viable embryos/oocytes

Where the viable, zona pellucida intact embryos from a donor are intended for export, all non-fertilized oocytes and degenerated or zona pellucida compromised embryos collected from that donor should be washed according to the IETS Manual² and pooled for testing if requested by the *importing country*. Non-viable embryos/oocytes from the donor should be processed and stored together.

- b) Embryo collection (flushing) fluids

The collection fluid should be placed in a sterile, closed container and, if there is a large amount, it should be allowed to stand undisturbed for one hour. The supernatant fluid should then be removed and the bottom 10-20 ml, along with accumulated debris, decanted into a sterile bottle. If a filter is used in the collection of embryos/oocytes then any debris that is retained on the filter should be rinsed off into the retained fluid.

- c) Washing fluids

The last four washes of the embryos/oocytes should be pooled (IETS Manual²).

- d) Samples

The samples referred to above should be stored at 4°C and tested within 24 hours. If this is not possible, then samples should be stored frozen at -70°C or lower.

Annex 8 (contd)

2. When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see paragraph 2c) in Article 4.7.5.), the procedure should be carried out according to the IETS Manual². Enzyme treatment is necessary only when pathogens for which the IETS recommends this additional treatment (such as with trypsin) may be present.

It should be noted that such treatment is not always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme.

Article 4.7.8.

Conditions applicable to the storage and transport of embryos

1. The embryos for export should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the *Veterinary Authority* of the *exporting country* where there is no risk of contamination of the embryos.
2. Only embryos from the same individual donor should be stored together in the same ampoule, vial or straw.
3. The embryos should if possible, depending on the species, be frozen, stored with fresh liquid nitrogen in cleaned and sterilized tanks or containers under strict hygienic conditions at the approved storage place.
4. Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible), and they should be clearly identified by labels according to the standardised system recommended in the IETS Manual².
5. Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.
6. Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.7.9.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.7.5. and conducted in accordance with Chapter 4.9.

Article 4.7.10.

Specific conditions applicable to porcine embryos

The *herd* of origin should be free of clinical signs of swine vesicular disease and brucellosis.

The development of effective cryopreservation methods for the storage of zona pellucida-intact porcine embryos is still at a very early stage.

Annex 8 (contd)

Article 4.7.11.

Specific conditions/comments applicable to equine embryos

The recommendations apply principally to embryos from *animals* continuously resident in national equine populations and therefore may be found unsuitable for those from equines routinely involved in events or competitions at the international level. For instance, in appropriate circumstances horses travelling with an *international veterinary certificate* (e.g. competition horses) may be exempt where mutually agreed upon on a bilateral basis between the respective *Veterinary Authorities*.

EU comment

The word "equines" in the second line of article 4.7.11 above should be deleted and replaced by "horses". "Equine" should only be used as an adjective that refers to horses or equids.

Article 4.7.12.

Specific conditions/comments applicable to camelid embryos

South American camelid embryos recovered from the uterine cavity by the conventional non-surgical flushing technique at 6.5 to 7 days post-ovulation are almost invariably at the hatched blastocyst stage, and thus the zona pellucida has already been shed. Since the embryos do not enter the uterus and cannot be recovered before 6.5 to 7 days, it would be unrealistic to stipulate for these species that only zona pellucida-intact embryos can be used in *international trade*. It should be noted however that in 2008 the development of cryopreservation methods for storage of camelid embryos is still at a very early stage, and also that pathogen interaction studies with camelid embryos have not yet been carried out.

Article 4.7.13.

Specific conditions/comments applicable to cervid embryos

The recommendations apply principally to embryos derived from *animals* continuously resident in national domestic or ranched cervid populations and therefore may be found to be unsuitable for those from cervids in feral or other circumstances related to biodiversity or germplasm conservation efforts.

Article 4.7.14.

Recommendations regarding the risk of disease transmission via *in vivo* derived embryos

Based on the conclusions of the Research Subcommittee of the Health and Safety Advisory Committee (HASAC) of the IETS¹, the following *diseases* and pathogenic agents are categorised into four categories, which applies only to *in vivo* derived embryos.

1. Category 1

- a) Category 1 *diseases* or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual².
- b) The following *diseases* or pathogenic agents are in category 1:
 - Aujeszky's disease (pseudorabies) (swine): trypsin treatment required
 - Bluetongue (cattle)
 - Bovine spongiform encephalopathy (cattle)

- *Brucella abortus* (cattle)
- Enzootic bovine leukosis
- Foot and mouth disease (cattle)
- Infectious bovine rhinotracheitis: trypsin treatment required
- Scrapie (sheep).

2. Category 2

- a) Category 2 *diseases* are those for which substantial evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual², but for which additional transfers are required to verify existing data.
- b) The following *diseases* are in category 2:
 - Bluetongue (sheep)
 - Caprine arthritis/encephalitis
 - Classical swine fever (hog cholera).

3. Category 3

- a) Category 3 *diseases* or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual², but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.
- b) The following *diseases* or pathogenic agents are in category 3:
 - Bovine immunodeficiency virus
 - Bovine spongiform encephalopathy (goats)
 - Bovine viral diarrhoea virus (cattle)
 - *Campylobacter fetus* (sheep)
 - Foot and mouth disease (swine, sheep and goats)
 - *Haemophilus somnus* (cattle)
 - Maedi-visna (sheep)
 - *Mycobacterium paratuberculosis* (cattle)
 - *Neosporacanium* (cattle)
 - Ovine pulmonary adenomatosis
 - Porcine reproductive and respiratory disease syndrome (PRRS)
 - Rinderpest (cattle)
 - Swine vesicular disease.

Annex 8 (contd)4. Category 4

- a) Category 4 *diseases* or pathogenic agents are those for which studies have been done, or are in progress, that indicate:
- i) that no conclusions are yet possible with regard to the level of transmission risk; or
 - ii) the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual² between collection and transfer.
- b) The following *diseases* or pathogenic agents are in category 4:
- African swine fever
 - Akabane (cattle)
 - Bovine anaplasmosis
 - Bluetongue (goats)
 - Border disease (sheep)
 - Bovine herpesvirus-4
 - *Chlamydia psittaci* (cattle, sheep)
 - Contagious equine metritis
 - Enterovirus (cattle, swine)
 - Equine rhinopneumonitis
 - *Escherichia coli* 09:K99 (cattle)
 - *Leptospira borg petersenii* serovar *hardjo bovis* (cattle)
 - *Leptospira* sp. (swine)
 - Lumpy skin disease
 - *Mycobacterium bovis* (cattle)
 - *Mycoplasma* spp. (swine)
 - Ovine epididymitis (*Brucella ovis*)
 - Parainfluenza-3 virus (cattle)
 - Parvovirus (swine)
 - Porcine circovirus (type 2) (pigs)
 - Scrapie (goats)

Annex 8 (contd)

- *Trichostrongylus axei* (cattle)
- *Ureaplasma/Mycoplasma* spp. (cattle, goats)
- Vesicular stomatitis (cattle, swine).

– Equine coital exanthema (EHV-3).

¹ Based on available research and field information, the Research Subcommittee of the Health and Safety Advisory Committee (HASAC) of the International Embryo Transfer Society (IETS) has categorised some diseases based on their relative risk of dissemination by properly processed and handled *in vivo* derived embryos. This chapter that contains the complete list of IETS categorised diseases is shown in Article 4.7.14.

² Manual of the International Embryo Transfer Society.

– text deleted

CHAPTER 5.2.

CERTIFICATION PROCEDURES

EU position

The EU supports the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 5.2.1.

Protection of the professional integrity of the certifying veterinarian

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the certifying *veterinarian* should be respected and safeguarded according to Chapters 3.1. and 3.2.

It is essential to include in any requirements only those specific statements that can be accurately and honestly signed by a certifying *veterinarian*. For example, these requirements should not include certification of an area as being free from *diseases other than that are not notifiable diseases*, or the occurrence of which the signing *veterinarian* is not necessarily informed about. It is unacceptable to ask for certification for events which will take place after the document is signed when these events are not under the direct control and supervision of the signing *veterinarian*.

Certification of freedom from *diseases* based on purely clinical freedom and *herd* history is of limited value. This is also true of *diseases* for which there is no specific diagnostic test, or the value of the test as a diagnostic aid is limited.

The note of guidance referred to in Article 5.1.1. is not only to inform the signing *veterinarian* but also to safeguard professional integrity.

Article 5.2.2.

Certifying veterinarians

Certifying *veterinarian* should:

1. be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;
2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party ;
3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying *veterinarian* should have verified or be in possession of that documentation before signing;
4. have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.

Article 5.2.3.

Preparation of international veterinary certificates

Certificates should be drawn up in accordance with the following principles:

1. Certificates should be designed so as to minimize the potential for fraud including use of a unique identification number, or other appropriate means to ensure security. Paper certificates should bear the signature of the certifying *veterinarian* and the official identifier (stamp) of the issuing *Veterinary Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.
2. Certificates should be written using terms that are simple, unambiguous and as easy to understand as possible, without losing their legal meaning.
3. If so required, certificates should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the certifying *veterinarian*.
4. Certificates should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).
5. Certificates should not require a *veterinarian* to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.
6. Where appropriate, when presented to the certifying *veterinarian*, certificates should be accompanied by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.
7. The text of a certificate should not be amended except by deletions which should be signed and stamped by the certifying *veterinarian*.
8. The signature and stamp should be in a colour different from that of the printing of the certificate. The stamp may be embossed instead of being a different colour.
9. Replacement certificates may be issued by a *Veterinary Authority* to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These replacements should be provided by the issuing authority and be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.
10. Only original certificates are acceptable.

Article 5.2.4.

Electronic certification

1. Certification may be provided by electronic documentation sent directly from the *Veterinary Authority* of the *exporting country* to the *Veterinary Authority* of the *importing country*. Such systems also normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The certifying *veterinarian* should have access to all information such as *laboratory* results and *animal identification* data.

Annex 9 (contd)

2. Electronic certificates may be in a different format but should carry the same information as conventional paper certificates.
3. The *Veterinary Authority* should have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.
4. The certifying *veterinarian* should be officially responsible for the secure use of his/her electronic signature.

— text deleted

CHAPTER 5.9.

QUARANTINE MEASURES APPLICABLE TO NON-HUMAN PRIMATES**EU position****The EU strongly supports the adoption of this modified chapter.**

Article 5.9.1.

General principles

The present chapter defines the standards to be followed in the case of a non-human primate being imported directly from a country within the natural range of the animal's species concerned, and where only limited health guarantees can be given, or in cases where Article 6.11.2., last paragraph, applies.

Quarantine programmes are designed to both facilitate the detection of communicable diseases and to make accurate assessments of the overall health status of individuals and/or groups entering a new population. Prudence dictates that for public health and safety the infectious disease status of all incoming animals is considered at best uncertain. Non-human primates can harbour infectious organisms that cause only mild disease for their species but can be severely pathogenic to other species of non-human primate, either in captive collections or in wild populations, or to humans.

Quarantines are defined by their duration and by the activities and procedures practised to assess health status.

The minimal duration of the quarantine period, as defined by Articles 6.11.4., 6.11.5. and 6.11.6., may be extended until any adverse events during the quarantine period are fully investigated and resolved, and no evidence of transmission of infectious agents within the quarantined group exists.

Quarantine activities and procedures should be directed towards defining as much as possible the health status of quarantined animals, while protecting persons and other animals from inadvertent exposure to communicable agents and providing for the health and well-being of quarantined animals. Therefore, quarantine practices should:

1. encompass measures which effectively isolate animals or groups of animals thereby preventing the spread of communicable diseases;
2. protect the health of personnel working in the quarantine;
3. encompass measures to promote the health and welfare of quarantined animals including social and behavioural needs of non-human primates.

At a minimum, quarantine programmes should have the following key components:

Article 5.9.2.

Management policies

Management should restrict access to the quarantine facility to authorised and essential personnel, who do not pose a communicable disease risk to non-human primates.

Management should instruct personnel about the potential risks of working in the quarantine facility, and the need to conduct all activities in a safe manner. There should be periodic retraining of personnel.

Management may prohibit persons who may be at increased risk of acquiring infections or for whom an infection might be unusually hazardous from the quarantine facility. Management may require other personnel health promotion activities, such as those mentioned in point 5 of Article 6.11.7.

Article 5.9.3.

Quarantine facility infrastructure design and equipment

1. The construction or location, and the operation of the quarantine facility should provide for strict segregation and isolation of quarantined animals from other animals and from personnel not essential to the operation of the quarantine.
2. Methods to attain this isolation include:
 - a) The use of security measures such as physical barriers and procedural access control systems.
 - b) As part of the security system, a hazard warning sign should be posted at the entrance to the quarantine stating that exposure to infectious diseases may occur in the quarantine. The names and telephone numbers of contact persons responsible for the quarantine area should be provided, and all special requirements for entering the quarantine area should be listed.
 - c) The implementation of an effective rodent, feral animal, and insect control programme, which does not pose a health risk to the quarantined animals.
 - d) The complete physical separation of groups of quarantined animals from other groups of quarantined animals to prevent exposure to and the introduction of infectious agents from one group to another during the quarantine period. As a rule, only animals arriving in one shipment from the same exporter should be grouped together. Animals may not be exchanged between groups or groups mixed during the quarantine period, unless the newly formed group restarts the entire quarantine process.
3. The quarantine facility should be designed to allow for the secure holding of quarantined animals and to allow for the safe, easy and efficient cleaning and decontamination of the animal holding area and the access area during and after use.
 - a) A quarantine facility should consist of a minimum of two discrete areas physically separated from the outside and from each other, including an access area where clothes, footwear and protective articles are changed, and where locker, hand-washing and, if possible, showering facilities are provided.
 - b) Procedures should be in place to prevent the cross-contamination of clothes and footwear worn outside the quarantine facility from potentially contaminated protective clothing worn inside the animal holding area.

Annex 10 (contd)

- c) Animal holding room wall, floor, and ceiling surfaces should be water resistant to facilitate cleaning and disinfecting. Any holes or penetrations in these surfaces should be sealed or be capable of being sealed to facilitate fumigation or space decontamination. Doors to animal rooms should open inward, and should always be kept closed when animals are present. Any windows should be closed and sealed, unless the facility is sufficiently separated (distance, fences, other means of separation) from non-quarantined area.
- d) In facilities that are operated with the windows closed and sealed, a ventilation system should be operated and monitored in such a manner to assure the provision of an optimal isolation of these animals, while also providing for their health and comfort. The direction of the airflow in the quarantine facility should be inward from the outside of the quarantine facility, to quarantine access areas, to animal holding rooms. Air exhausted or re-circulated within the facility must be filtered. In addition, exhaust air should be dispersed away from the building and other occupied areas. Heating, ventilating, and air-conditioning systems should be designed so that their operation can be continued, even at reduced capacity in the event of electrical or other support system failure.
- e) If floor drains are present, their drain traps should always be filled with water or a suitable disinfectant.
- f) A hand washing sink should be available in the animal holding room for personnel usage.
- g) Adequate equipment and space should be available both in the animal holding area and in the quarantine facility in general for the adequate decontamination and the proper disposal or processing and storing of all supplies and equipment used in the quarantine.

Article 5.9.4.

Personnel protection practices

1. Eating, drinking, smoking and storing of food for human use should not be permitted in the quarantine facility.
2. All staff entering the quarantine should wear (preferably disposable) protective clothing and devices.
3. Protective clothing, gloves, and mucus membrane protection should not be used in more than one quarantine animal holding room. This may require the changing of protective clothing by staff as they go between rooms in the performance of their duties.
4. Foot or shoe baths should be provided and used at the exits of the animal holding area and of each animal holding room. They should be changed often enough to remain fresh and free of organic matter.
5. Showering after contact with non-human primates, their body waste or secretions or at a minimum before leaving the quarantine facility is highly recommended.
6. Intermittent and frequent hand washing while working in the quarantine facility is highly recommended. This is especially important as protective gloves may become inadvertently torn or ruptured.
7. Baseline serum samples from quarantine personnel should be collected and stored. Additional serum samples may be collected periodically, as an aid to epidemiological investigations.
8. Management should encourage quarantine staff developing signs of illness to seek medical attention.

Annex 10 (contd)

Article 5.9.5.

Husbandry and animal care practices

1. If a quarantine facility maintains more than one animal holding room, husbandry practices should be designed so as to minimise the risk of transmission of zoonotic diseases between rooms. In particular, there should be separate cleaning tools and other animal care equipment for each room.

All cages and other non-disposable equipment should be decontaminated when removed from the room.

2. All husbandry and animal care procedures should be carefully performed to minimise the creation of aerosols and limit the spread of potentially infectious materials, while also providing for the appropriate care and well-being of the animals concerned.
3. Waste, uneaten food, and other potentially contaminated materials leaving the quarantine area must be suitably contained, while being transported to a site of physical or chemical decontamination, or incineration.
4. Work surfaces should always be decontaminated after use or whenever soiled. Equipment should not be stored on the floor.
5. Care should be taken to avoid scratches, bites or other injuries from non-human primates through anaesthesia, tranquillisation or physical restraint of the animals during handling. Physical restraint should only be performed by personnel knowledgeable and experienced in handling non-human primates, and it should never be done by persons working alone.
6. Caution must be used to prevent injury to personnel or the spread of infectious materials between animals through the use of potentially contaminated needles, scalpels, or other sharp instruments, particularly during the disposal of these items. Only single use disposable syringes and needles, scalpel blades, and other sharp items should be used. They should never be recapped, bent, broken or otherwise manipulated by hand, and they should be discarded into puncture-resistant containers kept as close to the work site as practical. Containers should be decontaminated before disposal.
7. If multiple-dose vials of materials or medications are used, care must be taken to avoid contamination of such vials and their contents between uses.
8. Dead animals should be removed from their animal holding room and taken to a dedicated necropsy room in a sealed, impervious, leakproof container or bag.
9. Responsible quarantine officials should immediately notify the Veterinary Authority of a severe and/or unusual illnesses and deaths occurring in quarantined non-human primates.
10. After animals are removed from quarantine, a thorough decontamination of the animal holding room is necessary whether there is a history of communicable disease presence in the room or not.

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CHAPTER 5.10.
**MODEL VETERINARY CERTIFICATES
 FOR INTERNATIONAL TRADE IN
 LIVE ANIMALS, HATCHING EGGS AND
 PRODUCTS OF ANIMAL ORIGIN**

EU position: The EU supports the adoption of this modified chapter.

Article 5.10.1.

Notes for guidance on the veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

1. General

Please complete the certificate on paper in capitals. To confirm an option, mark the box with a cross (X). Ensure that no portion of certificate is left blank in a manner that would allow it to be amended. Non-applicable fields may be crossed out.

2. Part I. Details of dispatched consignment

Country:	Name of the country that issues the certificate.
Box I.1.	Name and full address of the natural or legal person dispatching the consignment. Information on telephone and fax numbers or e-mail address is recommended.
Box I.2.	The certificate reference number is the number used by the Veterinary Authority of the country to identify the certificate.
Box I.3.	Name of the Veterinary Authority.
Box I.4.	Name and full address of the natural or legal person to whom the consignment is destined at the time the certificate is issued.
Box I.5.	Name of the country from which the animals, hatching eggs, embryos, semen, ova or brood combs are being exported. For products, name the country(ies) where the finished products were produced, manufactured or packed.
	“ISO code” refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.
Box I.6.	Name of the zone or compartment of origin, if relevant, in part II of the certificate.
Box I.7.	Name of the country of destination. “ISO code” refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.
Box I.8.	Name of the zone or compartment of destination, if relevant, in part II of the certificate.

Annex 10 (contd)

Box I.9.	Name and full address of the place(s) from which the animals or products are being exported; and official approval or registration number when required.
	For animals and hatching eggs: the establishment(s), wildlife or hunting reserves.
Box I.9. (contd)	For semen: the artificial insemination centre.
	For embryos and ova: the name, address and official approval number of the collection team (not the premises of storage).
	For products of animal origin: the premises from which the products are to be dispatched.
Box I.10.	Name of the place from which the animals or products are being shipped (this will be a land, sea or airport).
Box I.11.	Date of departure. For animals include the expected time of departure.
Box I.12.	Details of the means of transport.
	Identification of the means of transport at the time the certificate is issued: for air transport, the flight number; for maritime transport, the name of the vessel; for rail transport, the number of the train and the wagon and for road transport, the registration number of the road vehicle and the number of the trailer where used.
Box I.13.	Name of expected border post and, if available, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).
Box I.14.	CITES permit number(s) if the commodity concerns species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora.
Box I.15.	Describe the commodity or use the titles as they appear in the Harmonised System of the World Customs Organization.
Box I.16.	Heading or HS Code of the Harmonized System set up by the World Customs Organization.
Box I.17.	Total quantity of the commodity.
	For animals, hatching eggs and animal products (semen, ova, embryos) give the total count of animals, eggs or straws.
	For products give the gross weight and the net weight in kg of the whole consignment.

Annex 10 (contd)

Box I.18.	Temperature of products for transport and storage.
Box I.19.	Total number of boxes, cages or stalls in which the animals or hatching eggs are being transported. Total number of cryogenic containers for semen, ova, embryos. Total number of packages for products.
Box I.20.	Identify the containers/seal numbers where required.
Box I.21.	Identify the type of packaging of products as defined in Recommendation No. 21 – Code of Passengers, Type of Cargo, Package and Packaging Materials of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business).
Box I.22.	Intended use of the imported animals or products.
	Breeding/rearing: applies to animal for breeding or rearing and hatching eggs.
	Slaughter: applies to animal for slaughter.
	Game restocking Wildlife management : applies to gamewildlife for the purpose of rebuilding stocks managing populations .
	Pet: applies to animals kept for companionship or enjoyment. This excludes livestock species.
	Circus/e-Exhibition/education : applies to animals used exhibited in zoos , a circuses , sporting activities show or educational purposes exhibition .
	Human consumption: applies to products intended for human consumption.
	Animal feed: means any product of animal origin (single or multiple), whether processed, semi-processed or raw, which is intended to be fed to animals.
	Further processing: applies to products of animal origin which have to be further processed before being suitable for end use.
	Technical use: applies to products not intended for human or animal consumption. These include animal products that are intended for use in the pharmaceutical, medical, cosmetic and other industries. Such products may be subjected to extensive further processing.
	Other: intended for purposes not listed elsewhere in this classification.
Box I.23.	Mark, if appropriate.

Annex 10 (contd)

Box I.24.	Details on the nature of the commodity sufficient to identify it.
	For animals and hatching eggs: Species (scientific name); Identification system; Identification number or other identification details; Quantity and if required, Breed / Category (e.g. heifer, steer, layer, broiler); Age; Sex. For animals holding an official passport, the international animal passport number should be provided, and a copy of the details on the passport attached to the certificate.
	For embryos, ova and semen: Species (Scientific name); Identification mark according to the International Embryo Transfer Society (IETS) or the International Committee for Animal Recording (ICAR); Collection date; Approval number of the centre/team; Identification of the donor animal; Quantity. If required, Breed.
	For bees and brood combs: Category means hive with bees, swarm, consignment of bees (worker bees, drones), queen bees, brood-combs, royal cells, etc. Identification details include peculiarities (e.g. Marks or age or weight or surface). Breed / Variety if required.
	For products of animal origin: Species (Scientific name); Nature of commodity; Treatment type; approval number of establishment(s) (e.g. abattoir; cutting plant; processing plant; cold store); Lot identification/date code; Quantity; Number of packages; Net weight.

3. Part II. Zoosanitary information

Box II.	Complete this part in accordance with the requirements agreed between the Veterinary Authorities of the importing and exporting countries in accordance with the recommendations in the <i>Terrestrial Code</i> .
Box II.a.	Reference number: see box I.2.
Official veterinarian	Name, address, official position, date of signature and official stamp of the Veterinary Services.

Article 5.10.2.

Model Veterinary Certificate for International Trade in Live Animals and Hatching Eggs

COUNTRY :

Part I: Details of dispatched consignment	I.1. Consignor: Name:		I.2. Certificate reference number:		
	Address:		I.3. Veterinary Authority:		
	I.4. Consignee: Name:				
	Address:				
	I.5. Country of origin:		ISO code*	I.6. Zone or compartment of origin**:	
	I.7. Country of destination:		ISO code*	I.8. Zone or compartment of destination**:	
	I.9. Place of origin: Name:				
	Address:				
	I.10. Place of shipment:		I.11. Date of departure:		
	I.12. Means of transport:		I.13. Expected border post:		
	Aeroplane <input type="checkbox"/>		Ship <input type="checkbox"/>	Railway wagon <input type="checkbox"/>	
	Road vehicle <input type="checkbox"/>		Other <input type="checkbox"/>		
	Identification:		I.14. CITES permit No(s)**:		
	I.15. Description of commodity:		I.16. Commodity code (HS code):		
		I.17. Total quantity:			
I.18.		I.19. Total number of packages:			
I.20. Identification of container/seal number:		I.21.			
I.22. Commodities intended for use as:					
Breeding/rearing <input type="checkbox"/>		Competition <input type="checkbox"/>	Slaughter <input type="checkbox"/>	Game restocking <input type="checkbox"/>	
Pets <input type="checkbox"/>		Circus/exhibition <input type="checkbox"/>	Other <input type="checkbox"/>	Wildlife management <input type="checkbox"/>	
I.23. For import or admission:					
Definitive import <input type="checkbox"/>		Re-entry <input type="checkbox"/>	Temporary admission <input type="checkbox"/>		
I.24. Identification of commodities:					
Species (Scientific name)		Breed*/Category *	Identification system		
Identification number/details		Age *	Sex *		
		Quantity			

* Optional and ** If referenced in Part II.

Article 5.10.4.

Model Veterinary Certificate for International Trade in Products of Animal Origin

COUNTRY :

Part I: Details of dispatched consignment	I.1. Consignor: Name:		I.2. Certificate reference number:		
	Address:		I.3. Veterinary Authority:		
	I.4. Consignee: Name:				
	Address:				
	I.5. Country of origin:		ISO code*		I.6. Zone or compartment of origin**:
	I.7. Country of destination:		ISO code*		I.8. Zone or compartment of destination**:
	I.9. Place of origin: Name:				
	Address:				
	I.10. Place of shipment:		I.11. Date of departure:		
	I.12. Means of transport:		I.13. Expected border post:		
	Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/>		I.14. CITES permit No(s).**:		
	Road vehicle <input type="checkbox"/> Other <input type="checkbox"/>				
	Identification:				
	I.15. Description of commodity:		I.16. Commodity code (HS code):		
			I.17. Total quantity:		
	I.18. Temperature of product:		I.19. Total number of packages:		
	Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				
	I.20. Identification of container/seal number:		I.21. Type of packaging:		
	I.22. Commodities intended for use as:				
	Human consumption <input type="checkbox"/>		Animal feed <input type="checkbox"/>		
	Further processing <input type="checkbox"/>		Technical use <input type="checkbox"/>		
	Other <input type="checkbox"/>		<u>Exhibition / Education</u> <input type="checkbox"/>		
	I.23.				
I.24. Identification of commodities:					
Species (Scientific name)		Nature of commodity	Treatment type		
		Approval number of establishments			
Number of packages		Net weight	Lot ID/date code		

* Optional and ** If referenced in Part II.

Article 5.10.5.

Model Veterinary Certificate for International Trade in Bees and Brood Combs

COUNTRY :

Part I: Details of dispatched consignment	I.1. Consignor: Name:		I.2. Certificate reference number:		
	Address:		I.3. Veterinary Authority:		
	I.4. Consignee: Name:				
	Address:				
	I.5. Country of origin:		ISO code*	I.6. Zone or compartment of origin**:	
	I.7. Country of destination:		ISO code*	I.8. Zone or compartment of destination**:	
	I.9. Place of origin: Name:				
	Address:				
	I.10. Place of shipment:		I.11. Date of departure:		
	I.12. Means of transport:		I.13. Expected border post:		
	Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/>		I.14. CITES permit No(s).**:		
	Identification:				
	I.15. Description of commodity:		I.16. Commodity code (HS code):		
			I.17. Total quantity:		
I.18.		I.19. Total number of packages:			
I.20. Identification of container/seal number:		I.21.			
I.22. Commodities intended for use as:					
Breeding/rearing <input type="checkbox"/>		Other <input type="checkbox"/>			
I.23.					
I.24. Identification of commodities:					
Category		Breed* / Variety*			
Quantity		Identification details			

* Optional and ** If referenced in Part II.

CHAPTER 6.3.

**THE CONTROL OF HAZARDS OF
ANIMAL HEALTH AND
PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED**

EU position

The EU thanks the OIE TAHSC and supports the adoption of this modified chapter, which should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 6.3.1.

Introduction

Animal feed is a critical component of the food chain that has a direct impact on animal health and welfare and also on food safety and public health.

Historically, the OIE primarily addressed animal feed as an important pathway for the entry and spread of contagious epidemic *diseases*, such as foot and mouth disease, swine vesicular disease and avian influenza. In recent years, the role of feed as a *vector* for disease agents, including zoonotic organisms, was a focus of standards development in regards to bovine spongiform encephalopathy. Animal feed and feed ingredients are widely traded internationally and trade disruptions have the potential to impact economies in both developed and developing countries. Since 2002 the OIE has expanded its zoonotic *disease* mandate to encompass animal production food safety, working in collaboration with the Codex Alimentarius Commission (CAC) and other international organisations. In 2006 the International Committee resolved that the OIE should develop guidance on foodborne *zoonoses* and animal feeding, complementing relevant CAC texts.

Article 6.3.2.

Objective and scope

The objective of this chapter is to provide guidance on animal feeding in relation to animal health and to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety, and related other Codex texts covering animal feeding, e.g. Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001).

This chapter aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (growing, procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for terrestrial *animals*.

This chapter applies to the production and use of all products destined for animal feed and feed ingredients at all levels whether produced commercially or on farm. It also includes grazing or free-range feeding, forage crop production and water for drinking. Swill feeding is a particular aspect of on-farm practice that is specifically addressed because of its recognised role in *disease* transmission.

This chapter deals with feed for terrestrial *animals* (except bees).

Article 6.3.3.

Definitions

Contamination: means the unwanted presence of a material, infectious agent or product in a feed or feed ingredient that is potentially harmful to animal or public health or restricted under current regulations.

Feed: means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial *animals* (except bees).

Feed additive: means any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value or other effect on the *animal*, which affects the characteristics of feed or of the animal products. Microorganisms, enzymes, pH regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration. This excludes veterinary drugs.

Feed ingredient: means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the *animal's* diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.

Article 6.3.4.

General principles

1. Roles and responsibilities

The *Competent Authority* has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 3.1. and 3.2. of the *Terrestrial Code*.

Those involved in the production and use of animal feed and feed ingredients have the primary responsibility to ensure that these products meet regulatory requirements. Records and, as appropriate, contingency plans should be in place to enable tracing and recall of non-compliant products. All personnel involved in the manufacture, storage and handling of feed and feed ingredients should be adequately trained and aware of their role and responsibility in preventing the introduction or spread of hazards. Manufacturing equipment, storage and transport facilities should be adequate and maintained in good working order and in a sanitary condition.

Those providing specialist services to producers and to the feed industry (e.g. private *veterinarians*, nutritionists and laboratories) may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. disease reporting, quality standards, transparency).

2. Regulatory safety standards

All feed and feed ingredients should meet regulatory safety standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account in defining limits and tolerances for hazards.

3. Risk analysis (risk assessment, risk management and risk communication)

Internationally accepted principles and practices on *risk analysis* (Section 2 of the *Terrestrial Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while recognising the different *risk assessment* methodologies used in animal and public health.

Annex 11 (contd)4. Good practices

Where national guidelines exist, good agricultural practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them or adopt suitable international standards or recommendations.

Where appropriate, Hazard Analysis and Critical Control Point (HACCP) principles should be followed to control hazards that may occur in the manufacture, distribution and feeding of feed and feed additives and feed ingredients.

5. Geographic and environmental considerations

Epidemiological links between potential sources of hazards for animal health or food safety should be considered when assessing water sources, land or facilities for suitability for the production of animal feed and feed ingredients. Animal health considerations include factors such as disease status, location of quarantined premises and existence of *zones/compartments* of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

6. Zoning and compartmentalisation

Feed is an important component of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 4.3. of the *Terrestrial Code*.

7. Sampling and analysis

Sampling and analysis should be based on scientifically recognised principles and procedures.

8. Labelling

Labelling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and Section 4.2.10 Labelling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), including listing of ingredients and instructions on the handling, storing and use. All claims made on a label should be able to be substantiated.

9. Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Competent Authorities* contribute through the inspection or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Feed and feed ingredients business operators and other relevant parts of industry should practice self-regulation to secure compliance with required standards for procurement, handling, storage, processing, distribution and use. Operators have full responsibility for implementing systems for quality control. The *Competent Authority* should verify that process control systems and safety standards achieve all regulatory requirements.

Annex 11 (contd)

10. Assurance and certification

Feed business operators are responsible for demonstrating the safety of the establishments under their control. *Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory safety standards have been met. For *international trade* in animal product based feeds, *Veterinary Services* are required to provide *international veterinary certificates*.

11. Hazards associated with animal feed

a) Biological hazards

Biological hazards that may occur in feed and feed ingredients include agents such as bacteria, viruses, prions, fungi, ~~and parasites~~ and poisonous plants.

b) Chemical hazards

Chemical hazards that may occur in feed and feed ingredients include naturally occurring chemicals (such as mycotoxins and gossypol), industrial and environmental contaminants (such as dioxins and PCBs), residues of veterinary drugs and pesticides and also radionuclides.

c) Physical hazards

Physical hazards that may occur in feed and feed ingredients include foreign objects (such as pieces of glass, metal, plastic or wood).

12. Contamination

Procedures to minimise the risk of contamination during the ~~manufacture~~ production, processing, storage, distribution (including transport) and the use of feed and feed ingredients should be included in current regulations and standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Procedures, such as flushing, sequencing and physical clean-out, should be used to reduce the likelihood of contamination between batches of feed or feed ingredients.

13. Antimicrobial resistance

Concerning the use of antimicrobials in animal feed refer to Chapters 6.7. to 6.10. of the *Terrestrial Code*.

14. Management of information

The *Competent Authority* should establish clear requirements for the provision of information by the private sector as this relates to regulatory requirements.

Records should be maintained in a readily accessible form regarding the production, distribution and use of feed and feed ingredients. These records are required to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source, and trace-forward to the next subsequent recipients, to address identified animal health or public health concerns (see Section 4.3. of CAC/RCP 54-2004).

Annex 11 (contd)

Animal identification and *animal traceability* are tools for addressing animal health (including zoonoses), and food safety risks arising from animal feed (see Chapters 4.1. and 4.2. of the *Terrestrial Code*).

— text deleted

CHAPTER 6.5.

PREVENTION, DETECTION AND CONTROL OF
SALMONELLA IN POULTRY**EU position**

The EU supports in general the adoption of this modified chapter but has a comment.

Article 6.5.1.

Introduction

This chapter provides recommendations on the prevention, detection and control of *Salmonella* in *poultry*.

Salmonellosis is one of the most common foodborne bacterial *diseases* in the world. The great majority of *Salmonella* infections in humans are foodborne with *Salmonella* Enteritidis and *Salmonella* Typhimurium accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries and therefore, *surveillance* and identification of the prevalent *Salmonella* serotypes in humans and *poultry* should be carried out in order to develop a control programme for the area.

In most food animal species, *Salmonella* can establish a clinically inapparent *infection* of variable duration, which is significant as a potential *zoonosis*. Such animals may be important in relation to the spread of *infection* between *flocks* and as causes of human foodborne *infection*. In the latter case, this can occur when *meat* and eggs, or their products, enter the food chain thus producing contaminated food.

Article 6.5.2.

Purpose and scope

This chapter deals with methods for on farm prevention, detection and control of *Salmonella* in *poultry*, and complements the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in reducing the presence of foodborne pathogens in eggs and *meat*.

Hygiene and biosecurity procedures to be implemented in *poultry flocks* farms and hatcheries are described in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production.

The recommendations presented in this Chapter are relevant to the control of all *Salmonella* with special attention to *S. Enteritidis* and *S. Typhimurium*, as these are common *Salmonella* serotypes in many countries. It should be noted that the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Salmonella*.

Article 6.5.3.

Definitions (for this Chapter only)

Breeders: means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing *day-old birds*.

Competitive exclusion: means the administration of defined or undefined bacterial flora to *poultry* to

prevent gut colonisation by enteropathogens, including *Salmonella*.

Culling: means the ~~depopulation~~ destruction or slaughter of a *flock* before the end of its normal production period.

Layers: means *poultry* during the period of laying eggs for human consumption.

Article 6.5.4.

Surveillance of poultry flocks for *Salmonella*

Where justified by *risk assessment*, *surveillance* should be carried out to identify infected *flocks* in order to take measures that will reduce the prevalence in *poultry* and the risk of transmission of *Salmonella* to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broilers *flocks* and higher specificity in breeders and *layer flocks*. In the framework of regulatory programmes for the control of *Salmonella* in *poultry* and salmonellosis in humans, confirmatory testing may be required.

Sampling

1. Available methods for sampling

Drag swabs: sampling is done by dragging swabs throughout the *poultry building house*.

Boot swabs: sampling is done by walking throughout the *poultry building house* with absorbent material placed over the footwear of the sampler.

Dust samples: sampling is done by collecting dust from exhaust fans, screens and other equipment in the *poultry building house*.

Faecal samples: multiple fresh faecal/caecal samples collected from different areas in the *poultry building house*.

Meconium, chick box liners papers, dead in shell and culled ~~chicks~~ day-old birds at the hatchery.

Hatchery samples: throughout the hatchery, including inside the incubators.

2. Sample size

Refer to the *Terrestrial Manual* (under development).

3. Laboratory methods

Refer to the *Terrestrial Manual* (under development).

4. Time and frequency of testing

Time and frequency of sampling for each *poultry* type are listed below:

a) Breeders and hatcheries

i) Breeder flocks before lay

- Before the end of the first week of life when the status of the breeder ~~ing flock farm~~ and/or the hatchery is not known or does not comply with this chapter.

Annex 12 (contd)

- Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
 - One or more times during the growing period if there is a culling policy in place. The frequency would be determined on commercial considerations.
- ii) Breeder flocks in lay
- At least at monthly intervals during the laying period.
 - Additional testing should be determined by the *Veterinary Services*.
- iii) Hatcheries
- Testing at hatcheries should complement on farm testing.
 - The minimal frequency should be determined by the *Veterinary Services*.
- b) Poultry for the production of eggs for human consumption
- i) Flocks grown to be layers
- Before the end of the first week of life when the status of the ~~breeding flock farm~~ ~~and/or~~ the hatchery is not known or does not comply with this chapter.
 - Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
 - One or more times during the growing period if there is a culling policy in place. The frequency would be determined by commercial considerations.
- ii) Layer flocks
- At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).
 - One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should be determined by the *Veterinary Services*.
- c) Poultry for the production of meat
- i) *Flocks* should be sampled at least once ~~before slaughter~~.
- ii) When sampling occurs on farms and when there is a long period (2 weeks or more) between thinning and final depopulation further testing should be considered.
- iii) When sampling occurs on farms, *flocks* should be sampled as late as possible before the first birds are transported to the *slaughterhouse*. In order to allow for the implementation of control measures during processing, this should be done at a time that ensures the results are available before *slaughter*.

Whether sampling occurs on the farm which is more appropriate for consequent control measures or at the processing plant, there should be an integrated system in place that allows for investigation of

the source of positive *flocks*.

Annex 12 (contd)

- d) ~~Testing of empty building poultry houses testing~~
- i) Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when *Salmonella* have been detected in the previous *flock*.

As appropriate, sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty ~~building poultry house~~ after depopulation, cleaning and *disinfection*.

Results from *surveillance* may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of *Salmonella* to humans:

- a) In breeders, control measures may be implemented to reduce the transmission of *Salmonella* to the next generation, especially for trans-ovarian transmitted serotypes such as *S. Enteritidis*.
- b) In *layer flocks* control measures will reduce and may eliminate contamination of eggs with *Salmonella*.
- c) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article 6.5.5.

Prevention and Control measures

Salmonella prevention and control may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.4. **Hygiene and Biosecurity Procedures in Poultry Production**, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective *Salmonella* control.

Additional prevention and control measures include: vaccination, competitive exclusion, ~~flock culling~~, use of organic acids, culling and product diversion to processing.

Antimicrobials should not be used to control *infection* with *Salmonella* in *poultry* because the effectiveness of the treatment is limited, may mask the infection at sampling, has the potential to produce residues in *meat* and eggs and can contribute to the development of antimicrobial resistance. Antimicrobials may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella*. In special circumstances antimicrobials may be used to salvage birds with high genetic value.

EU comment

The word "antimicrobials" at the beginning of the two first sentences and at the last line of the paragraph above should be replaced by the words "Antimicrobial agents" to reflect the definition in the Glossary.

1. *Day-old birds* used to stock a *poultry* house should be obtained from ~~breeder~~ *flocks* and hatcheries that have been monitored according to this Chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
2. *Layer* and breeder *flocks* should be stocked from *flocks* that have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
3. Feed contamination with *Salmonella* is known to be a source of *infection* for *poultry*. Therefore, it is

recommended to monitor the *Salmonella* status of *poultry* feed, and if found positive to take corrective measures.

~~The use of h~~Heat treated feeds with or without the addition of ~~or feeds subjected to other bacteriocidalstatic or bacteriostaticicidal treatments (e.g. addition of organic acids).~~ ~~(e.g. organic acids)~~ is are recommended (e.g. organic acids). Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended.

EU comment

The EU reiterates its comment that "bacteriostatic or bactericidal treatments" exclude the use of antimicrobial agents in feed.

Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

4. Competitive exclusion may be used in *day-old birds* to reduce colonisation by *Salmonella*.

When used, competitive exclusion should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

5. Vaccines are used against *Salmonella* infections caused by different serotypes in various *poultry* species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

If live vaccines are used it is important that field and vaccine strains be easily differentiated in the laboratory. If serology is used as the *surveillance* method, it may not be possible to distinguish between vaccination and *infection* with a field strain.

Vaccination can be used as part of an overall *Salmonella* control programme. It is recommended that vaccination not be used as the sole control measure.

When the status of the ~~breeding flock farm and/or~~ the hatchery from which the *flock* originates is not known or does not comply with this Chapter, vaccination of *flocks*, starting with *day-old birds*, against the *Salmonella* serotypes known to be significant should be considered.

Vaccination against the *Salmonella* serotypes known to be significant should be considered when moving *day-old birds* to a previously contaminated shed so as to minimise the risk of the birds contracting *Salmonella* infection.

When used, vaccines should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

Vaccination against *S. Enteritidis* can cause cross reactions in *Salmonella* Pullorum/*S. Gallinarum* serological tests and needs to be considered when implementing measures for these pathogens.

6. Depending on animal health, *risk assessment*, and public health policies, culling is an option to manage infected breeder and *layer flocks*. Infected *flocks* should be destroyed or *slaughtered* and processed to minimise human exposure to *Salmonella*.

~~If culling is not applied poultry are not culled,~~ eggs for human consumption should be diverted for processing for inactivation of *Salmonella*.

7. *S. Enteritidis* is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *S. Enteritidis* from egg-producing *flocks* through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent *flocks* through breeder *flocks* to *layer flocks*.

8. The responsible *veterinarian* should evaluate the results of *surveillance* testing for *Salmonella* and supervise the implementation of appropriate control measures. ~~This information~~ These results should be available to the veterinarian before marketing if a veterinary certificate for *flock Salmonella* status is required. When required by the *Competent Authority*, the veterinarian or other person responsible for notification should notify the *Competent Authority* if the presence of *Salmonella* of the relevant serotype is confirmed.

Article 6.5.6.

Prevention of *Salmonella* spread from infected flocks

If a *flock* is found infected with specific *Salmonella* serotypes of concern, the following actions should be taken in addition to general measures detailed in Chapter 6.4. ~~Hygiene and~~ Biosecurity Procedures in Poultry Production:

1. According to the epidemiological situation, investigations should be carried out to determine the origin of the *infection*.
2. Movement of *poultry flocks* at the end of the production cycle should only be allowed for *slaughter* or destruction. Special precautions should be taken in the transport, *slaughter* and processing of the birds, e.g. they could be sent to a separate *slaughterhouse* or processed at the end of a shift before cleaning and *disinfection* of the equipment.
3. Litter should not be reused. Used ~~P~~*poultry litter* ~~/faeces, carcasses~~ and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and wildlife to *Salmonella*. Particular care needs to be taken when utilising ~~in regard to~~ used ~~poultry litter/faeces used~~ to fertilise plants intended for human consumption. If litter is not removed, then it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.
4. Particular care should be taken in cleaning and *disinfection* of the *poultry* house and equipment.
5. Before restocking the facility, a bacteriological examination should be carried out as detailed in this Chapter and the *Terrestrial Manual*.

Article 6.5.7.

Recommendations for importation of live poultry (other than day-old birds)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* originated from an ~~establishment~~ flock that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
2. the *poultry* originated from an ~~establishment~~ flock in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected prior to shipment and have had no contact with birds or other material from ~~establishment~~ flocks that do not comply with this chapter;
3. the *poultry* originated from an ~~establishment~~ flock that complies with the recommendations of Chapter 6.4.

Article 6.5.8.

Recommendations for importation of day-old birds

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *day-old birds* showed no clinical signs of salmonellosis on the day of shipment;
2. the *day-old birds* originated from a breeder ~~establishment~~ flock and hatchery that participate in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
3. the *day-old birds* originated from a breeder ~~establishment~~ flock and hatchery in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected and have had no contact during setting, incubation or hatching with *hatching eggs* or other material from an *establishment* that do not comply with this chapter;
4. the *day-old birds* originated from a breeder ~~establishment~~ flock and hatchery that complies with the recommendations of Chapter 6.4.;
5. the *day-old birds* were shipped in new and clean *containers*.

Article 6.5.9.

Recommendations for importation of hatching eggs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *hatching eggs* originated from a breeder ~~establishment~~ flock that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
2. the *hatching eggs* originated from a breeder ~~establishment~~ flock in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected and have had no contact with *poultry* or other material from an *establishments* that do not comply with this Chapter;
3. the *hatching eggs* originated from a breeder ~~establishment~~ flock that complies with the recommendations of Chapter 6.4.;
4. the *hatching eggs* were shipped in new and clean packaging materials.

— text deleted

Annex 12 (contd)

CHAPTER 6.4.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

EU position

The EU supports in general the adoption of this modified chapter.

Article 6.4.1.

Introduction

This chapter provides recommended biosecurity procedures in *poultry* production and is not specifically related to trade.

Infectious ~~disease~~ agents of *poultry* are a threat to *poultry* health and, at times, human health and have significant social and economic implications. In *poultry* production, especially under intensive conditions, prevention is the most viable and economically feasible approach to the control of infectious ~~disease~~ agents.

Biosecurity procedures should be implemented with the objective of preventing the introduction and dissemination of infectious ~~disease~~ agents in the *poultry* production chain. Biosecurity will be enhanced with the adoption and implementation of the principles of Good Agricultural Practices and the Hazard Analysis Critical Control Point (HACCP) system ~~will help to achieve these objectives~~.

Article 6.4.2.

Purpose and scope

This chapter deals with biosecurity procedures in *poultry* production. It should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 ~~Revision 2007~~).

~~This chapter provides general recommendations for infectious *disease* agents of *poultry*. Recommendations on specific *diseases* may be found in relevant *disease* chapters in the *Terrestrial Code*.~~

This chapter identifies several ~~relevant~~ biosecurity measures. The choice of measures to be implemented will vary according to national conditions, including *poultry ~~disease~~ infection* status, the risk of introduction and dissemination of infectious ~~disease~~ agents and the cost effectiveness of control measures.

Recommendations on specific infectious agents may be found in relevant *disease* chapters in the *Terrestrial Code*.

Article 6.4.3.

Definitions (for this Chapter only)

Breeders: means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing *day-old birds*.

~~**Culling:** means the depopulation of a *flock* before the end of its normal production period.~~

Live bird markets: means markets where live birds from various sources and species are sold for *slaughter*, ~~or~~ further rearing or production.

Article 6.4.4.

Recommendations on the location and construction of poultry establishments

1. All establishments (poultry farms and hatcheries)

- a) A suitably isolated geographical location is recommended, ~~taking into account~~ Factors to consider include the ~~direction of the prevailing winds~~, location of other poultry and livestock establishments, wild bird concentrations and the distance from roads used to transport *poultry*.
- b) *Poultry establishments* should be located and constructed to provide adequate drainage ~~away from~~ for the site. Run-off or untreated site wastewater should not discharge into waterfowl habitats.
- c) *Poultry* houses and hatcheries should be designed and constructed (preferably of smooth impervious materials) so that cleaning and *disinfection* can be carried out effectively. Ideally, the area immediately surrounding the *poultry* houses and hatcheries should be paved with concrete or other impervious material to facilitate cleaning and *disinfection*.
- d) The *establishment* should be surrounded by a security fence to prevent the entry of unwanted animals and people.
- e) A sign indicating restricted entry should be posted at the entrance to the ~~farm~~ establishment.

2. Additional measures for poultry farms

- a) *Establishments* should be designed ~~for use with~~ to house a single species and a single production type purpose. ~~Whenever possible, the design should also consider the~~ 'all-in all-out' single age group principle ~~should be used~~. If this is not feasible ~~and several flocks are maintained on one establishment, the establishment should be designed so that~~ each *flock* can ~~should~~ be managed as a separate *epidemiological unit*.
- b) *Poultry* houses, and buildings used to store feed, ~~or~~ eggs, ~~or other material~~, should be constructed and maintained to prevent the entry of wild birds, rodents and ~~insects~~ arthropods.
- c) Where feasible, the floors of *poultry* houses should be constructed using concrete or other impervious materials and designed so that cleaning and *disinfection* can be carried out effectively.
- d) Where feasible, feed should be delivered into the farm from outside the security fence.

3. Additional measures for hatcheries

- a) The design of the hatchery should take account of work flow and air circulation needs, with 'one way flow' movement of eggs and *day-old birds* and one way air flow in the same direction.
- b) The hatchery buildings should include physical separation of areas used for the following:
 - i) personnel changing, showering and sanitary facilities;
 - ii) receipt, storage and transfer of eggs;
 - iii) incubation;
 - iv) hatching;

- v) sorting, sexing and other handling ~~placing~~ of *day-old birds* ~~in boxes~~;
- vi) storage of egg boxes and ~~chick~~ boxes for *day-old birds*, egg flats, chick box ~~pads~~ liners, chemicals and other items;
- vii) ~~washing~~ equipment washing;
- viii) waste disposal;
- ix) dining facilities for personnel;
- x) office space.

Article 6.4.5.

Recommendations applicable to the operation of poultry establishments

1. All establishments (poultry farms and hatcheries)
 - a) All establishments should have a written biosecurity plan. Personnel in the establishments should have access to basic training in biosecurity relevant to poultry production and understand the implications to animal health, human health and food safety.
 - ~~a)b)~~ There should be good communication between ~~all those personnel~~ involved in the *poultry* production chain ~~from breeding to production and consumption~~ to ensure that steps are taken to minimise the introduction and dissemination of infectious ~~disease~~ agents. ~~Personnel should have access to basic training in biosecurity relevant to poultry production and food safety.~~
 - ~~b)c)~~ Traceability at all levels of the *poultry* production chain should be possible.
 - ~~e)d)~~ Records ~~of production~~ should be maintained: on an individual flock basis and include data on bird health, production, On farm, this includes cleaning and disinfection, treatment medications, vaccination, flock history, mortality and disease surveillance data. This should be maintained on an individual flock basis. In hatcheries, relevant records should include data on fertility, hatchability, vaccination and treatments. Records should be maintained on cleaning and disinfection of farm and hatchery buildings and equipment. Records should be readily available for inspection on site.
 - ~~d)e)~~ ~~A veterinarian should be responsible for m~~Monitoring of poultry health on the *establishment* should be under the supervision of a veterinarian.
 - ~~e)f)~~ ~~Access to the establishment should be controlled to ensure only authorised persons and vehicles enter the site.~~
 - ~~g)f)~~ ~~Establishments should be free from control~~ be free from unwanted vegetation and be free from debris that could attract or harbour pests.
 - ~~g)h)~~ Procedures for the prevention of entry of wild birds into poultry houses and buildings, and the control of vermin such as rodents and arthropods should be implemented ~~on a routine basis~~.
 - ~~i)~~ Access to the establishment should be controlled to ensure only authorised persons and vehicles enter the site.

- hi) All personnel and visitors entering an *establishment* should follow a biosecurity procedure. The preferred procedure is for visitors and personnel entering the establishment to shower and change into clean clothes and footwear provided by the *establishment*. Where this is not practical, clean outer garments (coveralls or overalls, head covering hats and footwear) should be provided.

~~Before entering and after leaving a poultry house, personnel and visitors should wash their hands with soap and water use a properly maintained disinfectant footbath. The disinfectant solution in the footbath should be changed on a regular basis to ensure its efficacy, according to the manufacturer's instructions.~~

- ij) Personnel and visitors should not have had recent contact with other *poultry*, *poultry* waste, or *poultry* processing plant(s). This time period should be based on the level of risk of transmission of infectious ~~disease~~ agents. This will depend on the *poultry* production purpose, biosecurity procedures and ~~disease~~ infection status (e.g. the time between visiting a breeder *flock* and then a broiler *flock* would be less than the time between visiting a broiler *flock* and then a breeder *flock*).
- jk) Any vehicle entering an establishment should be cleaned and disinfected according to a biosecurity plan. Delivery *vehicles* should be cleaned, and *disinfected* before loading each consignment of *hatching* eggs, ~~day-old birds~~ or *poultry*.

2. Additional measures for all poultry farms

- a) Whenever possible, the 'all-in all-out' single age group principle should be used. If this is not feasible and several flocks are maintained on one establishment, each flock should be managed as a separate epidemiological unit.
- b) All personnel and visitors entering a poultry house should wash their hands with soap and water or sanitize them using a disinfectant. Personnel and visitors should also change footwear, use a boot spray or use a properly maintained disinfectant footbath. The disinfectant solution in the footbath should be changed on a regular basis to ensure its efficacy, according to the manufacturer's instructions.
- c) Animals, other than *poultry* of the appropriate (resident) species and age, should not be permitted access to *poultry* houses. No animals should have access to other buildings (e.g. those used to store feed, ~~or~~ eggs or other material).
- bd) The drinking water supply to *poultry* houses should be potable according to the World Health Organization or to the relevant national standard, and microbiological quality should be monitored if there is any reason to suspect contamination. The water delivery system should be cleaned and disinfected between *flocks* when the *poultry* house is empty.
- ce) Birds used to stock a *poultry* house should preferably be obtained from breeder *flocks* and hatcheries that are free from vertically transmitted infectious ~~disease~~ agents.
- df) Heat treated feeds with or without the addition of other bacteriocidal ~~static~~ or ~~bacteriostatic~~ ~~cecidal~~ treatments (e.g. addition of organic acids) is are recommended (e.g. ~~organic acids~~). Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended.

Feed should be stored in a manner to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents. The movement of feed between flocks should be avoided.

Annex 12 (contd)

- eg) The litter in the *poultry* house should be kept dry and in good condition.
- fh) Dead birds should be removed from *poultry* houses as quickly as possible ~~but~~ or at least daily. These should be disposed of in a safe and effective manner.
- gi) Personnel involved in the catching of birds should be adequately trained in bird handling and basic biosecurity procedures.
- hj) To minimise stress ~~p~~*Poultry* should be transported in well ventilated *containers* and should not be over crowded. Exposure to extreme temperatures should be avoided.
- ik) *Containers* should be cleaned and disinfected between each use, or disposed of in a safe manner.
- jl) When a *poultry* house is depopulated, it is recommended that all faeces and litter be removed from the house and disposed of in a safe manner to minimise the risk of dissemination of infectious agents ~~approved by the Veterinary Services~~.

If litter is not removed and replaced between *flocks* then the litter should be treated in a manner to ~~inactivate infectious disease agents, to prevent~~ minimise the risk of dissemination of infectious ~~disease~~ agents from one *flock* to the next.

After removal of faeces and litter, cleaning and *disinfection* of the *poultry house* ~~building~~ and equipment should be done in accordance with Chapter 4.13.

~~All litter removed from a *poultry* house should be disposed of in a safe manner to prevent the dissemination of infectious agents.~~

- km) For *poultry flocks* that are allowed to range outdoors, feeders, feed and other items which may attract wild birds should be kept indoors. attractants to wild birds should be minimised e.g. feeders should be kept inside the poultry house. *Poultry* should not be allowed access to sources of contamination (e.g. household waste, litter storage areas, other ~~farm~~ animals, stagnant water and water of unknown quality and litter storage areas). The nesting area should be inside the *poultry* house.
- ln) To avoid the development of antimicrobial resistance, antimicrobials should be used according to relevant directions of the *Veterinary Services* and manufacturer's instructions and in accordance with *Terrestrial Code* Chapters 6.8, 6.9., 6.10. and 6.11.

3. Additional measures for layers

Refer to Section 3 of the Codex Alimentarius Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976).

34. Additional measures for breeders ~~farms~~

- a) Nest box litter and liners should be kept clean.
- b) *Hatching eggs* should be collected at frequent intervals, at least daily, and placed in ~~a~~ new or clean and *disinfected* packaging material.
- c) Grossly dirty, ~~broken~~, cracked, broken, or leaking eggs should be collected separately and should not be used as *hatching eggs*.

- d) *Hatching eggs* should be cleaned and sanitized as soon as possible after collection using an approved sanitising agent, in accordance with the manufacturer's instructions.
- e) *Hatching eggs* or their packaging materials should be marked to assist traceability and veterinary investigations.
- f) The ~~sanitised~~ *hatching eggs* should be stored in a dedicated room as soon as possible after cleaning and sanitisation ~~collection~~. Storage conditions should minimise the potential for microbial contamination and growth and ensure maximum hatchability. The room should be well ventilated, kept clean, and regularly *disinfected* using disinfectants approved for this purpose.

45. Additional measures for hatcheries

- a) Dead in shell embryos should be removed from hatcheries as soon as they are found and disposed of in a safe and effective manner.
- b) All hatchery waste, garbage and discarded equipment should be contained or at least covered while on site and removed from the hatchery and its environs as soon as possible.
- c) After use, hatchery equipment, tables and surfaces should be promptly and thoroughly cleaned and *disinfected* with an approved disinfectant.
- d) Egg handlers, ~~chick~~ sexers and ~~chick~~ handlers of day-old birds should wash their hands with soap and water before commencing work and between working with batches of *hatching eggs* or *day-old birds* from different breeder *flocks*.
- e) *Hatching eggs* and *day-old birds* from different breeder *flocks* should be ~~kept separate~~ identifiable during incubation, hatching, sorting and transportation.
- f) *Day-old birds* should be delivered to the farm in new *containers* or in clean, *disinfected containers*.

Article 6.4.6.

Prevention of further dissemination of infectious ~~disease~~ agents of poultry

When a *flock* is suspected or known to be infected or determined to be infected, in addition to the general biosecurity measures described previously, management procedures should be adjusted to effectively isolate ~~the infected flock~~ it from other *flocks* on the *establishment* and other epidemiologically related *establishments*. The following measures are recommended:

1. Personnel should ~~be trained in the management of~~ suspected or infected *flocks* to ~~prevent~~ minimise the risk of the dissemination of infectious ~~disease~~ agents to other *flocks* and *establishments*, and to humans. ~~(Relevant measures include: handling of an infected flock separately, last in sequence and the use of dedicated personnel, and clothing and equipment).~~
2. A veterinarian should be consulted immediately.
3. When infection has been confirmed, ~~e~~ Epidemiological investigations should be carried out to determine the origin and route of transmission of the infectious ~~disease~~ agent.
34. Poultry carcasses, litter, ~~faeces~~ and other potentially contaminated farm waste should be disposed of in a safe manner to ~~prevent~~ minimise the risk of dissemination of infectious ~~disease~~ agents. The disposal method used will depend on the infectious agent involved.

Annex 12 (contd)

45. Depending on the epidemiology of the ~~disease~~ infectious agent disease, the results of a *risk assessment*, and public and animal health policies, ~~caulling destruction or slaughter of a flock before the end of the normal production period~~ may be used to manage infected flocks. When infected flocks are destroyed or *slaughtered* they should be processed in a manner to minimise exposure of humans and other flocks to the infectious ~~disease~~ agent, and in accordance with recommendations of the *Veterinary Service* and relevant Chapters in the *Terrestrial Code*. Based on *risk assessment*, non-infected, high risk flocks may be ~~caulling destroyed or slaughtered before the end of their normal production period~~. Movement of culled poultry should only be allowed for *slaughter* or destruction.

Before restocking, the poultry house including equipment ~~or establishment~~ should be cleaned, *disinfected* and tested to verify that the cleaning has been effective. Special attention should be paid to feed equipment and water systems.

Microbiological monitoring of the efficacy of *disinfection* procedures is recommended when pathogenic agents have been detected in the previous flock.

56. Depending on the epidemiology of the ~~disease~~ infectious agent disease, *risk assessment*, vaccine availability and public and animal health policies, vaccination is an option to minimise the dissemination of the infectious ~~disease~~ agent. When used, vaccines ~~poultry~~ should be administered ~~vaccinated~~ in accordance with the directions of the *Veterinary Services* and the manufacturer's instructions. Recommendations in the *Terrestrial Manual* should be followed as appropriate.

Article 6.4.7.

Recommendations to prevent the dissemination of infectious ~~disease~~ agents to and from live bird markets

1. Personnel should be educated on the significance of infectious ~~disease~~ agents and the need to apply biosecurity practices to prevent dissemination of these agents. Education should be targeted to personnel at all levels of operations in these markets (e.g. drivers, owners, handlers, processors).

Programmes should be implemented to raise consumer awareness ~~of consumers about~~ of the risks associated with activities of live bird markets

2. Personnel should wash their hands with soap and water before and after handling birds.
 3. Birds from diseased flocks should not be transported to live bird markets.
34. All *containers* and *vehicles* should be cleaned and *disinfected* every time they leave the market.
45. Live birds that leave the market and go to a farm should be housed kept separately from other birds for a period of time to minimise the potential dissemination of infectious ~~disease~~ agents of *poultry*.
 56. Periodically the market should be emptied, cleaned and *disinfected*. This is of particular importance when an infectious ~~disease~~ agent of *poultry* deemed significant by the *Veterinary Services* has been identified in the market or the region.

67. Where feasible, *surveillance* should be carried out in these markets to detect infectious ~~disease~~ agents of *poultry*, ~~especially those agents of zoonotic significance~~. The *surveillance* programme should be determined by the *Veterinary Services*, and in accordance with recommendations in relevant ~~disease specific~~ chapters of the *Terrestrial Code*.
78. ~~Attempts~~ Efforts should be made to ensure the possibility of tracing all birds entering and leaving the markets.

— text deleted

CHAPTER 7.3.

TRANSPORT OF ANIMALS BY LAND

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of the proposed changes in the chapter.

However, the EU has one important comment on the chapter.

Preamble: These recommendations apply to the following live domesticated *animals*: cattle, buffaloes, camels, sheep, goats, pigs, *poultry* and equines. They will also be largely applicable to some other *animals* (e.g., deer, other camelids and ratites). Wild, and feral and partly domesticated *animals* may need different conditions.

Article 7.3.1.

The amount of time *animals* spend on a *journey* should be kept to the minimum.

Article 7.3.2.

1. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns, which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed.

The desire of some *animals* to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers*.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans (i.e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape and compromise the *welfare* of the *animals*.

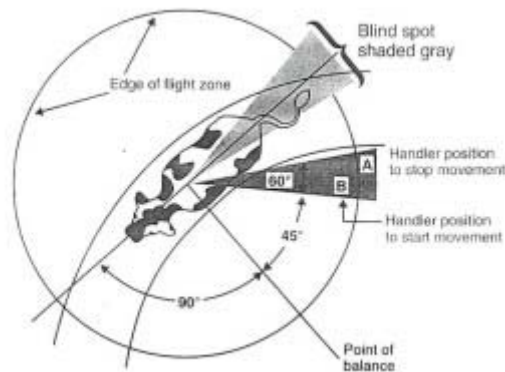
Animal handlers should use the point of balance at the *animal's* shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have a wide-angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

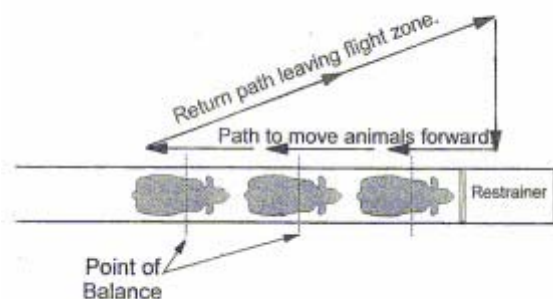
Although domestic *animals* have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noises and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



2. Distractions and their removal

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching *animals* to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

- reflections on shiny metal or wet floors - move a lamp or change lighting;
- dark entrances — illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;
- animals* seeing moving people or equipment up ahead — install solid sides on chutes and races or install shields;
- dead ends — avoid if possible by curving the passage, or make an illusory passage;

- e) chains or other loose objects hanging in chutes or on fences — remove them;
- f) uneven floors or a sudden drop in floor levels — avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment — install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects — install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of *animals* — redirect or reposition equipment.

Article 7.3.3.

Responsibilities

Once the decision to transport the *animals* has been made, the *welfare* of the *animals* during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this article.

The roles of each of those responsible are defined below:

1. The owners and managers of the *animals* are responsible for:
 - a) the general health, overall *welfare* and fitness of the *animals* for the *journey*;
 - b) ensuring compliance with any required veterinary or other certification;
 - c) the presence of an *animal handler* competent for the species being transported during the *journey* with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole *animal handler* during the *journey*;
 - d) the presence of an adequate number of *animal handlers* during *loading* and *unloading*;
 - e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the *journey*.
2. Business agents or buying/selling agents are responsible for:
 - a) selection of animals that are fit to travel;
 - b) availability of suitable facilities at the start and at the end of the *journey* for the assembly; *loading*, transport, *unloading* and holding of *animals*, including for any stops at *resting points* during the *journey* and for emergencies.
3. *Animal handlers* are responsible for the humane handling and care of the *animals*, especially during *loading* and *unloading*, and for maintaining a *journey* log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.
4. Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the *animals*; in particular they are responsible for:
 - a) choosing appropriate *vehicles* for the species transported and the *journey*;

- b) ensuring that properly trained staff are available for *loading/unloading of animals*;
 - c) ensuring adequate competency of the driver in matters of *animal welfare* for the species being transported in case a separate *animal handler* is not assigned to the truck;
 - d) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
 - e) producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of *resting places*;
 - f) *loading* only those *animals* which are fit to *travel*, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising; if its fitness to *travel* is in doubt, the *animal* should be examined by a *veterinarian* in accordance with point 3a) of Article 7.3.7.;
 - g) *welfare* of the *animals* during the actual *transport*.
5. Managers of facilities at the start and at the end of the *journey* and at *resting points* are responsible for:
- a) providing suitable premises for *loading, unloading* and securely holding the *animals*, with water and feed when required, and with protection from adverse weather conditions until further transport, sale or other use (including rearing or slaughter);
 - b) providing an adequate number of *animal handlers* to load, unload, drive and hold *animals* in a manner that causes minimum stress and injury; in the absence of a separate *animal handler*, the driver is the *animal handler*;
 - c) minimising the opportunities for disease transmission;
 - d) providing appropriate facilities, with water and feed when required;
 - e) providing appropriate facilities for emergencies;
 - f) providing facilities for washing and disinfecting *vehicles* after *unloading*;
 - g) providing facilities and competent staff to allow the humane *killing* of *animals* when required;
 - h) ensuring proper rest times and minimal delay during stops.
6. The responsibilities of *Competent Authorities* include:
- a) establishing minimum standards for *animal welfare*, including requirements for inspection of *animals* before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;
 - b) setting standards for facilities, *containers* and *vehicles* for the transport of *animals*;
 - c) setting standards for the competence of *animal handlers*, drivers and managers of facilities in relevant issues in *animal welfare*;
 - d) ensuring appropriate awareness and training of *animal handlers*, drivers and managers of facilities in relevant issues in *animal welfare*;
 - e) implementation of the standards, including through accreditation of / interaction with other organisations;
 - f) monitoring and evaluating the effectiveness of standards of health and other aspects of *welfare*;

- g) monitoring and evaluating the use of veterinary medications;
 - h) giving animal consignments priority at frontiers in order to allow them to pass without unnecessary delay.
7. All individuals, including *veterinarians*, involved in transporting *animals* and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.
 8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant *animal welfare* problems which occurred during the *journey*.

Article 7.3.4.

Competence

1. All people responsible for *animals* during *journeys*, should be competent according to their responsibilities listed in Article 7.3.3. Competence may be gained through formal training and/or practical experience.
2. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
 - a) planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements;
 - b) responsibilities for *animals* during the *journey*, including *loading* and *unloading*;
 - c) sources of advice and assistance;
 - d) animal behaviour, general signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and fatigue, and their alleviation;
 - e) assessment of fitness to travel; if fitness to travel is in doubt, the *animal* should be examined by a *veterinarian*;
 - f) relevant authorities and applicable transport regulations, and associated documentation requirements;
 - g) general disease prevention procedures, including cleaning and *disinfection*;
 - h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading* and *unloading*;
 - i) methods of inspecting *animals*, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including humane *killing*;
 - j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and
 - k) maintaining a *journey* log and other records.

Article 7.3.5.

Planning the journey

1. General considerations
 - a) Adequate planning is a key factor affecting the *welfare* of *animals* during a *journey*.

- b) Before the *journey* starts, plans should be made in relation to:
- i) preparation of *animals* for the *journey*;
 - ii) choice of road, rail, roll-on roll-off vessels or *containers*;
 - iii) nature and duration of the *journey*;
 - iv) *vehicle* design and maintenance, including roll-on roll-off vessels;
 - v) required documentation;
 - vi) *space allowance*;
 - vii) rest, water and feed;
 - viii) observation of *animals* en route;
 - ix) control of *disease*;
 - x) emergency response procedures;
 - xi) forecast weather conditions (e.g. conditions being too hot or too cold to travel during certain periods of the day);
 - xii) transfer time when changing mode of transport, and
 - xiii) waiting time at frontiers and inspection points.
- c) Regulations concerning drivers (for example, maximum driving periods) should take into account *animal welfare* whenever possible.

2. Preparation of animals for the journey

- a) When *animals* are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. For all *animals* it is essential that the rest stops during long journeys are long enough to fulfil each *animal's* need for feed and water. Species-specific short period of feed deprivation prior to *loading* may be desirable
- b) *Animals* more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. *Animal handlers* should handle and load *animals* in a manner that reduces their fearfulness and improves their approachability.
- c) Behaviour-modifying compounds (such as tranquillisers) or other medication should not be used routinely during transport. Such compounds should only be administered when a problem exists in an individual *animal*, and should be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

3. Nature and duration of the journey

The maximum duration of a *journey* should be determined according to factors such as:

- a) the ability of the *animals* to cope with the stress of transport (such as very young, old, lactating or pregnant *animals*);
- b) the previous transport experience of the *animals*;
- c) the likely onset of fatigue;

- d) the need for special attention;
- e) the need for feed and water;
- f) the increased susceptibility to injury and *disease*;
- g) *space allowance*, *vehicle* design, road conditions and driving quality;
- h) weather conditions;
- i) *vehicle* type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver.

4. Vehicle and container design and maintenance

- a) *Vehicles* and *containers* used for the transport of *animals* should be designed, constructed and fitted as appropriate for the species, size and weight of the *animals* to be transported. Special attention should be paid to avoid injury to *animals* through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should be emphasised.
- b) *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for *animals* to escape.
- c) In order to minimise the likelihood of the spread of infectious *disease* during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a *journey*.
- d) *Vehicles* and *containers* should be maintained in good mechanical and structural condition.
- e) *Vehicles* and *containers* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be effective when the *vehicle* is stationary, and the airflow should be adjustable.
- f) *Vehicles* should be designed so that the faeces or urine from *animals* on upper levels do not soil *animals* on lower levels, nor their feed and water. This condition is not applicable for *poultry*. They are generally transported in plastic crates which are designed to let air flow through in all directions to obtain a better ventilation.
- g) When *vehicles* are carried on board ferries, facilities for adequately securing them should be available.
- h) If feeding or watering while the *vehicle* is moving is required, adequate facilities on the *vehicle* should be available.
- i) When appropriate, suitable bedding should be added to *vehicle* floors to assist absorption of urine and faeces, to minimise slipping by *animals*, and protect *animals* (especially young *animals*) from hard flooring surfaces and adverse weather conditions.

5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers

- a) *Vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.
- b) *Vehicles* and *containers* should be secured to the *vessel* before the start of the sea *journey* to prevent them being displaced by the motion of the *vessel*.
- c) Roll-on/roll-off *vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the *animals* are transported in a secondary *vehicle/container* on enclosed decks.

6. Space allowance

- a) The number of *animals* which should be transported on a *vehicle* or in a *container* and their allocation to compartments should be determined before *loading*.
- b) The space required on a *vehicle* or in a *container* depends upon whether or not the *animals* need to lie down (for example, cattle, sheep, pigs, camels and *poultry*), or to stand (horses). *Animals* which will need to lie down often stand when first loaded or when the *vehicle* is driven with too much lateral movement or sudden braking.
- c) When *animals* lie down, they should all be able to adopt a normal lying posture, without being on top of one another, and allowing necessary thermoregulation.
- d) When *animals* are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported.
- e) The amount of headroom necessary depends on the species of *animal*. Each *animal* should be able to assume its natural standing position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vehicle*, and there should be sufficient headroom to allow adequate airflow over the *animals*. These conditions will not normally apply to *poultry* except for one day old chicks. However, under tropical and subtropical conditions *poultry* benefit from having adequate head room to allow head cooling.

EU comment

In the last sentence of point 6.e) of Art 7.3.5, the EU proposes to delete the following text "~~under tropical and subtropical conditions~~".

Justification: most regions of the world can at certain times become hot enough to risk heat stress and other welfare detriments as subtropical environments.

- f) Calculations for the *space allowance* for each *animal* should be carried out using the figures given in a relevant national or international document. The number and size of pens on the *vehicle* should be varied to where possible accommodate already established groups of *animals* while avoiding group sizes which are too large.
- g) Other factors which may influence space allowance include:
 - i) vehicle/container design;
 - ii) length of *journey*;
 - iii) need to provide feed and water on the *vehicle*;
 - iv) quality of roads;
 - v) expected weather conditions;
 - vi) category and sex of the *animals*.
- h) Rest, water and feed
 - i) Suitable water and feed should be available as appropriate and needed for the species, age, and condition of the *animals*, as well as the duration of the *journey*, climatic conditions, etc.
 - ii) *Animals* should be allowed to rest at *resting points* at appropriate intervals during the *journey*. The type of transport, the age and species of the *animals* being transported, and climatic conditions should determine the frequency of rest stops and whether the *animals* should be unloaded. Water and feed should be available during rest stops.

7. Ability to observe animals during the journey

- a) *Animals* should be positioned to enable each *animal* to be observed regularly during the *journey* to ensure their safety and good *welfare*. This condition will not normally apply to *poultry*. However, efforts should be made to observe the general conditions within the crates.
- b) If the *animals* are in crates or on multi-tiered *vehicles* which do not allow free access for observation, for example where the roof of the tier is too low, *animals* cannot be inspected adequately, and serious injury or *disease* could go undetected. In these circumstances, a shorter *journey* duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

8. Control of disease

As animal transport is often a significant factor in the spread of infectious *diseases*, *journey* planning should take the following into account:

- a) mixing of *animals* from different sources in a single consignment should be minimised;
- b) contact at *resting points* between *animals* from different sources should be avoided;
- c) when possible, *animals* should be vaccinated against *diseases* to which they are likely to be exposed at their destination;
- d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *exporting country* and the *importing country* and should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

9. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

10. Other considerations

- a) Extreme weather conditions are hazardous for *animals* undergoing transport and require appropriate *vehicle* design to minimise risks. Special precautions should be taken for *animals* that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, *animals* should not be transported at all.
- b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 7.3.6.

Documentation

1. *Animals* should not be loaded until the documentation required to that point is complete.
2. The documentation accompanying the consignment should include:
 - a) *journey* travel plan and emergency management plan;
 - b) date, time and place of *loading* and *unloading*;

- c) veterinary certification, when required;
 - d) *animal welfare* competencies of the driver (under study);
 - e) *animal identification* to allow *animal traceability* to the premises of departure and, where possible, to the premises of origin;
 - f) details of any *animals* considered at particular risk of suffering poor *welfare* during transport (point 3e of Article 7.3.7.);
 - g) documentation of the period of rest, and access to feed and water, prior to the *journey*;
 - h) *stocking density* estimate for each load in the consignment;
 - i) the *journey* log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.
3. When veterinary certification is required to accompany consignments of *animals*, it should address:
- a) fitness of *animals* to travel;
 - b) *animal identification* (description, number, etc.);
 - c) health status including any tests, treatments and vaccinations carried out;
 - d) when required, details of *disinfection* carried out.

At the time of certification, the *veterinarian* should notify the *animal handler* or the driver of any factors affecting the fitness of *animals* to travel for a particular *journey*.

Article 7.3.7.

Pre-journey period

1. General considerations

- a) Pre-*journey* rest is necessary if the *welfare* of *animals* has become poor during the collection period because of the physical environment or the social behaviour of the *animals*. The need for rest should be judged by a *veterinarian* or other competent person.
- b) Pre-*journey* assembly/holding areas should be designed to:
 - i) securely hold the *animals*;
 - ii) maintain a safe environment from hazards, including predators and *disease*;
 - iii) protect *animals* from exposure to severe weather conditions;
 - iv) allow for maintenance of social groups;
 - v) allow for rest, and appropriate water and feed.
- c) Consideration should be given to the previous transport experience, training and conditioning of the *animals*, if known, as these may reduce fear and stress in *animals*.

- d) Feed and water should be provided pre-journey if the *journey* duration is greater than the normal inter-feeding and drinking interval for the *animal*. Recommendations for specific-species are described in detail in Article 7.3.12.
- e) When *animals* are to be provided with a novel diet or method of feed or water provision during the *journey*, an adequate period of adaptation should be allowed.
- f) Before each *journey*, *vehicles* and *containers* should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress and risks to the *animals*.
- g) Where an *animal handler* believes that there is a significant risk of *disease* among the *animals* to be loaded or significant doubt as to their fitness to travel, the *animals* should be examined by a *veterinarian*.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse *animal welfare* consequences. The following recommendations should be applied when assembling groups of *animals*:

- a) *Animals* reared together should be maintained as a group; *animals* with a strong social bond, such as a dam and offspring, should be transported together.
- b) *Animals* of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 7.3.12.). For some species, *animals* from different groups should not be mixed because poor *welfare* occurs unless they have established a social structure.
- c) Young or small *animals* should be separated from older or larger *animals*, with the exception of nursing mothers with young at foot.
- d) *Animals* with horns or antlers should not be mixed with *animals* lacking horns or antlers unless judged to be compatible.
- e) *Animals* of different species should not be mixed unless they are judged to be compatible.

3. Fitness to travel

- a) Each *animal* should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the *animal* should be examined by a *veterinarian*. *Animals* found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary attention.
- b) Humane and effective arrangements should be made by the owner and the agent for the handling and care of any *animal* rejected as unfit to travel.
- c) *Animals* that are unfit to travel include, but may not be limited to:
 - i) those that are sick, injured, weak, disabled or fatigued;
 - ii) those that are unable to stand unaided and bear weight on each leg;
 - iii) those that are blind in both eyes;
 - iv) those that cannot be moved without causing them additional suffering;
 - v) newborn with an unhealed navel;

- vi) pregnant *animals* which would be in the final 10% of their gestation period at the planned time of *unloading*;
 - vii) females travelling without young which have given birth within the previous 48 hours;
 - viii) those whose body condition would result in poor *welfare* because of the expected climatic conditions.
- d) Risks during transport can be reduced by selecting *animals* best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- e) *Animals* at particular risk of suffering poor *welfare* during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include:
- i) large or obese individuals;
 - ii) very young or old *animals*;
 - iii) excitable or aggressive *animals*;
 - iv) *animals* which have had little contact with humans;
 - v) *animals* subject to motion sickness;
 - vi) females in late pregnancy or heavy lactation, dam and offspring;
 - vii) *animals* with a history of exposure to stressors or pathogenic agents prior to transport;
 - viii) *animals* with unhealed wounds from recent surgical procedures such as dehorning.

4. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 7.3.12.

Article 7.3.8.

Loading

1. Competent supervision

- a) *Loading* should be carefully planned as it has the potential to be the cause of poor *welfare* in transported *animals*.
- b) *Loading* should be supervised and/or conducted by *animal handlers*. The *animals* are to be loaded quietly and without unnecessary noise, harassment or force. Untrained assistants or spectators should not impede the process.
- c) When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor *animal welfare*.

2. Facilities

- a) The facilities for *loading* including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the *animals* with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.
- b) *Loading* facilities should be properly illuminated to allow the *animals* to be observed by *animal handler(s)*, and to allow the ease of movement of the *animals* at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside *vehicles/containers*, in order to minimise baulking. Dim light levels may be advantageous for the catching of *poultry* and some other *animals*. Artificial lighting may be required. Loading ramps and other facilities should have a non-slippery flooring.
- c) Ventilation during *loading* and the *journey* should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each *animal*. In some instances, adequate ventilation can be achieved by increasing the *space allowance* for *animals*.

3. Goads and other aids

When moving *animals*, their species-specific behaviour should be used (see Article 7.3.12.). If goads and other aids are necessary, the following principles should apply:

- a) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.
- b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
- c) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.
- d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.
- e) Excessive shouting at *animals* or making loud noises (e.g., through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.
- f) The use of well trained dogs to help with the *loading* of some species may be acceptable.
- g) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.
- h) Conscious *animals* should not be thrown, dragged or dropped.

- i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling as a result of their usage.

Article 7.3.9.

Travel

1. General considerations

- a) Drivers and animal handlers should check the load immediately before departure to ensure that the *animals* have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip, especially at rest or refuelling stops or during meal breaks when the *vehicle* is stationary.
- b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the *animals*.

2. Methods of restraining or containing animals

- a) Methods of restraining *animals* should be appropriate to the species and age of *animals* involved and the training of the individual *animal*.
- b) Recommendations for specific species are described in detail in Article 7.3.12.

3. Regulating the environment within vehicles or containers

- a) *Animals* should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the environment within *vehicles* or *containers* will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented.
- b) The environment within *vehicles* or *containers* in hot and warm weather can be regulated by the flow of air produced by the movement of the *vehicle*. In warm and hot weather, the duration of *journey* stops should be minimised and *vehicles* should be parked under shade, with adequate and appropriate ventilation.
- c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

4. Sick, injured or dead animals

- a) A driver or an *animal handler* finding sick, injured or dead *animals* should act according to a predetermined emergency response plan.
- b) Sick or injured *animals* should be segregated.
- c) Ferries (roll-on roll-off) should have procedures to treat sick or injured *animals* during the *journey*.
- d) In order to reduce the likelihood that animal transport will increase the spread of infectious *disease*, contact between transported *animals*, or the waste products of the transported *animals*, and other farm *animals* should be minimised.

- e) During the *journey*, when disposal of a dead *animal* becomes necessary, this should be carried out in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.
 - f) When *killing* is necessary, it should be carried out as quickly as possible and assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures. Recommendations for specific species are described in Chapter 7.6. on killing of *animals* for disease control purposes.
5. Sick, injured or dead animals Water and feed requirements
- a) If *journey* duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the *animals* (appropriate for their species and age) carried in the *vehicle* should be provided. There should be adequate space for all *animals* to move to the feed and water sources and due account taken of likely competition for feed.
 - b) Recommendations for specific species are described in detail in Article 7.3.12.
6. Rest periods and conditions
- a) *Animals* that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.
 - b) Suitable facilities should be used en route, when resting requires the *unloading* of the *animals*. These facilities should meet the needs of the particular animal species and should allow access of all *animals* to feed and water.
7. In-transit observations
- a) *Animals* being transported by road should be observed soon after a *journey* is commenced and whenever the driver has a rest stop. After meal breaks and refuelling stops, the *animals* should be observed immediately prior to departure.
 - b) *Animals* being transported by rail should be observed at each scheduled stop. The responsible rail transporter should monitor the progress of trains carrying *animals* and take all appropriate action to minimise delays.
 - c) During stops, it should be ensured that the *animals* continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 7.3.10.

Unloading and post-journey handling

1. General considerations
- a) The required facilities and the principles of animal handling detailed in Article 7.3.8. apply equally to *unloading*, but consideration should be given to the likelihood that the *animals* will be fatigued.
 - b) *Unloading* should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. *Animals* should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force.
 - c) Facilities should provide all *animals* with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.

- d) For details regarding the *unloading* of *animals* at a *slaughterhouse*, see Chapter 7.5. on slaughter of animals for human consumption.

2. Sick or injured animals

- a) An *animal* that has become sick, injured or disabled during a *journey* should be appropriately treated or humanely killed (see Chapter 7.6. on killing of *animals* for disease control purposes). If necessary, veterinary advice should be sought in the care and treatment of these *animals*. In some cases, where *animals* are non-ambulatory due to fatigue, injury or sickness, it may be in the best *welfare* interests of the *animal* to be treated or killed aboard the *vehicle*. Assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures.
- b) At the destination, the *animal handler* or the driver during transit should ensure that responsibility for the *welfare* of sick, injured or disabled *animals* is transferred to a *veterinarian* or other suitable person.
- c) If treatment or humane *killing* is not possible aboard the *vehicle*, there should be appropriate facilities and equipment for the humane *unloading* of *animals* that are non-ambulatory due to fatigue, injury or sickness. These *animals* should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured *animals*.
- d) Feed, if appropriate, and water should be available for each sick or injured *animal*.

3. Addressing disease risks

The following should be taken into account in addressing the greater risk of *disease* due to animal transport and the possible need for segregation of transported *animals* at the destination:

- a) increased contact among *animals*, including those from different sources and with different disease histories;
- b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;
- c) exposure of *animals* to pathogens which may contaminate *vehicles*, *resting points*, *markets*, etc.

4. Cleaning and disinfection

- a) *Vehicles*, crates, *containers*, etc. used to carry the *animals* should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.
- b) Manure, litter, bedding and the bodies of any *animals* which die during the *journey* should be disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.
- c) Establishments like livestock *markets*, *slaughterhouses*, resting sites, railway stations, etc. where *animals* are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

Article 7.3.11.

Actions in the event of a refusal to allow the completion of the journey

- 1. The *welfare* of the *animals* should be the first consideration in the event of a refusal to allow the completion of the *journey*.

2. When the *animals* have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of *animals* from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:
 - a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;
 - b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a *veterinarian*, where possible an OIE *veterinarian(s)* appointed by the Director General, to assess the health status of the *animals* with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing;
 - c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*;
 - d) if the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.
3. In the event that a *Competent Authority* requires the *animals* to remain on the *vehicle*, the priorities should be:
 - a) to allow provisioning of the *vehicle* with water and feed as necessary;
 - b) to provide urgently in writing the reasons for the refusal;
 - c) to provide urgent access to an independent *veterinarian(s)* to assess the health status of the *animals*, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons;
 - d) to provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*, and the necessary actions to deal with any animal issues which arise.
4. The OIE should utilise its informal procedure for dispute mediation to identify a mutually agreed solution which will address animal health and any other *welfare* issues in a timely manner.

Article 7.3.12.

Species-specific issues

Camelids of the new world in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single *animal* will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the *animals* rise.

Cattle are sociable *animals* and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the *animals* try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross *animals* are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid “dead end” in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to *animals* should be avoided. Bullying is particularly serious in goats and can reflect demands for personal space. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include donkeys, mules and hinnies. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an *animal* by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed. Horses are prone to respiratory *disease* if they are restricted by period by tethers that prevent the lowering and lifting of their heads.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good ‘rule-of-thumb’ is that no step should be higher than the pig’s front knee. Serious aggression may result if unfamiliar *animals* are mixed. Pigs are highly susceptible to heat stress. Pigs are susceptible to motion sickness when in transit. Feed deprivation prior to loading may be beneficial to prevent motion sickness.

Sheep are sociable *animals* with good eyesight, a relatively subtle and undemonstrative behaviour and a tendency to “flock together”, especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Crowding of sheep may lead to damaging aggressive and submissive behaviours as *animals* try to maintain personal space. Sheep may become agitated if they are singled out for attention, or kept alone, and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

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CHAPTER 7.4.

TRANSPORT OF ANIMALS BY AIR

EU position

The EU thanks the OIE TAHSC and supports the adoption of the proposed changes in the chapter.

Preamble: These recommendations apply to the following live domesticated *animals*: cattle, buffaloes, camels, sheep, goats, pigs, *poultry* and equines. They will also be largely applicable to some other *animals* (e.g., deer, other camelids and ratites). Wild, and feral and partly domesticated *animals* may need different conditions.

Article 7.4.1.

Livestock containers1. Design

a) General principles of design

The *container* should:

- conform to the size of the standard pallet of the aircraft that will be used to transport *animals*; ~~the common sizes are: 224 x 318 cm (88 x 125 in.) and 244 x 318 cm (96 x 125 in.);~~
- not be constructed of material that could be harmful to the *animals* health or *welfare*;
- allow observation of the *animals* and be marked on opposite sides with the International Air Transport Association (IATA) symbols which indicate *animals* and the upright position;
- allow emergency access to *animals*;
- allow the *animal* to stand in its normal position without touching the roof of the *container* or, in the case of open *containers*, the restraining nets, and provide at least 10 cm (4 in.) clearance above the *animal's* head when standing in its normal position; in the case of horses, provide sufficient space above the horses head (21 cm, 8 in. recommended) to allow for the movement required to maintain the horses balance;
- protect the *animals* from adverse weather;
- ensure *animals* stand on a suitable floor to prevent slipping or injury;
- have adequate strength to ensure the safety of the *animals* and to prevent the *animals* from escaping;
- ensure doors can be opened and closed easily, but be secured so that they cannot be opened accidentally;
- be free of any nails, bolts and other protrusions or sharp edges that could cause injuries;
- be designed to minimise the risk of any opening or space entrapping any portion of the *animals* body;

- if reusable, crates should be constructed of impermeable material that is easily cleaned and disinfected;
- ensure faeces and urine cannot escape from the crate; this requires a minimum upturn of 20 cm but it should not block any ventilation openings;
- if designated for stacking be stable, not block any ventilation space and prevent urine and faeces from leaking into the containers below when stacked;
- allow for a facility for provision of water and possibly food during transportation of longer than 6 hours duration.

b) Ventilation

The *container* design should:

- provide adequate ventilation taking into consideration the species *stocking densities*, maximum temperature and humidity of the points of departure, destination, and any interim technical stops;
- allow the normal resting or sleeping position to be assumed for certain species and juvenile *animals*;
- ensure there is no dead air space in the *container*;
- provide ventilation openings on the walls equal to at least 16% of the wall area; this may be reduced if the *container* has an open top;
- in the case of two-tiered *containers*, ventilation in the sides should be for cattle equivalent to not less than 20% of the floor area of each deck, and for pigs and sheep up to 40% of the floor area of each deck;
- have ventilation openings on all four sides of the crate except that two walls may have reduced ventilation space and the other walls have increased space where required by the positioning of the crates during transportation and/or the ventilation pattern of the aircraft;
- ensure that any internal supports or dividers do not block the cross ventilation;
- not have a solid wall above the height of the *animal's* head in normal resting position;
- in those species where the mouth is normally held near the floor, have at least 25 cm (10 in.) of ventilation space at the level of the *animal's* head; this opening should be divided in two with a maximum height for any opening of 13 cm; in all *containers*, there should be a sufficiently large ventilation opening at a height of 25 cm to 30 cm (10 to 11 in.) above floor level on all four sides to allow for circulation;
- have some physical means of ensuring the ventilation space is not blocked, such as the use of cleats (wedges) or allowing space between the outside of the *container* and the pallet.

2. Species requirements

In general, fractious *animals* or *animals* in late pregnancy should not be transported by air (see Article 7.4.2).

a) Horses

Should be transported in *containers* and be separated from each other if they are more than 145 cm (57 in.) in height.

Crates used to transport horses should:

- be strong enough to prevent unruly horses from breaking or escaping from the *container* under any circumstances;
- in the case of multi-horse *containers*, have partitions of sufficient strength and size to separate the horses and to support each horse's weight;
- adjust to allow mare and foal to travel together;
- provide the same percentage of open space for ventilation as required in point 1 above, divided between the two side walls; however, if the access doors are constructed in such a manner that they may be left open during the flight, the door space may be included in the ventilation space;
- be constructed to minimise noise;
- allow access to the head during the flight;
- have the front end notched and padded to accept the neck of the *animal*;
- have a secure point for attaching restraining devices;
- have a front and rear barrier that will restrict the movement of the horse and will ensure that liquids are deflected into the *container*;
- ensure horses cannot bite other *animals*;
- be constructed to resist kicking;
- have no fittings or projections in the area likely to be kicked, metal plates should be covered with a protective material;
- ramps shall be non-skid in nature, have foot battens, and be of a maximum slope of 25 degrees when the *container* is on a standard 50 cm (20 in.) dolly;
- not have a step up or down of more than 25 cm (10 in.).

b) Swine

- Crate design and shipment planning should recognise that swine are extremely susceptible to high heat and humidity and that they normally carry their head near the floor.
- In the use of multi-tiered crates, special attention should be paid to ensure air can move through the crate, in accordance with the aircraft's ventilation pattern and capacity to remove heat.
- Crate construction should take into consideration the tendency for mature swine to chew.
- Litter should be dust-free, shavings or other non toxic materials may be used but not sawdust.
- *Containers* for immature swine should only be constructed when flight is imminent, since rapid growth can result in undersized containers if the flight is delayed.
- In order to reduce fighting, swine shipped in group pens should be housed together as a group prior to shipment and not be mixed with other swine before loading on the aircraft.
- Mature boars and incompatible females should be shipped in individual crates.
- Individual crates should be 20 cm (8 in.) longer than the body, 15 cm (6 in.) higher than the loin of the pig and of sufficient width, to allow the pigs to lie on their side.

c) Cattle

Crates used to transport cattle should:

- if multi-tiered or roofed, have at least 33% of the roof and four walls as open space;
- have at least one ventilation opening 20-25 cm (8-10 in.) above the floor which is of such width that it will not cause injuries to the feet.

Adult bulls should be transported separately unless they have been accustomed to each other. Cattle with and without horns should be separated from each other.

d) Poultry

The most current *container* requirement published by IATA should be adhered to.

Crates/*containers* containing *poultry* should be handled and carried carefully with no unnecessary tilting.

The majority of birds transported by air will be newly hatched chicks. These *animals* are very vulnerable to sudden changes in temperature.

e) Other species

- *Animals* that normally exhibit a herding instinct, including buffalo and deer, can be shipped in group *containers* providing the mental and physical characteristics of the species are taken into consideration.
- All crates used to move such *animals* should have a roof or other method of preventing the *animals* from escaping.
- *Animals* in which the horns or antler cannot be removed, should be transported individually.
- Deer should not be transported in velvet nor in rut.

Article 7.4.2.

Recommendations for pregnant animals

Heavily pregnant *animals* should not be carried except under exceptional circumstances. Pregnant *animals* should not be accepted when the last service or exposure to a male prior to departure has exceeded the following time given here for guidance only:

Females	Maximum number of days since the last service
Horses	300
Cows	250
Deer (axis, fallow and sika)	170
(red deer, reindeer)	185
Ewes (sheep)	115
Nannies (goats)	115
Sows (pigs)	90

Where service dates or date of last exposure to a male are not available, the *animals* should be examined by a *veterinarian* to ensure that pregnancy is not so advanced that *animals* are likely to give birth during transport or suffer unnecessarily.

Any *animal* showing udder engorgement and slackening of the pelvic ligament should be refused.

Article 7.4.3.

Stocking density

The current *stocking densities* agreed by the International Air Transport Association (IATA) should continue to be accepted. However, the graphs giving the space requirements should be extended to take into account *animals* larger and smaller than those dealt with currently.

1. General considerations

When calculating stocking rates, the following should be taken into account:

- a) it is essential that accurate weights of *animals* are obtained in view of the limitations imposed by the load capabilities of the aircraft and the space required per *animal*;
- b) in narrow bodied aircraft, there is a loss of floor area in the upper tier of two-tier penning due to the contours of the aircraft;
- c) space available should be calculated on the inside measurements of the crates or penning system used, not on the floor space of the aircraft;
- d) multi-tiered crates, high outdoor temperatures at departure, arrival or stopover points, or extreme length of the trip will require an increase in the amount of space per *animal*; a 10% decrease in *stocking density* is recommended for trips in excess of 24 hours;
- e) special attention should be paid to the transport of sheep in heavy wool which require an increase in space allotted per *animal* and to pigs which have limited ability to dissipate heat;
- f) *animals* confined in groups, especially in pens, should be stocked at a high enough density to prevent injuries at take-off, during turbulence and at landing, but not to the extent that individual *animals* cannot lie down and rise without risk of injury or crushing;
- g) in multi-tiered shipments, it should be recognised that the ventilation and cooling capacity of the aircraft is the limiting factor, especially in narrow bodied aircraft. Ventilation capacity varies on each individual aircraft and between aircraft of the same model.

2. Recommendations for stocking densities

The following table gives *stocking density* recommendations for different domestic species. The values are expressed in kilograms and metres.

Species	Weight	Density	Space/ animal	No. of animals per	Animals per single tier pallet		
					10 m ²	214x264 cm	214x308 cm
	kg	kg/m ²	m ²	10 m ²	214x264 cm	214x308 cm	234x308 cm
Calves	50	220	0.23	43	24	28	31
	70	246	0.28	35/6	20	23	25
	80	266	0.30	33	18	21	24
	90	280	0.32	31	17	20	22
Cattle	300	344	0.84	11-12	6	7	8
	500	393	1.27	8	4	5	5
	600	408	1.45	6-7	3-4	4	4-5
	700	400	1.63	6	3	3-4	4
Sheep	25	147	0.17	59	32	37	42
	70	196	0.36	27/8	15	18	20
Pigs	25	172	0.15	67	37	44	48
	100	196	0.51	20	10	12	14

Article 7.4.4.

Preparation for air transport of livestock

1. Health and customs requirements

The legal requirements including animal health, *welfare* and species conservation, should be ascertained from the country of destination and any in *transit countries* before the *animals* are assembled or the transportation is arranged.

Contact the *Veterinary Authorities* in the country of origin regarding veterinary certification.

Planning of the transportation should take into account weekends, holidays and airport closures.

Verify that any proposed intransit stops or alternates will not jeopardise the importing or in *transit countries* health requirements.

Waiting time at customs (cargo handling and clearance) should be reduced as much as possible to avoid *welfare* problems.

2. Environment

Animals are affected by extremes of temperature. This is especially true of high temperature when compounded by high humidity. Temperature and humidity should therefore be taken into consideration when planning the shipment.

Times of arrival, departure and stopovers should be planned so that the aircraft lands during the coolest hours.

At outside temperatures of below 25°C at the landing point, the aircraft doors should be opened to ensure adequate ventilation. Confirmation should be received from government authorities that animal health legislation does not prevent opening of aircraft doors.

When outside temperatures at any landing point exceed 25°C, prior arrangements should be made to have an adequate air-conditioning unit available when the plane lands.

3. Facilities and equipment

Specific arrangements should be made to ensure that holding and *loading* facilities including ramps, trucks, and air-conditioning units are available at departure, all in transit and arrival airports. This should include identification of specific staff who are responsible and the method of contacting them, e.g. telephone number and address.

Specific notification should be given to all those responsible for providing facilities or equipment at the destination and in transit stops immediately before departure.

Containers should be loaded so as to ensure access can be made to the *animals* at all times.

4. Preparation of animals

Vaccination should be done far enough in advance of the departure date to allow for immunity to develop.

Veterinary certification and serological testing should be arranged several weeks in advance of livestock shipment.

Many *animals* require acclimatisation before they are transported. *Animals* such as swine and wild herbivores should be separated and held in the groups that will occupy *containers*. Mixing of such *animals* immediately before or during transport is extremely stressing and should be avoided.

Incompatible *animals* should be transported singly.

Article 7.4.5.

Disinfection and disinfestation

1. Disinfection

- a) Those parts of the interior of the aircraft destined for the carriage of *animals* should be thoroughly cleaned of all foreign matters using methods acceptable to aircraft management before being loaded.
- b) These parts should be sprayed with a disinfectant:
 - i) suitable for the *diseases* which could be carried by the *animals*;
 - ii) that does not cause problems with the aircraft;
 - iii) that will not leave a residue hazardous to the *animals* being transported.

If in doubt, the airline should be consulted on the suitability of the disinfectant. A mechanical nebuliser should be used to minimise the amount of disinfectant used.

Suggested disinfectants currently in use are:

- iv) 4% sodium carbonate and 0.1% sodium silicate;
- v) 0.2% citric acid.
- c) All removeable equipment, penning and *containers* including loading ramps should be thoroughly cleaned and disinfected in accordance with the requirements of both the *exporting* and *importing countries*.
- d) After *disinfection*, all equipment to be replaced in the aircraft should be washed with clean water to remove any traces of disinfectant to avoid any damage to the aircraft structures.

2. Disinfestation

Where *disinfestation* is required, the country requesting the action should be consulted for appropriate procedures.

The World Health Organisation (WHO) Recommendations on the Disinsectisation of Aircraft (*WHO Weekly Epidem. Rec.*, No. 7, 1985) are recognised as standard.

Article 7.4.6.

Radiation

Radioactive materials should be separated from live *animals* by a distance of at least 0.5 metre for journeys not exceeding 24 hours, and by a distance of at least 1.0 metre for journeys longer than 24 hours (reference: Technical instructions on storage and loading-separation of the International Civil Aviation Organisation). Special care should be taken with regard to pregnant *animals*, semen and embryos/ova.

Article 7.4.7.

Tranquilisation

Experience has shown that there is considerable risk in sedating *animals* transported by air. Tranquilisers reduce the ability of the *animals* to respond to stress during transportation. In addition, the reaction of various species to tranquilisation cannot always be foreseen. For these reasons, routine tranquilisation is not recommended. Tranquilisers should only be used when a specific problem exists, and should be administered by a *veterinarian* or by a person who has been instructed in their use. Persons using these drugs should understand the full implications of the effects of the drug in air transport, e.g. certain *animals* such as horses and elephants should not go down in *containers*. Drugs should only be administered during the flight with the knowledge and consent of the captain.

In all cases, when tranquilisers are used, a note should be attached to the *container* stating the weight of the individual *animal*, the generic name of the drug used, the dose, the method and time of administration.

Article 7.4.8.

Destruction of carcasses

In the event of any animal *death* on board, the competent authority of the airport of destination should be notified in advance of landing.

Carcasses should be disposed of under the supervision of and to the satisfaction of the *Veterinary Authority* of the country the aircraft is in.

The method of disposal should be based on the risk of introducing a controlled *disease*.

For carcasses which represent a high risk of introducing *disease*, the following is recommended:

1. destruction by incineration, rendering or deep burial under the supervision of the *Veterinary Authority*;
2. if removed from the airport site, transportation in a closed, leakproof *container*.

Article 7.4.9.

Emergency slaughter killing

Emergency *slaughter* of *animals* in aircraft should, in general, only occur when the safety of the aircraft, crew or other *animals* are involved.

EU comment

In the first sentence of Article 7.4.9, the word "slaughter" should be replaced with the word "killing".

Justification: consistency with the revised title of the Article.

Every aircraft transporting *animals* should have a method of killing the *animals* with minimum pain and someone trained in that method.

In all cases when horses or other large *animals* are to be carried, the method of killing should be discussed with the airline during the planning stages. Suitable methods are:

1. Captive bolt stunner, followed by an injection of a lethal chemical

- a) Operator should be trained to use the captive bolt stunner on the species or type of *animal* being transported.
 - b) An expert should determine that the type of captive bolt pistol **and cartridge power** is adequate for all the *animals* being transported.
 - c) Some airlines and countries may prohibit the carriage of captive bolt pistols.
 - d) The user should recognise that the noise associated with the captive bolt may excite other *animals*.
 - e) The requirement that the captive bolt pistol is accurately **centered-positioned** may be difficult to achieve with an excited *animal*.
2. Injection of a chemical
- a) Various chemicals may be used to sedate, immobilise or kill *animals*.
 - b) Central nervous system depressants such as barbiturate euthanasia solutions should be injected directly into a vein to be effective. This is not normally practical for anyone but an experienced *veterinarian* or an especially trained and experienced attendant, where the *animal* is sufficiently fractious to require euthanasia.
 - c) Sedatives such as promazine and its derivatives may make the *animal* more fractious (see Article 7.4.7.).
 - d) Immobilising solutions such as succinylcholine are not humane.
3. Firearms
- Airlines do not permit the use of firearms which discharge a free bullet because of the danger to the aircraft.

Article 7.4.10.

Handling of food and waste material

Waste material which contains anything of animal origin including food, litter, manure, or animal feed should be handled, collected and disposed of in a manner that ensures it will not be fed to livestock. It should be collected in specified areas, and stored and transported in closed, leakproof *containers*.

Some *importing countries* legislation may prohibit or restrict the use of hay or straw during the transportation period. Unloading of hay, straw, other animal feed and litter may be restricted or prohibited by in *transit countries*.

Article 7.4.11.

Disposal of food and waste material

Recommended methods of disposal are:

1. incineration to an ash;
2. heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;
3. controlled burial in a land fill site.

— text deleted

CHAPTER 7.5.

SLAUGHTER OF ANIMALS

EU position

The EU thanks the OIE TAHSC and supports the adoption of the proposed changes in the chapter.

The EU would like to resubmit previous comments and would ask the OIE to reconsider these points at the next revision of the text. These specific EU comments are presented in the text.

Article 7.5.1.

General principles

1. Object

These recommendations address the need to ensure the *welfare* of food *animals* during pre-slaughter and *slaughter* processes, until they are dead.

These recommendations apply to the *slaughter* in *slaughterhouses* of the following domestic *animals*: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and *poultry*. Other *animals*, wherever they have been reared, and all *animals* slaughtered outside *slaughterhouses* should be managed to ensure that their *transport, lairage, restraint* and *slaughter* is carried out without causing undue stress to the *animals*; the principles underpinning these recommendations apply also to these *animals*.

2. Personnel

Persons engaged in the *unloading, moving, lairage, care, restraint, stunning, slaughter* and bleeding of *animals* play an important role in the *welfare* of those *animals*. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the recommendations outlined in the present chapter and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of *animal welfare*.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic *animals* should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

The desire of some *animals* to control their personal space should be taken into account in designing facilities.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans i.e. tame have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

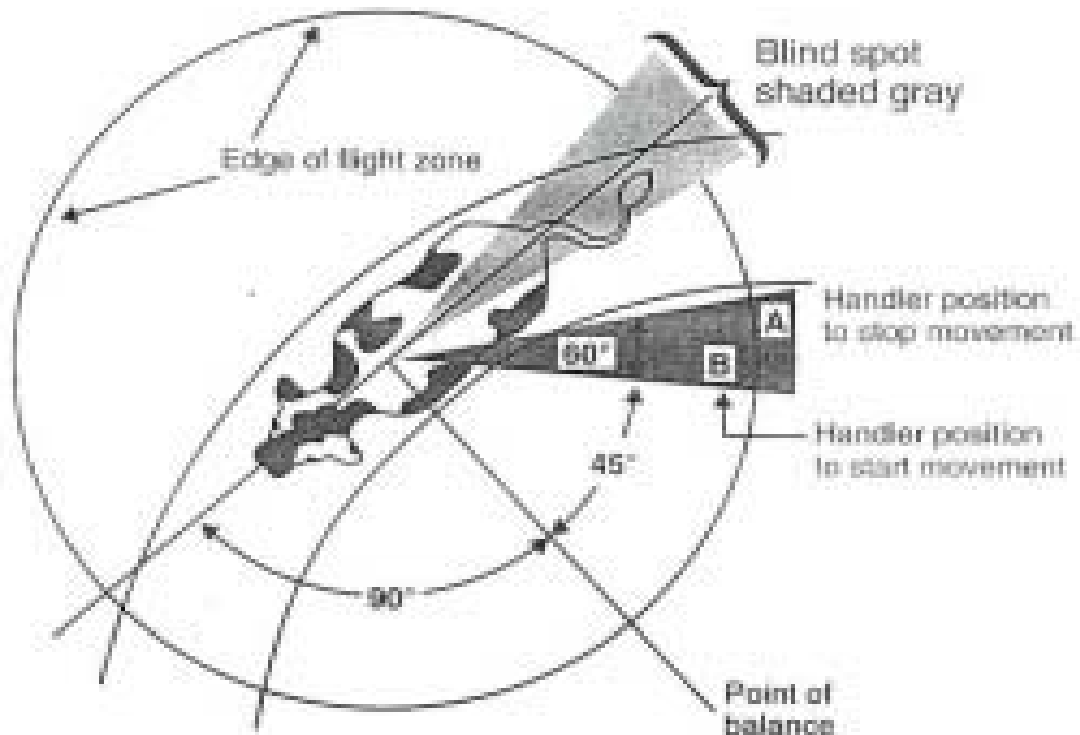
Animal handlers should use the point of balance at the *animal's* shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

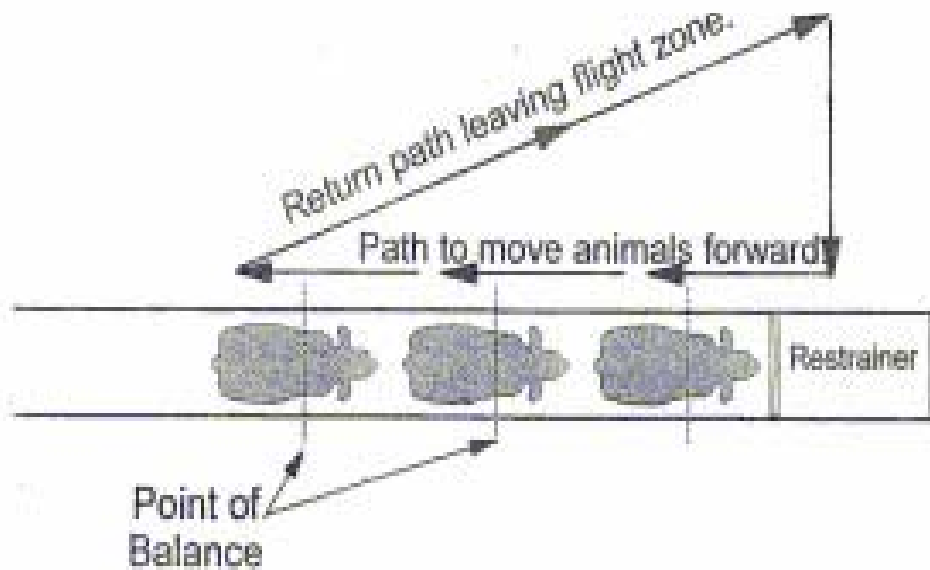
Although most domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



4. Distractions and their removal

Distractions that may cause approaching *animals* to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors — move a lamp or change lighting;
- b) dark entrances to chutes, races, stun boxes or conveyor restrainers — illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*; **or create areas of sharp contrast;**
- c) *animals* seeing moving people or equipment up ahead — install solid sides on chutes and races or install shields;
- d) dead ends — avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences — remove them;
- f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers — avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment — install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects — install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of animals — redirect or reposition equipment.

Article 7.5.2.

Moving and handling animals

1. General considerations

Each slaughterhouse should have a dedicated plan for animal welfare. The purpose of such plan should be to maintain good level of animal welfare at all stages of the handling of animals until they are killed. The plan should contain standard operating procedures for each step of animal handling as to ensure that animal welfare is properly implemented based on relevant indicators. It also should include specific corrective actions in case of specific risks, like power failures or other circumstances that could negatively affect the welfare of animals.

Animals should be transported to *slaughter* in a way that minimises adverse animal health and *welfare* outcomes, and the transport should be conducted in accordance with the OIE recommendations for the transportation of *animals* (Chapters 7.2. and 7.3.).

The following principles should apply to *unloading animals*, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

- a) The conditions of the *animals* should be assessed upon their arrival for any *animal welfare* and health problems.
- b) Injured or sick *animals*, requiring immediate *slaughter*, should be killed humanely and without delay, in accordance with the recommendations of the OIE.

Previous EU Comment

The EU would like to reiterate its previous comment, and strongly suggests adding to paragraph 1b) of Article 7.5.2 the following sentence:

"Animals that are unable to walk should not be dragged to the place of slaughter but should be killed where they lie."

Justification: to move a conscious animal that is not able to walk on its own is highly likely to induce further pain and suffering.

- c) *Animals* should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of *animals* slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99% of *animals* without their falling.
- d) *Animals* for *slaughter* should not be forced to walk over the top of other *animals*.
- e) *Animals* should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move *animals*, such as crushing or breaking tails of *animals*, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to *animals* and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of *animals*, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small *animals* is permissible.
- f) When using goads and other aids, the following principles should apply:
 - i) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.
 - ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region

or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

- iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.
- iv) Painful procedures (including whipping, **kicking**, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.
- v) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.
- vi) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting such *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.
- vii) Conscious *animals* should not be thrown, dragged or dropped.
- ~~viii) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of animals moved with an electric instrument and the percentage of animals slipping or falling at a point in the slaughterhouse. Any risk of compromising animal welfare, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of welfare of the animals.~~
- g) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of *welfare* of the *animals*.

2. Specific considerations for poultry

Stocking density in transport crates should be optimum to suit climatic conditions and to maintain species-specific thermal comfort within *containers*.

Care is especially necessary during *loading* and *unloading* to avoid ~~wings or legs~~ body parts being caught on crates, leading to dislocated or broken ~~wing~~ bones in conscious birds. Such injuries will adversely affect *animal welfare*, carcass and *meat* quality.

Modular systems that involve tipping of live birds are not conducive to maintaining good *animal welfare*. These systems, when used, should be incorporated with a mechanism to facilitate birds sliding out of the transport system, rather than being dropped or dumped on top of each other from heights of more than a metre.

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, ~~and/or~~ **and/or** constructed **or maintained** transport systems. Under this situation, operators *unloading* birds should ensure gentle release of trapped birds.

Drawers in modular systems and crates should be stacked and de-stacked carefully so as to avoid injury to birds.

Birds should have sufficient space so that all can lie down at the same time without being on top of each other.

Birds with broken bones and/or dislocated joints should be humanely killed before being hung on shackles for processing.

The number of *poultry* arriving at the processing plant with broken bones and/or dislocated joints should be recorded in a manner that allows for verification. For *poultry*, the percentage of chickens with broken or dislocated wings should not exceed 2%, with less than 1% being the goal (under study).

Previous EU comment

The EU wishes to reiterate its previous comment.

In the last two paragraphs of point 2) of Art 7.5.2, the word "visible" should be included before the words "broken bones". In addition the expression "and severe bruising" should be added on the same sentence.

Justification: broken bones in poultry are not always visible where animals are alive. Severe bruising is also a visible sign of improper handling.

3. Provisions relevant to animals delivered in containers

- a) *Containers* in which *animals* are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.
- b) *Animals* delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, *animals* should be unloaded from the *containers* individually.
- c) *Animals* which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of *poultry* for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. *Animals* which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

4. Provisions relevant to restraining and containing animals

- a) Provisions relevant to *restraining animals* for *stunning* or *slaughter* without *stunning*, to help maintain *animal welfare*, include:
 - i) provision of a non-slippery floor;

Previous EU comment

The EU wishes to reiterate its previous comment.

In the above point 4.a) i) of Art 7.5.2, the words "and level" should be added after the words "non-slippery".

Justification: a level floor allows cattle to stand in a stable manner whilst bleeding. Unlevel (stepped) floors tend to cause unnecessary agitation and movement impacting on the bleeding process.

Reference: (UK to provide further details-page number of the reference) Improving Animal Welfare: A Practical Approach. Ed By Temple Grandin. UK Will reference above Book.

- ii) avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals;

- iii) equipment engineered to reduce noise of air hissing and clanging metal;
 - iv) absence of sharp edges in *restraining* equipment that would harm *animals*;
 - v) avoidance of jerking or sudden movement of restraining device;
 - vi) the restrainer should not look like a dead end.
- b) Methods of *restraint* causing avoidable suffering should not be used in conscious *animals* because they cause severe pain and stress:
- i) suspending or hoisting *animals* (other than *poultry*) by the feet or legs;
 - ii) indiscriminate and inappropriate use of *stunning* equipment;
 - iii) mechanical clamping of the legs or feet of the *animals* (other than shackles used in *poultry* and ostriches) as the sole method of *restraint*;
 - iv) breaking legs, cutting leg tendons or blinding *animals* in order to immobilise them;
 - v) severing the spinal cord, for example using a puntilla or dagger, to immobilise *animals* using electric currents to immobilise *animals*, except for proper *stunning*.

Article 7.5.3.

Lairage design and construction

1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of *animals* in relation to the throughput rate of the *slaughterhouse* without compromising the *welfare* of the *animals*.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the *animals*, the *lairage* should be designed and constructed so as to allow the *animals* to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following recommendations may help to achieve this.

2. Design of lairage

- a) The *lairage* should be designed to allow a one-way flow of *animals* from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.
- b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of *animals* at any time, and to permit the removal of sick or injured *animals* when considered to be appropriate, for which separate appropriate accommodation should be provided.
- c) Each *animal* should have room to stand up and lie down and, when confined in a pen, to turn around, except where the *animal* is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious *animals* should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid *welfare* problems. The *lairage* should have sufficient accommodation for the number of *animals* intended to be held. Drinking water should always be available to the *animals*, and the method of delivery should be appropriate to the type of *animal* held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in *animals*, and should not hinder the movement of *animals*.

Previous EU comment

The EU would like to reiterate its previous comment.

In point 2c) of Art 7.5.3, the text "confined in pen" should be replaced by "kept in group".

Justification: new systems are used where bovine animals are kept individually, able to stand up and lie down but still are able to see, hear, and smell each other, are developed for safety reasons and may be used. The animals can still feel that they are part of a group in those systems.

- d) Holding pens should be designed to allow as many *animals* as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all *animals* to feed. The feed trough should not hinder the movement of *animals*.
- e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the *animals* and should also allow the *animals* to stand, lie down and access any food or water that may need to be provided.
- f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent *animals* to see each other. For pigs and sheep, passageways should be wide enough to enable two or more *animals* to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the *animals*.
- g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of *animals* to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of *animals* without injury.
- h) In slaughterhouses with high throughput, there should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of *animals* for *stunning* or *slaughter* and to avoid having *animal handlers* trying to rush *animals* from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that *animals* cannot be trapped or trampled.
- i) Ramps or lifts should be used for the *loading* and *unloading* of *animals* where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit *animals* to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent *animals* escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of *animals* without causing distress or injury.

3. Construction of lairage

- a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the *animals*.
- b) Floors should be well drained and not slippery; they should not cause injury to the feet of the *animals*. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where *animals* would have to cross them. Discontinuities or changes in floor, wall or gate, colour, patterns or texture which could cause baulking in the movement of *animals* should be avoided.
- c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the *animals* or affect their movement. The fact that *animals* will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

- d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of *animals* the *lairage* will be expected to hold.
- e) Care should be taken to protect the *animals* from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noises to the areas where *animals* are held and slaughtered.
- f) Where *animals* are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 7.5.4.

Care of animals in lairages

Animals in *lairages* should be cared for in accordance with the following recommendations:

1. As far as possible, established groups of *animals* should be kept together ~~and each~~ *animal* should have enough space to stand up, lie down and turn around. *Animals* hostile to each other should be separated.

Previous EU comment

The EU would like to reiterate its previous comment.

In point 1 of Art 7.5.4, the text "when kept in group," should be added in the following sentence as follows:

"Each animal should have enough space to stand up, lie down and, when kept in group, turn around."

Justification: see previous comment in Art 7.5.3 point 2) c).

2. Where tethers, ties or individual stalls are used, they should allow *animals* to stand up and lie down without causing injury or distress.
3. Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the *animals*, and sufficient bedding should be used so that *animals* do not become soiled with manure.
4. *Animals* should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.
5. Suitable drinking water should be available to the *animals* on their arrival and at all times to *animals* in *lairages* unless they are to be slaughtered without delay.
6. Waiting time should be minimised and should not exceed 12 hours. If *animals* are not to be slaughtered within 12 hours of their arrival ~~this period~~ as soon as possible, suitable feed should be available to the *animals* on arrival and at intervals appropriate to the species. Unweaned *animals* should be slaughtered as soon as possible.
7. In order to prevent heat stress, *animals* subjected to high temperatures, particularly pigs and *poultry*, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of *animals* to thermoregulate (especially *poultry*) should be considered in any decision to use water sprays. The risk of *animals* being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.
8. The *lairage* area should be well lit in order to enable the *animals* to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all *animals*. Subdued lighting, and for example blue light, may be useful in *poultry lairages* in helping to calm birds.
9. The condition and state of health of the *animals* in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian's* responsibility, by another competent person, such as an *animal handler*. *Animals* which are sick, weak, injured or showing visible signs of distress should be separated,

and veterinary advice should be sought immediately regarding treatment or the *animals* should be humanely killed immediately if necessary.

10. Lactating dairy *animals* should be slaughtered as soon as possible. Dairy *animals* with obvious udder distension should be milked to minimise udder discomfort.
11. *Animals* which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for their *welfare* and the *welfare* of the newborn. Under normal circumstances, *animals* which are expected to give birth during a *journey* should not be transported.
12. *Animals* with horns, antlers or tusks capable of injuring other *animals*, if aggressive, should be penned separately.
13. *Poultry* awaiting *slaughter* should be protected from adverse weather conditions and provided with adequate ventilation.
- ~~14. Waiting time should be minimised and should not exceed 12 hours when no food or water is provided during waiting.~~
15. *Poultry* in transport *containers* should be examined at the time of arrival. *Containers* should be stacked with sufficient space between the stacks to facilitate inspection of birds and air movement.
16. Forced ventilation or other cooling systems may be necessary under certain conditions to avoid build up of temperature and humidity. Temperature and humidity should be monitored at appropriate intervals.

Recommendations for specific species are described in detail in Articles 7.5.5. to 7.5.9.

Article 7.5.5.

Management of foetuses during slaughter of pregnant animals

Under normal circumstances, pregnant *animals* that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately, and the specific procedures described below are applied. In all cases, the *welfare* of foetuses and dams during *slaughter* should be safeguarded.

Foetuses should not be removed from the uterus sooner than 5 minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-*slaughter* processing of pregnant *animals*, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15–20 minutes after the maternal neck or chest cut.

If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.

The above recommendations do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at the evisceration of the dam, should not be attempted during normal commercial *slaughter* as it may lead to serious *welfare* complications in the newborn *animal*. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Article 7.5.6.

Summary analysis of handling and restraining methods and the associated animal welfare issues

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down	Competent animal handlers	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handler	Breeding pigs (boars and sows)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
	Upright restraint	Beak holding	Captive bolt Electrical-head only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head only	Stress of capture and positioning	Competent animal handler	Ostriches
	Holding body upright- manual	Manual restraint	Captive bolt Electrical-head only Slaughter without	Stress of capture and restraint; accuracy of stunning/ slaughter	Competent animal handlers	Sheep, goats, calves, ratites, small camelids, poultry

			stunning			
	Holding body upright mechanical	Mechanical clamp / crush / squeeze / V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/ cradle/crush	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining methods (contd)	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches
Restraining and/or conveying methods	Mechanical - upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
	Mechanical - upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical - upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones; Keep restraint as short as possible	Competent animal handlers; proper design and operation of equipment; birds should be hung by both legs	Poultry

	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint Preferable to rotating box with fixed sides Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/implications	Key animal welfare requirements	Applicable species

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/implications	Key animal welfare requirements	Applicable species
Body restraint	Casting/hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, calves, small camelids, pigs
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Article 7.5.7.

Stunning methods1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

- a) the *animal* is adequately restrained;
- b) *animals* in *restraint* are stunned as soon as possible;

Previous EU comment

The EU would like to reiterate its previous comment.

In Article 7.5.7 (1) (b), the following text should be included: "animals should not be restrained until the personnel carrying out the stunning is ready to do so."

Justification: maintaining the animal in the restraining equipment increases the stress of the animal.

- c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the *animal*;
- d) the equipment is applied correctly;
- e) stunned *animals* are bled out (slaughtered) as soon as possible;
- f) *animals* are not stunned when *slaughter* is likely to be delayed; and
- g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails. Provision of a manual inspection area and simple intervention like captive bolt ~~and/or~~ cervical dislocation for *poultry* would help prevent potential *welfare* problems.

Previous EU comment

The EU would like to reiterate its previous comment.

In point 1.g) of Article 7.5.7, in the text "like captive bolt ~~and~~ or cervical dislocation", the word "or" should be replaced by "which is more humane than"; furthermore, the sentence "In poultry, it is preferable to use a captive bolt which is more humane than cervical dislocation when feasible" should be added.

Justification

In the EFSA opinion from 15 June 2004 it is stated that neck dislocation may not concuss poultry and it is therefore uncertain whether it causes immediate unconsciousness.

In addition, such persons should be able to recognise when an *animal* is not correctly stunned and should take appropriate action.

2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. For a more detailed explanation on the different methods for mechanical *stunning*, see Chapter 7.6. and Articles 7.6.6., 7.6.7. and 7.6.8. The following diagrams illustrate the proper application of the device for certain species.

Cattle

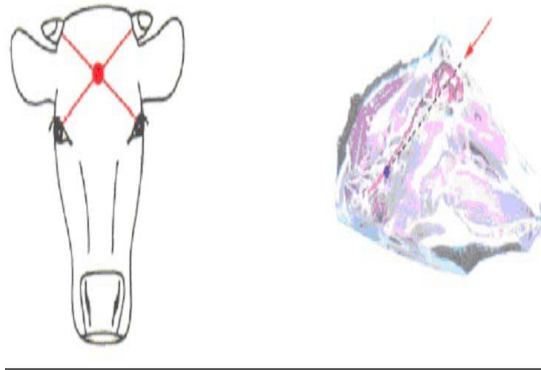


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Pigs

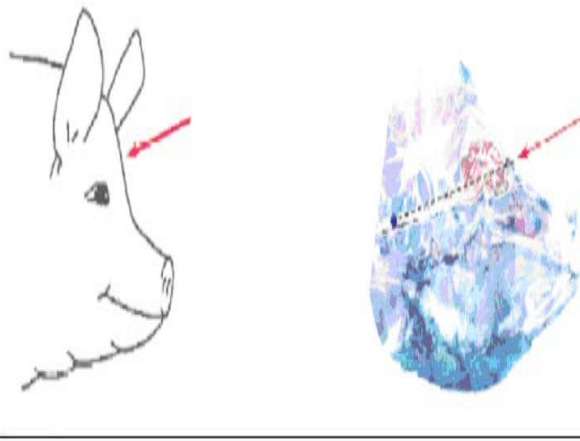


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Sheep

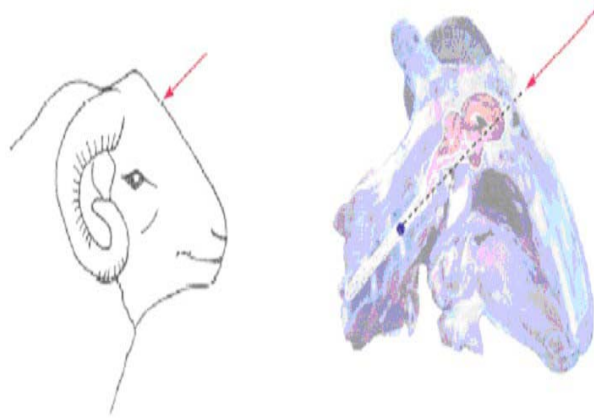


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for hornless sheep and goats is on the midline.

Goats

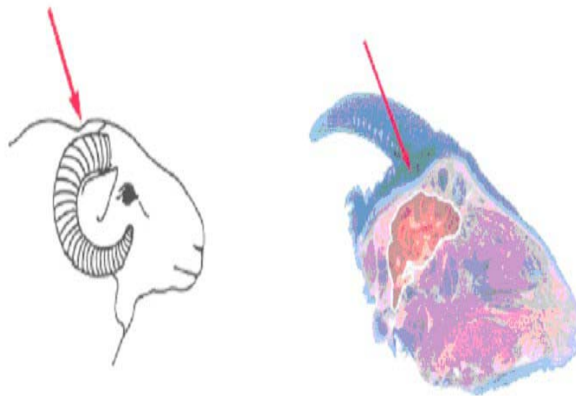


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

Horses

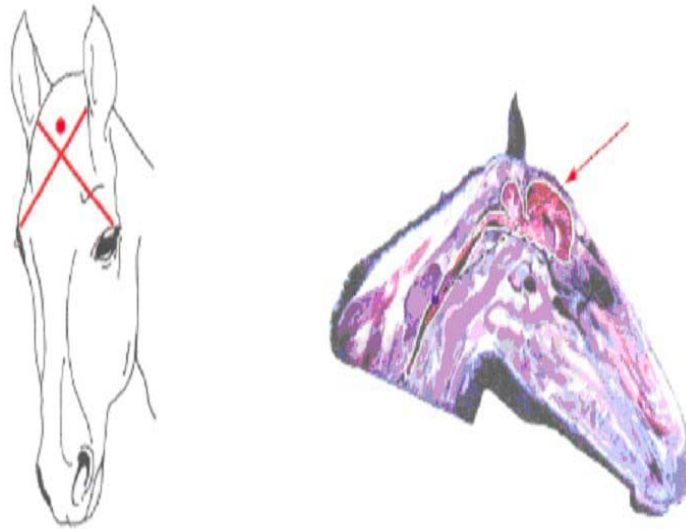


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Signs of correct *stunning* using a mechanical instrument are as follows:

- a) the *animal* collapses immediately and does not attempt to stand up;
- b) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;
- c) normal rhythmic breathing stops; and
- d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

Poultry



Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Poultry



Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.

Firing of a captive bolt according to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.

3. Electrical stunning

a) General considerations

An electrical device should be applied to the *animal* in accordance with the following recommendations.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the *animal* has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the *animal* is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on *animals* as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the *animal* before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on *animals* using appropriate resistors or dummy loads to ensure the power output is adequate to stun *animals*.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The *stunning* apparatus should be appropriate for the species. Apparatus required for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only *stunning* are shown in the following table.

Species	Minimum current levels for head-only stunning
Cattle	1.5 amps
Calves (bovines of less than 6 month of age)	1.0 amps

Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks. The shackle size should be appropriate to fit the size of the shanks (metatarsal bones) of birds.

Birds should be hung on shackles by both legs.

Birds with dislocated or broken legs or wings should be humanely killed rather than shackled.

The duration between hanging on shackles and *stunning* should be kept to the minimum. In any event, the time between shackling and *stunning* should not exceed one minute.

Waterbaths for poultry should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

Previous EU comment

The EU would like to reiterate its previous comment.

In Art 7.5.7 point 3.b), the following sentence should be added in the above paragraph:

"The entrance to the water bath should be designed in a way which prevents pre-stun shocks."

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve the electrical conductivity of the water, it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may should be required.

EU comment

In the last sentence of the above paragraph of point 3.b) of Article 7.5.7, the word "may" should be deleted.

Justification: editorial change.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of stunning and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately. The height of the waterbath stunner should be adjusted according to the size of birds to ensure even the small birds are immersed in the water bath up to the base of the wings.

Waterbath stunning equipment should be fitted with a device which displays and records the details of the electrical key parameter.

Minimum current for stunning poultry when using 50Hz is as follows:

Minimum current for stunning poultry when using high frequencies is as follows:

Species	Current (milliamperes per bird)	
Broilers	100	
Layers (spent hens)	100	
Turkeys	150	
Ducks and geese	130	
	Minimum current (milliamperes per bird)	
Frequency (Hz)	Chickens	Turkeys
From 50 to < 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

34. Gas stunning (under study)

a) Stunning of pigs by exposure to carbon dioxide (CO₂)

The concentration of CO₂ for stunning should be preferably 90% by volume but in any case no less than 80% by volume. After entering the stunning chamber, the animals should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until death occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO₂ for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the animal prior to loss of consciousness.

The chamber in which animals are exposed to CO₂ and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the animals. The animal density within the chamber should be such to avoid stacking animals on top of each other.

The conveyor and the chamber shall be adequately lit to allow the animals to see their surroundings and, if possible, each other.

It should be possible to inspect the CO₂ chamber whilst it is in use, and to have access to the animals in emergency cases.

Previous EU comment

The EU would like to reiterate its previous comment.

We suggest deleting the last part of the paragraph above: "~~and to have access to the animals in emergency cases.~~"

Justification: practically there is no simple way to inspect CO₂ chambers when it is in use and due to the gas concentration human intervention is unlikely to be performed any way.

The chamber shall be equipped to continuously measure and display register at the point of stunning the CO₂ concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO₂ falls below the required level.

Emergency stunning equipment should be available at the point of exit from the stunning chamber and used on any pigs that do not appear to be ~~dead or~~ completely stunned.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to animals. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

- i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or
- ii) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious *poultry* under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to *poultry*.

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO₂ until the birds are properly stunned. No bird should recover consciousness during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live *poultry* should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure

that all *animals* are properly stunned without unnecessary suffering. Some monitoring points for gas *stunning* could be the following:

- ensure smooth entry and passage of crates or birds through the system;
 - avoid crowding of birds in crates or conveyors;
 - monitor and maintain gas concentrations continuously during operation;
 - provide visible and audible alarm systems if gas concentrations are inappropriate to the species;
 - calibrate gas monitors and maintain verifiable records;
 - ensure that duration of exposure is adequate to prevent recovery of consciousness;
 - make provision to monitor and deal with recovery of consciousness;
 - ensure that blood vessels are cut to induce *death* in unconscious birds;
 - ensure that all birds are dead before entering scalding tank;
 - provide emergency procedures in the event of system failure.
- i) Gas mixtures used for stunning *poultry* include:
- a minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or
 - a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
 - a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
 - a minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air; or
 - a minimum of one minute exposure to 30% carbon dioxide in air, followed by a minimum of one minute exposure to at least 60% carbon dioxide in air.
- ii) Requirements for effective use are as follows:
- Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.
 - Gas mixtures should be humidified.
 - Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

From the point of view of *animal welfare*, *animals* which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no *animals* recover consciousness during bleeding. In any case the following time limits should be applied.

Previous EU comment

The EU would like to reiterate its previous comment.

In point 5 of Art 7.5.7, the following text should be added at the end of the paragraph above:

"The stun-stick interval should commence from when the animal collapses into the tonic phase when stunned by electricity."

Justification: it is important to precisely specify the starting point of the stun-to-stick interval.

All *animals* should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the *stunning* method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of view of *animal welfare*.

It should be possible for staff to observe, inspect and access the *animals* throughout the bleeding period. Any *animal* showing signs of recovering consciousness should be re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the *animals* for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

Stunning method	Maximum delay for bleeding to be started Maximum stun –stick interval
Electrical methods and non-penetrating captive bolt	20 seconds
CO ₂	60 seconds (after leaving the chamber)

EU comment

In the table above, CO₂ should be replaced by "CO₂ (80-90% during 140 seconds)" and a footnote after 60 seconds should be added "For increasing exposure times, the duration of unconsciousness increases and the stun-stick interval can be increased proportionally without animals recovering consciousness"(text from EFSA opinion).

Justification: EFSA Scientific Opinion 2004, Humane Slaughter. Pg 109.

Article 7.5.8.

Summary analysis of stunning methods and the associated animal welfare issues

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	Operator competence; achieving outright kill with first shot	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites,	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot

				<u>poultry</u>	
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites, <u>poultry</u>	Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available.
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used.
	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	
Gaseous	CO ₂ air/O ₂ mixture; CO ₂ inert gas mixture	Aversiveness of high CO ₂ ; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	

Article 7.5.9.

Summary analysis of slaughter methods and the associated animal welfare issues

Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut	High level of operator competency. A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	No further procedure should be carried out before the bleeding out is completed (i.e. at least 30 seconds for mammals). The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.
Bleeding with prior stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats	

	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; inadequate size of stick wound; inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	
	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord. Acceptable only when slaughtering small numbers of small birds.
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Methods, procedures or practices unacceptable on animal welfare grounds

1. The restraining methods which work through electro-immobilisation or immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in *animals*. Those methods are not acceptable in any species.
2. The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.
3. The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning* is not acceptable in any species.

— text deleted

CHAPTER 7.6.

**KILLING OF ANIMALS FOR
DISEASE CONTROL PURPOSES**

EU position

The EU thanks the OIE TAHSK and supports the adoption of the proposed changes in the chapter.

A number of previous EU comments are reiterated in the text in addition to some new ones and are submitted to OIE consideration at the next revision of the chapter.

Article 7.6.1.

General principles

These recommendations are based on the premise that a decision to kill the *animals* has been made, and address the need to ensure the *welfare* of the *animals* until they are dead.

1. All personnel involved in the humane *killing* of *animals* should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.
2. As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from *animal welfare*, aesthetics of the method of euthanasia, cost of the method, operator safety, biosecurity and environmental aspects.
3. Following the decision to kill the *animals*, *killing* should be carried out as quickly as possible, and normal husbandry should be maintained until the *animals* are killed.
4. The handling and movement of *animals* should be minimised and when done, it should be carried out ~~done~~ in accordance with the recommendations described below.
5. Animal *restraint* should be sufficient to facilitate effective *killing*, and in accordance with *animal welfare* and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.
6. When *animals* are killed for disease control purposes, methods used should result in immediate *death* or immediate loss of consciousness lasting until *death*; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or the least aversive possible and should not cause avoidable anxiety, pain, distress or suffering in *animals*.
7. For *animal welfare* considerations, young *animals* should be killed before older *animals*; for biosecurity considerations, infected *animals* should be killed first, followed by in-contact *animals*, and then the remaining *animals*.
8. There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to *animal welfare*, operator safety and biosecurity.
9. When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on *animal welfare*, operator safety and biosecurity.
10. These general principles should also apply when *animals* need to be killed for other purposes such as after natural disasters or for culling animal populations.

Article 7.6.2.

Organisational structure

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; *animal welfare* considerations should

be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel competent in the humane *killing* of *animals* is available. Local level plans should be based on national plans and be informed by local knowledge.

Disease control contingency plans should address the *animal welfare* issues that may result from animal movement controls.

The operational activities should be led by an *official Veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required *animal welfare* and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.

The *official Veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official Veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE *animal welfare* and animal health recommendations.

A specialist team, led by a team leader answerable to the *official Veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

In considering the *animal welfare* issues associated with *killing animals*, the key personnel, their responsibilities and competencies required are described in Article 7.6.3.

Article 7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader

a) Responsibilities

- i) plan overall operations on affected premises;
- ii) determine and address requirements for *animal welfare*, operator safety and biosecurity;
- iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant *animals* on the premises in accordance with national regulations and these recommendations;
- iv) determine logistics required;
- v) monitor operations to ensure *animal welfare*, operator safety and biosecurity requirements are met;
- vi) report upwards on progress and problems;
- vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the *animal welfare*, operator safety and biosecurity outcomes.

b) Competencies

- i) appreciation of normal animal husbandry practices;
- ii) appreciation of *animal welfare* and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;

- iii) skills to manage all activities on premises and deliver outcomes on time;
- iv) awareness of psychological effects on farmer, team members and general public;
- v) effective communication skills;
- vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian

a) Responsibilities

- i) determine and supervise the implementation of the most appropriate *killing* method to ensure that *animals* are killed without avoidable pain and distress;
- ii) determine and implement the additional requirements for *animal welfare*, including the order of *killing*;
- iii) ensure that confirmation of the *death* of the *animals* is carried out by competent persons at appropriate times after the *killing* procedure;
- iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;
- v) continuously monitor *animal welfare* and biosecurity procedures;
- vi) in cooperation with the leader, prepare a written report at the conclusion of the *killing*, describing the practices adopted and their effect on *animal welfare*.

b) Competencies

- i) ability to assess *animal welfare*, especially the effectiveness of *stunning* and *killing* and to correct any deficiencies;
- ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

- i) review on-site facilities in terms of their appropriateness;
- ii) design and construct temporary animal handling facilities, when required;
- iii) move and restrain *animals*;
- iv) continuously monitor *animal welfare* and biosecurity procedures.

b) Competencies

- i) animal handling in emergency situations and in close confinement is required;
- ii) an appreciation of biosecurity and containment principles.

4. Animal killing personnel

a) Responsibilities

Humane *killing* of the *animals* through effective *stunning* and *killing* should be ensured.

- b) Competencies
 - i) when required by regulations, licensed to use necessary equipment;
 - ii) competent to use and maintain relevant equipment;
 - iii) competent to use techniques for the species involved;
 - iv) competent to assess effective *stunning* and *killing*.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure *killing* operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

- i) assist when requested.

b) Competencies

- ii) specific knowledge of his/her animals and their environment.

Article 7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane *killing* of *animals*. The team leader should develop a plan for humanely *killing animals* on the premises which should include consideration of:

1. minimising handling and movement of *animals*;
2. *killing* the *animals* on the affected premises; however, there may be circumstances where the *animals* may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the recommendations in Chapter 7.5. on the *slaughter* of *animals* should be followed;
3. the species, number, age and size of *animals* to be killed, and the order of *killing* them;
4. methods of *killing* the *animals*, and their cost;
5. housing, husbandry, location of the *animals* as well as accessibility of the farm;
6. the availability and effectiveness of equipment needed for *killing* of the *animals*, as well as the time necessary to kill the required number of *animals* using such methods;
7. the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;
8. biosecurity and environmental issues;

9. the health and safety of personnel conducting the *killing*;
10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;
11. the presence of other nearby premises holding *animals*;
12. possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative *welfare* impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the *animals*.

Competences and skills of the personnel handling and *killing animals*.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all *animals* are humanely and quickly killed.

Article 7.6.5.

Table summarising killing methods described in Articles 7.6.6.-7.6.18.

The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an *animal welfare* viewpoint.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt - followed by pithing or bleeding	yes	ineffective stunning	7.6.7.
	adults only	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	7.6.8.
	calves only	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	7.6.6.
Sheep and goats (contd)	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO ₂ / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.

	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Pigs	all, except neonates	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all ¹	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO ₂ / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
Pigs (contd)	neonates only	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	7.6.15.
Poultry	adults only	non-penetrating captive bolt	yes	ineffective stunning	7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non-immediacy	7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	7.6.11.
	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	7.6.11.
	all	CO ₂ / air mixture Method 1 Method 2	yes no	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	all	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
	<u>all</u>	<u>cervical dislocation</u>	<u>no</u>		<u>7.6.17.1</u>
	<u>all</u>	<u>decapitation</u>	<u>no</u>		<u>7.6.12.2</u>
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	7.6.16.

EU comments

1. In the above table, for cervical dislocation and decapitation, the following text should be added in the column under animal welfare concerns "ineffective stunning - possible consciousness of the animals"

Justification: this is a welfare risk of the method.

2. In the above table and in the Article reference for decapitation, "7.6.12.2" should be replaced with "7.6.17.2"

Justification: decapitation is dealt with in Article 7.6.17.2.

Article 7.6.6.

Free bullet1. Introduction

- a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.
- b) The most commonly used firearms for close range use are:
 - i) humane killers (specially manufactured/adapted single-shot weapons);
 - ii) shotguns (12, 16, 20, 28 bore and .410);
 - iii) rifles (.22 rimfire);
 - iv) handguns (various calibres from .32 to .45).
- c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).
- d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the *animals* (high neck shot) and to cause irreversible concussion and *death* and should only be used by properly trained and competent marksmen.

2. Requirements for effective use

- a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.
- b) The marksman should ensure that the *animal* is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the head of the *animals*.
- c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally, the ammunition should expand upon impact and dissipate its energy within the cranium.
- d) Shot *animals* should be checked to ensure the absence of brain stem reflexes.

3. Advantages

- a) Used properly, a free bullet provides a quick and effective method for *killing*.
- b) It requires minimal or no *restraint* and can be use to kill from a distance by properly trained and competent marksmen.
- c) It is suitable for *killing* agitated *animals* in open spaces.

4. Disadvantages

- a) The method is potentially dangerous to humans and other *animals* in the area.
- b) It has the potential for non-lethal wounding.
- c) Destruction of brain tissue may preclude diagnosis of some *diseases*.
- d) Leakage of bodily fluids may present a biosecurity risk.
- e) Legal requirements may preclude or restrict use.
- f) There is a limited availability of competent personnel.

5. Conclusion

The method is suitable for cattle, sheep, goats and pigs, including large *animals* in open spaces.

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for hornless sheep and goats is on the midline.

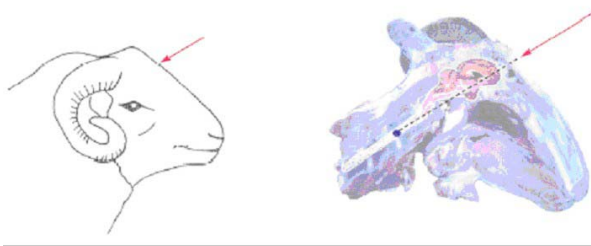


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

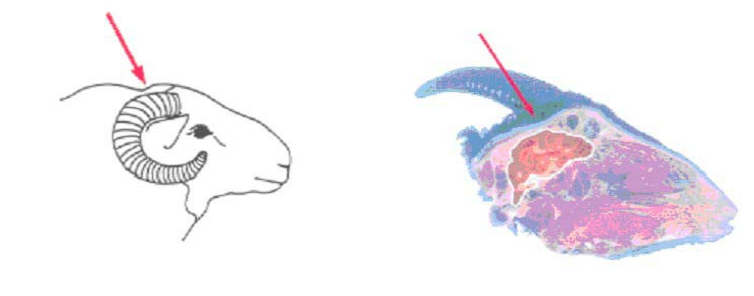


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 4. The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.

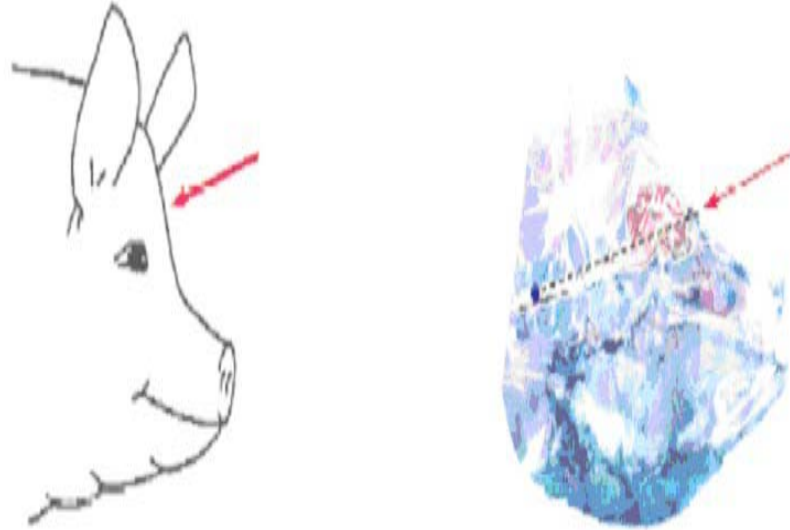


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 7.6.7.

Penetrating captive bolt

1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the *animal*. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in *death*; however, pithing or bleeding should be performed as soon as possible after the shot to ensure the *death* of the *animal*. Shooting *poultry* species with the captive bolts results in immediate destruction of the skull and brain, causing *death*. For a detailed description on the use of this method, see Chapter 7.5. of the *Terrestrial Code*.

2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- d) *Animals* should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.

- e) The operator should ensure that the head of the *animal* is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).
- g) To ensure the *death* of the *animal*, pithing or bleeding should be performed as soon as possible after *stunning*.
- h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

- a) Mobility of cartridge powered equipment reduces the need to move *animals*.
- b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

- a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.
- b) Post stun convulsions may make pithing difficult and hazardous.
- c) The method is difficult to apply in agitated *animals*.
- d) Repeated use of a cartridge powered gun may result in over-heating.
- e) Leakage of bodily fluids may present a biosecurity risk.
- f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for *poultry*, cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

Article 7.6.8.

Non-penetrating captive bolt

1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and *death* in poultry and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the *death* of the *animal*.

2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- d) *Animals* should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
- e) The operator should ensure that the head of the *animal* is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1–4).
- g) To ensure *death* in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.
- h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

- a) The method induces an immediate onset of unconsciousness, and *death* in birds and neonates.
- b) Mobility of equipment reduces the need to move *animals*.

4. Disadvantages

- a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.
- b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.
- c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.
- d) Post stun convulsions may make bleeding difficult and hazardous.
- e) Difficult to apply in agitated *animals*; such *animals* may be sedated in advance of the *killing* procedure.
- f) Repeated use of a cartridge powered gun may result in over-heating.
- g) Bleeding may present a biosecurity risk.

5. Conclusions

The method is suitable for *killing* poultry, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

Article 7.6.9.

Maceration

1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and *death* in day-old *poultry* and embryonated eggs.

2. Requirements

- a) Maceration requires specialised equipment which should be kept in excellent working order.
- b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

3. Advantages

- a) Procedure results in immediate *death*.
- b) Large numbers can be killed quickly.

4. Disadvantages

- a) Specialised equipment is required.
- b) Macerated tissues may present biosecurity or human health risks.
- c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old poultry and embryonated eggs.

Article 7.6.10.

Electrical – two-stage application

1. Introduction

A two-stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce ‘tonic/clonic’ epilepsy and unconsciousness. Once the *animal* is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in *death*. The second stage (the application of low frequency current across the chest) should only be applied to unconscious *animals* to prevent unacceptable levels of pain.

2. Requirements for effective use

- a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	220	1.5
Sheep	220	1.0
Pigs over 6 weeks of age	220	1.3
Pigs less than 6 weeks of age	125	0.5

- b) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- c) *Animals* should be restrained, at a minimum free-standing in a pen, close to an electrical supply.

- d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the *animal* to allow the second application to be made.
- e) A *stunning* current should be applied via scissor-type *stunning* tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.
- f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- g) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.
- h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

3. Advantages

- a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.
- b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

- a) The method requires a reliable supply of electricity.
- b) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.
- c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).
- d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).



Article 7.6.11.

Electrical – single application

1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the *animal* and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the *animal* will not recover consciousness.

a) Requirements for effective use

- i) The stunner control device should generate a low frequency (30–60 Hz) current with a minimum voltage of 250 volts true RMS under load.
- ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- iii) *Animals* should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the *stunning* electrodes and the *animal* is necessary for effective use.
- iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.
- v) Electrodes should be cleaned regularly between *animals* and after use, to enable optimum electrical contact to be maintained.
- vi) Water or saline may be necessary to improve electrical contact with sheep.
- viii) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

- i) Method 1 stuns and kills simultaneously.
- ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.
- iii) A single team member only is required for the application.
- iv) Non-invasive technique minimises biosecurity risk.

c) Disadvantages

- i) Method 1 requires individual mechanical animal *restraint*.
- ii) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.
- iii) Method 1 requires a reliable supply of electricity.

d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over one week of age).

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled poultry through an electrified waterbath stunner. Electrical contact is made between the ‘live’ water and earthed shackle and, when sufficient current is applied, poultry will be simultaneously stunned and killed.

a) Requirements for effective use

- i) A mobile waterbath stunner and a short loop of processing line are required.

- ii) A low frequency (50–60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.
 - iii) Poultry need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.
 - iv) The required minimum currents to stun and kill dry birds are:
 - Quails – 100 mA/bird
 - Chickens – 160 mA/bird
 - Ducks & geese – 200 mA/bird
 - Turkeys – 250 mA/bird.

A higher current is required for wet birds.
 - v) An effective stun and kill should be verified by the absence of brain stem reflexes.
- b) Advantages
- i) Method 2 stuns and kills simultaneously.
 - ii) It is capable of processing large numbers of birds reliably and effectively.
 - iii) This non-invasive technique minimises biosecurity risk.
- c) Disadvantages
- i) Method 2 requires a reliable supply of electricity.
 - ii) Handling, inversion and shackling of birds are required.
- d) Conclusion

Method 2 is suitable for large numbers of poultry.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (see Article 7.6.17.).

- a) Requirements for effective use
- i) The stunner control device should generate sufficient current (more than 600 mA/duck and more than 300 mA/bird) to stun.
 - ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
 - iii) Birds should be restrained, at a minimum manually, close to an electrical supply.
 - iv) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

- v) Birds should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

b) Advantages

Non-invasive technique (when combined with cervical dislocation) minimises biosecurity risk.

c) Disadvantages

- i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations.
- ii) The electrodes should be applied and maintained in the correct position to produce an effective stun.
- iii) Birds should be individually restrained.
- iv) It should be followed by a *killing* method.

d) Conclusion

Method 3 is suitable for small numbers of *poultry*.

Article 7.6.12.

CO₂ / air mixture

1. Introduction

Controlled atmosphere killing is performed by exposing *animals* to a predetermined gas mixture, either by placing them in a gas-filled *container* or apparatus (Method 1) or by placing transport modules or crates containing birds in a gas tight *container* and introducing a gas mixture (Method 2) or by the gas being introduced into a poultry house (Method 3). Method 2 3 should be used whenever possible, as it eliminates *welfare* issues resulting from the need to manually remove live birds. Although Method 2 requires handling and crating of the birds, it benefits bird *welfare* overall (in comparison with Method 1) as it reduces the risk of *death* by smothering or suffocation.

Inhalation of carbon dioxide (CO₂) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, *death*. Exposure to carbon dioxide does not induce immediate loss of consciousness, therefore the aversive nature of gas mixtures containing high concentrations of CO₂ and the respiratory distress occurring during the induction phase are important considerations for *animal welfare*.

2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus.

- a) Requirements for effective use in a *container* or apparatus
 - i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.
 - ii) When *animals* are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.
 - iii) *Animals* can also be introduced to low concentrations (as low concentrations are not aversive) and the concentration could be increased afterwards and the *animals* then held in the higher concentration until *death* is confirmed.

- iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.
 - v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.
- b) Advantages
- i) CO₂ is readily available.
 - ii) Application methods are simple.
 - iii) The volume of gas required can be readily calculated.
 - iv) As the units are operated outdoor, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.
 - v) The system uses skilled catching teams and equipment in daily use by the industry.
 - vi) Metal *containers* can be readily cleansed and disinfected.
- c) Disadvantages
- i) The need for properly designed *container* or apparatus.
 - ii) The aversive nature of high CO₂ concentrations.
 - iii) No immediate loss of consciousness.
 - iv) The risk of suffocation due to overcrowding.
 - v) Difficulty in verifying *death* while the *animals* are in the *container* or apparatus.

Previous EU comment

In point 2) c) of Article 7.6.12, the EU suggests adding after (c) (v) the sentence already used for other methods "However cessation of vocalisations and convulsing wing flapping sounds can be used to determine the onset of unconsciousness that will in due time lead to death".

Justification: cessation of vocalizations and convulsing wing flapping sounds occur when the animals become unconscious. Death occurs at a later stage. There is risk that the birds are taken out of the container too early before the birds are dead.

- d) Conclusion

Method 1 is suitable for use in poultry, and neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a chamber into which gas is introduced. As illustrated in the example below, a containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a single module. The chamber is fitted with gas lines and diffusers, with silencers that are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top to permit displaced air to escape when the *container* is filling with gas.

The procedures for the operation of CGU include (a) position the *container* on level, solid, open ground; (b) connect the gas cylinder to the *container* (c) load birds into the *container* (d) shut and secure the door, (e) deliver the gas until a concentration of 45% by volume of carbon dioxide has been achieved at the top of the *container*, (f) allow time for the birds to become unconscious and die (g) open the door and allow gas to

be dispersed in the air (h) remove the module (i) check each drawer for survivors (j) humanely kill any survivors; and (k) dispose of carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)

- i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.
- ii) The crates or module full of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas.
- iii) Ensure the *container* door is locked and administer the gas until a minimum concentration of ~~45~~50% carbon dioxide is achieved at the top of the crates.
- iv) An appropriate gas meter should be used to ensure the appropriate concentration of carbon dioxide is achieved and maintained until it can be confirmed that the birds have been killed.
- v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window that allows direct observation of birds during killing, cessation of vocalisation and convulsive wing flapping sounds, which can be listened to by standing near the *container*, can be used to determine that the birds are unconscious and that *death* is imminent. Remove the crates or modules from the *container* and leave them in the open air.
- vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing indicate *death*.
- vii) Any survivors should be humanely killed.
- viii) Ducks and geese are resilient to the effects of carbon dioxide and therefore require a minimum of 80% CO₂ and a longer period of exposure to die.

b) Advantages

- i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.
- ii) Gradual increase in the concentration of CO₂ minimises the aversive nature of this method for inducing unconsciousness.
- iii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.
- iv) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.
- v) CO₂ is readily available.
- vi) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.
- vii) The volume of gas required can be readily calculated.
- viii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.
- ix) The system uses skilled catching teams and equipment in daily use by the industry.
- x) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

- i) Requires trained operators, trained catchers, transport modules and fork lift. However, this equipment and suitable areas with hard surfaces are usually available.
- ii) The main limiting factors are speed of catching birds.
- iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping sounds can be used to determine onset of *death*.
- iv) The need for properly designed *container* or apparatus
- v) No immediate loss of consciousness.
- vi) The risk of suffocation due to overcrowding.

d) Conclusion

- i) Method 2 is suitable for use in a wide range of poultry systems, providing there is access to *vehicles* to carry the *containers* and equipment.
- ii) Birds should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the required gas concentrations, i.e. more than 40% CO₂. Birds are held in this atmosphere until *death* is confirmed.
- iii) Method 2 is suitable for use in poultry, and neonatal sheep, goats and pigs. However, CO₂ is likely to cause a period of distress in the *animals* before they lose consciousness.

4. Method 3

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

- i) Prior to introduction of the CO₂, the poultry house should be appropriately sealed to allow control over the gas concentration. The interval between sealing and gas administration should be kept to the minimum so as to avoid overheating.

Forced ventilation systems, where fitted, should only be switched off immediately prior to gas administration.

The main water supply to the poultry house may have to be turned off and water drained to avoid freezing and bursting of water pipes.

Feeders and water troughs should be lifted to avoid obstruction of the gas entry and prevent injury to birds.

- ii) Gas delivery pipes or lancets should be positioned appropriately such that birds are not hit directly by very cold gas delivered at high pressures. It may be necessary to exclude birds from the area in front of the delivery pipes, for a distance of about 20 meters, by partitioning the house with nets, wire mesh or similarly perforated materials.
- iii) The house should be gradually filled with CO₂ so that all birds are exposed to a concentration of >40% until they are dead; a vaporiser may be required to prevent freezing.
- iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

- i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.
- ii) CO₂ is readily available.
- iii) Gradual raising of CO₂ concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

- i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO₂ in some poultry houses.
- ii) It is difficult to verify *death* while the birds are in the poultry house.

The extremely low temperature of liquid CO₂ entering the house and formation of solid CO₂ (dry ice) may cause concern for bird *welfare*.

d) Conclusion

Method 32 is suitable for use in poultry in closed-environment sheds. This method could be developed for killing pigs. However, CO₂ is likely to cause a period of distress in the birds before they lose consciousness.

Article 7.6.13.

Nitrogen and/or inert gas mixed with CO₂

1. Introduction

CO₂ may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is <2% or <5% for chickens. Various mixtures of CO₂ and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 32 described under 7.6.12. Whole house gassing with mixtures of CO₂ and nitrogen, or an inert gas, has not been tested owing to the complex issues presented by mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO₂ and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

Pigs and poultry appear not to find low concentrations of CO₂ strongly aversive, and a mixture of nitrogen or argon with <30% CO₂ by volume and <2% O₂ by volume can be used for *killing* poultry, neonatal sheep, goats and pigs.

Previous EU comment

The EU would like to reiterate its previous comment.

In the above paragraph, the EU suggests modifying the last part of the sentence by the following "and 2% to 5% O₂ by volume can be used for killing all poultry except ducks and geese, and a. A mixture of nitrogen or argon with < 30% CO₂ by volume and < 2 % O₂ by volume can be also used for killing poultry, neonatal sheep, goats and pigs that require <2% oxygen by volume levels".

2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus.

- a) Requirements for effective use

- i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O₂ and CO₂ concentrations accurately measured during the *killing* procedure.
 - ii) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.
 - iii) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2% O₂), and held in this atmosphere until *death* is confirmed.
 - iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.
 - v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.
- b) Advantages
- i) Low concentrations of CO₂ cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.
 - ii) The volume of gas required can be readily calculated.
 - iii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.
 - iv) Metal containers can be readily cleansed and disinfected.
 - v) Mixtures containing up to 20% carbon dioxide in argon are readily available as welding gas cylinders.
- c) Disadvantages
- i) A properly designed *container* or apparatus is needed.
 - ii) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

Previous EU comment

The EU suggests adding after (2) (c) (ii) the sentence already used for other methods "However cessation of vocalisations and convulsing wing flapping sounds can be used to determine the onset of unconsciousness that will in due time lead to death".

- iii) There is no immediate loss of consciousness.
 - iv) Exposure times required to kill are considerable.
 - v) The risk of suffocation due to overcrowding.
- d) Conclusion

The method is suitable for poultry, and for neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a *container* and gas is introduced into the *container* (refer to Figures under Article 7.6.12.). As shown in the example below, each containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate poultry transport crates or a module. The *container* or chamber is fitted with gas lines and diffusers, with silencers, which in

turn are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top of the unit to permit displaced air to escape when filling the *container* with gas.

Procedures involved in the operation of CGU includes (a) position the *container* on a level, solid, open ground; (b) connect gas cylinder to the *container* (c) load a module of birds into the *container*, (d) shut and secure the door, (e) deliver the gas to the point where less than 2% by volume of oxygen is found at the top of the *container*, (f) allow time for the birds to become unconscious and die, (g) open the door and allow the gas to be dispersed in air, (h) remove the module, (i) check each drawer for survivors; (j) humanely kill survivors, if any; and (k) dispose carcasses appropriately.

- a) Requirements for effective use of containerised gassing units (CGU)
 - i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.
 - ii) The crates or module of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas mixture.
 - iii) Ensure the *container* door is locked and administer the gas mixture until <2% residual oxygen is achieved at the top of the crates.
 - iv) An appropriate gas meter should be used to ensure a concentration of oxygen <2% is achieved and maintained until it can be confirmed that the birds have been killed.
 - v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window, which allows direct observation of birds during killing, cessation of vocalisation and wing flapping sounds can be observed by standing close to the *container* and used to determine the onset of *death* in birds. Remove the crates or modules from the *container* and leave them in the open air.
 - vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements indicate *death*.
 - vii) Any survivors should be humanely killed.
 - viii) Ducks and geese do not appear to be resilient to the effects of a mixture of 20% carbon dioxide and 80% nitrogen or argon.
- b) Advantages
 - i) The gas mixture is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.
 - ii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.
 - iii) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.
 - iv) Mixtures containing up to 20% carbon dioxide in argon are readily available as welding gas cylinders.
 - v) Birds are exposed to gas in a more uniform manner and they do not smother each other when compared with Method 1.
 - vi) Two CGU can be operated in tandem and throughputs of up to 4,000 chickens per hour are possible.

- vii) The volume of gas required can be readily calculated.
 - viii) As the units are operated outdoor the gas is dispersed quickly at the end of each cycle by opening the door, improving operators' health and safety.
 - ix) The system uses skilled catching teams and equipment in daily use by the industry.
 - x) Metal *containers* can be readily cleansed and disinfected.
- c) Disadvantages
- i) Requires trained operators, trained catchers, transport modules and a fork lift. However, such equipment and suitable outdoor areas with a hard surface are usually available.
 - ii) The main limiting factors are speed of catching birds and availability of gas mixtures.
 - iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping can be used to determine the onset of *death*.
 - iv) CGU could be used to kill poultry on small to medium farms, e.g. up to 25 thousand birds on a single farm.
- d) Conclusion
- i) Method 2 is suitable for use in poultry and in neonatal sheep, goats and pigs.
 - ii) Method 2 is suitable for use in poultry in a wide range of poultry systems providing that these have access to *vehicles* to carry *containers* and equipment.
 - iii) *Animals* should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the gas mixture. A residual oxygen concentration of less than 2% should be achieved and maintained and birds should be held in this atmosphere until *death* is confirmed.





Article 7.6.14.

Nitrogen and/or inert gases1. Introduction

This method involves the introduction of *animals* into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

Research has shown that hypoxia is not aversive to pigs and poultry, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

- a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O₂ concentration accurately measured.
- b) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.
- c) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2% O₂), and held in this atmosphere until *death* is confirmed.
- d) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.
- e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid *animals* suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to *animals*.

4. Disadvantages

- a) A properly designed *container* or apparatus is needed.
- b) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.
- c) There is no immediate loss of consciousness.
- d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for poultry and neonatal sheep, goats and pigs.

Article 7.6.15.

Lethal injection1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and *death*. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use

- a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.
- b) Prior sedation may be necessary for some *animals*.
- c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.
- d) *Animals* should be restrained to allow effective administration.
- e) *Animals* should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

- a) The method can be used in all species.
- b) *Death* can be induced smoothly.

4. Disadvantages

- a) *Restraint* and/or sedation may be necessary prior to injection.
- b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious *animals*.
- c) Legal requirements and skill/training required may restrict use to veterinarians.
- d) Contaminated carcasses may present a risk to other wild or domestic *animals*.

5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs and poultry.

Article 7.6.16.

Addition of anaesthetics to feed or water1. Introduction

An anaesthetic agent which can be mixed with poultry feed or water may be used to kill poultry in houses. Poultry which are only anaesthetised need to be killed by another method such as cervical dislocation.

2. Requirements for effective use

- a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.
- b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.
- c) Should be followed by *killing* (see Article 7.6.17.) if birds are anaesthetised only.

3. Advantages

- a) Handling is not required until birds are anaesthetised.
- b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

- a) Non-target *animals* may accidentally access the medicated feed or water when provided in an open environment.
- b) Dose taken is unable to be regulated and variable results may be obtained.
- c) *Animals* may reject adulterated feed or water due to illness or adverse flavour.
- d) The method may need to be followed by *killing*.
- e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for *killing* large numbers of poultry in houses. However, a back-up method should be available to kill birds that are anaesthetised but not killed.

Article 7.6.17.

Cervical dislocation and decapitation

1. Cervical dislocation (manual and mechanical)

a) Introduction

Unconscious poultry may be killed by either manual or mechanical cervical dislocation (stretching the neck). This method results in *death* from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

b) Requirements for effective use

- i) *Killing* should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord.
- ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.
- iii) Birds should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

- i) It is a non-invasive *killing* method.
- ii) It can be performed manually on small birds.

d) Disadvantages

Previous EU comment

The EU would like to reiterate its previous comment.

The EU suggests adding the following disadvantage under point 1. d) of Article 7.6.17

"i) animals may not always have been stunned."

- i) Operator fatigue.
- ii) The method is more difficult in larger birds.
- iii) Requires trained personnel to perform humanely.
- iv) Human health and safety concerns due to handling of the birds.
- v) Additional stress to the *animals* from handling.

2. Decapitation

a) Introduction

Decapitation results in *death* by cerebral ischaemia using a guillotine or knife.

b) Requirements for effective use

The required equipment should be kept in good working order.

c) Advantages

The technique is effective and does not require monitoring.

d) Disadvantages

- i) The working area is contaminated with body fluids, which increases biosecurity risks.
- ii) Pain if consciousness is not lost immediately.

Article 7.6.18.

Pithing and bleeding

1. Pithing

a) Introduction

Pithing is a method of *killing animals* which have been stunned by a penetrating captive bolt, without immediate *death*. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

b) Requirements for effective use

- i) Pithing cane or rod is required.
- ii) An access to the head of the *animal* and to the brain through the skull is required.
- iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing immediate *death*.

d) Disadvantages

- i) A delayed and/or ineffective pithing due to convulsions may occur.
- ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

a) Introduction

Bleeding is a method of *killing animals* through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and *death*.

b) Requirements for effective use

- i) A sharp knife is required.
- ii) An access to the neck or chest of the *animal* is required.
- iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing *death* after an effective *stunning* method which does not permit pithing.

d) Disadvantages

- i) A delayed and/or ineffective bleeding due to convulsions may occur.
- ii) The working area is contaminated with body fluids, which increases biosecurity risks.-

— text deleted

The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.

CHAPTER 7.7.

STRAY DOG POPULATION CONTROL

EU Position

The EU thanks the OIE TAHSC and notes with satisfaction that most of the suggestions previously presented by the EU were taken onboard.

The EU can support the adoption of the proposed changes of this Chapter.

Nevertheless, the EU strongly encourages OIE to consider a previous specific comment which is reiterated within the text at Article 7.7.4, given its importance to the EU.

Preamble: The scope of these recommendations is to deal with stray and feral dogs, which pose serious human health, animal health and welfare problems and have a socio-economic, environmental, political and religious impact in many countries. Whilst acknowledging human health, is a priority including the prevention of zoonotic diseases, notably rabies is a priority. (Chapter 8.10), Dog population management is an integral part of rabies control programmes; Futhermore, the OIE recognises the importance of controlling dog populations without causing unnecessary or avoidable animal suffering. *Veterinary Services* should play a lead role in preventing zoonotic diseases and ensuring *animal welfare* and should be involved in dog population control, coordinating their activities with other competent public institutions and/or agencies.

EU comment

At the beginning of the last sentence of the above paragraph, the word "Futhermore" should be replaced with "Furthermore".

Justification: spelling.

Article 7.7.1.

Guiding principles

The following recommendations are based on those laid down in Chapter 7.1. Some additional principles are relevant to these recommendations:

1. The promotion of responsible dog ownership can significantly reduce the numbers of stray dogs and the incidence of zoonotic diseases.
2. Because dog ecology is linked with human activities, control of dog populations has to be accompanied by changes in human behaviour to be effective.

Article 7.7.2.

Definitions

Carrying capacity: means the upper limit of the dog population density that could be supported by the habitat based on the availability of resources (food, water, shelter), and human acceptance.

Dog population control programme: means a programme with the aim of reducing a stray dog population to a particular level and/or maintaining it at that level and/or managing it in order to meet a predetermined objective (see Article 7.7.3.).

~~**Euthanasia:** means the act of inducing death in a humane manner.~~

Owned dog: means a dog **with for which** a person **that** claims responsibility.

Person: this can include more than one individual, and could comprise family/household members or an organisation.

Responsible dog ownership: means the situation whereby a person (as defined above) accepts and commits to perform various duties according to the legislation in place and focused on the satisfaction of the behavioural, environmental and physical needs of a dog and to the prevention of risks (aggression, *disease* transmission or injuries) that the dog may pose to the community, other *animals* or the environment.

Stray dog: means any dog not under direct control by a person or not prevented from roaming. Types of stray dog:

1. free-roaming owned dog not under direct control or restriction at a particular time;
2. free-roaming dog with no owner;
3. feral dog: domestic dog that has reverted to the wild state and is no longer directly dependent upon humans for successful reproduction.

Article 7.7.3.

Dog population control programme objectives

The objectives of a programme to control the dog population may include the following:

1. improve health and welfare of owned and stray dog population;
2. reduce numbers of stray dogs to an acceptable level;
3. promote responsible ownership;
4. assist in the creation and maintenance of a rabies immune or rabies free dog population;
5. reduce the *risk* of zoonotic diseases other than rabies;
6. manage other *risks* to human health (e.g. parasites);
7. prevent harm to the environment and other *animals*;
8. prevent illegal trade and trafficking.

Article 7.7.4.

Responsibilities and competencies

1. Veterinary Authority

The *Veterinary Authority* is responsible for the implementation of animal health and *animal welfare* legislation, in coordination with other competent government agencies and institutions. Control of endemic zoonotic diseases such as rabies and parasitic *infections* (e.g. *Echinococcus* spp.) would require technical advice from the *Veterinary Authority*, as animal health and some aspects of public health are within this Authority's competence but organising and/or supervising dog control schemes can be the responsibility of non-governmental organisations and governmental agencies other than the *Veterinary Authority*.

EU comment

The EU would like to reiterate its previous comment given its importance and encourages the OIE to consider it. Moreover the EU would wish to receive explanation why the comment is not taken on board.

The title of Point 1 of Art 7.7.4 “*Veterinary Authority*” should be replaced by “*Veterinary Authority and other Competent Authority*”.

Furthermore, the following text should be inserted as second sentence of the paragraph in Point 1 “In some cases animal welfare is under the responsibility of other *Competent Authority* than the *Veterinary Authority*”.

Justification

As defined in the Glossary of the Terrestrial Code, “Competent Authority” includes the Veterinary Authority as well as other Governmental Authority of an OIE Member having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures.

2. Other government agencies

The responsibilities of other government agencies will depend on the risk being managed and the objective/nature of the dog population control measures employed.

The ministry or other agency responsible for public health would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases. Control of stray dogs with regard to other human health risks (e.g. stray dogs on roads; dog attacks within communities) may fall within the responsibility of the public health agency but is more likely to be the responsibility of the local government authorities or other agencies for public safety/security operating at the state/provincial or municipal level.

Environment protection agencies may take responsibility for control problems associated with stray dogs when they present a hazard to the environment (e.g. control of feral dogs in national parks; prevention of dog attacks on wildlife or transmission of *diseases* to wildlife) or where a lack of environmental controls is giving rise to stray dog populations that threaten human health or access to amenities. For example, environmental protection agencies may regulate and enforce measures to prevent dogs from accessing waste or human sewage.

3. Private sector veterinarians

The private sector *veterinarian* is responsible for providing advice to dog owners or handlers consulting the *veterinarian* for advice or treatment of a dog. The private sector *veterinarian* can play an important role in *disease surveillance* because he/she might be the first to see a dog suffering from a *notifiable disease* such as rabies. It is necessary that the private sector *veterinarian* follow the procedure established by the *Veterinary Authority* for responding to and reporting a suspected rabies case or a dog that is suffering from any other *notifiable disease*. Private sector *veterinarians* also play an important role (often in liaison with the police and/or local authorities) in dealing with cases of neglect that can lead to problems with stray and mismanaged dogs.

The private *veterinarian* has competence and will normally be involved in dog health programmes and population control measures, including health testing, vaccination, identification, kennelling during the absence of the owner, sterilisation and euthanasia. Two-way communication between the private sector *veterinarian* and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is very important and the *Veterinary Authority* is responsible for setting up appropriate mechanisms for this action.

4. Non governmental organisations

Non governmental organisations (NGOs) are potentially important partners of the *Veterinary Services* in contributing to public awareness and understanding and helping to obtain resources to contribute in a practical way to the design and successful implementation of dog control programmes. NGOs can supply local knowledge on dog populations and features of ownership, as well as expertise in handling and kennelling dogs and the implementation of sterilisation programmes. NGOs can also contribute, together with *veterinarians* and the authorities in educating the public in responsible dog ownership.

5. Local government authorities

Local government authorities are responsible for many services and programmes that relate to health, safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies in regard to aspects of public health, environmental health/hygiene and inspection/compliance activities.

In many countries local government agencies are responsible for the development and enforcement of legislation relating to dog ownership (e.g. registration, microchipping, vaccination, leash laws, abandonment), the control of stray dogs (e.g. dog catching and shelters) and the alleviation of the problems stray dogs cause in their jurisdiction. This would normally be done with advice from a higher level (national or state/provincial) authority with specialised expertise in regard to public health and animal health. Collaboration with the private sector *veterinarians* (e.g. in programmes to sterilise and vaccinate stray dogs) and NGOs is a common feature of dog control programmes. Regardless of the legislative basis, it is essential to have the co-operation of local government authorities in the control of stray dogs.

6. Dog owners

When a person takes on the ownership of a dog, there should be an immediate acceptance of responsibility for that dog, and for any offspring it may produce, for the duration of its life or until a subsequent owner is found. The owner should ensure that the welfare of the dog, including behavioural needs, are respected and the dog is protected, as far as possible, from infectious *diseases* (e.g. through vaccination and parasite control) and from unwanted reproduction (e.g. through contraception or sterilisation). Owners should ensure that the dog's ownership is clearly identified (preferably with permanent identification such as a tattoo or microchip) and, where required by legislation, registered on a centralised database. All reasonable steps should be taken to ensure that the dog does not roam out of control in a manner that would pose a problem to the community and/or the environment.

Article 7.7.5.

In the development of a dog population control programme it is recommended that the authorities establish an advisory group, which should include *veterinarians*, experts in dog ecology, dog behaviour and zoonotic diseases, and representatives of relevant stakeholders (local authorities, human health services/authorities, environmental control services/authorities, NGOs and the public). The main purpose of this advisory group would be to analyse and quantify the problem, identify the causes, obtain public opinion on dogs and propose the most effective approaches to use in the short and long term.

Important considerations are as follows:

1. Identifying the sources of stray dogs

- a) owned dogs that roam freely;
- b) dogs that have been abandoned by their owner, including puppies resulting from uncontrolled breeding of owned dogs;
- c) unowned dogs that reproduce successfully.

2. Estimating the existing number, distribution and ecology

Practical tools that are available include registers of dogs, population estimates, and surveys of dogs, owners, dog shelters and *veterinarians*. The important factors relevant to the dog carrying capacity of the environment include food, shelter, water and human attitudes and behaviour.

A methodology could be established to make an estimate of the total dog population. An overview of appropriate methodologies may be found in Article 7.7.8. The same methodology could be used at appropriate intervals to assess population trends.

3. Regulatory framework

A regulatory framework that would help authorities establish successful dog control programmes could include the following key elements:

- a) registration and identification of dogs and licensing of dog breeders;
- b) vaccination against rabies and other preventive measures against zoonotic disease, as appropriate;
- c) veterinary procedures (e.g. surgical procedures);
- d) control of dog movement (national and international);
- e) control of dangerous dogs;
- f) regulations on the breeding and sale of dogs;
- g) environmental controls (e.g. *abattoirs*, rubbish dumps, dead stock facilities);
- h) regulations for dog shelters;
- i) *animal welfare* obligations of owners and authorities.

4. Resources available to authorities

- a) Human resources;
- b) financial resources;
- c) technical tools;
- d) infrastructure;
- e) cooperative activities;
- f) public-private-NGO partnerships;
- g) central-state or province-local partnerships.

Article 7.7.6.

Control measures

The following control measures could be implemented according to the national context and local circumstances. Measures may be used in combination. Euthanasia of dogs, used alone, is not an effective control measure. If used, it should be done humanely (see point 11 of Article 7.7.6.) and in combination with other measures to achieve effective long term control. It is also important that authorities gain an understanding of people's attitudes towards dog ownership so that they can develop a cooperative approach to the control of dog populations.

1. Education and legislation for responsible ownership

Encouraging dog owners to be more responsible will reduce the number of dogs allowed to roam, improve the health and welfare of dogs, and minimise the risk that dogs pose to the community. The promotion of responsible dog ownership through legislation and education is a necessary part of a dog population control programme. Collaboration with local government authorities, *animal welfare*

NGOs, kennel clubs, private *veterinarians* and veterinary organisations will assist *Veterinary Authorities* in establishing and maintaining programmes.

Education on responsible dog ownership (for the currently owned dog and any offspring it produces) should address the following elements:

- a) the importance of proper selection for behaviour and care to ensure the welfare of the dog and any offspring; the latter may include preparing the dog to cope with its environment through attention to socialisation and training;
- b) registration and identification of dogs (see point 2 of Article 7.7.6.);
- c) *disease* prevention, in particular zoonotic disease, e.g. through regular vaccination in rabies endemic areas;
- d) preventing negative impacts of dogs on the community, via pollution (e.g. faeces and noise), risks to human health through biting or traffic accidents and risks to other dogs, wildlife, livestock and other companion animal species;
- e) control of dog reproduction.

In order to achieve a shift towards responsible ownership, a combination of legislation, public awareness, education, and promotion of these elements will be required. It may also be necessary to improve access to resources supporting responsible ownership, such as veterinary care, identification and registration services and measures for control of zoonotic diseases.

2. Registration and identification of dogs (licensing)

A core component of dog population control by the *Competent Authorities* is the registration and identification of owned dogs. This may include granting licences to owners and breeders. Registration and identification may be emphasised as part of responsible dog ownership and are often linked to animal health programmes, for example, mandatory rabies vaccination and traceability.

Registration of *animals* in a centralised database can be used to support the enforcement of legislation and the reuniting of lost *animals* with owners. The control of dog reproduction by sterilisation can be encouraged through financial incentives presented by differential licensing fees.

3. Reproductive control

Controlling reproduction in dogs prevents the birth of unwanted puppies and can help address the balance between demand for dogs and the size of the population. It is advisable to focus efforts to control reproduction on those individuals or groups in the dog population identified as the most productive and the most likely to be the sources of unwanted and stray dogs, to ensure best use of resources. Methods of controlling reproduction will require direct veterinary input to individual *animals*. Involvement of both private and public veterinary sectors may be required to meet demand for services. Subsidisation of sterilisation programmes by government or other organisations may be considered to encourage uptake. The control of reproduction is essentially the responsibility of owners and can be incorporated into education on responsible ownership (see point 1 of Article 7.7.6.). Methods for controlling reproduction in dogs include:

- a) surgical sterilisation;
- b) chemical sterilisation;
- c) chemical contraception;
- d) separation of female dogs during oestrus from unsterilised males.

Surgical sterilisation should be carried out by a *veterinarian* and include appropriate anaesthesia and pain management.

Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used according to the manufacturer's and *Competent Authority's* regulations. In the case of chemical sterilants and contraceptives, research and field trials may need to be completed before use.

4. Removal and handling

The *Competent Authority* should collect dogs that are not under direct supervision and verify their ownership. Capture, transport, and holding of the dogs should be done humanely. The *Competent Authority* should develop and implement appropriate legislation and training to regulate these activities. Capture should be achieved with the minimum force required and equipment should be used that supports humane handling. Uncovered wire loops should not be used for capture.

5. Capture and return, rehoming or release

Competent Authorities have the responsibility to develop minimum standards for the housing (physical facilities) and care of these dogs. There should be provision for holding the dogs for a reasonable period of time to allow for reunion with the owner and, as appropriate, for rabies observation.

- a) Minimum standards for housing should include the following provisions:
 - i) site selection: access to drainage, water and electricity are essential and environmental factors such as noise and pollution should be taken into account;
 - ii) kennel size, design and occupancy taking exercise into account;
 - iii) *disease* control measures including isolation and quarantine facilities.
- b) Management should address:
 - i) adequate fresh water and nutritious food;
 - ii) regular hygiene and cleaning;
 - iii) routine inspection of the dogs;
 - iv) monitoring of health and provision of required veterinary treatments;
 - v) policies and procedures for rehoming (adoption), sterilisation and euthanasia;
 - vi) training of staff in safe and appropriate handling of dogs;
 - viii) record keeping and reporting to authorities.

Dogs that are removed from a community may be reunited with the owner or offered to new owners for rehoming. This provides an opportunity to promote responsible ownership and good animal health care (including rabies vaccination). Prior to rehoming, authorities may consider sterilisation of dogs as a population control measure. The suitability of new owners to adopt dogs should be assessed and owners matched with available *animals*. The effectiveness of rehoming may be limited due to the suitability and number of dogs.

Dogs that are removed from a community may in some cases be provided with health care (including rabies vaccination), sterilised, and released to their local community at or near the place of capture. This method is more likely to be accepted in the situation where the presence of stray dogs is considered to be inevitable and is well tolerated by the local community.

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs. Problems caused by dogs, such as noise, faecal pollution, bite injuries and traffic accidents, would not be alleviated as dogs are returned to the local

community and their movements are not restricted. If the local community has owned dogs, and sterilised dogs are released, consideration should be given to the risk that this could encourage abandonment of unwanted dogs. In the situation where many dogs are owned, a population control programme that focuses on neutering and responsible ownership may be more appropriate.

It is recommended that before adopting this approach, a cost-benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for *disease* control and *animal welfare* as well as any societal benefits.

- c) If this method is adopted, the following factors should be addressed:
- i) raising awareness of the programme within the local community to ensure understanding and support;
 - ii) use of humane methods for catching, transporting and holding dogs;
 - iii) correct surgical technique, anaesthesia and analgesia, followed by post-operative care;
 - iv) *disease* control may include blanket vaccination (e.g. rabies) and treatments and testing for *diseases* (e.g. leishmaniasis) followed, as appropriate by treatment or euthanasia of the dog;
 - v) behavioural observation may be used to assess if dogs are suitable for release; if not suitable for release or rehoming, euthanasia should be considered;
 - vi) permanent marking (e.g. tattoo or microchip) to indicate that the *animal* has been sterilised; individual identification also allows for tracking of vaccination status and treatment history and identification of a level of 'ownership' by the organisation/authority responsible for carrying out this intervention; a visible identification (e.g. collar) may also be used to prevent unnecessary recapture;
 - vii) the dog should be returned to a place that is as near as possible to the place of capture;
 - viii) the welfare of dogs after release should be monitored and action taken if required.

Dogs that are removed from a community may be too numerous or may be unsuitable for any rehoming scheme. If euthanasia of these unwanted animals is the only option, the procedure should be conducted in accordance with the regulations of the Competent Authority (see point 11 of Article 7.7.6.).

6. Environmental controls

Steps should be taken to exclude dogs from sources of food (e.g. rubbish dumps and *abattoirs*, and installing animal-proof rubbish containers).

This should be linked to a reduction in the dog population by other methods, to avoid *animal welfare* problems.

7. Control of dog movement – international (export/import)

Chapter 8.10. provides recommendations on the international movement of dogs, with respect to provisions for between-rabies-free countries and countries considered to be infected with rabies.

8. Control of dog movements – within country (e.g. leash laws, roaming restrictions)

Measures for the control of dog movement in a country are generally invoked for the following reasons:

- a) for rabies control when the *disease* is present in a country;
- b) for public safety reasons;

- c) for the safety of ‘owned dogs’ in an area or locality when a stray dog control programme is in place;
- d) to protect wildlife and livestock.

It is necessary to have a regulatory framework and a national or local infrastructure comprising organisation, administration, staff and resources to encourage the finders of stray dogs to report to the *Competent Authority*.

9. Regulation of commercial dog dealers

Dog breeders and dealers should be encouraged to form or join an appropriate association. Such associations should encourage a commitment to the raising and selling of physically and psychologically healthy dogs, as unhealthy dogs may be more likely to be abandoned to become part of the stray population. They should encourage breeders and dealers to provide advice on proper care to all new owners of dogs. Regulations covering commercial dog breeders and dealers should include specific requirements for accommodation, provision of suitable food, drink and bedding, adequate exercise, veterinary care and disease control and may require breeders and dealers to allow regular inspection, including veterinary inspection.

10. Reduction in dog bite incidence

The most effective means of reducing prevalence of dog bites are education and placing responsibility on the owner. Dog owners should be educated in principles of responsible dog ownership as described in point 1 of Article 7.7.6.) Legal mechanisms that enable the Competent Authorities to impose penalties or otherwise deal with irresponsible owners are necessary. Mandatory registration and identification schemes will facilitate the effective application of such mechanisms. Young children are the group at highest risk for dog bites. Public education programmes focussed on appropriate dog-directed behaviour have been demonstrated to be effective in reducing dog bite prevalence and these programmes should be encouraged. Authorities should seek advice from dog behaviour experts in developing dog safety education programmes.

11. Euthanasia

When euthanasia is practised, the general principles in the Terrestrial Code should be followed, with the emphasis on using the most practical, rapid and humane methods and ensuring operator safety. Regardless of the method used, it is important to minimise distress, anxiety and pain by ensuring that operators are appropriately trained.

Table 1 shows a summary analysis of methods for the euthanasia of dogs.

Comments on methods for the euthanasia of dogs:

a) Restraint

When a dog needs to be restrained for any procedure, including euthanasia, this should always be done with full regard for operator security and *animal welfare*. Some euthanasia methods should be used in association with sedation or anaesthesia in order to be considered humane.

b) Special equipment

When special equipment is needed to perform euthanasia (e.g. gas chamber), the system should be designed for the purpose and regularly maintained in order to achieve operator security and *animal welfare*.

c) The following methods, procedures and practices are unacceptable on *animal welfare* grounds:

i) Chemical methods:

- Embutramide +Mebezonium +Tetracaine without sedation or by other than IV injection
 - Chloral hydrate
 - Nitrous oxide: may be used with other inhalants to speed the onset of anaesthesia, but alone it does not induce anaesthesia in dogs
 - Ether
 - Chloroform
 - Cyanide
 - Strychnine
 - Neuromuscular blocking agents (nicotine, magnesium sulphate, potassium chloride, all curariform agents): when used alone, respiratory arrest occurs before loss of consciousness, so the dog may perceive pain
 - Formalin
 - Household products and solvents.
- ii) Mechanical methods:
- Air embolism on conscious *animal*
 - Burning
 - Exsanguination of conscious animal
 - Decompression: expansion of gas trapped in body cavities may be very painful
 - Drowning
 - Hypothermia, rapid freezing
 - Stunning: stunning is not a euthanasia method, it should always be followed by a method which ensures death
 - Kill-trapping
 - Electrocutation of conscious *animal*.

Because neonatal animals and adults with impaired breathing or low blood pressure are resistant to hypoxia, methods that depend upon achieving a hypoxic state (e.g. CO₂, CO, N₂, Ar) should not be used. These methods should not be used in animals aged less than 2 months, except to produce loss of consciousness and should be followed by another method to cause death. Concussion and cervical dislocation. cervical dislocation.

EU comment

The EU would like to make an editorial comment on the above paragraph in point 11.c. ii) of Article 7.7.6.

Part of the last sentence of the paragraph has been lost by mistake, as the same text on the current on line Code reads as follow: "Concussion and cervical dislocation may be used in very small neonatal dogs and only in cases of emergency." The complete sentence should therefore be re-included in the text.

Justification: clarity

Operators should be well trained in the use of physical techniques to ensure that they are correctly and humanely carried out. The dog should be exsanguinated immediately after concussion or cervical dislocation.

d) Confirmation of death

For all methods of euthanasia used, *death* should be confirmed before *animals* are disposed of or left unattended. If an *animal* is not dead, another method of euthanasia should be performed.

f) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention should be paid to the risk of residues occurring in the carcass. Incineration is generally the safest way of carcass disposal

Table 1 Summary analysis of methods used for euthanasia of dogs

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Chemical via infection	Barbiturates	Correct restraint is needed. IP is slow and may be irritant. IC injection is a painful procedure.	Recommend to use IV injection. When using IP injection, the solution may be diluted or local anaesthetic agent used in conjunction. IC should only be performed on unconscious animal and by skilled operator.	Correct restraint is needed. Administered under veterinary supervision and requires trained personnel.	Speed of action generally depends on the dose, concentration, route and rate of injection. Barbiturates induce euthanasia smoothly, with minimal discomfort to the animal. Barbiturates are less expensive than many other euthanasia agents.	These drugs persist in the carcass and may cause sedation or death in animals that consume the cadaver.
	Embutramide + Mebezonium + Tetracaine	Muscle paralysis may occur before loss of consciousness if injection given rapidly.	Use slow IV injection with sedation to permit slow rate of injection.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Quite low cost.	Unavailable/ unlicensed in some countries.
	Anaesthetic agent overdose (thiopentone or propofenol)	Underdosing may lead to recovery.	IV injection of a sufficient dose.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Generally quick action and minimal discomfort to animal.	Large volume required (cost implications).

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
	Potassium chloride (KCl)	K+ is cardiotoxic and very painful if used without anaesthetic agent.	Only use on anaesthetised animals, IV injection.	Requires trained personnel.	Readily available without veterinary control.	Prior need for anaesthetic (cost and availability implications).
Mechanical	Free bullet	Can be inhumane if shot is inaccurate	Skilled operator essential.	Risk of injury to operators and	Not necessary to handle or	Brain tissue may be unavailable for

		and dog is only wounded; dog may also escape.		spectators.	capture dog.	rabies diagnosis. Risk of injury to bystanders. Legal constraints on use of firearms.
Mechanical (contd)	Penetrating captive bolt followed by pithing where necessary to ensure death	Can be inhumane if shot is inaccurate and dog is only wounded.	Skilled operator essential.	Animal should be restrained. Skilled operator essential.	No risk to operator (see free bullet) unless risk of dog infected with rabies, due to potential contact with brain tissue.	Brain tissue may be unavailable for rabies diagnosis. Legal constraints on use of firearms. May raise aesthetic objections.
	Exsanguination	Onset of hypovolaemia may cause dog to become anxious.	Only use on unconscious animal.	Danger to operator through use of sharp instrument.	Material requirements minimal.	Should be done on unconscious animal. <u>Need to render animal unconscious.</u> Aesthetically objectionable.
Gaseous	Carbon monoxide (CO)	Inadequate concentration of CO is not lethal and can cause suffering. Signs of distress (convulsions, vocalisation and agitation) may occur.	Compressed CO in cylinders should be used to achieve and maintain adequate concentration, which should be monitored. Note: fumes from gasoline engines are an irritant and this source of CO is not recommended.	Very hazardous for operator - gas is odourless and causes toxicity at both acute high levels and chronic low levels.	Dog dies quite rapidly if concentration of 4 to 6% used. No odour (therefore no aversive effect). Gas is not flammable or explosive except at concentration greater than 10%.	
	Carbon dioxide (CO ₂)	Gas is aversive. Inadequate concentration of CO ₂ is not lethal and can cause suffering. CO ₂ is heavier than air, so when incomplete filling of the chamber occurs, dogs may raise their head and avoid exposure. Few studies on adequate concentration and animal welfare.	Compressed CO ₂ gas chamber is the only acceptable method because the concentration can be monitored and regulated.	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and causes quite rapid anaesthesia when correct concentrations used. Low cost. Readily available as compressed gas.	Unconsciousness can occur in minutes, but death may take some time. Likelihood of suffering before unconsciousness.

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous (contd)	Inert gas (nitrogen, N ₂ argon, Ar)	Loss of consciousness is preceded by hypoxemia and ventilatory	Concentration above 98% should be achieved rapidly and maintained. Properly designed equipment should be	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and is odourless. Readily	High cost. Little data on animal welfare implications in dogs.

		low concentration of O ₂ (i.e. greater than or equal to 6%) in the chamber before death will allow immediate recovery.				
	Anaesthetic gas overdose (halothane or enflurane)	Animal may struggle and become anxious during induction. Vapours may be irritating and can induce excitement.	Supplementation with air or O ₂ required to avoid hypoxemia during induction phase.	Some gases may be hazardous, especially for pregnant women. General recommendation: avoid human exposure to greater than or equal to 2 ppm to avoid narcosis.	Gas is not flammable or explosive. Valuable for use with small animals (<7 kgs) and animals that are already anaesthetised with gas.	High cost. Anaesthetic and euthanasia properties of the gas used should be known. Isoflurane has a pungent odour. Methoxyflurane's action is slow and dog may become agitated.
Electrical	Electrocution	Cardiac fibrillation occurs before onset of unconsciousness, causing severe pain if dog is conscious. Pain can also be caused by violent extension of the limbs, head and neck. Method may not be effective if insufficient current applied.	<u>Only use on unconscious dog. Dogs should be unconscious before being electrocuted.</u> This can be accomplished by electrical stunning (current through the brain to produce an instantaneous stun) or anaesthesia. Electrodes should span the brain in order that the current passed through the brain in order to achieve an effective stun. Death would result from current passed through the heart of an unconscious animal. Proper equipment and trained operator is essential.	May be hazardous for operator, who should use protective equipment (boots and gloves).	Low cost.	<u>Need to render animal unconscious. Inhumane if performed on conscious dog.</u> May raise aesthetic objections.

KEY to abbreviations used in Table 1:
IV: intravenous
IP: intraperitoneal
IC: intracardiac

Article 7.7.7.

Monitoring and evaluation of dog population control programmes

1. Monitoring and evaluation allows for comparison of important indicators against the baselines measured during initial assessment (see Article 7.7.5.). The three main reasons for carrying out monitoring and evaluation are:
 - a. to help improve performance, by highlighting both problems and successful elements of interventions;
 - b. for accountability, to demonstrate that the programme is achieving its aims;

- c. assuming methods are standardised, to compare the success of strategies used in different locations and situations.
2. Monitoring is a continuous process that aims to check the programme progress against targets and allows for regular adjustments. Evaluation is a periodic assessment, usually carried out at particular milestones to check the programme is having the desired and stated impact. These procedures involve the measurement of 'indicators' that are chosen because they reflect important components of the programme at different stages. Selection of suitable indicators requires clear planning of what the programme is aiming to achieve, the best selection of indicators will be one that reflects the interest of all relevant stakeholders. Standardised methodology will facilitate comparison of data from subsequent evaluations and performance between different projects. Indicators can be direct measurements of an area targeted to change (e.g. population of free roaming dogs on public property) or indirect measures that reflect change in a targeted area.
 3. Elements that should generally be monitored and evaluated include:
 - a. dog population size, separated into sub-populations according to ownership and restriction of movement (i.e. roaming unrestricted or restricted by an owner);
 - b. dog welfare, in the target population (e.g. body condition score, skin conditions and injuries or lameness) and as a result of the programme (if interventions involve direct handling of dogs, the welfare of the dogs as result of this handling should be monitored);
 - c. prevalence of zoonotic diseases, such as rabies, in both the animal and human population;
 - d. responsible animal ownership, including measures of attitudes and understanding of responsible ownership and evidence that this is translating into responsible behaviour.
 4. There are many sources of information for monitoring and evaluation purposes, including:
 - a. feedback from the local community (e.g. through the use of structured questionnaires, focus groups or 'open format' consultation processes);
 - b. records and opinions obtained from relevant professionals (e.g. *veterinarians*, medical doctors, law enforcement agencies, educators);
 - c. animal based measurements (e.g. direct observation surveys of population size and welfare status).
 5. The output of activities against budget should be carefully recorded in order to evaluate the effort (or cost) against the outcomes and impact (or benefit) that are reflected in the results of monitoring and evaluation.

Article 7.7.8.

An overview of appropriate methods for estimating the size of dog populations

Population estimates are necessary for making realistic plans for dog population management and zoonosis control, and for monitoring the success of such interventions. However, for designing effective management plans, data on population sizes alone are insufficient. Additional information is required, such as degrees of supervision of owned dogs, the origin of ownerless dogs, accessibility, etc.

The term 'owned' may be restricted to a dog that is registered with licensing authorities, or it may be expanded to unregistered *animals* that are somewhat supervised and receive shelter and some form of care in individual households. Owned dogs may be well supervised and restrained at all times, or they may be

left without control for various time periods and activities. Dogs without owners that claim responsibility may still be accepted or tolerated in the neighbourhood, and individuals may provide food and protection. Such *animals* are sometimes called ‘community owned dogs’ or ‘neighbourhood dogs’. For an observer it is frequently impossible to decide if a free roaming dog belongs to someone or not.

The choice of methods for assessing the size of a dog population depends on the ratio of owned versus ownerless dogs, which may not always be easy to judge. For populations with a large proportion of owned dogs it may be sufficient to consult dog registration records or to conduct household surveys. These surveys should establish the number of owned dogs and the dog to human ratio in the area. In addition, questions on dog reproduction and demographics, care provided, zoonosis prevention, dog bite incidence, etc. may be asked. ~~Sample questionnaires can be found in the “Guidelines for Dog Population Management” (WHO/WSPA 1990).~~ Standard polling principles should be applied.

If the proportion of ownerless dogs is high or difficult to assess, then one should resort to more experimental approaches. Methods borrowed from wildlife biology can be applied. ~~These methods are described WHO/WSPA’s “Guidelines for Dog Population Management” (1990), and in more detail in numerous professional publications and handbooks, such as Bookhout (1994) and Sutherland (2006).~~ Being generally diurnal and tolerant to human proximity, dogs lend themselves to direct observation and the application of mark-recapture techniques. Nevertheless, a number of caveats and limitations have to be taken into account. Firstly, the risk of zoonotic disease transmission is increased through close physical contact. Also, the methods are relatively labour intensive, they require some understanding of statistics and population biology, and most importantly, they are difficult to apply to very large areas. One should take into account that dog distribution is non-random, that their populations are not static, and that individual dogs are fairly mobile.

Counting of dogs visible in a defined area is the simplest approach to getting information on population size. One has to take into account that the visibility of dogs depends on the physical environment, but also on dog and human activity patterns. The visibility of *animals* changes with the time of the day and with seasons as a function of food availability, shelter (shade), disturbance, etc. Repeated standardised counting of dogs visible within defined geographical localities (e.g. wards) and specific times will provide indications of population trends. Direct counting is most reliable if it is applied to small and relatively confined dog populations, e.g. in villages, where it might be possible to recognise individual dogs based on their physical appearance.

Methods using mark-recapture procedures are often considered more reliable. However, they also produce trustworthy results only when a number of preconditions are met. Mortality, emigration and recruitment into the population should be minimal during the census period. One may be able to incorporate corrective factors into the calculations.

It is therefore important that the recommended census procedures are applied at times of low dispersal and that one selects study plots of shape and size that minimise the effect of dog movements in and out of the observation area. Census surveys should be completed within a few days to a maximum of two weeks in order to reduce demographic changes. In addition, all individuals in the population should have an equal chance of being counted. This is a highly improbable condition for dogs, whose visibility depends on ownership status and degrees of supervision. It is therefore recommended that the investigator determines what fraction of the total population he/she might cover with an observational method and how much this part overlaps with the owned dog segment that he/she assesses with household surveys.

There are essentially two ways to obtain a population estimate if it is possible, in a defined area and within a few days, to tag a large number of dogs with a visible mark, e.g. a distinctive collar or a paint smudge. The first method requires that the capture (marking) effort remains reasonably constant for the whole length of the study. By plotting the daily number of dogs marked against the accumulated total of marked dogs for each day one can extrapolate the value representing the total number of dogs in the area. More commonly used in wildlife studies are mark recapture methods (~~Peterson-Jackson, Lincoln indices~~). Dogs are marked (tagged) and released back into the population. The population is subsequently sampled by

direct observation. The number of marked and unmarked dogs is recorded. One multiplies the number of dogs that were initially marked and released by the number of subsequently observed dogs divided by the number of dogs seen as marked during the re-observation to obtain a total population estimate. ~~Examples for the two methods are given in WHO/WSPA's "Guidelines for Dog Population Management" (1990).~~

Since the dog populations of entire countries, states, provinces or even cities are much too large for complete assessment, it is necessary to apply the methods summarised above to sample areas. These should be selected (using common sense) so that results can be extrapolated to larger areas.

~~BOOKHOUT T.A. (ed), 1994: Research and Management Techniques for Wildlife and Habitats, 5th ed. The Wildlife Society, Bethesda, Maryland, 740p.~~

~~SUTHERLAND W.J. (ed), 2006: Ecological Census Techniques – A Handbook, 2nd ed. Cambridge University Press, Cambridge, 448 p.~~

~~WHO/WSPA, 1990: Guidelines for Dog Population Management. WHO/ZOON/90.165. WHO, Geneva, 116 p.~~

— text deleted

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

EU Position

The EU notes with satisfaction that most of the suggestions were taken onboard in the latest proposal by the Code Commission for the adoption in May 2011.

However, there is an amendment proposed to Article 7.8.4 – 1(c) which cannot be supported by the EU.

Also the EU would like to reiterate its previous comment concerning Article 7.8.7 - Source of animals and request the Code Commission as to its reasoning for not accepting the mentioning of the now widely accepted long term goal as a policy objective.

Preamble: The purpose of this chapter is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live *animals* in research and education¹. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live *animals* in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and *animals* and emphasise the importance of the Three Rs (see Article 7.8.3.). Most scientists and members of the public agree that the *animals* should only be used when necessary; ethically justified (thereby avoiding unnecessary duplication of animal-based research); and when no other alternative methods, not using live *animals*, are available; that the minimum number of *animals* should be used to achieve the scientific or educational goals; and that such use of *animals* should cause as little pain and/or distress as possible. In addition, animal suffering is often recognised separately from pain and distress and should be considered alongside any lasting harm which is expected to be caused to *animals*.

The OIE emphasises the need for humane treatment of *animals* and that good quality science depends upon good *animal welfare*. It is the responsibility of all involved in the use of *animals* to ensure that they give due regard to these recommendations. In keeping with the overall approach to *animal welfare* detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the *animal*.

The OIE recognises the significant role of *veterinarians* in animal-based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of *animals* has an ethical responsibility for the *animals' welfare*. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum *welfare* for the *animals* used.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events and interventions should be recorded to aid decision making and promote good science and *welfare*. A summary of these records may be gathered on a national basis and be published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

Article 7.8.1.

Definitions

Biocontainment: means the system and procedures designed to prevent the accidental release of biological material including allergens.

Bioexclusion: means the prevention of the unintentional transfer of adventitious organisms with subsequent *infection of animals*, resulting in adverse effects on their health or suitability for research.

Biosecurity: means a continuous process of *risk assessment* and *risk management* designed to minimise or eliminate microbiological *infection* with adventitious organisms that can cause clinical *disease* in the infected *animals* or humans, or make *animals* unsuitable for biomedical research.

Cloned animal: means a genetic copy of another living or dead *animal* produced by somatic cell nuclear transfer or other reproductive technology.

Distress: means the state of an *animal*, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Endangered species: means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment: means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive *animal's* environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

Ethical review: means consideration of the validity and justification for using *animals* including: an assessment and weighing of the potential harms for *animals* and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

~~**Euthanasia:** means the act of inducing *death* using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to the *animal*.~~

Harm-benefit analysis: means the process of weighing the likely adverse effects (harms) to the *animals* against the benefits likely to accrue as a result of the proposed project.

Humane endpoint: means the point in time at which an experimental *animal's* pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal*.

Operant conditioning: means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal* can be modified (e.g. increased or decreased in frequency or intensity).

Pain: means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Project proposal (sometimes called protocol): means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the *animals*, and includes ethical considerations.

Suffering: means an unpleasant, undesired state of being **which that** is the outcome of the impact on an *animal* of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good *welfare*.

Article 7.8.2.

Scope

This chapter applies to *animals* as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research (including testing) and higher education. *Animals* to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the *animal* in implementing these standards.

Article 7.8.3.

The Three Rs

The internationally accepted tenet, the ‘Three Rs’, comprises the following alternatives:

1. replacement refers to the use of methods utilising cells, tissues or organs of *animals* (relative replacement), as well as those that do not require the use of *animals* to achieve the scientific aims (absolute replacement);
2. reduction refers to the use of methods that enable researchers to obtain comparable levels of information from fewer *animals* or to obtain more information from the same number of *animals*;
3. refinement refers to the use of methods that prevent, alleviate or minimise pain, suffering, distress or lasting harm and/or enhance *welfare* for the *animals* used. Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the *animal* and include, for example, housing and transportation as well as procedures and euthanasia.

Article 7.8.4.

The oversight framework

The role of a *Competent Authority* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance which may be assessed at the institutional, regional and/or national level.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and *welfare*. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve *animal welfare* officers, regional, national or local committees or bodies. An institution may utilise a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee, Animal Welfare Body or Animal Care Committee) to deliver some or all of this oversight framework. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given on how to ensure ensuring the impartiality and independence from of all those serving on the committees.

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

- a) one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;
- b) one *veterinarian*, with the necessary expertise to work with research *animals*, whose specific role is to provide advice on the care, use and *welfare* of such *animals*;

- c) one public member, where appropriate, to represent general community interests who is independent of the science and care of the *animals* and is not involved in the use of *animals* in research.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the *welfare* of *animals* used. Other participants, especially in relation to ethical review, may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve student representation.

Oversight responsibilities include three key elements:

1. Project proposal review

The purpose of the project proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

Project proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work. The proposal should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

- a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or *welfare*, the environment, or the advancement of biological knowledge;
- b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;
- c) the experimental design, including justification for choice of species, source and minimum number of *animals*, including any proposed reuse;

EU comment

In point c) of Art 7.8.4 above, the EU would like to remove the word "minimum": "c) the experimental design, including justification for choice of species, source and minimum number of animals, including any proposed reuse;"

Justification

The EU agrees that the aim is to use the minimum amount of animals that provides statistically satisfactory data. However, in the point above the requirement is not on the aims but on the contents of the project description and should thus detail the number of animals which is planned to be used with the justification thereof; detailing only 'minimum' number of animals in the project proposal would leave a question open as to the possible maximum number of animals that is planned to be used.

- d) the experimental procedures;
- e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;
- f) the methods to avoid or minimise pain, discomfort, distress, suffering or lasting impairment of physical or physiological function, including the use of anaesthesia and/or analgesia and other means to limit discomfort such as warmth, soft bedding and assisted feeding;
- g) application of humane endpoints and the final disposition of *animals*, including methods of euthanasia;
- h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;
- i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis; the benefits should be maximised and the harms, in terms of pain and distress, should be minimised;

- j) an indication of any special health and safety risks; and
- k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, staff trained and found competent to perform the procedures described in the proposed project).

The oversight body has a critical responsibility in determining the acceptability of project proposals, taking account of the animal welfare implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live animals.

Following approval of a project proposal, consideration should be given to implementing an independent (of those managing the projects) oversight method to ensure that animal activities conform with those described in the approved project proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body, which may be the local committee, animal welfare officer, compliance/quality assurance officer or government inspector.

l) the duration of approval of a project should normally be defined and progress achieved should be reviewed in considering renewal of a project approval.

2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

- a) the *animals* and their records, including cage labels and other methods of animal identification;
- b) husbandry practices;
- c) maintenance, cleanliness and security of the facility;
- d) type and condition of caging and other equipment;
- e) environmental conditions of the *animals* at the cage and room level;
- f) procedure areas such as surgery; necropsy and animal research laboratories;
- g) support areas such as washing equipment; animal feed, bedding and drug storage locations;
- h) occupational health and safety concerns.

Principles of *risk management* should be followed when determining the frequency and nature of inspections.

3. Ethical evaluation

The ethical evaluation reflects the policies and practices of the institution in complying with regulations and relevant guidance. It should include consideration of the functioning of the local committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly. A requirement for the components of such a programme should be included in relevant regulations to empower the *Competent Authority* to take appropriate action to ensure compliance.

Article 7.8.5.

Assurance of training and competency

An essential component of the animal care and use programme is the assurance that the personnel working with the *animals* are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. Scientific staff

Researchers using *animals* have a direct ethical and legal responsibility for all matters relating to the *welfare* of the *animals* in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory *animal veterinarian* is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research (e.g. surgery, anaesthesia, sampling and administration, etc.).

2. Veterinarians

It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used, ~~including normal behaviour, and they should understand research methodology. Furthermore, they should be educated and experienced in the normal behaviour, behavioural needs, stress responses and adaptability of the species, as well as research methodologies.~~ Relevant approvals issued by the *veterinary statutory body* and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3. Animal care staff

Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. Students

Students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of live *animals* and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving live *animals*, they should receive appropriate supervision in the use of *animals* until such time that they have demonstrated competency in the related procedure(s).

5. Members of the local oversight committee or others involved with oversight

Continuing education about the use of *animals* in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious *diseases* which may infect research *animals* and thus compromise research results, as well as possible *zoonoses*. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards.

Article 7.8.6.

Provision of veterinary care

Adequate veterinary care includes responsibility for promoting an *animal's* health and *welfare* before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the *animal*. The *veterinarian* should have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice and care should be available at all times. In exceptional circumstances, where species unfamiliar to the veterinarian are involved, a suitably qualified non-veterinary expert may provide advice.

1. Clinical responsibilities

Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical

practices appropriate to the particular animal species and source. Disease surveillance is a major responsibility of the *veterinarian* and should include routine monitoring of colony *animals* for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical *diseases*. The *veterinarian* should have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources, following diagnosis of an animal *disease* or injury. Where possible, the *veterinarian* should discuss the situation with the scientist to determine a course of action consistent with experimental goals. Controlled drugs prescribed by the veterinary staff should be managed in accordance with applicable regulations.

2. Post-mortem examinations

In the case of unexpected *diseases* or *deaths*, the *veterinarian* should provide advice based on post-mortem examination results. As part of health monitoring, a planned programme of post-mortem examinations may be considered.

3. Veterinary medical records

Veterinary medical records, including post-mortem records, are considered to be a key element of a programme of adequate veterinary care for *animals* used in research and education. Application of performance standards within the veterinary medical record programme allows the *veterinarian* to effectively employ professional judgment, ensuring that the *animal* receives the highest level of care available.

4. Advice on zoonotic risks and notifiable diseases

The use of some species of *animals* poses a significant risk of the transmission of zoonotic *disease* (e.g. some nonhuman primates). The *veterinarian* should be consulted to identify sources of *animals* that minimise these risks and to advice on measures that may be taken in the animal facility to minimise the risk of transmission (e.g. personal protective equipment, appropriate *désinfection* procedures, air pressure differentials in animal holding rooms, etc.). *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care

A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian*. A *veterinarian's* inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia

Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of euthanasia.

7. Advice on humane endpoints

Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* has the authority to ensure euthanasia or other measures are carried out as required to relieve pain and distress unless the project proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study's objectives. In consultation with the *veterinarian*, humane endpoints should be described in the project proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, *death* (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement

Animals should be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*. The use of wild caught nonhuman primates is generally discouraged.

EU comment

In the last sentence of the first paragraph of Art 7.8.7, the EU would like to reiterate its earlier comment as follows: "The use of wild caught nonhuman primates is generally strongly discouraged. Only purpose-bred animals should be used in line with the ultimate goal of shifting towards the use of second or higher generation purpose bred (F2+) animals."

Justification

For scientific, animal welfare and biodiversity reasons, the non-human primates used in experiments should be of second or higher generation, well characterised, purpose bred animals. Attempts should be made to move towards this goal and breeding strategies should be put in place to further this aim. This ultimate goal as a policy objective is now formally recognised in legislation by the 27 Member States of the EU as well as by the International Primate Plan grouping the countries of main users and breeders of non-human primates globally. Therefore, the EU feels strongly that the long term policy objective should be stated in this context.

Purpose bred *animals* should be used whenever these are available and *animals* that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm *animals*, non traditional breeds and species, and *animals* captured in the wild, non purpose bred *animals* are often used to achieve specific study goals. The use of wild caught nonhuman primates is generally discouraged.

2. Documentation

Relevant documentation related to the source of the *animals*, such as health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the *animals*.

3. Animal health status

The health status of *animals* can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. *Animals* should have appropriate health profiles for their intended use. The health status of *animals* should be known before initiating research.

4. Genetically defined animals

A known genetic profile of the *animals* used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined *animals* are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which should be validated by periodic genetic monitoring. Detailed and accurate documentation of the colony breeding records should be maintained.

5. Genetically altered (also genetically modified or genetically engineered) or cloned animals (also genetically modified animal and genetically engineered animal).

A genetically altered ~~or cloned~~ *animals* is one an animal that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an *animal(s)*, where they have inherited the modification. If genetically altered or cloned *animals* are used, such

use should be conducted in accordance with relevant regulatory guidance. With such *animals*, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and *welfare* needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised *animals*.

6. Animals captured in the wild

If wild *animals* are to be used, the capture technique should be humane and give due regard to human and animal health, *welfare* and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the project proposal.

7. Endangered species

Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a journey should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the *animals* and that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. Risks to biosecurity

In order to minimise the risk of contamination of *animals* with unwanted infectious microorganisms or parasites that may compromise the health of *animals* or make them unsuitable for use in research, the microbiological status of the *animals* should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.

Article 7.8.8.

Physical facility and environmental conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the *animals* to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. *Animals* should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the *animals* and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of *welfare* concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. Ventilation

The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an *animals*' primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of *animals* involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. Temperature and humidity

Environmental temperature is a physical factor which has a profound effect on the *welfare* of *animals*. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be appropriately limited to avoid repeated demands on the *animals*' metabolic and behavioural processes to compensate for large changes in the thermal environment as well as to promote reproducible and valid scientific data. Relative humidity may also be controlled where appropriate for the species.

3. Lighting

Light can affect the physiology, morphology and behaviour of various *animals*. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the *welfare* of the *animals* while facilitating good husbandry practices, adequate inspection of *animals* and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. Noise

Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the *welfare* of quieter *animals*, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

Article 7.8.9.

Husbandry

Good husbandry practices enhance the health and *welfare* of the *animals* used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal*. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals*' *welfare*.

1. Transportation

Transportation is a typically stressful experience. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social *animals* should be transported in established pairs or groups and maintained in these on arrival.

2. Acclimatisation

Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals*. Facilities should be available to isolate *animals* showing signs of ill health.

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals*.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the *animals* and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the *animals* or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each *animal* to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and animal welfare. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the animals clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading infection between animals through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. Animals may be identified individually or by group. Where it is desirable to individually identify animals, this should be done by a reliable and the least painful method.

10. Handling

Staff dealing with *animals* should have a caring and respectful attitude towards the *animals* and be competent in handling and restraint. Familiarising *animals* to handling during routine husbandry and procedures reduces stress both to *animals* and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the *animals*, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with wild *animals*. Consideration should be given to setting up habituation and training programmes suitable for the *animals*, the procedures and length of projects.



— text deleted



1. Wherever the term “research” is used, it includes basic and applied research, testing and the production of biological materials; “education” includes teaching and training.

**ANIMAL WELFARE AND
BROILER CHICKEN PRODUCTION**

EU position

The EU thanks the OIE on its work of drafting this draft chapter. The chapter recognizes the important aspects of welfare and the major indicators of its compromise in broilers.

However, the EU cannot support the adoption of the chapter at the coming General Session. One major reason is that the EU does not support that cages and slatted flooring for broilers should be recommended as these systems result in poor welfare outcomes. Furthermore, it is critical that specific benchmarks or references are provided when practical and as scientific knowledge permits in order to provide a clear means to implement this chapter. Finally, the chapter should provide more guidance on how outcome-based measures should actually be employed.

For this reason, the EU wishes to provide further technical comments that should be addressed at the revision of the chapter. Some comments are made to further improve broiler welfare and concern light, beak trimming, and environmental enrichment. Other comments address clarity, diction, and consistency of terminology. It is crucial the Code uses consistent terms and phrases so that it is clear and streamlined for those who will use the document.

ARTICLE ~~X-7~~. X . 1 .

Definitions

For the purpose of this chapter:

Broiler

means birds of the species *Gallus gallus* kept primarily for commercial meat production.

EU comments

1. The EU wishes to remove the word "primarily" from the definition of Broiler

Rationale: clarity. Broilers are kept for meat production, not other means.

2. The EU wishes to add qualifying statement to the definition of Broiler as follows: "**This does not include those birds kept for breeding.**"

Justification: the scope should clearly exclude breeding stock, as the Chapter is written with a focus on broilers kept for slaughter. This statement is needed to assure a clear scope: "kept primarily for meat production" could be unclear and cover those breeding broilers eventually sent to slaughter.

Cage housing system

In a cage housing system the caretaker accesses the birds from outside the enclosure in which the birds they are kept.

Deep litter housing system

In a deep litter housing system the birds are kept on floors that are is covered with bedding material.

EU comment

The EU suggests to reinstate definitions for "Litter" and "Poultry House" that do not appear in the current version but were in the former September 2010 version. Moreover the EU wishes to include a definition as below for "Environmental Enrichment".

"Environmental Enrichment: a process of making changes or additions to an animal's environment that promotes an animal's behavioral needs."

Justification: Partial depopulation should be defined for clarity. Environmental enrichment is an important aspect of animal welfare, and should thus be defined.

Reference: Kulpa-Eddy JA, Taylor S, Adams KM. USDA Perspective on Environmental Enrichment for Animals. *Inter Lab Anim Res.* 46(2):83-94. 2005.

Harvesting

means the catching and loading of birds on farm for transportation to the *slaughterhouse*.

EU comment

The term "birds" should be changed to "broilers" in the above definition, and in any other instances within the chapter.

Justification: consistency. The chapter is titled "broiler" and defines "broiler." Terminology use should therefore be consistent.

Slatted floor housing system

In a slatted floor means a housing system where the ~~birds~~ broilers are kept on raised floors, on which droppings do not accumulate, but fall through.

Backyard Flocks

Means village or backyard production with minimal biosecurity and birds/products consumed locally.

EU comment

The EU suggests that a numerical limit of broilers should be supplied to the definition of backyard flocks

Justification: It should be exceptionally clear what the jurisdiction of this chapter is. The term "consumed locally" does not give enough guidance in this regard.

ARTICLE ~~X-7~~. X . 2 .

Scope

These recommendations cover the production period from arrival of the chicks on the farm to harvesting the broilers in commercial production systems. These systems include broilers kept in cages, on slatted floors, litter or dirt and indoors or outdoors. Village or backyard production, with minimal biosecurity and birds or products consumed locally, backyard flocks ~~is~~ are not included in this scope even if the ~~animals~~ broilers or products are traded locally.

This chapter should be read in conjunction with Chapters 7.2., 7.3. and 7.4. on the welfare of the broiler during transport to the ~~abattoir~~ slaughterhouse.

Note 2: Recommendations on the management of the breeding flock and hatchery and for the period between hatching and arrival on the farm to be developed.

ARTICLE ~~X-7~~. X . 3 .

Commercial broiler production systems

Commercial broiler production systems include:

1. Intensive systems

~~Birds Broilers~~ are completely confined in a ~~roofed structure~~ poultry house, with or without environmental control and usually at a higher *stocking density* than in other production systems. ~~Birds Broilers~~ may be kept in cages, ~~with (e.g. wire or plastic floor or deep litter floor) or on deep litter, or slatted floors or a combination,~~

2. Semi-intensive systems

~~Birds Broilers~~ are confined in a ~~roofed structure~~ poultry house but provided with ~~an~~ access to a restricted outdoor area. ~~They may be kept in cages (e.g. wire or plastic floor or deep litter floor) or on deep litter, a slatted floor or a combination of the two.~~

3. Extensive systems

~~Birds Broilers~~ are not confined throughout their production period in a ~~roofed structure~~ poultry house and are usually kept at a lower *stocking density* than in intensive or semi intensive systems.

ARTICLE ~~X-7~~. X . 4 .

Criteria or measurables for the welfare of broilers

Measurables can be based on the outcomes for the broiler (outcome based criteria) or the design of the system (resource or design based criteria). Outcome based measurables may give a better indication of welfare than resource based measures because they reflect the complex interaction of several variables (e.g. experience and attitude of handlers and disease situation) that may be overlooked when relying on criteria that focus on the design of the system.

It would be impractical at this time to assign numeric values to measurables (e.g. to specify a certain mortality rate as 'acceptable' or 'optimum', due to the large variations in the commercial production systems used by OIE Members. However, numeric values can be valuable in benchmarking performance. Benchmarking can be accomplished by evaluating the current incidence of outcome based measurables on commercial farms, and then determining the extent to which those problems can be reduced by management and genetic selection. Some measurables can be measured in the farm setting (e.g. gait, mortality and morbidity rates), while others are best measured at the slaughterhouse. For example, at slaughter *flocks* can be assessed for presence of bruising, broken limbs and injuries. The age of these lesions can help to determine the source (e.g. catching) (Nicol & Scott, 1990). Back scratching, hock and feet burns and breast blisters are also easily observed. Other conditions such as ascites, leg deformities, dehydration and disease conditions can be assessed. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectoral or perhaps regional norms for commercial broiler production.

EU comments

1. The EU would like the first paragraph under Art 7.x.4 to be replaced with the following text:

"Measurables can be based on the outcomes for the broiler (outcome based criteria) or the design of the system (resource or design based criteria). Outcome based measurables indicate the physical and physiological impacts on the birds in response to the complex interaction of several variables such as the system design, the environment, disease, dietary management and the experience and attitude of the handlers throughout the rearing period, that may otherwise be overlooked when relying on criteria that focus solely on the resource inputs or the design of the system. Input-based measures may also be necessary to prevent poor animal welfare"

Justification: clarifies the meaning of "outcome measures". The EU supports the use of outcome based measures. However, resource based measures are a good and necessary tool to prevent poor welfare for some aspects and should be used in combination with outcome measures. OIE itself recognizes this, eg – using a limit of 25 ppm for ammonia within the code.

2. The EU suggests to insert text at the end of the second paragraph concerning criteria for the welfare of broilers

"Outcome measures that are assessed to indicate a compromise to the welfare of the broilers should prompt action taken to eliminate the cause and/or alleviate the result of poor welfare. The information gathered through these outcome measures collected at the slaughter house should be supplied back to producers so that this action can be taken."

Justification: clarifies and elucidates what action the outcome-measures should prompt; it is also important to encourage those measures taken-off farm be used by producers to correct problems on the farm, or elsewhere in the production system.

3. The text "indoor climate, litter condition" should be added after "attitude of handlers" in paragraph above.

Justification: Litter quality impacts broiler performance and welfare. This is an appropriate place to recognize litter quality as a consideration for housing and environmental needs of broilers.

Reference: Ritz CW, Farichild BD, Lacy MP. Litter quality and broiler performance. Publication of University of Georgia College of Agriculture and Environmental Science Cooperative Extension Service. 2005.

The following outcome based measurables are useful indicators of broiler welfare:

EU Comment

In this section, the EU suggests:

(1) OIE to carefully review these measurables and decide on their purpose. Some measurables are definitions of terms, whereas others go into detail about how they might be used. Therefore, the format is somewhat confusing, as sometimes their use is dealt with in Article 7.x.5.

(2) OIE to place the outcome measures in an order beginning with those involving normal health and physiology, and moving to those that deal with pathology and disease. This is a logical structure of how to think about herd husbandry and welfare management.

(3) OIE to consider giving some quantifiable limits or ranges of outcome measures for producers to use as a reference point when practical.

Justification: clarity, logic, comprehension.

1. Mortality (dead, culled) and morbidity

Daily, weekly and cumulative mortality (dead or culled) and morbidity rates should be within expected ranges. Any **abrupt-unforeseen** increase in the daily mortality or morbidity rate **not connected to a specific disease** could reflect an animal welfare problem.

EU comment

In point 1 of Article 7.X.4, the word "culled" should be changed to "killed".

Justification: Clarity and consistency. Culled is not defined, and "humanely killed" is used within the rest of the document and defined in 7.x.5 2.18. If culled is to intend a meaning different than just humanely killed, it should be clearly defined within the document and used accordingly.

2. Gait

Broilers are susceptible to developing a variety of infectious and non-infectious musculoskeletal disorders (see review in Mench, 2004). If severe these disorders may lead to overt lameness, and if less severe to gait abnormalities. Broilers that are lame or have more serious gait abnormalities may have difficulty reaching the food and water, may be trampled by other broilers, and may experience pain. Musculoskeletal problems have many causes, including related to genetics, nutrition, sanitation, lighting, litter quality, and other environmental and management factors (see Mench, 2004; Dawkins et al., 2004). Broilers in commercial flocks should be assessed for gait abnormalities, and corrective actions identified to reduce the incidence of problems in subsequent flocks. There are several gait scoring systems available (Kestin et al., 1992; Garner

et al., 2002; Webster et al., 2008; Weeks et al., 2002; Berg and Sanotra, 2003). Regardless of the scoring or assessment system used, broilers that are unable to access feed or water should be humanely euthanized as soon as possible after they have been observed.

EU comment

In line ten of the above paragraph, the term "euthanized" should be changed to "killed," as well as any other use of the term.

Justification: clarity and consistency.

Killed is a term that will be understood more readily by persons dealing with broilers in everyday situations. Euthanized is a term that is more esoteric in the veterinary and animal science profession. Killed is used in most other sections of the code, such as in 7.x.5, 2.18 "Humane Killing."

3. Contact dermatitis

Contact dermatitis affects skin surfaces which that have prolonged contact with litter or other flooring surfaces, including the foot pad, rear surface of the hock and, when severe, the breast area. The conditions are manifested as blackened skin progressing to erosions and fibrosis on the lower surface of the foot pad, at the back of the hocks, and sometimes in the breast area. If severe the foot and hock lesions may contribute to lameness or serve as a portal of entry for and lead to secondary *infections*. Scoring systems for contact dermatitis have been developed (Welfare Quality®, 2009).

EU comment

In the above paragraph, the EU wishes to change the word "blackened" to "darkened"

Justification: clarity and correct diction.

4. Feather condition

Evaluation of the feather condition of broilers provides useful information about aspects of welfare. Plumage dirtiness and naked area are is correlated with both hock burns and lameness for individual birds (Arnould and Colin, 2009). Plumage dirtiness can be assessed when the broilers are caught for *transport* to the *slaughterhouse*. A scoring system has been developed for this purpose (RSPCA, 2008).

5. Incidence of diseases, metabolic disorders and parasitic infestations

Ascites, sudden death syndrome and respiratory diseases (including infectious bronchitis, avian pneumovirus infection and mycoplasmosis) are of great economic and welfare significance in broilers (SCAHAW, 2000).

EU comment

The word "diarrhea" should be inserted after "sudden death syndrome" in the above paragraph (7.x.4, sec 5., line 1)

Justification: important diseases cause diarrhea (Coccidiosis, Campylobacteriosis, Salmonellosis, etc).

Reference: EFSA Panel on Animal Health and Animal Welfare, European Food Safety Authority 2010. *Scientific opinion on welfare aspects of the management and housing of the grand-parent and parent stocks raised and kept for breeding purposes*. Accessed at: <http://www.efsa.europa.eu/en/efsajournal/doc/1667.pdf>

6. Normal behaviour

EU comment

In point "6. Normal behaviour" and point "7. Abnormal behaviour" of Article 7.x.4, the EU suggests that OIE merge these titles into a single title "6. Behavioral Indicators"

Justification: the terms "normal behaviour" and "abnormal behaviour" are confusing. For example, panting is not a behavior for a broiler in normal health, but a normal behavior for a broiler in

abnormal state of thermal environment. Likewise, feather-pecking is not a behavior for a normal broiler, but perhaps a normal response to a barren environment. Thus, behavioral indicators are complex and should not be readily categorized into arbitrary normal and abnormal columns.

Broiler behaviour can be a sensitive indicator of welfare problems.

6.1. Fear behaviour

Fearful broilers show avoidance of humans, and this behaviour is seen in flocks where animal handlers walk through the poultry house quickly when performing their tasks rather than moving more slowly while interacting with the broilers (Cransberg et al., 2000). Fearfulness (e.g. of sudden loud noises) can also lead to the broilers piling on top of, and even suffocating, one another. Fearful broilers may be less productive (Hemsworth et al., 1994).

6.2. Spatial distribution

Changes in the spatial distribution of the birds may indicate thermal discomfort (e.g. broilers will huddle when they are cold) or the existence of areas of wet litter or uneven provision of light, food or water (if broilers are unevenly distributed).

6.3. Panting and wing spreading

Panting and wing spreading may indicate heat stress or high levels of ammonia.

6.4. Dust bathing

Dust bathing is an intricate body maintenance behaviour performed by many birds, including broilers (Olsson and Keeling, 2005). During a dust bathing bout, broilers work loose material, such as ~~dike~~ litter, in bedded systems through their feathers. Dust bathing helps to keep the feathers in good condition, which in turns helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the flock may indicate problems with litter or range quality, such as litter or ground that is wet or not friable.

6.5. Feeding, drinking and foraging

Reduced feeding or drinking behaviour can indicate management problems, including inadequate feeder or drinker space or placement, dietary imbalance, poor water quality, or feed contamination. Feeding and drinking behaviour are often depressed when broilers are ill, and feeding is also reduced during periods of heat stress and increased during cold stress. Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate; reduced foraging activity could suggest problems with litter quality or presence of conditions that decrease bird movement (e.g. gait problems).

7. Abnormal behaviour - feather pecking and cannibalism

Feather pecking is the pecking or pulling of the feathers of other broilers, and can result in significant feather loss. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury, and even the death of the pecked broiler. These are abnormal behaviours (Mench and Keeling, 2001; Rodenberg and Koene, 2004; Newberry, 2004) with multi-factorial causes that are not usually seen in commercial broiler stocks, although they can occur under some circumstances. Feather pecking may sometimes lead to cannibalism or may occur independently; once started, these problems can spread rapidly through the flock.

8. Water and feed consumption

Monitoring daily water consumption can be a useful tool to indicate disease and other welfare conditions, taking into consideration ambient temperature, relative humidity, feed consumption and other related factors. Problems with the water supply can result in wet litter, diarrhoea, dermatitis or dehydration.

Changes in feed consumption can also indicate the presence of disease and other welfare conditions of the flock as well as suitability of the feed.

EU comment

The word "dermititis" should be replaced with "dermatitis"

Justification: spelling.

9. Performance

9.1. Growth rate - an index that indicates the average daily gain (gr) of weight per average broiler of a flock.

EU comment

The following text should be added after the above sentence: "Low growth rates may indicate a welfare problem with broiler management; however, excessively high growth rates can indicate welfare problems as well regarding genetic selection."

Justification: producers should be aware that deviation on either end of the scale for growth rate can be an outcome of welfare problems. Interpretation requires this knowledge.

Reference: EFSA Panel on Animal Health and Animal Welfare, European Food Safety Authority 2010. *Scientific opinion on welfare aspects of the management and housing of the grand-parent and parent stocks raised and kept for breeding purposes*. Accessed at: <http://www.efsa.europa.eu/en/efsajournal/doc/1667.pdf>

9.2. Feed conversion - an index that indicates the quantity of feed (kg) that is necessary for a gain of bodyweight of one kilogram of the average broiler of a flock.

9.3. Liveability - an index that indicates the percentage of broilers present at the end of the production period; more commonly this indicator is measured as its opposite: mortality (see point 1 of Article X.X.4.).

EU comment

The EU wishes to add the following additional point:

"9.4. Large variation in bird weight /size - This may indicate disease issues, poor nutrition or husbandry or inadequate culling. "

Justification: Variation in bird size is a useful measurable.

10. Injury rate

Broilers are susceptible to a number of injuries, and the rate of these injuries can indicate welfare problems in the flock during production or capture. Injuries include those due to other broilers (scratches, feather loss or wounding due to feather pecking and cannibalism) and those due to environmental conditions (e.g. skin lesions) or and those due to humans intervention, eg catching. The most frequent injuries seen during catching are bruises, broken limbs and damaged wings. Fractures are located mainly on femur, radius, ulna, furcula and ischium. Dislocation of the femur at the hip joint is the most common traumatic injury.

EU comment

The following statement should be inserted between the words "cannibalism" and "and" in line 3 of the above paragraph (7.x.4, sec 10, paragraph 1, line 3):

" , those due to musculoskeletal disorders influenced by management and genetic selection."

Justification: musculoskeletal disorders are prevalent, cause significant injuries, and are probably responsible for a greater compromise to welfare than scratches. They should thus be included in this list.

Reference: EFSA Panel on Animal Health and Animal Welfare, European Food Safety Authority 2010. *Scientific opinion on welfare aspects of the management and housing of the grand-parent and*

parent stocks raised and kept for breeding purposes. Accessed at: <http://www.efsa.europa.eu/en/efsajournal/doc/1667.pdf>

11. Eye condition

Conjunctivitis can indicate the presence of irritants such as dust and ammonia. High ammonia levels will also cause corneal burns and eventual blindness (Morrow 2008:541).

12. Vocalisation

Vocalisation can indicate emotional state and distress in chickens (Jeon et al., 2005).

The following outcome (animal) based measurables can be useful indicators of welfare The following outcome (animal) based measurables can be useful indicators of welfare and should be measured at appropriate times by the caretaker (in no particular order):

- Mortality rate (dead, culled)
- Gait
- Contact dermatitis
- Feather condition
- Disease incidence / morbidity rates
- Ascites / sudden death syndrome (SDS)
- Respiratory disease
- Parasitic diseases
- Carcass and meat quality (condemnations)
- Behaviour: fear, thermal distress, illness
 - Human avoidance behaviour
 - Spatial distribution:
 - Panting and wing spreading.
 - Dust bathing
 - Feather pecking
 - Cannibalism
 - Feeding and drinking
- Water consumption
- Growth rate
- Feed conversion
- Injury rate
- Eye condition.

ARTICLE X-7. X . 5 .

Recommendations

EU comment

The EU wishes the OIE to add a preface here regarding the following:

(1) The purpose of these recommendations;

(2) How outcome based measures can and should be used to assess welfare problems;

(3) How outcome based measures should prompt remedial action;

Justification: gives clear purpose on how to use outcome measures, as well as what they should prompt producers to do in order to improve the welfare of broilers if it is compromised.

1. Biosecurity and animal health

1.1.a) Biosecurity and disease prevention

Biosecurity means a set of measures designed to ~~protect a flock from the entry of infectious agents~~ maintain a *flock* at a particular health status and to prevent the entry (or exit) of specific infectious agents.

~~Biosecurity programmes should be implemented, commensurate with the risk of disease and in accordance with relevant recommendations found in Terrestrial Code chapters on OIE listed diseases.~~

Biosecurity programmes should be designed and implemented, commensurate with the desired flock health status and current disease risk (endemic and exotic or transboundary) that is specific to each epidemiological group of broilers and in accordance with relevant recommendations found in *Terrestrial Code* chapters on OIE listed diseases.

These programmes should address the control of the major routes for disease and pathogen transmission:

a) Poultry

b) Other animals

c) People

d) Equipment

e) Vehicles.

a) direct transmission from other *poultry*, domesticated and wild animals and humans,

b) fomites, such as equipment, facilities and *vehicles*,

c) vectors (e.g., arthropods and rodents),

d) ~~via~~ aerosols ~~Air~~,

e) ~~via~~ water supply,

f) ~~via~~ feed.

Outcome based measurables: ~~disease incidence~~ of diseases, metabolic disorders and parasitic infestations, mortality ~~growth rate and feed conversion~~ and performance.

EU comment

For the last paragraph under 1.1, Article 7.x.5, and everywhere else within 7.x.5, after the words "outcome based measurables," the EU wishes the OIE to add the following text: "to evaluate the welfare of broilers"

Justification: Clarity. This provides a clear direction that these measures should be applied to formulate a picture of the welfare of broilers.

1.2.b) Animal health management / preventive medicine / veterinary treatment

Animal health management means a system designed to ~~prevent diseases occurring in a flock and provide treatment if disease occurs in order to~~ optimise the health and welfare of the *flock* broilers. It includes prevention, treatment and control of diseases and adverse conditions.

Those responsible for the care of ~~birds~~ broilers should be aware of the signs of ill-health or distress,

such as a change in reduced food feed and water intake, reduced growth, changes in behaviour, abnormal conditions appearance of their feathers, or droppings faeces, or other physical features.

If persons in charge are not able to identify the causes of ill-health or distress or to correct these or suspect the presence of a listed reportable disease, they should seek advice from those having training and experience, such as poultry *veterinarians* or other qualified advisers. Veterinary treatments should be prescribed by a qualified *veterinarian*.

EU comments

1. In the third paragraph of 1.2), the EU proposes to delete the text "those having training and experience, such as" and to add the words "qualified in poultry health" so that the phrase reads:

"If persons in charge are not able to identify the causes of ill-health or distress or to correct these or suspect the presence of a listed reportable disease, they should seek advice from ~~those having training and experience, such as~~ poultry *veterinarians* or other qualified advisers qualified in poultry health. Veterinary treatments should be prescribed by a qualified *veterinarian*."

Justification: the term "veterinarian" implies experience and training, and this is superlative to state prior to the term. Furthermore, the current text implies that the day-to-day caretaker would have no training or experience, which is not acceptable.

2. Moreover, the term "reportable" should be changed to "notifiable" in the second line of the third paragraph under 1.2 of Article 7.x.5

Justification: correct terminology.

There should be an effective programme for the prevention and treatment of *diseases* consistent with the programmes established by the *Veterinary Services* as appropriate.

Vaccinations and other administered treatments ~~to chickens~~ should be undertaken with consideration of the welfare of the ~~birds~~ broilers by qualified personnel ~~people~~ skilled in the procedures.

~~Culling of~~ Sick or injured ~~birds~~ broilers should be ~~done in a humane manner~~ culled humanely as soon as possible. Similarly, killing broilers ~~birds as may be required~~ for diagnostic purposes should be done in a humane manner according to Chapter 7.6. of the *Terrestrial Code*.

EU comment

The word "culled" should be changed to "killed" in line one of the preceding paragraph (7.x.5, Sec 1.2., paragraph 6, line 1)

Justification: Clarity and consistency. Culled is not defined, and "humanely killed" is used within the rest of the document and defined in 7.x.5 2.18. If culled is to intend a meaning different than just humanely killed, it should be clearly defined within the document and used accordingly.

Outcome based measurables: ~~disease~~ incidence of diseases, metabolic disorders and parasitic infestations, mortality and ~~poor~~ performance.

2. Environment and management

2.1. Thermal environment

~~In intensive and semi-intensive production systems every attempt should be made to keep thermal conditions within the recommended range.~~

A table of recommended ranges will be included

Thermal conditions for broilers should be appropriate for their stage of development, and extremes of heat, humidity and cold should be avoided. For the growing stage the Thermal Heat Index (THI) can assist in identifying the comfort zones for the broilers at varying temperature and relative humidity levels.

When environmental conditions move outside these zones, various strategies can be used in different production systems to mitigate the adverse effects on the broilers: e.g. high air speeds and **getting the birds to stand**, evaporative cooling and **reducing stocking density** can alleviate the effects of high heat and humidity in intensive systems.

EU comment

An additional paragraph should be inserted at the end of subsection 2.1 above entitled "Environment and management"

"During periods of high temperature and humidity, the housing system and its ventilation capacity may require the maximum stocking density to be reduced at certain times of the year. Health programmes should plan for any known high risk periods. Emergency procedures at times of unexpected climate change or effects of movement controls may require emergency depopulation or emergency culling of part of the flock."

Justification: A reduction in stocking density will also mitigate the adverse effects of high thermal environment on the flocks.

Reference: Skrbic Z, Pavlovski Z, Lukic M. Stocking density – factor of production performance, quality, and broiler welfare. J Biotech Anim Husb 25(5-6):3590372. 2009.

Ventilation should aim at controlling relative humidity to prevent the development of wet litter. Assessing litter condition on a regular basis is recommended.

Management **system** of the thermal environment should be checked at least twice a day.

Outcome based measurables: normal and abnormal behaviour, mortality, contact dermatitis, water and feed consumption, performance, feather condition.

In extensive production systems appropriate management to mitigate the effects of extreme thermal conditions should be implemented.

Outcome based measurables: rates of mortality, rate of contact dermatitis, water consumption, feed consumption, growth rate, feed conversion and behaviour.

2.2. Lighting

There should be an adequate period of continuous darkness during each 24 hour period to allow the ~~birds~~ broilers to rest. There should also be an adequate period of continuous light. Reference should be made to relevant national, regional or international recommendations.

The light intensity during the light period should be sufficient and homogeneously distributed to allow the ~~chicks~~ broilers to find feed and water in the first few days after they are placed in the poultry house, to stimulate ~~bird~~ activity, and to allow adequate inspection of the ~~birds~~.

~~Birds~~ Broilers should be gradually adjusted to lighting changes.

Outcome based measurables: gait lameness, metabolic disorders, performance feed and water consumption, normal and abnormal behavior, eye condition and injuries rate.

EU comments

1. The EU wishes to add the following sentence to the third paragraph of 2.2:

"Light changes can be employed under expert advice as a tool to correct welfare problems in a flock."

Justification: it is important advice for producers to realize the versatility of lighting schemes and the impact that light can have on welfare.

References: Kristensen HH, Aerts JM, Leroy T et al. Modeling the dynamic activity of broiler chickens in response to step-wise changes in light intensity. Appl Anim Behav Sci. 101:125-143. 2006

2. The "spatial distribution of bird" should be added as an outcome measure to 7.x.5, 2.2.

Justification: an uneven distribution of birds can indicate a problem in the light intensity, distribution, or other factor. This is an important measure of a need to address lighting as a management factor. Uneven distribution may not always indicate poor welfare, but should be considered. The last reference shows the complex interaction between behaviour, pathology, and lighting. This is reference in 2.3 below as an outcome measure.

References: Kristensen HH, Aerts JM, Leroy T et al. Modeling the dynamic activity of broiler chickens in response to step-wise changes in light intensity. *Appl Anim Behav Sci.* 101:125-143. 2006..
 Tabler GT, Berry IL et al. Spatial distribution of death losses in broiler flocks. *J Appl Poul Res.* 11:388-396. 2002.

3. The "foot pad disorders" and "musculoskeletal disorders" should also be included to the outcome measures list of 7.X.5, 2.2.

Justification: Lighting, when insufficient in intensities/duration can cause an increased incidence in foot-pad disorders.

References: Norwegian Scientific Committee for Food Safety. A Review: The effects of light intensity, gradual changes between light and dark and definition of darkness for the behaviour and welfare of broiler chickens, laying hens, pullets, and turkeys. Accessed at: <http://www.vkm.no/dav/7643446bd0.pdf>

4. The term "homogenously" should be removed from paragraph 2, line one of 7.x.5, 2.2 para 2 above.

Justification: Light intensity strongly impacts broilers behaviours. Gradients in light intensity can support different behaviours in broilers kept in complex environments. The chapter should be written to allow such flexibility given the plethora of system design options.

References: Kristensen HH, Aerts JM, Leroy T et al. Modeling the dynamic activity of broiler chickens in response to step-wise changes in light intensity. *Appl Anim Behav Sci.* 101:125-143. 2006.
 Olanrewaju HA, Thaxton JP, et al. A review of lighting programs for broiler production. *Inter Poul Sci.* 5(4):301-308. 2006.

2.3. Air quality

Adequate ventilation is required at all times to provide fresh air ~~and is one means of controlling temperature and humidity.~~

EU comment

The following text should be added at the end of the first sentence above: "and to control humidity and to remove waste gases from the environment."

Justification: expands on the purpose of ventilation.

Ammonia concentration should not routinely exceed 25 ppm at ~~bird~~ broiler level (Kristenssen and Waathes, 2000; Jones et al., 2005).

Dust levels should be kept to a minimum. Methods for doing that can include maintaining appropriate ventilation and ~~optimal relative humidity~~ satisfactory litter moisture levels (50%—80%). Where the health and welfare of broilers depends on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.

Outcome based measurables: incidence of ~~respiratory~~ respiratory diseases, metabolic disorders and parasitic infestations (respiratory diseases), behaviour (panting, huddling), eye condition, growth rate, feed conversion, performance, contact dermatitis and spatial distribution of the birds.

2.4. Acoustic environment Noise

Exposure of ~~birds~~ broilers to sudden or loud noises should be minimized where possible to prevent

stress and fear reactions (e.g. piling).

~~Note: Location of farms should, where possible, take into account existing environmental conditions local sources of noise.~~

~~Outcome based measurables: daily mortality rate, morbidity, performance growth rate, food conversion, injuries rate and fearfulness and fear behaviour.~~

EU comment

The following outcome measures should be removed: "~~mortality rate, morbidity, performance, injury rate~~" and "abnormal behaviors" should be added.

Justification:

Noise has not been demonstrated to cause increased mortality and morbidity rates. It is important but mainly impacts behavior, causes stress and fear, and perhaps if extreme can influence performance. Abnormal behaviors such as pecking have been implicated as correlated to aversive noise. More research needs to be completed regarding the effects of noise, but it is perhaps too bold to indicate noise is related to death and gross pathologies in broilers.

References: Chloupek P et al. Stress in broiler chickens due to acute noise exposure. Acta Vet Brno. 78:93-98. 2009. Campo JL, Gill MG, Davila SG. Effects of specific noise and music stimuli on stress and fear levels of laying hens of several breeds. Appl Anim Behav Sci. 91:74-85. 2005.

2.5. Nutrition

~~Broilers Birds~~ should always be fed a diet appropriate to their age and genetics, which contains adequate nutrients to meet their requirements for good health.

Feed and water should be palatable and free from contaminants potentially hazardous to ~~bird~~ broiler health.

~~Cleaning~~ ~~†~~The water system should be cleaned ~~done~~ regularly to prevent growth of hazardous microorganisms.

~~Broilers Birds~~ ~~must~~ should be provided with adequate accessibility to feed on a daily basis. Water should be available continuously.

Special provisions should be made to enable young chicks ~~to~~ access to appropriate feed and water.

Outcome based measurables: feed and water consumption, performance growth rate, food conversion, normal and abnormal behaviour, gait lameness, disease incidence of diseases, metabolic disorders and parasitic infestations, mortality ~~morbidity~~ and ~~carcass and meat quality~~ injury rate.

EU comment

The following paragraph should be added between paragraph 1 and 2 in the above section (7.x.5, sec 2.5):

"Qualitative or quantitative temporary feed restriction may be part of a flock management plan if employed under expert advice and as necessary to reduce the incidence of musculoskeletal disorders."

Justification: Quantitative and qualitative feed restrictions are welfare issues, but also employed to prevent welfare problems in breeders. Feed restriction should only be employed to combat worse welfare issues, and only as necessary, and in combination with other management options like genetic selection. Appropriate to support flexible feeding programs, while requiring that any feed restriction is supervised and appropriate.

Reference: EFSA Panel on Animal Health and Animal Welfare, European Food Safety Authority 2010. *Scientific opinion on welfare aspects of the management and housing of the grand-parent and parent stocks raised and kept for breeding purposes.* Accessed at: <http://www.efsa.europa.eu/en/efsajournal/doc/1667.pdf>

2.6. Flooring, bedding, resting surfaces (litter quality)

The floor of a poultry house should preferably be easy to clean and disinfect.

The provision of loose and dry material is desirable in order to encourage dust bathing and foraging.

The floor of a poultry house building should preferably be easy to clean and disinfect.

If Litter is recycled it should be managed to minimize any detrimental effects on welfare and health. Poor litter quality can lead to foot pad dermatitis, hock burns and breast blisters. Litter should be replaced or adequately treated when required to control a *disease outbreak* in the next *flock*.

Day-old birds chicks should be placed on a appropriate type of flooring housed on a floor suitable for their size to prevent injury. Flooring conditions have an important impact on the welfare of chickens.

If housed on litter based systems, before the one day-old birds chicks enter the building poultry house, the floor should have a bedding of uncontaminated new substrate (e.g. wood shavings, straw, rice husk, shredded paper, treated used litter) of sufficient depth to elicit normal behaviour and to protect them from the floor.

Litter quality is partly related to the type of substrate used and partly to different management practices. The type of substrate should be chosen carefully. Litter should be maintained so that it is dry and friable and not dusty, caked or wet.

The floors of cages and slatted systems Slatted floors should be designed, constructed and maintained to adequately support the birds broilers and prevent injuries and ~~to~~ ensure that manure can fall through or be adequately removed.

EU comment

The EU wishes to delete the following text: "Slatted floors should be designed, constructed and maintained to adequately support the broilers prevent injuries and ensure that manure can fall through or be adequately removed."

And add the text "Slatted flooring or cages should not be used for broilers."

Justification: cages and slatted floors are associated with poor welfare.

Reference: Fouad MA, Razek AHA, et al. Broiler welfare and economics under two management alternatives on commercial scale. Inter J Poult Sci 7(12):1167-1173. 2008.

Day-old birds should be placed on a appropriate type of flooring suitable for their size to prevent injury.

EU comment

The word "birds" should be changed to "chicks"

Justification: terminology.

If housed on litter based systems, before day-old birds enter the poultry house, the floor should have a bedding of uncontaminated substrate (e.g. wood shavings, straw, rice husk, shredded paper, treated used litter) of sufficient depth to elicit normal behaviour and to protect them from the floor.

Outcome based measurables: contact dermatitis, ~~breast blisters~~ feather condition, metabolic disorders ascites, gait lameness, behaviour (dust bathing and foraging), eye condition, incidence of diseases, metabolic disorders and parasitic infestations (respiratory disease) and performance growth rate.

2.7. Social environment

Management methods (e.g. reducing light intensity, providing foraging materials, nutritional modifications, reducing stocking density, selecting the appropriate genetic stock) should be implemented to reduce feather pecking and cannibalism in growing systems where these behaviours are a potential problem.

EU comment

The word "growing" should be changed to "production" in the third sentence of the paragraph above.

Justification: terminology.

If these management strategies fail, therapeutic beak trimming should be considered as the last option and after a thorough investigation.

EU comments

1. The following text should be added at the end of the second paragraph above after the word "investigation": "for the following flock."

Justification: logic. By the time an investigation is performed, broilers in the current flock will be too old for the practice to be performed "at an early age as possible." Thus, logically, it will be used on the next incoming flock as this practice is in reality only normally performed on young chicks.

2. Moreover the word "therapeutic" should be changed to "prophylactic",

Justification: logic as above; this practice would respond to the next progeny, and would not be used as therapy on the current flock.

Outcome based measurables: ~~injuries~~ rate, normal and abnormal behaviour, feather condition and mortality; ~~carcass and meat quality.~~

2.8. Stocking density

Broilers ~~chickens~~ should be housed ~~in at~~ an acceptable appropriate stocking density.

To determine the appropriate stocking density so that the floor space provided will ensure good welfare (comfort, ability to express normal postural adjustment and to access feed and water), the following factors should be taken into account: management capabilities, ambient conditions, housing systems, production systems, litter quality, ventilation, biosecurity strategy, ~~selection of genetic stocks~~, and market age and weight of broilers ~~birds should be taken into account so that the floor space provided will ensure good welfare (comfort, ability to express normal postural adjustment and to access feed and water).~~

Outcome based measurables: ~~rates of injuries~~ rate, ~~rates of contact dermatitis~~, ~~rates of mortality~~, normal and abnormal behaviour, gait, incidence of diseases, metabolic disorders and parasitic infestations, performance and ~~growth rate, feed conversion, plumage~~ feather condition and ~~carcass quality.~~

2.9. Outdoor areas

Broilers can be given access to outdoor areas as soon as they are old enough to range safely. There should be sufficient exit areas to allow ~~birds~~ broilers to enter and leave the poultry house freely.

Management of outdoor areas is important in extensive and semi-intensive production systems. Land (pasture) management measures should be taken to reduce the risk of ~~birds~~ broilers being infected by pathogens or infested by parasites ~~transmitted~~. This might include limiting the stocking density and / or using several pieces of land consecutively (rotation).

Outdoor areas should be managed appropriately to minimize swampy conditions and mud. Outdoor areas should preferably be placed on well drained grounds.

Outdoor areas should be managed appropriately to ensure that they are free of poisonous plants and other contaminants.

Particularly in extensive systems where ~~birds~~ broilers do not have access to an indoor area, protection from adverse climatic conditions (e.g. heat, cold, rain) should be provided.

Outcome based measurables: normal and abnormal behaviour, incidence of parasitic infestations diseases, performance growth rate, contact dermatitis, feather condition and mortality rate and morbidity.

EU comment

The words "spatial distribution of broilers" should be added to the outcome measures.

Justification: broilers may selectively choose to use or not to use space depending on the management of the environment of a particular area. As above comments regarding lighting, this measure is helpful.

References: Kristensen HH, Aerts JM, Leroy T et al. Modeling the dynamic activity of broiler chickens in response to step-wise changes in light intensity. *Appl Anim Behav Sci.* 101:125-143. 2006..
Tabler GT, Berry IL et al. Spatial distribution of death losses in broiler flocks. *J Appl Poul Res.* 11:388-396. 2002.

2.10. Protection from predators

Broilers should be protected from predators.

Outcome based measurables: fear behaviour, mortality and injuries rate.

EU comment

A section on environmental enrichment should be added as follows with the scope of Article 7.x.5, Section 2:

"2.XX Broilers can be provided environmental enrichment as a means to support behavioural needs, reduce abnormal behaviours and stress. Environmental enrichment can include foraging substrates, perches, and low barriers. If and when used, environmental enrichment should be properly maintained so as to minimize injury to broilers.

Outcome based measures: normal and abnormal behaviours"

Justification: Environmental enrichment is important; thus the draft should recognize that environmental enhancement supports welfare and should be considered by producers.

References:

Kulpa-Eddy JA, Taylor S, Adams KM. USDA Perspective on Environmental Enrichment for Animals. *Inter Lab Anim Res.* 46(2):83-94. 2005.

EFSA Panel on Animal Health and Animal Welfare, European Food Safety Authority 2010. *Scientific opinion on welfare aspects of the management and housing of the grand-parent and parent stocks raised and kept for breeding purposes.* Accessed at <http://www.efsa.europa.eu/en/efsajournal/doc/1667.pdf>

3. Management

2.11. Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a strain for a particular location or production system.

Outcome based measurables: gait lameness, metabolic disorders ascites, sudden death syndrome (SDS), mortality, normal and abnormal behaviour and performance feed conversion and growth rate.

EU comment

The EU would like to add "morbidity" as an outcome measure on 2.11

Justification: morbidity of many diseases can be at least partially of genetic cause.

Reference: EFSA Panel on Animal Health and Animal Welfare, European Food safety Authority 2010. *Scientific opinion on welfare aspects of the management and housing of the grand-parent and parent*

2.12. Painful interventions

~~Commercial broilers chickens are not typically subjected to management practices that cause pain. However, prophylactic beak trimming may be required in case of outbreaks of feather pecking and cannibalism, as described earlier. Guidelines for beak trimming to minimize negative impacts on bird health and performance are presented in Glatz and Miao (2005). Only the minimum amount of beak needed to prevent beak re-growth before market age (ideally, only the hook at the end of the upper beak) should be removed, and the trim should be performed so as to prevent subsequent distortion or deformation of the beak. The beak should be cauterized after cutting to minimise bleeding. Trimming at an early age (before 10 days of age; Hester and Shea-Moore, 2003) is preferred to prevent long-term pain, but since feather pecking and cannibalism develop when the birds are somewhat older prophylactic trimming will likely occur after this time.~~

~~There is a small specialty market for capons (castrated male broilers). Because the testes of male chickens are located inside the abdominal cavity, this procedure is a major surgery (Jacob and Mather, 2000) that should be performed only by skilled individuals and with measures to minimize pain, injury, and bleeding. The procedure is described in Jacob and Mather (2000).~~

Painful interventions (e.g. beak trimming, toe trimming, dubbing) should not be routinely practised on broilers.

If therapeutic beak trimming is required, it should be carried out by trained and skilled personnel at as early an age as possible and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding (Glatz and Miao, 2005; Hester and Shea-Moore, 2003).

EU comment

The two paragraphs above should read as follow:

"Painful interventions (e.g. beak trimming, ~~toe trimming, dubbing~~) should not be routinely practised performed on broilers except for therapeutic, diagnostic, or prophylactic reasons, such as to minimize injury or mortality rates in a flock and only as a last resort.

If ~~therapeutic~~ prophylactic beak trimming is required, it should be carried out by trained and skilled personnel at as early an age as possible and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding (Glatz and Miao, 2005; Hester and Shea-Moore, 2003)."

Justification

Toe trimming and dubbing are normally carried out on breeders which should not be covered by this draft chapter. "Routinely" is ambiguous. Simply, the procedures should only be performed if justified for responding to a problem, i.e. feather-pecking/cannibalism. "Therapeutic" implies the practice is done to a bird or flock to an existing flock, but logically when a problem is identified and an investigation carried out, the measure of beak trimming would be used on the next incoming flock.

Surgical caponisation should not be performed without adequate pain and *infection* control methods and should only be performed by veterinarians or trained and skilled personnel under veterinary supervision.

Outcome based measurables: use of any of the above procedures.

2.13. Handling and inspection

Broilers should be inspected at least twice every a day. ~~This inspection~~ This inspection should have three main objectives: ~~to pick up dead birds;~~ 1) to identify sick or injured birds broilers to treat or cull them, and 2) to detect and correct any welfare or health problem in the flock (e.g. related to the supply of feed and water, thermal conditions, ventilation, litter quality), and 3) to pick up dead broilers.

EU comment

The above paragraph's second sentence regarding the objectives of inspection should be rearranged as follows:

"Inspection should have three main objectives: 1) to detect and correct any welfare or health problems in the *flock* (e.g. ~~related to the supply of feed and water, thermal conditions, ventilation, litter quality~~); 2) to identify sick or injured broilers and to treat or ~~and~~ humanely kill them; ~~and~~ 3) to pick up dead broilers and (4) to reduce fearfulness and therefore reduce the risk of panic, smothering and sudden death."

Justification: the rearranged order places emphasis on the most critical aspects of flock management and aide in implementation by producers/personnel. Moreover, evidence shows that broilers accustomed to human contact are less fearful (Hemsworth et al, 19994). Other changes are for clarity and consistency in using terms "humanely kill" as they are used in the rest of the Code.

Inspection should be done in such a way that ~~birds~~ broilers are not unnecessarily disturbed, for example ~~personnel~~ animal handlers should move quietly and slowly through the *flock*.

When ~~birds~~ broilers are handled they should not be injured or unnecessarily frightened or stressed.

~~Birds~~ Broilers which have an incurable sickness, significant deformity or injury should be removed from the *flock* and humanely killed as soon as possible.

EU comment

In the above sentence, the word "incurable" should be deleted and the words "treated or" should be added before the word "humanely" so that the paragraph reads as follows:

"Broilers which have a sickness, significant deformity or injury should be removed from the flock and treated or humanely killed as soon as possible."

Justification: "incurable sickness" is ambiguous. Section 2.18 (humane killing) states clearly "*injured and sick birds should be killed humanely.*" There should be an attempt to treat a disease before killing the animals.

Cervical dislocation is an acceptable method for killing small numbers of ~~birds~~ broilers if carried out competently (see Article 7.6.17. of the *Terrestrial Code*). For a complete description of killing methods see Article 7.6.475. of the *Terrestrial Code*.

EU comment

The first sentence of the above paragraph should be deleted and for the second sentence on methods of killing, reference should be done to section 2.18.

Justification: Method of humane killing should be described in the section "humane killing" and not in "handling".

Outcome based measurables: normal and abnormal behaviour~~feaf~~, performance, injuries~~rate~~, mortality, vocalisation and morbidity.

2.14. Personnel training

All people responsible for the broilers should receive appropriate training so that they are ~~be~~ competent according to their to carry out their responsibilities and should have sufficient knowledge of broiler behaviour, handling techniques, emergency euthanasia procedures, biosecurity, general signs of disease, and indicators of poor *animal welfare* such as stress and pain ~~and fatigue~~, and their alleviation.

EU comments

1. In line 3 of the above paragraph, the term "euthanasia procedures" should be changed to "methods of humane killing".

Justification: clarity and consistency. Killed is a term that will be understood more readily by persons

dealing with broilers in everyday situations. Euthanized is a term that is more esoteric in the veterinary and animal science profession. Killed is used in most other sections of the code, such as in X.X.5, 2.18 "Humane Killing."

2. In line 4 "indicators of poor animal welfare" should be changed to "outcome-based measures of poor broiler welfare".

Justification: Consistency. The chapter stresses outcome-based measures, and terminology should be consistent so that those persons implementing this code have a streamlined understanding of the intent.

Outcome based measurables: all measurables could apply.

2.15. Emergency Plans

Poultry Broiler producers should have emergency plans to minimize and mitigate the consequences of: natural disasters, *disease* outbreaks and the failure of mechanical equipment. Planning may include the provision of fail-safe alarm devices to detect malfunctions, back up generators, access to maintenance providers, alternative heating arrangements, ability to store water on farm, access to water cartage services, adequate on farm storage of feed and alternative feed supply and emergency ventilation.

EU comment

At the end of the first paragraph under 2.15, the following text should be added:

"In emergencies, further contingencies should be planned for including minimizing the welfare impact of movement restrictions, requirement for indoor housing (for birds that would usually have access to outdoor ranges or verandas) and emergency killing options."

Justification: emergency movement of the broilers is a critical contingency in many circumstances, from natural disaster to a foreign animal disease outbreak.

An emergency plan for animal health should be developed consistent with national programs established or recommended by *Veterinary Services* as appropriate.

EU comments

1. The word "back up" should have a hyphen so as to read "back-up generators."

Justification: grammar.

2. In the above first paragraph, line 4 it should read "alternative heating and/or cooling arrangements based on the region's climate".

Justification: in some climate areas, heat stress and overheating are the preeminent welfare concern as opposed to cooling. In fact, in some areas, there may be the risk of both heat and cold stress. The chapter must conform to all environmental situations.

3. The following text should be added at the end of the first paragraph after the word "ventilation": "as necessary to ensure the health and welfare of the broilers."

Justification: gives an outcome-based of what emergency plans and equipment should achieve. It is needed to clarify what a producer will need to plan for, and what emergency supplies he may need to obtain.

4. In the last paragraph, line 1, after the word "developed" the text ", which is" should be added.

Justification: clarity and grammar.

2.16. Location, construction and equipment of farms

The location of poultry farms should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practical. In addition farms should be sited to avoid or minimize biosecurity risks, exposure of birds to chemical and physical contaminants, noise and adverse climatic conditions.

Housing Poultry houses, outdoor areas and equipment to which poultry broilers have access should be designed and maintained to avoid injury or pain to the birds.

Buildings Poultry houses should be constructed and electrical and fuel installations should be fitted to minimise the risk of fire and other hazards.

Poultry Broiler producers should have a maintenance programme in place for all equipment that, in case of failure, can jeopardize broiler welfare.

2.17. On farm harvesting

EU comment

The words "or catching" should be added to the title to 2.17

Justification: Clarity and scope. While most catching is done for harvesting, these principles should apply to any instances of catching. Using both terms lays a wide net for scope here.

~~Feed Broilers should not be removed at a suitable~~ be subject to an excessive period of feed withdrawal ~~time~~ prior to ~~catching~~ the expected *slaughter* time.

Water should be available ~~for as long as possible~~ up to the time of catching.

~~Injured and sick birds~~ Broilers that are not fit for *transport* (e.g. severely injured or severely ill) should be culled ~~or separated~~ prior to harvesting the *flock*.

Catching should be carried out ~~done~~ by skilled ~~workers~~ *animal handlers* and every attempt should be made to minimize stress and fear reactions, and injury. If a broiler is injured during catching it should be culled.

EU comments:

1. The word "reactions" should be deleted in the above paragraph, line 2.

Justification: clarity and consistency. This sentence has other outcome measures in singular form, not plural. Sentences below refer to "fear" and not "fear reactions."

2. The term "culled" should be deleted and replaced with "humanely killed" in the above paragraph, line 3.

Justification: clarity and consistency, as before.

~~The~~ Broilers should not be picked up by their neck or wings.

~~The~~ Broilers should be carefully ~~placed~~ in the *transport container* ~~carefully~~.

Mechanical catchers, where used, should be designed, operated and maintained to minimize injury, stress and fear to the ~~birds~~ broilers. A ~~c~~ontingency plan is advisable in case of mechanical failure.

Catching should preferably be carried out under dim or blue light to calm the broilers ~~birds~~.

Catching should be scheduled to minimize the time to *slaughter* as well as climatic stress during catching, *transport* and holding.

Stocking density in *transport containers* should suit climatic conditions and maintain comfort.

Containers should be clean and disinfected and designed and maintained to avoid injury to the broilers ~~birds~~.

Outcome based measurables: ~~incidence of injuries~~ rate and mortality rate (at catching and dead on arrival) ~~and carcass quality~~.

2.18. Humane killing

Injured and sick birds should be killed humanely.

EU comments

1. The word "birds" should be changed to "broilers" in the first line under title 2.18 above.

Justification: consistency.

2. In the first paragraph under 2.18, after humanely the following should be added: "unless otherwise receiving treatment".

Rationale: gives producers the opportunity to address disease with treatment.

Cervical dislocation is considered a humane method for killing small numbers of broilers ~~birds~~ (see Article 7.6.17. of the *Terrestrial Code*).

EU comment

The EU would suggest reformatting the second paragraph under 2.18, and delete the last paragraph:

"Cervical dislocation can be used for a small number of broilers if other methods of humane killing are not feasible, and if chosen should be done according to Article 7.6.5 of the Terrestrial Code."

Justification: Cervical dislocation is not a preferable method of humane killing, though sometimes it may be the best practical option; and it should be allowed but not encouraged for these reasons.

Reference: EFSA Panel on Animal Health and Animal Welfare. European Food Safety Authority 2004. *Scientific Opinion on Welfare aspects of animal stunning and killing methods*. Accessed at: <http://www.efsa.europa.eu/de/scdocs/doc/45ax1.pdf>.

For a description of other methods for the humane killing of broilers see Article 7.6.5. of the *Terrestrial Code*.

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CHAPTER 8.1

ANTHRAX

EU position

The EU thanks the OIE TAHSC and supports the adoption of this modified chapter.

Article 8.1.1.

General provisions

This chapter is intended to manage the human and animal health risks associated with the presence of *Bacillus anthracis* in *commodities* and the environment.

There is no evidence that anthrax is transmitted by *animals* before the onset of clinical and pathological signs. Early detection of *outbreaks*, quarantine of affected premises, destruction of diseased *animals* and fomites, and implementation of appropriate sanitary procedures at *abattoirs* and dairy factories will ensure the safety of products of animal origin intended for human consumption.

For the purposes of the *Terrestrial Code*, the *incubation period* for anthrax shall be 20 days.

Anthrax should be notifiable in the whole country.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of *commodities* covered in the chapter, with the exception of those listed in Article 8.1.2., *Veterinary Authorities* should require the conditions prescribed in this chapter.

Article 8.1.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any anthrax related conditions: semen and *in vivo* derived cattle embryos collected and handled processed in accordance with Chapters 4.5., 4.6. ~~and 4.7.~~ 4.8. and 4.9., as relevant.

Article 8.1.3.

Recommendations for the importation of ruminants, equines and pigs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of anthrax on the day of shipment;

AND

2. were kept for the 20 days prior to shipment in an *establishment* where no *case* of anthrax was officially declared during that period; or
3. were vaccinated, not less than 20 days and not more than 612 months prior to shipment in accordance with the *Terrestrial Manual*.

Article 8.1.4.

Recommendations for the importation of fresh meat and meat products destined for human consumptionAnnex 15 (contd)

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the products originate from *animals* ~~which that~~:

1. have shown no sign of anthrax during ante-~~mortem~~ and post-mortem inspections; and
2. were not vaccinated against anthrax using live vaccine during the ~~21~~ 14 days prior to *slaughter* or a longer period depending on the manufacturer's recommendations; and
3. come from *establishments* ~~which that~~ are not placed under movement restriction ~~on account for the control~~ of anthrax and ~~in which where~~ there has been no *case* of anthrax during the 20 days prior to *slaughter*.

Article 8.1.5.

Recommendations for the importation of hides, skins and hair (from ruminants, equines and pigs)

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the products originate from *animals* which:

1. originate from animals ~~which that~~:
 - a. have shown no sign of anthrax during ante-~~mortem~~ and post-mortem inspections; and
 - b. come from *establishments* ~~which that~~ are not placed under movement restriction ~~on account for the control~~ of anthrax;

OR

2. for hair from ruminants or equines, have ~~has~~ been treated in accordance with the recommendations in Article 8.1.11.

Article 8.1.6.

Recommendations for the importation of wool

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the products:

1. originates from live animals; and
2. originates from establishments where no case of anthrax has been reported since the previous shearing of all animals ~~which that~~, at the time of shearing, were part of a *flock* that was not subject to movement restrictions imposed for the control of anthrax;

OR

23. have been treated in accordance with the recommendations in Article 8.1.11.

Article 8.1.7.

Recommendations for the importation of milk and milk products intended for human consumption

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

1. the *milk* originates from *animals* showing no clinical signs of anthrax at the time of milking;
2. if the *milk* originates from *herds* or *flocks* that have had a *case* of anthrax within the previous 20 days, it has been chilled promptly and processed using a heat treatment at least equivalent to pasteurisation.

Article 8.1.8.

Recommendations for the importation of bristles (from pigs)

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the products originate from *animals* which:

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and
2. come from establishments that which are not placed under movement restriction on account for the control of anthrax control;

OR

3. have been processed to ensure the destruction of *B. anthracis* by:
 - a) boiling for 60 minutes; and
 - b) drying in hot air.

Article 8.1.9.

Procedures for the inactivation of *B. anthracis* spores in skins and trophies from wild animals

In situations in which skins and trophies from wild *animals* may be contaminated with *B. anthracis* spores, the following *disinfection* procedure is recommended:

1. fumigation with ethylene oxide 500 mg/L, at relative humidity 20 – 40%, at 55°C for 30 minutes; or
2. fumigation with formaldehyde 400 mg/m³ at relative humidity 30%, at >15°C for 4 hours; or
3. gamma irradiation with a dose of 40 kGy.

Article 8.1.10.

Procedures for the inactivation of *B. anthracis* spores in bone-meal and meat-and-bone meal

In situations where raw materials used to produce bone meal or meat-and-bone meal may be contaminated with *B. anthracis* spores, the following inactivation procedure should be used to inactivate any *B. anthracis* spores which may be present during the production of bone-meal or meat-and-bone meal from ruminants, equines and pigs:

1. the raw material should be reduced to a maximum particle size of 50 mm before heating; and
2. the raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar. Other industrial process demonstrating equivalent efficacy is also acceptable. subjected to moist heat at one of the following temperature and time regimes:

Annex 15 (contd)

- a) 105 °C for at least 8 minutes; or
- b) 100°C for at least 10 minutes; or
- c) 95 °C for at least 25 minutes; or
- d) 90°C for at least 45 minutes; or
- e) an industrial process demonstrated to be of equivalent efficacy.

OR

3. the raw material should be subjected to dry heat at one of the following temperature and time regimes:

- a) 130 °C for at least 20 minutes; or
- b) 125 °C for at least 25 minutes; or
- c) 120 °C for at least 45 minutes;

OR

4. an industrial process demonstrated to be of equivalent efficacy.

Article 8.1.11.

Procedures for the inactivation of *B. anthracis* spores in wool and hair

In situations in which wool or hair may be contaminated with *B. anthracis* spores, the following ~~five-step disinfection~~ procedures ~~is~~ are recommended:

- 1. gamma irradiation with a dose of 50-25 kGy; or
- 2. a five step washing procedure:
 - a) immersion in 0.25 – 0.3% soda liquor for 10 minutes at 40.5°C;
 - 2b) immersion in soap liquor for 10 minutes at 40.5°C;
 - 3c) immersion in 2% formaldehyde solution for 10 minutes at 40.5°C;
 - 4d) a second immersion in 2% formaldehyde solution for 10 minutes at 40.5°C;
 - 5e) rinsing on cold water followed by drying in hot air.

~~Article 8.1.12.~~

Procedures for the inactivation of *B. anthracis* spores in manure, dung and bedding

In situations in which manure, dung or bedding may be contaminated with *B. anthracis* spores, the following are recommended:

- 1. small volumes by incineration; or
- 2. chemothermal treatment by composting as follows:
 - a) mix with one of the following at a rate of 1 – 1.5L/m³;
 - i) 10% formaldehyde (approximately 30% formalin), or
 - ii) 4% gluteraldehyde (pH 8.0 – 8.5);

b) turn the material after 5 weeks;

c) leave for a further 5 weeks.

[Note: spontaneous combustion of the composting pile is possible.]

Article 8.1.13.

Procedures for the inactivation of *B. anthracis* spores in liquid manure (slurry)

In situations in which liquid manure (slurry) may be contaminated with *B. anthracis* spores, disinfection with formalin (35% aqueous solution of formaldehyde) with stirring for one hour daily is recommended:

1. for slurry up to 5% dry matter, 50 kg formalin per m³ for 4 days;

2. for slurry >5% and <10% dry matter, 100 kg formalin per m³ for 4 days.

Article 8.1.14.

Procedures for the disinfection of surfaces in animal houses, buildings contaminated with *B. anthracis*

In situations in which surfaces in animal houses, stables, vehicles, etc. may be contaminated with *B. anthracis* spores, the following three-step approach is recommended:

1. a preliminary disinfection should be carried out using one of the following disinfectants at a rate of 1–1.5 L/m³ for 2 hours;

a) 10% formaldehyde (approximately 30% formalin); or

b) 4% glutaraldehyde (pH 8.0–8.5);

2. all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;

3. a final disinfection step should be carried out using one of the following disinfectants applied at a rate of 0.4 L/m³ for 2 hours;

a) 10% formaldehyde (approximately 30% formalin), repeated after one hour; or

b) 4% glutaraldehyde (pH 8.0–8.5), repeated after one hour; or

c) 3% hydrogen peroxide; or

d) 1% peracetic acid, repeated after one hour

[Note: Formaldehyde and glutaraldehyde should not be used at temperatures below 10°C. Hydrogen peroxide and peracetic acid are not suitable in the presence of blood.]

Article 8.1.15.

Procedures for the fumigation of rooms contaminated with *B. anthracis*

Contaminated rooms which cannot be cleared before cleaning and disinfection can be fumigated to eliminate *B. anthracis* spores. The following procedure is recommended:

Annex 15 (contd)

1. all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and
2. for rooms up to 30 m³, 4 L of water containing 400 ml of concentrated formalin (37% w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15°C.

[Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of B. subtilis var globigii or B. cereus or Sterne vaccine strain of B. anthracis and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1% histidine and incubated overnight at 37°C. If fumigation has been effective, there will be no bacterial growth.]

— text deleted

CHAPTER 4.13.

GENERAL RECOMMENDATIONS ON DISINFECTION
AND DISINSECTISATION

EU position

The EU thanks the OIE TAHC and supports the adoption of this modified chapter.

Article 4.13.1.

General provisions

Veterinary Authorities are requested to draw up regulations in their respective countries concerning the use of disinfectants and insecticides on the basis of the principles described below:

1. The choice of disinfectants and of procedures for *disinfection* should be made taking into account the causal agents of *infection* and the nature of the premises, *vehicles* and objects which are to be treated.
2. Disinfectants and insecticides should be authorised only after thorough tests have been carried out under field condition.
3. The following should be considered:
 - a) few universal disinfectants exist;
 - b) whereas hypochlorite, which is very often used, may be regarded as a universal disinfectant, its effectiveness is diminished by prolonged storage and it is therefore necessary to check its activity before use; a concentration of 0.5% active chlorine appears necessary for satisfactory *disinfection*;
 - ~~e) foot and mouth disease virus is easily destroyed by a high or low pH but the disinfectants used may be caustic or corrosive in concentrated form;~~
 - ~~d) tubercle bacillus is very resistant to disinfectants and a high concentration is required to destroy the organism, as well as prolonged action;~~
 - ce) no matter what substances are used, *disinfection* techniques should comprise the following:
 - i) thorough soaking of bedding and litter as well as faecal matter with the disinfectant;
 - ii) washing and cleaning by careful brushing and scrubbing of the ground, floors and walls;
 - iii) then further washing with the disinfectant;
 - iv) washing and disinfecting the outside of *vehicles*; these procedures will be carried out, if possible, with liquids applied under pressure and the washing, disinfecting or destroying of articles used for tying up the animals (ropes, reins, etc.) should not be omitted.

Article 4.13.2.**Pathogen specific disinfection**

1. Foot and mouth disease virus is easily destroyed by a high or low pH but the disinfectants used may be caustic or corrosive in concentrated form.

2. Mycobacteria are very resistant to disinfectants and a high concentration is required to destroy the organisms, as well as prolonged action.

3. *Bacillus anthracis*

a) In situations in which manure, dung or bedding may be contaminated with *B. anthracis* spores, the following are recommended:

i) small volumes by incineration; or

ii) chemothermal treatment by composting as follows:

– mix with one of the following at a rate of 1–1.5L/m³:

– 10% formaldehyde (approximately 30% formalin), or

– 4% glutaraldehyde (pH 8.0–8.5);

– turn the material after 5 weeks;

– leave for a further 5 weeks.

[Note: Spontaneous combustion of the composting pile is possible. Also note: Formalin is a dangerous chemical and as such the appropriate personal protective equipment should be used and safety training on the handling of this chemical should be provided.]

b) In situations in which liquid manure (slurry) may be contaminated with *B. anthracis* spores, disinfection with formalin (35% aqueous solution of formaldehyde) with stirring for one hour daily is recommended:

i) for slurry up to 5% dry matter, 50 kg formalin per m³ for 4 days;

ii) for slurry >5% and <10% dry matter, 100 kg formalin per m³ for 4 days.

[Note: Formalin is a dangerous chemical and as such the appropriate personal protective equipment should be used and safety training on the handling of this chemical should be provided.]

c) In situations in which surfaces in animal houses, stables, vehicles, etc. may be contaminated with *B. anthracis* spores, the following three-step approach is recommended:

i) a preliminary disinfection should be carried out using one of the following disinfectants at a rate of 1–1.5 L/m³ for 2 hours;

– 10% formaldehyde (approximately 30% formalin); or

– 4% glutaraldehyde (pH 8.0–8.5);

ii) all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;

iii) a final disinfection step should be carried out using one of the following disinfectants applied at a rate of 0.4 L/m³ for 2 hours;

– 10% formaldehyde (approximately 30% formalin), repeated after one hour; or

– 4% glutaraldehyde (pH 8.0–8.5), repeated after one hour; or

– 3% hydrogen peroxide; or

Annex 15 (contd)

– 1% peracetic acid, repeated after one hour; or

– 5-10% sodium hypochloride solution.

[Note: Formaldehyde and glutaraldehyde should not be used at temperatures below 10°C. Hydrogen peroxide and peracetic acid are not suitable in the presence of blood. As with all chemicals the appropriate personal protective equipment should be worn and appropriate safety training should be provided to staff handling dangerous chemicals.]

d) Contaminated rooms which cannot be cleared before cleaning and disinfection can be fumigated to eliminate *B. anthracis* spores. The following procedure is recommended:

i) all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and

ii) for rooms up to 30 m³, 4 L of water containing 400 ml of concentrated formalin (37% w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15°C.

[Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of *B. subtilis* var *globigii* or *B. cereus* or Sterne vaccine strain of *B. anthracis* and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1% histidine and incubated overnight at 37°C. If fumigation has been effective, there will be no bacterial growth.]

– text deleted

CHAPTER 8.2.

AUJESZKY'S DISEASE

EU position

The EU thanks the OIE TAHSC for these important changes and supports in general the adoption of this modified chapter.

However, in light of the new definitions of captive wild and feral animals in the Glossary, two minor but important changes should be done before adoption or taken into account by the TAHSC in its next meeting.

Article 8.2.1.

General provisions

Pigs are the natural host for Aujeszky's disease (AD) virus, although it can infect cattle, sheep, cats, dogs and rats causing fatal disease. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild.

For the purposes of the *Terrestrial Code*, Aujeszky's disease (AD) is defined as an *infection of domestic pigs and captive wild pigs*.

EU comment

Linguistic: the "and" should be an "or": "*infection of domestic ~~and~~ or captive wild pigs*".

For the purposes of this chapter, a distinction is made between domestic pig and captive wild pig populations on the one hand and wild pig and feral pig populations on the other hand.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

A Member should not impose trade bans in response to a notification of *infection with Aujeszky's disease virus in wild pigs according to Article 1.2.3. of the *Terrestrial Code**.

EU comment

The words "and feral" should be added after the word "wild" in the paragraph above, for consistency with the approach of the third paragraph.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the AD status of the *exporting country or zone*.

Article 8.2.1.bis**Determination of the AD status of a country, zone or compartment**

The Aujeszky's disease (AD) free or provisionally free status of a country or *zone* can only be determined ~~if~~ after considering the following ~~conditions are fulfilled~~ criteria in domestic and wild pigs, as applicable:

1. ~~a risk assessment has been conducted identifying all potential factors for AD occurrence and their historic perspective;~~

21. AD is notifiable in the whole country, and all clinical ~~case signs~~ suggestive of AD ~~are should be~~ subjected to field and/or laboratory investigations;
32. an on-going awareness programme ~~is should be~~ in place to encourage reporting of all cases suggestive of AD ~~in susceptible species~~;
43. the *Veterinary Authority* ~~has should have~~ current knowledge of, and authority over, all ~~establishments containing domestic~~ pigs in the ~~whole~~ country ~~or zone~~;

EU comment

The words "and captive wild" should be added in the point above after "domestic" for consistency with the Article 8.2.1.

54. ~~the *Veterinary Authority* should have current knowledge about the population and habitat of wild and feral pigs in the country or zone~~

5. ~~appropriate surveillance, capable of detecting the presence of infection even in the absence of clinical signs, is in place; this may be achieved through a surveillance programme in accordance with Chapter 1.4.~~

~~domestic pigs are properly identified when leaving their establishment of origin with an indelible mark giving the identification number of their herd of origin; a reliable tracing back procedure is in place for all pigs leaving their establishment of origin.~~

~~An AD infected establishment means an establishment in which the virus has been isolated or identified, or a positive serological result (total or gE antibodies) has been confirmed in a laboratory.~~

~~Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.~~

~~When authorising import or transit of the commodities covered in the chapter, with the exception of those listed in Article 8.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the AD status of the exporting country or zone.~~

Article 8.2.2.

Safe commodities

When authorising import or transit of the following *commodities* and any products made from these, *Veterinary Authorities* should not require any AD related conditions, regardless of the AD status of the the *exporting country* or *zone*:

1. *fresh meat* of domestic and wild pigs not containing offal (head, and thoracic and abdominal viscera);
2. *meat products* of domestic and wild pigs not containing offal (head, and thoracic and abdominal viscera);
3. products of animal origin not containing offal (head, and thoracic and abdominal viscera).

Article 8.2.3.

AD free country or zone

1. Qualification

- a) A country or *zone* may be considered free from the *disease* without formally applying a specific *surveillance* programme (historical freedom) if the *disease* has not been reported for at least 25 years, and if for at least the past 10 years:

- ai) it has been a *notifiable disease*;
 - bii) an early detection system has been in place;
 - ecii) measures to prevent the introduction of the AD virus into the country or *zone* have been in place;
 - ediv) no vaccination against the *disease* has been carried out;
 - eev) *infection* is not known to be established in wild swine, or measures have been implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.
- b) A country or *zone* which does not meet the conditions of the above paragraph may be considered free from AD when:
- fi) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.2. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least 2 years;
 - gii) vaccination against AD has been banned for all domestic pigs in the country or *zone* for at least 2 years;
 - hiii) if AD has never been reported in the country or *zone*, serological surveys, with negative results, have been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter ~~X.X.~~ 1.4. (under study) **at an acceptable level of confidence**, no more than 3 years prior to qualification; the serological surveys should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or
 - iiiv) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect every infected *establishment* and eradicate AD from it; the *surveillance* programme should be carried out in conformity with the recommendations in Chapter ~~X.X.~~ 1.4. (under study) and demonstrate that no *establishments* within the country or *zone* have had any clinical, virological or serological evidence of AD for at least 2 years.

~~In order for a country to reach free status, all of its *zones* should have reached AD free status.~~

- y) In countries or *zones* with wild swine, measures should be implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.

2. Maintenance of free status

In order to maintain its free status, a country or *zone* should comply with the following requirements:

- Fa) periodic serological surveys directed at the detection of antibodies to the whole AD virus should be carried out on a statistically significant number of breeding pigs, in conformity with the recommendations in Chapter ~~X.X.~~ 1.4. (under study);
- Gb) the importation of the *commodities* with the exception of those listed in Article 8.2.2. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter;
- Hc) the ban on AD vaccination remains in force;
- Id) measures aimed at preventing the transmission of the AD virus from wild swine to domestic pigs remain in force.

3. Recovery of free status

Should an AD *outbreak* occur in an *establishment* of a free country or *zone*, the status of the country or *zone* may be restored if either:

- a) all the pigs in the *outbreak* have been slaughtered; and, during and after the application of this measure, an epidemiological investigation including clinical examination, and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a ~~5-kilometre~~ prescribed radius ~~of~~ from the *outbreak*, demonstrating that these *establishments* are not infected; or
- b) vaccination with gE- deleted vaccines has been applied and:
 - i) a serological testing procedure (differential ELISA) has been implemented in the *establishments* where vaccination has been applied to demonstrate the absence of *infection*;
 - ii) the movement of pigs from these *establishments* has been banned, except for immediate *slaughter*, until the above procedure has demonstrated the absence of *infection*;

~~iii) all vaccinated *animals* have been slaughtered;~~

~~iv) during and after the application of the measures described in points i) to iii) above, a thorough epidemiological investigation including clinical examination and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a ~~5-kilometre~~ prescribed radius ~~of~~ from the *outbreak*, demonstrating that these *establishments* are not infected.~~

EU comment

Editorial: if the deletion of iii) is adopted, replace in the above paragraph "i) to iii)" by "i) and ii)"

Article 8.2.4.

AD provisionally free country or zone

1. Qualification

A country or *zone* may be considered as provisionally free from AD if the following conditions are complied with:

- a) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.2. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least 2 years;
- b) if AD has never been reported in the country or *zone*, a serological survey, with negative results, has been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter ~~X.X. 1.4. (under study)~~ (but not at an acceptable level of confidence not sufficient to meet requirements for freedom); the serological survey should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or
- c) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect infected *establishments* and eradicate AD from these *establishments*, the *herd*

prevalence rate in the country or *zone* has not exceeded 1% for at least 3 years (the sampling procedure described in point 1e) of the definition of ‘AD free establishment’ should be applied within the *establishments* of the country or *zone*), and at least 90% of the *establishments* in the country or *zone* are qualified free;

- d) in countries or *zones* with wild swine, measures should be taken to prevent any transmission of the AD virus between wild swine and domestic pigs.

2. Maintenance of provisionally free status

In order to maintain its provisionally free status, a country or *zone* should comply with the following requirements:

- a) the measures described in points 1b) and 1d) above should be continued;
- b) the percentage of infected *establishments* remains <1%;
- c) the importation of the *commodities* with the exception of those listed in Article 8.2.2. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter.

3. Recovery of provisionally free status

Should the percentage of infected *establishments* exceed 1% in a provisionally free country or *zone*, the status of the country or *zone* is cancelled and may be restored only once the percentage of infected *establishments* has remained <1% for at least 6 months, and this result is confirmed by a serological survey conducted in conformity with point 1c) above.

Article 8.2.5.

AD infected country or zone

For the purpose of this chapter, countries and *zones* which do not fulfil the conditions to be considered free or provisionally free of AD should be considered as infected.

Article 8.2.6.

AD free establishment

1. Qualification

To qualify as free from AD, an *establishment* should satisfy the following conditions:

- a) it is under the control of the *Veterinary Authority*;
- b) no clinical, virological or serological evidence of AD has been found for at least one year;
- c) the introduction of pigs, semen and embryos/ova into the *establishment* is carried out in conformity with the import conditions for these *commodities* contained in the relevant articles of the present chapter;
- d) vaccination against AD has not been carried out in the *establishment* for at least 12 months, and any previously vaccinated pigs are free from gE antibodies;
- e) a **number representative sample** of breeding pigs from the *establishment* has been subjected, with negative results, to serological tests to the whole AD virus, applying a sampling procedure set out in conformity with the recommendations in Chapter ~~X.X~~ 1.4. (~~under study~~); these tests

should have been carried out on two occasions, at an interval of 2 months; for *establishments* that contain no breeding pigs, the tests should be carried out only once on a comparable number of fattening or weaning pigs;

- f) a *surveillance* and control programme has been in place to detect infected *establishments* located within a ~~5-kilometre~~ prescribed radius ~~of~~ from the *establishment* and no *establishment* is known to be infected within this *zone*.

2. Maintenance of free status

For *establishments* located in an infected country or *infected zone*, the testing procedure described in point 1e) above should be carried out every 4 months.

For *establishments* located in a provisionally free country or *zone*, the testing procedure described in point 1e) above should be carried out every year.

3. Recovery of free status

Should a free *establishment* become infected, or should an *outbreak* occur within a ~~5-kilometre~~ prescribed radius ~~of~~ from a free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met:

- a) in the infected *establishment*:
- i) all the pigs in the *establishment* have been slaughtered, or
 - ii) at least 30 days after removal of all infected *animals*, all breeding *animals* have been subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of 2 months;
- b) in other *establishments* located within the ~~5-kilometre~~ prescribed radius *zone*: a number of breeding pigs from each *establishment* has been subjected, with negative results, to serological tests to the whole AD virus (non vaccinated *establishments*) or to gE antibodies (vaccinated *establishments*), applying the sampling procedure described in point 1e) above.

Article 8.2.7.

Recommendations for importation from AD free countries or zones

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

Annex XV (contd)

1. showed no clinical sign of AD on the day of shipment;
2. come from an *establishment* located in an AD free country or *zone*;
3. have not been vaccinated against AD.

Article 8.2.8.

Recommendations for importation from AD provisionally free countries or zonesfor domestic pigs for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of AD on the day of shipment;
2. have been kept exclusively in AD free *establishments* since birth;
3. have not been vaccinated against AD;
4. were subjected to a serological test to the whole AD virus, with negative results, within 15 days prior to shipment.

Article 8.2.9.

Recommendations for importation from AD infected countries or zonesfor domestic pigs for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of AD on the day of shipment;
2. were kept exclusively in AD free *establishments* since birth;
3. have not been vaccinated against AD;
4. were isolated in the *establishment* of origin or a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.10.

Recommendations for importation from AD provisionally free countries or zones or AD infected countries or zonesfor domestic pigs for slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. a *surveillance* and control programme is in place in the country or *zone* to detect infected *establishments* and eradicate AD;
2. the *animals*:
 - a) are not being eliminated as part of an eradication programme;
 - b) showed no clinical sign of AD on the day of shipment;

Annex 16 (contd)

- c) have been kept exclusively in AD free *establishments* since birth; or
- d) have been vaccinated against AD at least 15 days prior to shipment.

[*Note: Appropriate precautions should be taken both by the exporting country and the importing country to ensure that the pigs are transported directly from the place of shipment to the abattoir for immediate slaughter.*]

Article 8.2.11.

Recommendations for importation from AD free countries or zonesfor wild swine**EU comment**

Linguistic: the word "swine" should be changed to "pigs": as already stated by former EU comments (and achieved by the TAHSC in many places of the Code), for better clarity throughout the Code, "swine" should only be used as an adjective.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of AD on the day of shipment;
2. were captured in an AD free country or *zone*;
3. have not been vaccinated against the *disease*;
4. were isolated in a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.12.

Recommendations for importation from AD free countries or zonesfor semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) showed no clinical sign of AD on the day of collection of the semen;
 - b) were kept in an *establishment* or *artificial insemination centre* located in an AD free country or *zone* at the time of semen collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.6. and 4.5.

Article 8.2.13.

Recommendations for importation from AD provisionally free countries or zonesfor semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) have been kept for at least 4 months prior to semen collection in an *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every 4 months;
 - b) showed no clinical sign of AD on the day of collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.6. and 4.5.

Article 8.2.14.

Recommendations for importation from AD infected countries or zones

for semen of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) were kept in an AD free *establishment* for at least 6 months prior to entering the *artificial insemination centre*;
 - b) have been kept for at least 4 months prior to semen collection in the *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every 4 months;
 - c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to or 21 days after semen collection;
 - d) showed no clinical sign of AD on the day of collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.6. and 4.5.

Article 8.2.15.

Recommendations for importation from AD free countries or zones

for *in vivo* derived embryos of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) showed no clinical sign of AD on the day of collection of the embryos;
 - b) were kept in an *establishment* located in an AD free country or *zone* prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Annex 16 (contd)

Article 8.2.16.

Recommendations for importation from AD provisionally free countries or zonesfor *in vivo* derived embryos of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) showed no clinical sign of AD on the day of collection of the embryos;
 - b) were kept in an AD free *establishment* for at least 3 months prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.17.

Recommendations for importation from AD infected countries or zonesfor *in vivo* derived embryos of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) showed no clinical sign of AD on the day of collection of the embryos;
 - b) were kept in an AD free *establishment* for at least 3 months prior to collection;
 - c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.2.18.

Recommendations for importation from AD free countries or zonesfor offal (head, and thoracic and abdominal viscera) of pigs or products containing pig offal

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal or products containing pig offal comes from *animals* which come from *establishments* located in an AD free country or *zone*.

Article 8.2.19.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones

Annex 16 (contd)for offal (head, and thoracic and abdominal viscera) of pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal comes from *animals*:

1. which have been kept in an AD free *establishment* since birth;
2. which have not been in contact with *animals* from *establishments* not considered free from AD during their transport to the approved *abattoir* and therein.

Article 8.2.20.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones

for products containing pig offal (head, and thoracic and abdominal viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. either the entire consignment of offal used to prepare the products complied with the conditions referred to in Article 8.2.19.; or
2. the products have been processed to ensure the destruction of the AD virus; and
3. the necessary precautions were taken after processing to avoid contact of the products with any source of AD virus.

— text deleted

CHAPTER 8.3.

BLUETONGUE

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter.

However, there are still some uncertainties as regards the efficiency of vector-protected establishments. It would be valuable to collect and assess data from practical experience when applying such management procedures. Furthermore, the vector protected establishments used should be approved by the competent authority.

Article 8.3.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be 60 days.

Historically, the global BTV distribution has been confined between the latitudes of approximately 53°N and north of 34°S with a recent extension in Northern Europe.

In the absence of clinical *disease* in a country or *zone*, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant population of the *exporting country* or *zone*.

Article 8.3.2.

Safe trade commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any BTV related conditions regardless of the BTV status of the ruminant population of the *exporting country* or *zone*.

1. *milk* and *milk products*;
2. *meat* and *meat products*;
3. hides and skins;
4. wool and fibre;
5. *in vivo* derived bovine embryos and oocytes collected, processed and stored in conformity with the provisions of Chapter 4.7. except for BTV8 (under study).

Article 8.3.3.

BTV free country or zone

1. A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:
 - a) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or
 - b) an **ongoing** *surveillance* programme has demonstrated no evidence of *Culicoides* in the country or *zone*.
2. A BTV free country or *zone* in which ongoing *vector surveillance*, performed according to point 5 of Article 8.3.19., has found no evidence of *Culicoides* will not lose its free status through the importation of vaccinated, seropositive or infective *animals*, or semen or embryos/ova from infected countries or *infected zones*.
3. A BTV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the importation of vaccinated or seropositive *animals* from infected countries or *infected zones*, provided:
 - a) the *animals* have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and the *animals* are identified in the accompanying certification as having been vaccinated; or
 - b) the *animals* are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the *exporting country* or *zone*; ~~or~~
 - ~~c) the *animals* are not vaccinated and a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of at least 60 days immediately prior to dispatch and no evidence of BTV transmission has been detected.~~
4. A BTV free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. *Animals* within this *zone* should be subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 8.3.4.

BTV seasonally free zone

A BTV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a year, *surveillance* demonstrates no evidence either of BTV transmission or of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to conclude either:

1. at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or
2. immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

A BTV seasonally free *zone* in which **ongoing** *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the importation of vaccinated, seropositive or infective *animals*, or semen or embryos/ova from infected countries or *infected zones*.

Article 8.3.5.

BTV infected country or zone

For the purpose of this chapter, a BTV infected country or *infected zone* is a clearly defined area where evidence of BTV has been reported during the past 2 years. **Such a country or zone may contain a BTV seasonally free zone.**

Article 8.3.6.

Recommendations for importation from BTV free countries or zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *animals* were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or
2. the *animals* were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or
3. the *animals* were kept in a BTV free country or *zone* for at least 7 days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual*, and remained in the BTV free country or *zone* until shipment; or
4. the *animals*:
 - a) were kept in a BTV free country or *zone* for at least 7 days;
 - b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.;
 - c) were identified as having been vaccinated; and
 - d) remained in the BTV free country or *zone* until shipment;

AND

5. if the *animals* were exported from a free *zone* **within an infected country** either:
 - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from attack from *Culicoides* at all times when transiting through an *infected zone*; or
 - c) had been vaccinated in accordance with point 4 above.

Article 8.3.7.

Recommendations for importation from BTV seasonally free zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. were kept during the seasonally free period in a BTV seasonally free *zone* since birth or for at least 60 days prior to shipment; or
2. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, with negative results, carried out at least 28 days after the commencement of the residence period; or
3. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after the commencement of the residence period; or
4. were kept during the seasonally free period in a BTV seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. and were identified as having been vaccinated and remained in the BTV free country or *zone* until shipment;

AND

5. **if the animals were exported from a free zone**, either:
 - a) did not transit through an *infected zone* during transportation to the *place of shipment*; or
 - b) were protected from attack from *Culicoides* at all times when transiting through an *infected zone*; or
 - c) were vaccinated in accordance with point 4 above.

Article 8.3.8.

Recommendations for importation from BTV infected countries or zones

for ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. were protected from attack from *Culicoides* in an **insect-proof vector protected** establishment for at least 60 days prior to shipment and during transportation to the *place of shipment*; or
2. were protected from attack from *Culicoides* in an **insect-proof vector protected** establishment for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the **insect-proof vector protected** establishment; or
3. were protected from attack from *Culicoides* in an **insect-proof vector protected** establishment for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the **insect-proof vector protected** establishment; or
4. were vaccinated, at least 60 days before shipment, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated or, if demonstrated to have antibodies, have been protected from *vectors* for at least 60 days prior to shipment; or

5. demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. ~~or~~

~~6. are not vaccinated and a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of at least 60 days immediately prior to dispatch and no evidence of BTV transmission has been detected, and were protected from attack from *Culicoides* during transportation to the *place of shipment*.~~

Article 8.3.9.

Recommendations for importation from BTV free countries or zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.10.

Recommendations for importation from BTV seasonally free zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) were kept during the BTV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.11.

Recommendations for importation from BTV infected countries or zones

for semen of ruminants and other BTV susceptible herbivores

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) were ~~protected from attack from *Culicoides*~~ kept in a vector-protected establishment for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.12.

Recommendations for importation from BTV free countries or zones

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) were kept in a BTV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.13.

Recommendations for importation from BTV seasonally free zones

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.14.

Recommendations for importation from BTV infected countries or zones

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) were protected from attack from *Culicoides* kept in a vector-protected establishment for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.15.

Protecting animals from *Culicoides* attack

1. Vector-protected establishment or facility

The means of protection of the *establishment* or facility should at least comprise the following:

- a) Appropriate physical barriers at entry and exit points, for example, double-door entry-exit system;
- b) openings of the building are vector screened with mesh of appropriate gauge aperture size (under study) impregnated regularly with an approved insecticide according to manufacturers' instruction;
- c) vector surveillance and control within and around the building;
- d) measures to limit or eliminate breeding sites for vectors in the vicinity of the *establishment* or facility;
- e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of horses animals to the place of loading.

2. During transportation

When transporting *animals* through BTV infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect *animals* from attack from *Culicoides* during transport, taking into account the local ecology of the *vector*.

Potential *risk management* strategies include:

- 1a) treating *animals* with insect repellents prior to and during transportation;
- 2b) loading, transporting and unloading *animals* at times of low *vector* activity (i.e. bright sunshine, low temperature);

- 3c) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect proof netting;
- 4d) darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shadecloth;
- 5e) *surveillance* for *vectors* at common stopping and offloading points to gain information on seasonal variations;
- 6f) using historical information and/or information from appropriately verified and validated BTV epidemiological models to identify low risk ports and transport routes.

Article 8.3.16.

Surveillance: introduction

Articles 8.3.16. to 8.3.21. define the principles and provide a guide on the *surveillance* for BT complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5., applicable to Members seeking to determine their BT status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of BT status is also provided.

BT is a *vector*-borne infection transmitted by different species of *Culicoides* insects in a range of ecosystems. An important component of BT epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for BT should focus on transmission in domestic ruminants.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. It is incumbent upon Members to provide scientific data that explain the epidemiology of BT in the region concerned and adapt the *surveillance* strategies for defining their infection status (free, seasonally free or infected country or *zone*) to the local conditions. There is considerable latitude available to Members to justify their infection status at an acceptable level of confidence.

Surveillance for BT should be in the form of a continuing programme.

Article 8.3.17.

Surveillance: case definition

For the purposes of *surveillance*, a *case* refers to an *animal* infected with BT virus (BTV).

For the purposes of *international trade*, a distinction should be made between a *case* as defined below and an *animal* that is potentially infectious to *vectors*. The conditions for trade are defined in Articles 8.3.1. to 8.3.15. of this chapter.

The purpose of *surveillance* is the detection of virus circulation in a country or *zone* and not determination of the status of an individual *animal* or *herds*. *Surveillance* deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of *infection* with BTV in the absence of clinical signs.

The following defines the occurrence of BTV infection:

1. BTV has been isolated and identified as such from an *animal* or a product derived from that *animal*, or
2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more *animals* showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or

3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more *animals* that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with BTV.

Article 8.3.18.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
 - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of BT to a *laboratory* for BT diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
2. The BT *surveillance* programme should:
 - a) in a country/*zone* free or seasonally free, include an early warning system for reporting suspicious *cases*. Farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *Veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of BT should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;
 - b) conduct random or targeted serological and virological *surveillance* appropriate to the infection status of the country or *zone*.

Generally, the conditions to prevent exposure of susceptible *animals* to BTV infected *vectors* will be difficult to apply. However, under specific situations, in establishments such as *artificial insemination centres* or *quarantine stations* exposure to *vectors* may be preventable. The testing requirements for *animals* kept in these facilities are described in Articles 8.3.11. and 8.3.14.

Article 8.3.19.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. Active and passive *surveillance* for BTV infection should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the infection status of the country or *zone*.

The strategy employed may be based on *surveillance* using randomised sampling that would demonstrate the absence of BTV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A Member should justify the *surveillance* strategy chosen as being adequate to detect the presence of BTV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be

appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member wishes to declare freedom from BTV infection in a specific *zone*, the design of the *surveillance* strategy would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease/infection* are technically well defined. The design of *surveillance* programmes to prove the absence of BTV *infection/circulation* needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of BT at the *flock/berd* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

BT suspects detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV infection, and the species available, in the local area. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

Surveillance may include serological surveys, for example *abattoir* surveys, the use of cattle as sentinel *animals* (which should be individually identifiable), or a combination of methods. *Surveillance* may also be conducted by sampling and testing of bulk milk using an ELISA, as prescribed in the *Terrestrial Manual*.

The objective of serological *surveillance* is to detect evidence of BTV circulation. Samples should be examined for antibodies against BTV using tests prescribed in the *Terrestrial Manual*. Positive BTV antibody tests results can have four possible causes:

- a) natural *infection* with BTV,
- b) vaccination against BTV,
- c) maternal antibodies,
- d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for BTV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of BTV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no BTV infection is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the *animals* being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable to select *herds* and/or *animals* for testing.

A *protection zone* within a free country or *zone* should separate it from a potentially infected country or *infected zone*. Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors.

Serological *surveillance* in *infected zones* will identify changes in the boundary of the zone, and can also be used to identify the BTV types circulating. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected *animals* is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* using tests described in the *Terrestrial Manual* can be conducted:

- a) to identify virus circulation in at risk populations,
- b) to confirm clinically suspect *cases*,
- c) to follow up positive serological results,
- d) to better characterize the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel *animals* are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for BTV *surveillance*. They comprise groups of unexposed *animals* managed at fixed locations and sampled regularly to detect new BTV *infections*.

The primary purpose of a sentinel animal programme is to detect BTV infections occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of *infected zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use *animals* of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of BTV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise *animals* selected to be of similar age and susceptibility to BTV infection. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that BTV *infections* are not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on BTVs circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of *vector surveillance* is to determine areas of different levels of risk and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess *vector* suppression measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminant *animals*.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used in *vector surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel *animals* is advisable.

Annex 17 (contd)

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector* infection rates mean that such detections can be rare. Other *surveillance* strategies (e.g. the use of sentinel *animals* of domestic ruminants) are preferred to detect virus circulation.

Article 8.3.20.

Documentation of BTV infection free status

1. Members declaring freedom from BTV infection for the country or zone: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring freedom from BTV infection for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of BTV infection during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of BTV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* should be targeted to non-vaccinated *animals*. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of BTV *infection* in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

In countries or *zones* that practise vaccination, there is a need to perform virological and serological tests to ensure the absence of virus circulation. These tests should be performed on non-vaccinated subpopulations or on sentinels. The tests have to be repeated at appropriate intervals according to the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

Article 8.3.21.

The use and interpretation of serological and virus detection tests

1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do *animals* vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

2. Virus detection

The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

- a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.
- b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect *vectors* or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

Fig. 1. Application of laboratory tests in serological surveillance

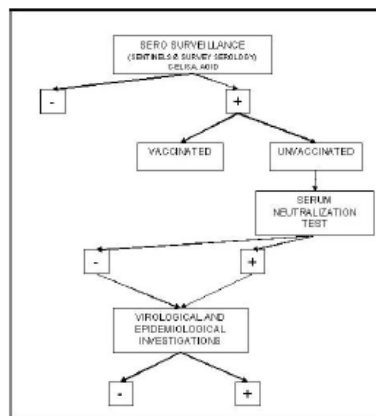
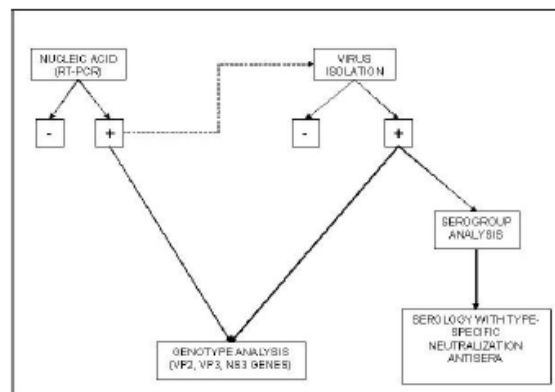


Fig. 2. Application of laboratory tests in virological surveillance



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CHAPTER 8.5.

FOOT AND MOUTH DISEASE

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter.

However, the EU wishes to reiterate its comment about the recommendations for importation of milk and milk products intended for use in animal feeding, which is not covered by Article 8.5.27: in a future revision of the chapter, this should be addressed. EU comment is inserted in the text below.

Some editorial comments are also inserted for consistency.

Article 8.5.1.

Introduction

For the purposes of the *Terrestrial Code*, the *incubation period* for foot and mouth disease (FMD) shall be 14 days.

For the purposes of this Chapter, ruminants include *animals* of the family of Camelidae (except *Camelus dromedarius*).

For the purposes of this Chapter, a case ~~includes~~ **is** an *animal* infected with FMD virus (FMDV).

~~For the purposes of international trade, this~~ **The** Chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV infection:

1. FMDV has been isolated and identified as such from an *animal* or a product derived from that *animal*; or
2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more *animals*, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more *animals* showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.5.2.

FMD free country where vaccination is not practised

Susceptible *animals* in the FMD free country where vaccination is not practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
 - a) there has been no *outbreak* of FMD during the past 12 months;
 - b) no evidence of FMDV infection has been found during the past 12 months;
 - c) no vaccination against FMD has been carried out during the past 12 months;
 - d) no vaccinated *animal* has been introduced since the cessation of vaccination;
3. supply documented evidence that:
 - a) *surveillance* for FMD and FMDV infection in accordance with Articles 8.5.42. to 8.5.48. is in operation;
 - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
4. describe in detail the boundaries and measures of a *protection zone*, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.3.

FMD free country where vaccination is practised

Susceptible *animals* in the FMD free country where vaccination is practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free countries where vaccination is practised, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that:
 - a) there has been no *outbreak* of FMD during the past 2 years;
 - b) no evidence of FMDV circulation has been found during the past 12 months;
3. supply documented evidence that:
 - a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.42. to 8.5.48. is in operation;
 - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

- c) routine vaccination is carried out for the purpose of the prevention of FMD;
 - d) the vaccine used complies with the standards described in the *Terrestrial Manual* and is appropriate for the strains of virus currently circulating;
4. describe in detail the boundaries and measures of a *protection zone*, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in point 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of a FMD free country where vaccination is practised wishes to change its status to FMD free country where vaccination is not practised, the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred during that period.

Article 8.5.4.

FMD free zone where vaccination is not practised

An FMD free *zone* where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that within the proposed FMD free *zone*.
 - a) there has been no *outbreak* of FMD during the past 12 months;
 - b) no evidence of FMDV infection has been found during the past 12 months;
 - c) no vaccination against FMD has been carried out during the past 12 months;
 - d) no vaccinated *animal* has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.;
3. supply documented evidence that:
 - a) *surveillance* for FMD and FMDV infection in accordance with Articles 8.5.42. to 8.5.48. is in operation;
 - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
 - a) the boundaries of the proposed FMD free *zone*,
 - b) the boundaries and measures of a *protection zone*, if applicable,

Annex 18 (contd)

- c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMDV free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is not practised only after the submitted evidence has been accepted by the OIE.

The information required in points 2, 3 and 4b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 ~~b)-c)~~ should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.5.

FMD free zone where vaccination is practised

An FMD free *zone* where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* where vaccination is practised should be protected from neighbouring countries or *zones* if they are of a lesser *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where vaccination is practised, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE that within the proposed FMD free *zone*;
 - a) there has been no *outbreak* of FMD for the past 2 years;
 - b) no evidence of FMDV circulation has been found during the past 12 months;
3. supply documented evidence that:
 - a) *surveillance* for FMD and FMDV infection ~~/circulation~~ in accordance with Articles 8.5.42. to 8.5.48. is in operation;
 - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
 - c) routine vaccination is carried out for the purpose of the prevention of FMD;
 - d) the vaccine used complies with the standards described in the *Terrestrial Manual* ~~and is appropriate for the strains of virus currently circulating;~~
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
 - a) the boundaries of the proposed FMD free *zone*,
 - b) the boundaries and measures of a *protection zone*, if applicable,

Annex 18 (contd)

- c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 b)-c) should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a *zone* which meets the requirements of a FMD free *zone* where vaccination is practised wishes to change the status of the *zone* to FMD free *zone* where vaccination is not practised, the status of this *zone* remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred in the said *zone* during that period.

Article 8.5.6.

FMD free compartment

A FMD free *compartment* can be established in either a FMD free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible *animals* in the FMD free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member wishing to establish a FMD free *compartment* should:

1. have a record of regular and prompt animal disease reporting and if not FMD free, have an *official control programme* and a *surveillance* system for FMD in place according to Articles 8.5.42. to 8.5.44. that allows an accurate knowledge of the prevalence of FMD in the country or *zone*;
2. declare for the FMD free *compartment* that:
 - a) there has been no *outbreak* of FMD during the past 12 months;
 - b) no evidence of FMDV infection has been found during the past 12 months;
 - c) vaccination against FMD is prohibited;
 - d) no *animal* vaccinated against FMD within the past 12 months is in the *compartment*;
 - e) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant Articles in this chapter;
 - f) documented evidence shows that *surveillance* in accordance with Articles 8.5.42. to 8.5.48. is in operation for FMD and FMDV infection;
 - g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
3. describe in detail the animal subpopulation in the *compartment* and the biosecurity plan for FMD and FMDV infection.

Annex 18 (contd)

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *outbreak* of FMD has occurred within the *zone* in which the *compartment* is situated, during the last 3 months.

Article 8.5.7.

FMD infected country or zone

For the purpose of this Chapter, an FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.

For the purpose of this Chapter, an FMD ~~infected~~ **infected** *zone* is a *zone* that does not fulfil the requirements to qualify as either an FMD free *zone* where vaccination is not practised or an FMD free *zone* where vaccination is practised.

Article 8.5.7bis.**OIE endorsed national FMD control programme**

Countries may apply for endorsement of their national FMD control programme when they have implemented measures that could potentially lead to OIE official recognition of FMD free status.

For a Member's national FMD control programme to be endorsed by the OIE, the Member should:

1. have submitted documented evidence on the capacity of the veterinary services to control FMD; this evidence can be provided by countries following the OIE PVS pathway to identify gaps and the strategies to strengthen the veterinary services to sustainably control FMD;
2. submit documentation indicating that the national FMD control programme consistent with the recommendation of Chapter 8.5. is applicable to the entire territory or *zone*;
3. have a record of regular and prompt animal disease reporting according to the requirements in Chapter 1.1.;
4. have submitted a dossier on the epidemiology of FMD in the country describing the following:
 - a) the general epidemiology of FMD in the country highlighting the current knowledge and gaps;
 - b) the measures to prevent introduction of *infection* from neighbouring countries;
 - c) the prevailing livestock production systems and movement patterns of FMD susceptible *animals* and their products within and into the country;
5. have submitted a detailed plan on the approach to control and eventually eradicate FMD in the country or *zone* including:
 - a) the timeline of the control programme;
 - b) the performance indicators to assess the efficacy of the control measures implemented in the framework of the programme;
6. have submitted evidence that FMD *surveillance*, taking into account provisions in Chapter 1.4. of the *Terrestrial Code* and the provisions on *surveillance* of this Chapter, is in place;

Annex 18 (contd)

~~7. have diagnostic capability and procedures which include regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*;~~

~~8. where vaccination is practised as a part of national FMD control programme, provide legislation making vaccination compulsory on selected populations;~~

~~9. if applicable, provide detailed information on vaccination campaigns in particular on:~~

~~a) target populations for vaccination;~~

~~b) monitoring of vaccination coverage, including serological monitoring of population immunity;~~

~~c) technical specification of the vaccines used and description of the licensing procedures in place;~~

~~d) the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the *Terrestrial Manual*;~~

~~10. provide an Emergency Preparedness and Response Plan which is implemented in case of outbreaks;~~

~~The Member's national programme will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the FMD control programme and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~The OIE may withdraw the endorsement of the national FMD control programme if there is evidence of:~~

~~11. a decreased capability of the veterinary services, or~~

~~12. an uncontrolled increase in incidence of FMD.~~

Article 8.5.8.

Establishment of a containment zone within an FMD free country or zone

In the event of limited *outbreaks* within an FMD free country or *zone*, including within a *protection zone*, with or without vaccination, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*. For this to be achieved and for the Member to take full advantage of this process, the *Veterinary Authority* should ~~provide~~ submit documented evidence as soon as possible to the OIE that:

1. the *outbreaks* are limited based on the following factors:

a) immediately on suspicion, a rapid response including notification has been made;

b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;

c) epidemiological investigation (trace-back, trace-forward) has been completed;

d) the *infection* has been confirmed;

Annex 18 (contd)

- e) the primary *outbreak* has been identified and investigations on the likely source of the outbreak has been identified ~~have been carried out~~;
 - f) all *cases* have been shown to be epidemiologically linked;
 - g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;
2. a *stamping-out policy* has been applied;
 3. the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*;
 4. increased passive and targeted *surveillance* in accordance with Articles 8.5.42. to 8.5.48. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;
 5. animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place;
 6. ongoing *surveillance* in the *containment zone* is in place.

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated irrespective of the provisions of Article 8.5.9., once the *containment zone* is clearly established, by complying with points 1 to 6 above. The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.5.9.

Article 8.5.9.

Recovery of free status

1. When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is not practised:
 - a) 3 months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.5.42. to 8.5.48.; or
 - b) 3 months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency vaccination and serological *surveillance* are applied in accordance with Articles 8.5.42. to 8.5.48.; or
 - c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated *animals*, and serological *surveillance* are applied in accordance with Articles 8.5.42. to 8.5.48., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. or 8.5.4. applies.

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2. When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where vaccination is practised:
 - a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological *surveillance* in accordance with Articles 8.5.42. to 8.5.48. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or
 - b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological *surveillance* in accordance with Articles 8.5.42. to 8.5.48. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.
3. When a FMD *outbreak* or FMDV infection occurs in a FMD free *compartment*, Article 8.5.6. applies.

Article 8.5.10.

Direct transfer directly to slaughter of FMD susceptible animals from an infected zone for slaughter to in a free zone (where vaccination either is or is not practised) within a country

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *infected zone* if ~~moved transported by mechanised transport~~ directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1. no FMD susceptible *animal* has been introduced into the *establishment* of origin and no *animal* in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
2. the *animals* were kept in the *establishment* of origin for at least 3 months prior to movement;
3. FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least 3 months prior to movement;
4. the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;
5. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *infected zone*;
6. *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be treated according to Article 8.5.25. or Article 8.5.26. Other products obtained from the *animals* and any products coming into contact with them should be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.5.34. to 8.5.41.

Animals moved into a free *zone* for other purposes should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.5.14.

Annex 18 (contd)

Article 8.5.11.

Transfer directly to slaughter of FMD susceptible animals from a containment zone to a free zone (where vaccination either is or is not practised) within a country

EU comment

The wording of title of Article 8.5.11 should be changed for consistency with Article 8.5.10 and read:

Direct-Transfer directly to slaughter of FMD susceptible animals from an containment zone for slaughter to in a free zone (where vaccination either is or is not practised) within a country

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *containment zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

EU comment

The wording of the paragraph above should be changed for consistency with Article 8.5.10 and the words "moved by mechanised transport" should be replaced by "transported".

1. the *containment zone* has been officially established according to the requirements in Article 8.5.8.;
2. the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the establishment of origin to the *abattoir* without coming into contact with other susceptible *animals*;
3. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *containment zone*;
4. *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be treated according to point 2 of Article 8.5.25. or Article 8.5.26. Other products obtained from the *animals* and any products coming into contact with them should be treated in such a way as to destroy any residual virus in accordance with Articles 8.5.34. to 8.5.41.

Article 8.5.12.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

for FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of FMD on the day of shipment;
2. were kept since birth or for at least the past 3 months in a FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*;
3. have not been vaccinated;
4. if transiting an *infected zone*, were not exposed to any source of FMD~~V~~ infection during transportation to the *place of shipment*.

Article 8.5.13.

Recommendations for importation from FMD free countries or zones where vaccination is practisedfor domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in an FMD free country or *zone* since birth or for at least the past 3 months; and
3. have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, when destined to an FMD free country or *zone* where vaccination is not practised;
4. if transiting an *infected zone*, were not exposed to any source of FMDV infection during transportation to the *place of shipment*.

Article 8.5.14.

Recommendations for importation from FMD infected countries or zonesfor domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of FMD on the day of shipment;
2. were kept in the *establishment* of origin since birth, or
 - a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or
 - b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*,
 and that FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and
3. were isolated in an *establishment* for the 30 days prior to shipment, and all *animals* in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* during that period; or
4. were kept in a *quarantine station* for the 30 days prior to shipment, all *animals* in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;
5. were not exposed to any source of FMDV infection during their transportation from the *quarantine station* to the *place of shipment*.

Article 8.5.15.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

for fresh semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept for at least 3 months prior to collection in a FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.16.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments

for frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least 3 months prior to collection in an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.17.

Recommendations for importation from FMD free countries or zones where vaccination is practised

for semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least 3 months prior to collection in a FMD free country or *zone*;
 - c) if destined to an FMD free country or *zone* where vaccination is not practised:
 - i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
 - ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

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2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
3. the semen:
 - a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;
 - b) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.18.

Recommendations for importation from FMD infected countries or zones

for semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept in an *establishment* where no *animal* had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;
 - c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or
 - d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;
2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;
3. the semen:
 - a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;
 - b) was subjected, with negative results, to a test for FMDV *infection* if the donor *animal* has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.19.

Recommendations for the importation of *in vivo* derived embryos of cattle

Irrespective of the FMD status of the *exporting country, zone or compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

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Article 8.5.20.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartmentsfor *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept at the time of collection in a FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*;
2. fertilisation was achieved with semen meeting the conditions referred to in Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18., as relevant;
3. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.21.

Recommendations for importation from FMD free countries or zones where vaccination is practisedfor *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least 3 months prior to collection in a FMD free country or *zone* where vaccination is practised;
 - c) if destined for an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*:
 - i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or
 - ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;
2. no other *animal* present in the *establishment* has been vaccinated within the month prior to collection;
3. fertilization was achieved with semen meeting the conditions referred to in Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18., as relevant;
4. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.22.

Recommendations for importation from FMD free countries or zones where vaccination is ~~or is~~ not practised or ~~from~~ FMD free compartments

for fresh meat or meat products of FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1. have been kept in the FMD free country or *zone* where vaccination is ~~or is~~ not practised, or ~~in~~ a FMD free *compartment* since birth, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;
2. have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

Article 8.5.23.**Recommendations for importation from FMD free countries or zones where vaccination is practised**

for fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1. have been kept in the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;
2. have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

Article 8.5.24.**Recommendations for importation from FMD free countries or zones where vaccination is practised**

for fresh meat or meat products of pigs and ruminants other than cattle and buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1. have been kept in the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;
2. have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

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Article 8.5.25.

Recommendations for importation from FMD infected countries or zones, where an official national FMD control programme for FMD exists, involving compulsory systematic vaccination of cattle, exists has been endorsed by the OIE

for fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat*:

1. comes from *animals* which:
 - a) have remained in the *exporting country* for at least 3 months prior to *slaughter*;
 - b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;
 - c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to *slaughter*;
 - d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;
 - e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;
 - f) have been slaughtered in an approved *abattoir*:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
 - g) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;
2. comes from deboned carcasses:
 - a) from which the major lymphatic nodes have been removed;
 - b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 8.5.26.

Recommendations for importation from FMD infected countries or zones

for meat products of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

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1. the entire consignment of *meat* comes from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;
2. the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.34.;
3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.5.27.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised) or FMD free compartments

for milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.

EU comment

The article 8.5.27 is not clear enough and could lead to confusion. Indeed, it clearly does not apply to milk for animal consumption, but could nevertheless be interpreted as such, because there is no other article covering this situation, where the risk would be higher.

Thus the EU proposes to add a new article 8.5.27 bis as follows:

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised) or FMD free compartments

for milk and milk products intended for use in animal feeding

***Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in a FMD free country or *zone* where vaccination is not practised or a free compartment, or that the products have been processed in conformity with the procedures referred to in article 8.5.39.**

Article 8.5.28.

Recommendations for importation from FMD infected countries or zones where an *official control programme* exists

EU comment

The words "for FMD" should be added after "*official control programme*" for consistency with title of Article 8.5.25.

for milk, cream, milk powder and milk products

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. these products:

- a) originate from *herds* or *flocks* which were not infected or suspected of being infected with FMD at the time of *milk* collection;
 - b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.38. and in Article 8.5.39.;
2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.29.

Recommendations for importation from FMD infected countries

for blood and meat-meals (from domestic or wild ruminants and pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 8.5.30.

Recommendations for importation from FMD infected countries

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.35., 8.5.36. and 8.5.37.;
2. the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather - e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.5.31.

Recommendations for importation from FMD infected countries or zones

for straw and forage

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these *commodities*:

1. are free of grossly identifiable contamination with material of animal origin;
2. have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least 10 minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least 8 hours and at a minimum temperature of 19°C;

OR

3. have been kept in bond for at least 3 months (under study) before being released for export.

Article 8.5.32.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

for skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from *animals* that have been killed in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where vaccination either is or is not practised).

Article 8.5.33.

Recommendations for importation from FMD infected countries or zones

for skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 8.5.40.

Article 8.5.34.

Procedures for the inactivation of the FMD virus in meat

For the inactivation of viruses present in *meat*, one of the following procedures should be used:

1. Canning

Meat is subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

When *rigor mortis* is complete, the *meat* must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 8.5.35.

Procedures for the inactivation of the FMD virus in wool and hair

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
2. chemical depilation by means of slaked lime or sodium sulphide;
3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;

Annex 18 (contd)

4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;
5. storage of wool at 18°C for 4 weeks, or 4°C for 4 months, or 37°C for 8 days.

Article 8.5.36.

Procedures for the inactivation of the FMD virus in bristles

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1. boiling for at least one hour;
2. immersion for at least 24 hours in a 1% solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 8.5.37.

Procedures for the inactivation of the FMD virus in raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2% sodium carbonate.

Article 8.5.38.

Procedures for the inactivation of the FMD virus in milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1. a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or
2. if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or
3. if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 8.5.39.

Procedures for the inactivation of the FMD virus in milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1. the HTST process applied twice;
2. HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation;
3. UHT combined with another physical treatment referred to in point 2 above.

Article 8.5.40.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of viruses present in skins and trophies from wild *animals* susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;
2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
3. soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate - Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours;
4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na₂CO₃).

Article 8.5.41.

Procedures for the inactivation of the FMD virus in casings of ruminants and pigs

For the inactivation of viruses present in casings of ruminants and pigs, the following procedures should be used:

salting for at least 30 days either with dry salt (NaCl) or with saturated brine ($A_w < 0.80$), or with phosphate supplemented dry salt containing 86.5% NaCl, 10.7% Na₂HPO₄ and 2.8% Na₃PO₄ (weight/weight/weight) salts/sodium chloride mixture, and kept at room temperature of greater than 12 of about 20°C during this entire period.

EU comment

The inactivation procedure above should also allow the use of the same phosphate salts / sodium chloride mixture as saturated brine since this is a standard industrial process for the preservation of casings.

Article 8.5.42.

Surveillance: introduction

Articles 8.5.42. to 8.5.48. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from FMD, either with or without the use of vaccination. Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination, or a *compartment*, following an *outbreak* and for the maintenance of FMD status.

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*. It is incumbent upon the Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

Surveillance for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.

For the purposes of this Chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 8.5.43.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect *cases* of FMD to a *laboratory* for FMD diagnoses as described in the *Terrestrial Manual*.
2. The FMD *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect *cases* of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control;
 - b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to an FMD infected country or *infected zone* (for example, bordering a game park in which infected wildlife are present).

An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV *infection*/circulation should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 8.5.44.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country, *zone* or *compartment*.

The design of *surveillance* programmes to prove the absence of FMDV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.

Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection*/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* which may be epidemiologically linked to it.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of FMD by close physical examination of susceptible *animals*. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical *cases* is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such *animals*. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.

3. Virological surveillance

Virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted:

- a) to monitor at risk populations;
- b) to confirm clinically suspect *cases*;
- c) to follow up positive serological results;
- d) to test “normal” daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against FMDV. Positive FMDV antibody test results can have four possible causes:

- a) natural *infection* with FMDV;
- b) vaccination against FMD;
- c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);
- d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD *surveillance*. However, the principles of survey design described in this Chapter and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV *infection* is not present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Annex 18 (contd)

Article 8.5.45.

Members applying for recognition of freedom from FMD for the whole country or a zone where vaccination is not practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of FMD freedom for the country or a *zone* where vaccination is not practised should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Chapter, to demonstrate absence of FMDV *infection*, during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 8.5.46.

Members applying for recognition of freedom from FMD for the whole country or a zone where vaccination is practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with vaccination should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this Chapter. Absence of clinical *disease* in the country or *zone* for the past 2 years should be demonstrated. Furthermore, *surveillance* should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should, ~~in general,~~ be for to vaccinate at least 80% of the animals in each vaccinated the susceptible population to be have protective immunity ~~see~~. The vaccine must comply with the *Terrestrial Manual*. Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme should be provided.

Article 8.5.47.

Members re-applying for recognition of freedom from FMD for the whole country or a zone where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a country re-applying for country or *zone* freedom from FMD where vaccination is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection*/circulation. This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

Annex 18 (contd)

Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection* following an *outbreak*:

1. *slaughter* of all clinically affected and in-contact susceptible *animals*;
2. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, with subsequent *slaughter* of vaccinated *animals*;
3. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals*;
4. vaccination used without *slaughter* of affected *animals* or subsequent *slaughter* of vaccinated *animals*.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.

In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active *surveillance* programme implemented according to general conditions and methods in this Chapter.

Article 8.5.47bis.OIE endorsed official control programme for FMD

The overall objective of an OIE endorsed official control programme for FMD is for countries to progressively improve the situation and eventually attain free status for FMD.

Members may, on a voluntary basis, apply for endorsement of their official control programme for FMD when they have implemented measures in accordance with this article.

For a Member's official control programme for FMD to be endorsed by the OIE, the Member should:

1. submit documented evidence on the capacity of the veterinary services to control FMD. This evidence can be provided by countries following the OIE PVS Pathway;
2. submit documentation indicating that the official control programme for FMD is applicable to the entire territory;
3. have a record of regular and prompt animal disease reporting according to the requirements in Chapter 1.1.;
4. submit a dossier on the epidemiology of FMD in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps;
 - b) the measures to prevent introduction of infection;
 - c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;

Annex 18 (contd)

5. submit a detailed plan on the programme to control and eventually eradicate FMD in the country or zone including:
 - a) the timeline;
 - b) the performance indicators to assess the efficacy of the control measures to be implemented;
6. submit evidence that FMD surveillance, taking into account provisions in Chapter 1.4. and the provisions on surveillance of this Chapter, is in place;
7. have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual*;
8. where vaccination is practised as a part of the *official control programme* for FMD, provide evidence (such as copies of legislation) that vaccination of selected populations is compulsory;
9. if applicable, provide detailed information on vaccination campaigns, in particular on:
 - a) target populations for vaccination;
 - b) monitoring of vaccination coverage, including serological monitoring of population immunity;
 - c) technical specification of the vaccines used and description of the licensing procedures in place;
 - d) the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the *Terrestrial Manual*;
10. provide an emergency preparedness and response plan to be implemented in case of outbreaks.

The Member's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the *Veterinary Services*; or
- an increase in the incidence of FMD that cannot be addressed by the programme.

Annex 18 (contd)

Article 8.5.48.

The use and interpretation of serological tests (see Figure 1)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. *Animals* vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected *animals* that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection/circulation* if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results.

In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However, NSP antibody tests should be used to monitor for FMDV *infection/circulation*. NSP-ELISAs may be used for screening sera for evidence of *infection/circulation* irrespective of the vaccination status of the *animal*. All *herds* with seropositive reactors should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection/circulation* for each positive *herd*. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

1. The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination

Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor *animal* at hand, of susceptible *animals* of the same *epidemiological unit* and of susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal*. If the follow-up investigations provide no evidence for FMDV *infection*, the reactor *animal* shall be classified as FMD negative. In all other cases, including the absence of such follow-up investigations, the reactor *animal* should be classified as FMD positive.

Annex 18 (contd)2. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination

In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

It is suggested that in the primary sampling units where at least one *animal* reacts positive to the NSP test, the following strategy(ies) should be applied:

- a. Following clinical examination, a second serum sample should be taken from the *animals* tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of *animals* with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.

The *animals* sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all *animals* tested are individually identified. These *animals* should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

- b. Following clinical examination, serum samples should be collected from representative numbers of susceptible *animals* that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.
- c. Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.
- d. Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence.

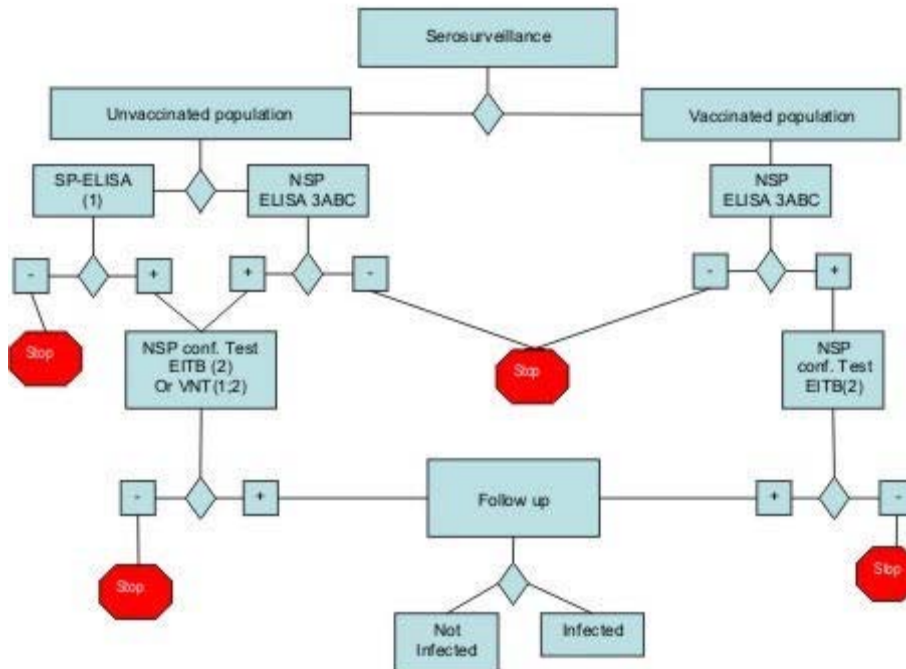
Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- characterization of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- quantification of vaccinations performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;
- control of *animal identification* and movements;
- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

Annex 18 (contd)

Fig. 1. Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys



Key:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Electro-immuno transfer blotting technique (Western blot for NSP antibodies of FMDV)
SP	Structural protein test
S	No evidence of FMDV

 — text deleted

CHAPTER 1.6.

**~~STATUS FOR OIE LISTED DISEASES:~~
PROCEDURES FOR SELF DECLARATION AND
FOR OFFICIAL RECOGNITION BY THE OIE**

EU position

The EU supports in general the adoption of this modified chapter.

Article 1.6.1.

General principles

Members may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), rinderpest and contagious bovine pleuropneumonia (CBPP).

Members may request official recognition by the OIE as to:

1. the risk status of a country or *zone* with regard to BSE;
2. the freedom of a country or *zone* from FMD, with or without vaccination;
3. the freedom of a country from rinderpest;
4. the freedom of a country or *zone* from CBPP.

The OIE does not grant official recognition for other *diseases*.

In these cases, Members should present documentation setting out the compliance of the *Veterinary Services* of the applicant country or *zone* with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant *disease* chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status, the Member should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.2. (for BSE), 1.6.3. (for FMD), 1.6.4. (for rinderpest) or 1.6.5. (for CBPP).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXII (administrative procedures) and Resolution N° XXIII (financial obligations) adopted during the 76th General Session in May 2008.

Article 1.6.1.bis**Endorsement by the OIE of an official control programme for FMD**

Members may wish to request an endorsement by the OIE of their official control programme for FMD.

When requesting endorsement by the OIE of an official control programme for FMD, the Member should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.5.bis.

Annex 19 (contd)

[Article 1.6.2. BSE: no change]

Article 1.6.3.

Questionnaires on foot and mouth disease**FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED**

Report of a Member which applies for recognition of status, under Chapter 8.5. of the *Terrestrial Animal Health Code* (2010), as a FMD free country not practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication.
- c) Vaccines and vaccination. Was FMD vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated?
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

Annex 19 (contd)

- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
- i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of participation in inter-laboratory validation tests (ring tests).
 - iii) Is live virus handled?
 - iv) Biosecurity measures applied.
 - v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.5.42. to 8.5.48. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

Annex 19 (contd)

- d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.
- b) Are there controls in place for the swill feeding to pigs of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and surveillance measures.

b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past two years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of an FMD *outbreak*:
 - i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
 - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
 - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
 - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

- a) In addition to the documentary evidence that the provisions of Article 8.5.2. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:
 - i) there has been no *outbreak* of FMD during the past 12 months;
 - ii) no evidence of FMDV *infection* has been found during the past 12 months;
 - iii) no vaccination against FMD has been carried out during the past 12 months,
- b) and should confirm that since the cessation of vaccination no *animals* vaccinated against FMD have been imported.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 19 (contd)**FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED**

Report of a Member which applies for recognition of status, under Chapter 8.5. of the *Terrestrial Animal Health Code* (2010), as a FMD free country practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country, provide date of first detection, origin of *infection*, date of eradication (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication.
- c) Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability, including vaccination data. How are animal movements controlled in the country?

Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to and the follow-up procedures and the timeframe for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of participation in inter-laboratory validation tests (ring tests).
 - iii) Is live virus handled?
 - iv) Biosecurity measures applied.
 - v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.5.42. to 8.5.48. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.46.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?

- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and surveillance measures.

bc) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past two years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
- *animals*,
 - genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.

- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of an FMD *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
 - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
 - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
 - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:

- a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.42. to 8.5.48. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- b) routine vaccination is carried out for the purpose of the prevention of FMD;
- c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 19 (contd)**FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED**

Report of a Member which applies for recognition of status, under Chapter 8.5. of the *Terrestrial Animal Health Code* (2010), as a FMD free zone not practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out), provide timeframe for eradication.
- c) Vaccines and vaccination. If vaccination is used in the rest of the country, what type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).

- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.5.10. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
 - a) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - b) Give details of participation in inter-laboratory validation tests (ring tests).
 - c) Is live virus handled?
 - d) Biosecurity measures applied.
 - e) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with the provisions of Articles 8.5.42. to 8.5.48. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past 2 years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* without vaccination is situated in an FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and surveillance measures.

bc) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 2 years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - genetic material (semen and embryos),

- animal products,
 - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of an FMD *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
 - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
 - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
 - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.4. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) there has been no *outbreak* of FMD during the past 12 months;
- b) no evidence of FMDV *infection* has been found during the past 12 months;
- c) no vaccination against FMD has been carried out during the past 12 months;
- d) no vaccinated animal has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 19 (contd)**FMD FREE ZONE WHERE VACCINATION IS PRACTISED**

Report of a Member which applies for recognition of status, under Chapter 8.5. of the *Terrestrial Animal Health Code* (2010), as a FMD free zone practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out), provide timeframe for eradication.
- c) Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme in the country and in the *zone*, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

Annex 19 (contd)

- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability, including vaccination data. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.5.10. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points.
- i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of participation in inter-laboratory validation tests (ring tests).
 - iii) Is live virus handled?
 - iv) Biosecurity measures applied.
 - v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with the provisions of Articles 8.5.42. to 8.5.48. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.46.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past 2 years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

Annex 19 (contd)

- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country and in the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* with vaccination is situated in an FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and surveillance measures.

bc Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying the country or *zone* of origin, the species and the volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 2 years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,

- genetic material (semen and embryos),
 - animal products,
 - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of an FMD *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
 - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
 - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
 - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the Terrestrial Code

In addition to the documentary evidence that the provisions of Article 8.5.5. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) that there has been no *outbreak* of FMD for the past 2 years,
- b) no evidence of FMDV circulation for the past 12 months,
- c) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.42. to 8.5.48. is in operation.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.9. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

[Article 1.6.4. RP: no change]

Questionnaire on contagious bovine pleuropneumonia**CBPP FREE COUNTRY**

Report of a Member which applies for recognition of status, under Chapter 11.8. of the *Terrestrial Animal Health Code* (2010), as a CBPP free country

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to CBPP.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all CBPP related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in CBPP *surveillance* and control (include a description of training and awareness programmes on CBPP).
- d) Role of private veterinary profession in CBPP *surveillance* and control.

3. CBPP eradication

- a) History. Provide a description of the CBPP history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*).
- b) Strategy. Describe how CBPP was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), and provide timeframe for eradication.

Annex 19 (contd)

- c) Vaccines and vaccination. Was CBPP vaccine ever used? If so, when was the last vaccination carried out?
- d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the CBPP approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of participation in inter-laboratory validation tests (ring tests).
 - iii) Biosecurity measures applied.
 - iv) Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.8.12. to 11.8.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Slaughterhouses, *slaughter* slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).

Annex 19 (contd)

- c) Provide details on training programmes for personnel involved in clinical and *slaughter* facilities *surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.
- d) For countries where a significant proportion of *animals* are not slaughtered in controlled *abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programmes, laboratory follow-up).
- e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds* of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- f) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?
- g) Provide a description of the means employed during the 2 years preceding this application to rule out the presence of any *MmmSC* strain in the susceptible population. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.
- b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
 - *animals*,
 - semen, embryos and oocytes,

- veterinary medicinal products (i.e. biologics).
- iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of CBPP.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of a CBPP *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;
 - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken;
 - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
 - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 11.8.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) no clinical CBPP has been detected for at least 2 years;
- b) no CBPP vaccines have been used for at least 2 years in any susceptible species;
- c) the country operates both clinical *surveillance* and *disease* reporting systems for CBPP adequate to detect clinical *disease* if it were present;
- d) all clinical and pathological evidence suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;
- e) there are effective measures in force to prevent the re-introduction of the *disease*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 11.8.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 19 (contd)**CBPP FREE ZONE**

Report of a Member which applies for recognition of status, under Chapter 11.8. of the *Terrestrial Animal Health Code* (2010), as a CBPP free zone

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above. The boundaries of the *zone* must be clearly defined. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to CBPP.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all CBPP related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in CBPP *surveillance* and control (include a description of training and awareness programmes on CBPP).
- d) Role of private veterinary profession in CBPP *surveillance* and control.

3. CBPP eradication

- a) History. Provide a description of the CBPP history in the *zone*, date of first detection, origin of *infection*, date of eradication (date of last *case*).
- b) Strategy. Describe how CBPP was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out, zoning) and provide timeframe for eradication.
- c) Vaccines and vaccination. Was CBPP vaccine ever used? In the entire country? If vaccination was used, when was the last vaccination carried out? Where in the country?
- d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the *zone*? Provide evidence on the

effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the CBPP approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of participation in inter-laboratory validation tests (ring tests).
 - iii) Biosecurity measures applied.
 - iv) Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.8.12. to 11.8.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Slaughterhouses, *slaughter* slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- c) Provide details on training programmes for personnel involved in clinical and *slaughter* facilities *surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.
- d) For countries where a significant proportion of *animals* in the *zone* are not slaughtered in controlled abattoirs, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programme, laboratory follow-up).
- e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds* of each susceptible species are in the *zone*? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.

- f) Slaughterhouses and *markets*. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country and the *zone*? How are the *animals* transported and handled during these transactions?
- g) Provide a description of the means employed during the 2 years preceding this application to rule out the presence of any *MmmSC* strain in the susceptible population of the *zone*. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals examined* and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

- a) Coordination with neighbouring countries and *zones*. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. If the CBPP free *zone* is situated in a CBPP infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the *zone* and/or their final destination, concerning the import and follow-up of the following:
- *animals*,
 - semen, embryos and oocytes,
 - veterinary medicinal products (i.e. biologics).
- iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of CBPP.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

- c) In the event of a CBPP *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;
 - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken;
 - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
 - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes.

8. Compliance with the Terrestrial Code

In addition to the documentary evidence that the provisions of Article 11.8.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that in the *zone*:

- a) no clinical CBPP has been detected for at least 2 years;
- b) no CBPP vaccines have been used for at least 2 years in any susceptible species;
- c) the country operates both clinical *surveillance* and *disease* reporting systems for CBPP adequate to detect clinical *disease* if it were present in the *zone*;
- d) all clinical and pathological suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;
- e) there are effective measures in force to prevent the re-introduction of the *disease*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 11.8.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

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- 1 Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed. Therefore, for the purposes of serosurveillance, it should be noted that a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffalos 24-48 months) and b) cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffalos 48-60 months).

Annex 19 (contd)

Article 1.6.5.bis

COUNTRY WITH AN OIE ENDORSED OFFICIAL NATIONAL FMD CONTROL PROGRAMME FOR FMD

Report of a Member which applies for endorsement of status, under Chapter 8.5. of the *Terrestrial Code* (2010), as a Member with an endorsed national FMD control programme.

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Provide a general description of geographical factors in the country and any zones, including physical, geographical and other factors that are relevant to FMD dissemination, countries or zones sharing common borders and other countries or zones that, although not adjacent, present a risk for the introduction of disease.
- b) If the endorsed plan is gradually implemented to specific parts of the country, the boundaries of the zone(s) should be clearly defined, including the protection zone, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone(s).
- c) Provide a general description of the livestock industry in the country and any zones.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to the FMD control programme.
- b) Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the veterinary services supervise and control all FMD related activities in the country and any zones. Provide maps and tables wherever possible.
- c) Provide a description on the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in FMD surveillance and control. Include a description of training and awareness programmes on FMD.
- d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

3. FMD control

- a) Provide a description of the FMD history in the country and any zones, including date of first detection, origin of infection, date of implementation of the control programme in the country and any zones, and types and subtypes of the FMD virus present.
- b) Describe the general epidemiology of FMD in the country and the surrounding countries or zones highlighting the current knowledge and gaps.

- c) Describe how FMD is controlled in the country or any *zones*. Submit a detailed plan on the measures to control and eventually eradicate FMD in the country. Include the timelines of the control programme and the performance indicators to assess the efficacy of the control measures and plan.
- d) Provide a description of the legislation, organisation and implementation of the FMD control programme at the different levels. Indicate if detailed operational guidelines exist and give a brief summary. Describe the funding for the control programme and annual budgets for the duration of the control programme.
- e) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process of the vaccines used. Describe the vaccination programme in the country and in any *zones*, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, population immunity, etc.). Provide details on the studies carried out to determine the population immunity, including indicating the study design, including threshold levels for within-herd protective immunity and minimal herd level immunity. Provide details, if applicable, on a proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual* to enable demonstration of absence of virus circulation.
- f) Provide a description of the methods of animal identification (at the individual or group level), herd registration and traceability; and how the movements of *animals* and products are assessed and controlled, including movement of infected *animals* to slaughter. Describe Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of the virus from neighbouring countries or *zones* and through trade.

4. FMD surveillance

Provide documentary evidence on whether surveillance for FMD in the country complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Describe the criteria for raising a suspicion of FMD and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.
- b) Describe how clinical surveillance is conducted, including which levels of the livestock production system are included in clinical surveillance (e.g. farms, markets, fairs, slaughterhouses, check points, etc.). Provide criteria for selection of populations for targeted surveillance and numbers of *animals* examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the surveillance system including indicators. Explain whether serological and virological surveys are conducted and, if so, how frequently and for what purpose.
- c) Provide a summary table indicating, for at least the past 2 consecutive years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.
- d) Provide information on livestock demographics and economics, including the susceptible animal population by species and production systems in the country and the *zone*. Identify how many herds, flocks, etc., of each susceptible species are in the country and how they are distributed (e.g., herd density, etc.). Provide tables and maps as appropriate.
- e) Provide information on wildlife the demographics and migration patterns of FMD susceptible wildlife species, including which susceptible species are present in the country and any *zones*.

Provide estimates of population sizes and geographic distribution. Identify whether susceptible wildlife are included in surveillance. Identify the measures in place to prevent contact between domestic and susceptible wildlife.

- f) Identify the major livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how animals are transported and handled during these transactions.

5. FMD laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the competent authority to diagnose FMD. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratory(ies) where samples originating from any zone are diagnosed. Is there regular submission of samples from the country or zone to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*?
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points.
- i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.
 - ii) Give details on participation in inter-laboratory validation tests (ring tests).
 - iii) Is live virus handled?
 - iv) Biosecurity measures applied.
 - v) Details of the type of tests undertaken.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular provide details on:

- a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and zones that should be taken into account (e.g. size, distance from adjacent borders to affected herds or animals, surveillance carried in adjacent countries). Describe coordination, collaboration and information sharing activities with neighbouring countries and zones. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or zone and through trade.
- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and surveillance measures.
- bc) Provide information on countries or zones from which the country authorises the import of susceptible animals or their products into the country or zone. Describe the criteria applied to approve such countries or zones, the controls applied on entry of such animals and products, and

subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported *animals* of susceptible species are required to undergo a quarantine or isolation period, and if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible *animals* and their products for at least the past 2 consecutive years, specifying country or zone of origin, the species and the number or volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the official service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste food from international traffic, who is responsible to supervise this and provide a summary, for the past 2 years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:
 - = *animals*,
 - = genetic material (semen and embryos),
 - = animal products,
 - = veterinary medicinal products (i.e. biologics),
 - other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports, if available.

7. Control measures and emergency response

- a) Give details of any written guidelines, including emergency response plans, available to the official services for dealing with suspected or confirmed outbreaks of FMD.
- b) Advise whether quarantine is imposed on premises with suspicious cases, pending final diagnosis and any other procedures followed in respect of suspicious cases.
- c) In the event of a FMD outbreak:
 - i) provide a detailed description of procedures that are followed in case of an outbreak including forward and backward tracing;
 - ii) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - iii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
 - iv) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial slaughter/vaccination, etc.) that would be taken, the movement control, the control of wildlife, pastured livestock and livestock as pets, the control of the livestock waste, the campaign to promote awareness of farmers, etc.) that would be taken;
 - v) describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;

- vi) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for disease control or eradication purposes and their prescribed timetable.

8. Recovery of status

Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.5.747.bis of the *Terrestrial Code*.

- text deleted

CHAPTER 8.15.

VESICULAR STOMATITIS

EU position

The EU thanks the OIE TAHSC and supports in general the adoption of this modified chapter and has one comment.

Article 8.15.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for vesicular stomatitis (VS) shall be 21 days.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

When authorizing the import or transit of the following commodities and any products made from these commodities, Veterinary Authorities should not require any VS related conditions, regardless of the VS status of the exporting country:

a) milk and milk products;

b) hides and skins;

c) meat and meat products;

d) tallow;

e) gelatin and collagen.

Article 8.15.2.

VS free country

A country may be considered free from VS when:

1. VS is notifiable in the country;
2. no clinical, epidemiological or other evidence of VS has been found during the past 2 years.

Article 8.15.3.

Trade in commodities

Veterinary Authorities of countries shall consider whether there is a risk with regard to VS in accepting importation or transit through their territory, from other countries, of ruminants, swine, Equidae, and their semen and embryos.

Article 8.15.4.

Recommendations for importation from VS free countries

for domestic cattle, sheep, goats, pigs and horses

Annex 20 (contd)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VS on the day of shipment;
2. were kept in a VS free country since birth or for at least the past 21 days.

Article 8.15.5.

Recommendations for importation from VS free countriesfor wild bovine, ovine, caprine, porcine and equine animals and deer

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VS on the day of shipment;
2. come from a VS free country;

if the country of origin has a common border with a country considered infected with VS:

3. were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
4. were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.15.6.

Recommendations for importation from countries considered infected with VSfor domestic cattle, sheep, goats, pigs and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VS on the day of shipment;
2. ~~either:~~
 - a) were kept, since birth or for the past 21 days, in an *establishment* where no *case* of VS was officially reported during that period; ~~or~~

EU comment

The word "officially" should be deleted for consistency with other Articles, e.g. Article 8.15.9.

- 3.~~b)~~ were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
- 4.~~a)~~ were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.15.7.

Recommendations for importation from countries considered infected with VS

for wild bovine, ovine, caprine, porcine and equine animals and deer

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of VS on the day of shipment;
2. were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;
3. were protected from insect vectors during quarantine and transportation to the *place of shipment*.

Article 8.15.8.

Recommendations for importation from VS free countries or zones

for *in vivo* derived embryos of ruminants, swine and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females were kept in an *establishment* located in a VS free country or zone at the time of collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.15.9.

Recommendations for importation from countries or zones considered infected with VS

for *in vivo* derived embryos of ruminants, swine and horses

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:
 - a) were kept for the 21 days prior to, and during, collection in an *establishment* where no *case* of VS was reported during that period;
 - b) were subjected to a diagnostic test for VS, with negative results, within the 21 days prior to embryo collection;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

— text deleted

CHAPTER 10.4.

AVIAN INFLUENZA

EU position

The EU supports the adoption of this modified chapter, which now should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 10.4.1.

General provisions

1. For the purposes of ~~international trade~~ the Terrestrial Code, avian influenza in its notifiable form (NAI) is defined as an *infection of poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

- a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI;
- b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2. *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

3. For the purposes of the Terrestrial Code, the incubation period for NAI shall be 21 days.

~~3.4. For the purposes of international trade, t~~his chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of infection with NAI virus in the absence of clinical signs.

~~4. For the purposes of international trade, a Member should not impose immediate bans on the trade in poultry commodities in response to a notification, according to Article 1.2.3. of the Terrestrial Code, of infection with HPNAI and LPNAI virus in birds other than poultry, including wild birds.~~

5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in *poultry* and are not a consequence of vaccination, have to be immediately investigated. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of NAI infection.

6. The following defines the occurrence of infection with NAI virus:

- a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in *poultry* or a product derived from *poultry*; or
- b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in *poultry* or a product derived from *poultry*.

7. For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the *poultry* have shown no evidence of NAI infection, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

~~For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.~~

8. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

9. A Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Articles 1.1.3. and 1.2.3. of the *Terrestrial Code*, of infection with HPAI and LPAI virus in birds other than *poultry*, including wild birds.

Article 10.4.2.

Determination of the NAI status of a country, zone or compartment

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, *laboratory* investigations;
2. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the risk posed by birds other than *poultry*; this may be achieved through a NAI *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;
3. consideration of all epidemiological factors for NAI occurrence and their historical perspective.

Article 10.4.3.

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection in *poultry* has been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, NAI free status can be regained:

1. In the case of HPNAI infections, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.
2. In the case of LPNAI infections, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Article 10.4.19. or a *stamping-out policy* may be applied; in either case, 3 months after the *disinfection* of all affected *establishments*, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.4.

HPNAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from HPNAI when:

1. it has been shown that HPNAI infection in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown; or
2. when, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, HPNAI free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.5.

Recommendations for importation from a NAI free country, zone or compartment

for live poultry (other than day-old poultry)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* showed no clinical sign of NAI on the day of shipment;
2. the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry*;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;

Annex 21 (contd)

3. a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered NAI in *poultry*;
4. the birds are transported in new or appropriately sanitized *containers*;
5. if the birds have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.7.

Recommendations for importation from a NAI free country, zone or compartmentfor day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched;
2. the *poultry* were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.8.

Recommendations for importation from a HPNAI free country, zone or compartmentfor day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* were kept in a HPNAI free country, *zone* or *compartment* since they were hatched;
2. the *poultry* were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

Annex 21 (contd)

1. on the day of shipment, the birds showed no clinical signs of *infection* with a virus which would be considered NAI in *poultry*;
2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;
3. the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;
4. the birds are transported in new or appropriately sanitized *containers*;
5. if the birds or parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.10.

Recommendations for importation from a NAI free country, zone or compartment

for hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from a NAI free country, *zone* or *compartment*;
2. the eggs were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs are transported in new or appropriately sanitized packaging materials;
4. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.11.

Recommendations for importation from a HPNAI free country, zone or compartment

for hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from a HPNAI free country, *zone* or *compartment*;
2. the eggs were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
4. the eggs are transported in new or appropriately sanitized packaging materials;
5. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Annex 21 (contd)

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the parent *flock* birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from infection with NAIIV;
2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
3. the eggs are transported in new or appropriately sanitized packaging materials;
4. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.13.

Recommendations for importation from a NAI free country, zone or compartmentfor eggs for human consumption

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in a NAI free country, *zone* or *compartment*;
2. the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.

Recommendations for importation from a HPNAI free country, zone or compartmentfor eggs for human consumption

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in a HPNAI free country, *zone* or *compartment*;
2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
3. the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from eggs which meet the requirements of Articles 10.4.13. or 10.4.14.; or

Annex 21 (contd)

2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.25.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.16.

Recommendations for importation from a NAI free country, zone or compartment

for poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*:

1. showed no clinical sign of NAI on the day of semen collection;
2. were kept in a NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a HPNAI free country, zone or compartment

for poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*:

1. showed no clinical sign of HPNAI on the day of semen collection;
2. were kept in a HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;
2. showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;
3. were tested within 14 days prior to semen collection and shown to be free of NAI infection.

Annex 21 (contd)

Article 10.4.19.

Recommendations for importation from either a NAI or HPNAI free country, zone or compartmentfor fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *poultry*:

1. which have been kept in a country, *zone* or *compartment* free from HPNAI since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an approved *abattoir* in a country, *zone* or *compartment* free from HPNAI and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of NAI.

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.4.19.; or
2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.26.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.21.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Annex 21 (contd)

Article 10.4.22.

Recommendations for the importation of feathers and down of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* originated from *poultry* as described in Article 10.4.19. and were processed in a NAI free country, *zone* or *compartment*; or
2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* have been processed to ensure the destruction of NAI virus (under study); and
2. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.24.

Recommendations for the importation of feather meal and poultry meal

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
2. these *commodities* have been processed either:
 - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
 - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or
 - c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Annex 21 (contd)

Article 10.4.25.

Procedures for the inactivation of the AI virus in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of AI virus present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	513 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.26.

Procedures for the inactivation of the AI virus in meat

The following times for industry standard temperatures are suitable for the inactivation of AI virus present in *meat*.

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 seconds

Annex 21 (contd)

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.27.

Surveillance: introduction

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* for NAI complementary to Chapter 1.4., applicable to Members seeking to determine their NAI status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of NAI status is also provided.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no Member can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in this chapter refers to the *infection in poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV infection.

Article 10.4.28.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
 - a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or NAI infection should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a *laboratory* for NAI diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
2. The NAI *surveillance* programme should:

Annex 21 (contd)

- a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of NAI should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;
- b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of *animals*, such as those adjacent to a NAI infected country, *zone* or *compartment*, places where birds and *poultry* of different origins are mixed, such as live bird markets, *poultry* in close proximity to waterfowl or other potential sources of NAIV.

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is NAIV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NAIV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.4.29.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for NAI should be ongoing. The frequency of active *surveillance* should be at least every 6 months. *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of NAIV infection at an acceptable level of confidence. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results should be followed up with molecular or virological methods.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the NAI status of high risk populations.

A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NAIV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation, including *cases* of HPAI detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

Annex 21 (contd)

If a Member wishes to declare freedom from NAIIV infection in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease/infection* are technically well defined. The design of *surveillance* programmes to prove the absence of NAIIV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of NAI at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of NAIIV infection. In some cases, the only indication of LPNAIV infection may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should have restrictions imposed upon it until NAI infection is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of NAIIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

Annex 21 (contd)3. Virological surveillance

Virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted:

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against NAIIV. Positive NAIIV antibody test results can have four possible causes:

- a) natural *infection* with NAIIV;
- b) vaccination against NAI;
- c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 4 weeks;
- d) false positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for NAI *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NAIIV should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to *infection* or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no NAIIV infection is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The *surveillance* strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological and/or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of vaccination is described in Article 10.4.33.

Article 10.4.30.

Documentation of NAI or HPNAI free status1. Members declaring freedom from NAI or HPNAI for the country, zone or compartment: additional surveillance procedures

In addition to the general conditions described in above mentioned articles, a Member declaring freedom from NAI or HPNAI for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Chapter, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the support of a *laboratory* able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of HPNAI virus may be part of a *disease* control programme. The level of *flock* immunity required to prevent transmission will depend on the *flock* size, composition (e.g. species) and density of the susceptible *poultry* population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual*. Based on the epidemiology of NAI in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other *poultry* subpopulations.

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 10.4.31.

Countries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring that it has regained country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

A Member declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active *surveillance* programme in which the NAI or HPNAI susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Annex 21 (contd)

Article 10.4.32.

NAI free establishments within HPNAI free compartments: additional surveillance procedures

The declaration of NAI free *establishments* requires the demonstration of absence of NAIV infection. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

Article 10.4.33.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. *Poultry* vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In *poultry* vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. *Infection* is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual*.

All *flocks* with seropositive results should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of NAI infection/circulation for each positive *flock*.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

Annex 21 (contd)1. The follow-up procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on NAI-vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated *animals*.

- a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:
 - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;
 - ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;
 - iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.
- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

2. The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Annex 21 (contd)

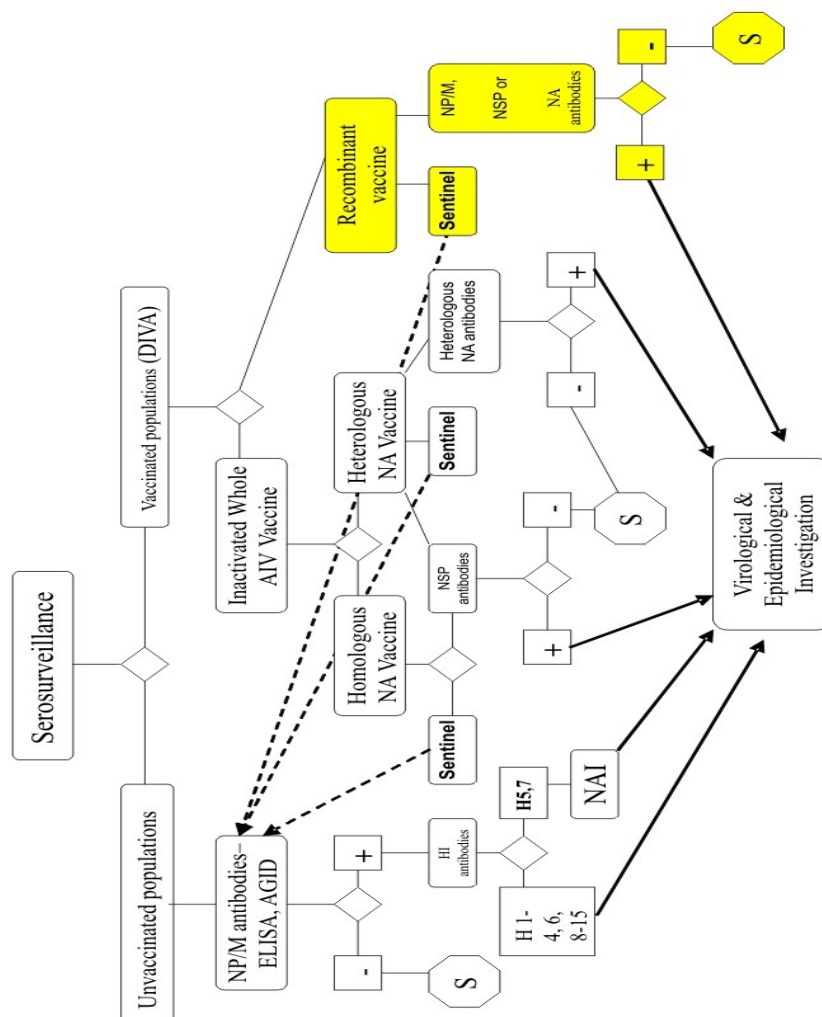
Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for *infection* by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- a) characterization of the existing production systems;
- b) results of clinical *surveillance* of the suspects and their cohorts;
- c) quantification of vaccinations performed on the affected sites;
- d) sanitary protocol and history of the affected *establishments*;
- e) control of *animal identification* and movements;
- f) other parameters of regional significance in historic NAIV transmission.

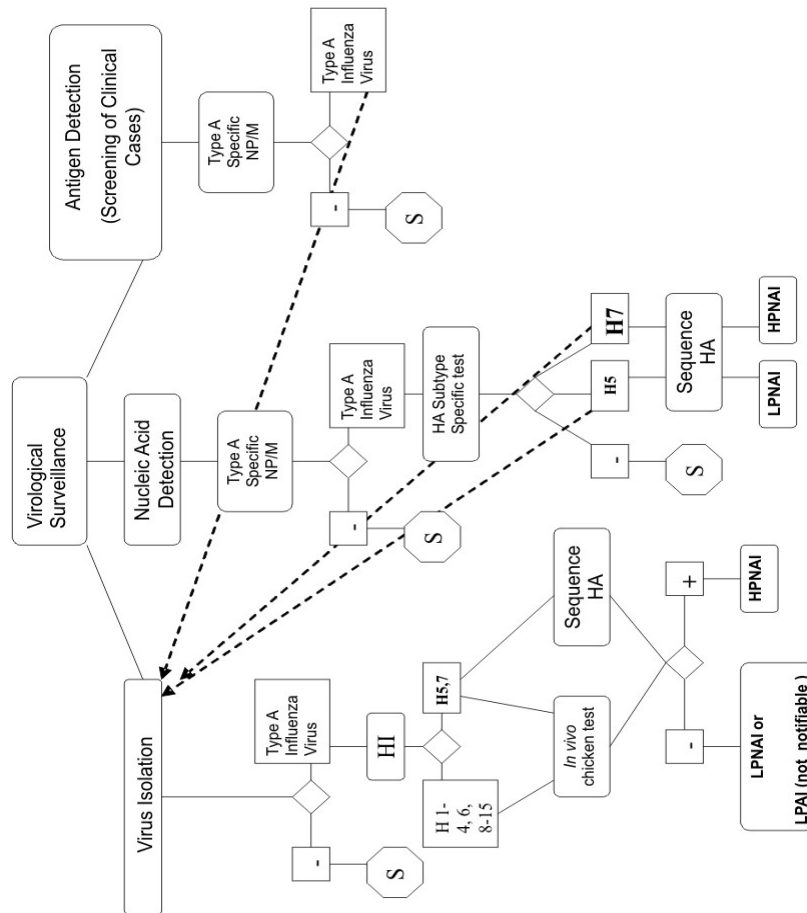
The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

Fig. 1. Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys



Key:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAI

Fig. 2. Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods



The above diagrams indicate the tests which are recommended for use in the investigation of *poultry flocks*.

Key:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAI

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CHAPTER 10.13.

NEWCASTLE DISEASE

EU position

The EU supports the adoption of this modified chapter, which now should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 10.13.1.

General provisions

1. For the purposes of ~~international trade~~ the Terrestrial Code, Newcastle disease (ND) is defined as an *infection of poultry* caused by a virus (NDV) of avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:
 - a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or
 - b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term ‘multiple basic amino acids’ refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.’

2. *Poultry* is defined as ‘all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose’.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

3. For the purposes of the Terrestrial Code, the incubation period for ND shall be 21 days.
- ~~34.~~ This chapter deals with NDV *infection of poultry* as defined in point 2 above, in the presence or absence of clinical signs. ~~For the purposes of international trade, a Member should not impose immediate bans on the trade in poultry commodities in response to a notification, according to Article 1.2.3. of the Terrestrial Code, of infection with NDV in birds other than poultry, including wild birds.~~
45. The occurrence of infection with NDV is defined as the isolation and identification of NDV as such or the detection of viral RNA specific for NDV.
5. ~~For the purposes of the Terrestrial Code, the incubation period for ND shall be 21 days.~~

6. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.
7. A Member should not impose immediate bans on the trade in poultry commodities in response to a notification, according to Article 1.21.3. of the Terrestrial Code, of infection with NDV in birds other than poultry, including wild birds.

Article 10.13.2.

Determination of the ND status of a country, zone or compartment

The ND status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, *laboratory* investigations;
2. appropriate *surveillance* is in place to demonstrate the presence of NDV infection in the absence of clinical signs in *poultry*, this may be achieved through an ND *surveillance* programme in accordance with Articles 10.13.22. to 10.13.26.;
3. consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.13.3.

ND free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that NDV infection in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.13.22. to 10.13.26.

If infection has occurred in *poultry* in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.13.22. to 10.13.26. has been carried out during that three-month period.

Article 10.13.4.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for live poultry (other than day-old poultry)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* showed no clinical sign suggestive of ND on the day of shipment;
2. the *poultry* were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.5.

Recommendations for the importation of live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* during the isolation period;
3. a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.13.24., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from infection with NDV;
4. the birds are transported in new or appropriately sanitised *containers*;
5. if the birds have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.6.

Recommendations for importation from an ND free country, zone or compartmentfor day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *poultry* were hatched and kept in an ND free country, *zone* or *compartment* since they were hatched;
2. the *poultry* were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the *poultry* are transported in new or appropriately sanitized *containers*;
4. if the *poultry* or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.7.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;
2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;
3. the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from infection with NDV;

Annex 22 (contd)

4. the birds are transported in new or appropriately sanitized *containers*;
5. if the birds or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.8.

Recommendations for importation from an ND free country, zone or compartmentfor hatching eggs of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from an ND free country, *zone* or *compartment*;
2. the eggs were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the eggs are transported in new or appropriately sanitized packaging materials;
4. if the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.9.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the parent *flock* birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from infection with NDV;
2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
3. the eggs are transported in new or appropriately sanitized packaging materials;
4. if the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.10.

Recommendations for importation from an ND free country, zone or compartmentfor eggs for human consumption

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in an ND free country, *zone* or *compartment*;
2. the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.13.11.

Recommendations for importation of egg products of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from eggs which meet the requirements of Article 10.13.10.; or
2. the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.13.20.;

AND

3. the necessary precautions were taken to avoid contact of the egg products with any source of NDV.

Article 10.13.12.

Recommendations for importation from an ND free country, zone or compartmentfor poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*:

1. showed no clinical sign suggestive of ND on the day of semen collection;
2. were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.13.13.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to and on the day of semen collection;
2. showed no clinical sign suggestive of infection with NDV during the isolation period and on the day of semen collection;
3. were subjected to a diagnostic test within 14 days prior to semen collection to demonstrate freedom from infection with NDV.

Article 10.13.14.

Recommendations for importation from an ND free country, zone or compartmentfor fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *poultry*:

Annex 22 (contd)

1. which have been kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an approved *abattoir* in an ND free country, *zone* or *compartment* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of ND.

Article 10.13.15.

Recommendations for importation of meat products of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.13.14.; or
2. the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.13.21.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.16.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
2. these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.17.

Recommendations for the importation of feathers and down of poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* originated from *poultry* as described in Article 10.13.14. and were processed in a ND free country, *zone* or *compartment*; or
2. these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.18.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* have been processed to ensure the destruction of NDV (under study); and
2. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.19.

Recommendations for the importation of feather meal and poultry meal

Regardless of the ND status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
2. these *commodities* have been processed either:
 - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
 - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or
 - c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C for a minimum of 280 seconds;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of ND virus.

Article 10.13.20.

Procedures for the inactivation of the ND virus in eggs and egg products

The following times and temperatures are suitable for the inactivation of ND virus present in eggs and egg products:

Annex 22 (contd)

	Core temperature (°C)	Time
Whole egg	55	2,521 seconds
Whole egg	57	1,596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2,278 seconds
Liquid egg white	57	986 seconds
Liquid egg white	59	301 seconds
10% salted yolk	55	176 seconds
Dried egg white	57	50.4 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.13.21.

Procedures for the inactivation of the ND virus in meat

The following times for industry standard temperatures are suitable for the inactivation of ND virus present in *meat*.

	Core temperature (°C)	Time
Poultry meat	65.0	840 <u>39.8</u> seconds
	70.0	574 <u>3.6</u> seconds
	74.0	280 <u>0.5</u> seconds
	80.0	203 <u>0.03</u> seconds

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.13.22.

Surveillance: introduction

Articles 10.13.22. to 10.13.26. define the principles and provide a guide on the *surveillance* for ND as defined in Article 10.13.1. and is complementary to Chapter 1.4. It is applicable to Members seeking to determine their ND status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of ND status is also provided.

Surveillance for ND is complicated by the known occurrence of avian paramyxovirus serotype 1 (APMV-1) infections in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic *poultry*.

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific recommendations for all situations. Therefore, *surveillance* strategies employed for demonstrating freedom from ND at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels, production systems and the commingling of different susceptible species require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Members to provide a well-reasoned argument to prove freedom from NDV infection.

Surveillance for ND should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NDV infection.

Article 10.13.23.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular there should be in place:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or NDV *infection*;
 - b) a procedure for the rapid collection and transport of samples from suspect cases of ND to a *laboratory* for ND diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data.
2. The ND *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of ND to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in ND diagnosis and control;
 - b) implement, when relevant, regular and frequent clinical, virological and serological *surveillance* of high risk groups of *poultry* within the target population (e.g. those adjacent to an ND infected country, *zone*, *compartment*, places where birds and *poultry* of different origins are mixed, or other sources of NDV).

Annex 22 (contd)

An effective *surveillance* system may identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to NDV infection. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NDV infection should provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.13.24.

Surveillance strategies1. Introduction

Any *surveillance* programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of *surveillance* programmes to prove the absence of NDV infection / circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a Member wishes to declare freedom from NDV infection in a country, *zone* or *compartment*, the subpopulation used for the *surveillance* for the *disease / infection* should be representative of all *poultry* within the country, *zone* or *compartment*. Multiple *surveillance* methods should be used concurrently to accurately define the true ND status of *poultry* populations. Active and passive *surveillance* for ND should be ongoing with the frequency of active *surveillance* being appropriate to the disease situation in the country. *Surveillance* should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods as described in the *Terrestrial Manual*. If alternative tests are used they should have been validated as fit-for-purpose in accordance with OIE standards. A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NDV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation.

In surveys, the sample size selected for testing should be statistically justified to detect *infection* at a predetermined target prevalence. The sample size and expected prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The Member should justify the choice of survey design and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 10.13.2.) of ND and are not routinely vaccinated (e.g. ducks). *Surveillance* may also target *poultry* populations at specific risk, for example direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live *poultry* markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, *surveillance* of wild birds may be of value in alerting *Veterinary Services* to the possible exposure of *poultry* and, in particular, of free ranging *poultry*.

Annex 22 (contd)

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination / *infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The results of active and passive *surveillance* are important in providing reliable evidence that no NDV infection is present in a country, *zone* or *compartment*.

2. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs suggestive of ND at the *flock* level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of NDV infection in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious *animals* are detected should be considered as infected until evidence to the contrary is produced. Identification of infected *flocks* is vital to the identification of sources of NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in a *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterization if required.

3. Virological surveillance

Virological *surveillance* should be conducted using tests described in the *Terrestrial Manual* to:

- a) monitor at risk populations;
- b) confirm suspect clinical *cases*;
- c) follow up positive serological results in unvaccinated populations or sentinel birds;
- d) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of vaccination or in establishments epidemiologically linked to an *outbreak*).

4. Serological surveillance

Where vaccination is carried out, serological *surveillance* is of limited value. Serological *surveillance* cannot be used to discriminate between NDV and other APMV-1. Test procedures and interpretations of results are as described in the *Terrestrial Manual*. Positive NDV antibody test results can have five possible causes:

- a) natural infection with APMV-1;
- b) vaccination against ND;
- c) exposure to vaccine virus;
- d) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 4 weeks;

Annex 22 (contd)

- e) non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated *flocks* should be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of *infection*, virological methods should be used to confirm the presence of NDV in such populations. Until validated strategies and tools to differentiate vaccinated *animals* from those infected with field APMV-1 are available, serological tools should not be used to identify NDV infection in vaccinated populations.

5. Use of sentinel poultry

There are various applications of the use of sentinel *poultry* as a *surveillance* tool to detect virus circulation. They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel *poultry* should be immunologically naïve and may be used in vaccinated *flocks*. In case of the use of sentinel *poultry*, the structure and organisation of the *poultry* sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel *poultry* should be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel *poultry* should be observed regularly for evidence of clinical *disease* and any disease incidents investigated by prompt *laboratory* testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel *poultry* do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel *poultry*). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population. Sentinel birds should be used only if no appropriate *laboratory* procedures are available.

Article 10.13.25.

Documentation of ND free status: additional surveillance procedures

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article 10.13.3.

A Member declaring freedom of a country, *zone* or *compartment* (with or without vaccination) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

1. Members declaring freedom from ND for the country, zone or compartment

In addition to the general conditions described in the *Terrestrial Code*, a Member declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The *surveillance* programme should be planned and implemented according to general conditions and methods described in this chapter to demonstrate absence of NDV infection in *poultry* during the preceding 12 months.

2. Additional requirements for countries, zones or compartments that practice vaccination

Vaccination against ND may be used as a component of a disease prevention and control programme. The vaccine used should comply with the provisions of the *Terrestrial Manual*.

In vaccinated populations there is a need to perform *surveillance* to ensure the absence of NDV circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The *surveillance* should be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*, or evidence to show the effectiveness of the vaccination programme is regularly provided.

Article 10.13.26.

Countries, zones or compartments regaining freedom from ND following an outbreak: additional surveillance procedures

A Member regaining country, *zone* or *compartment* freedom from ND should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*.

A Member declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND (with or without vaccination) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

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CHAPTER 11.8.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

EU position

The EU supports the adoption of this modified chapter, which now should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 11.8.1

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be 6 months.

For the purpose of this chapter, a *case* of CBPP means an *animal* infected with *Mycoplasma mycoides* subsp. *mycoides* SC (*Mmm* SC), and freedom from CBPP means freedom from *Mmm* SC infection.

For the purpose of this chapter, susceptible *animals* include cattle (*Bos indicus*, and *B. Taurus* and *B. grunniens*) and water buffalo (*Bubalus bubalis*).

For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by *Mmm* SC, but also with the presence of infection with *Mmm* SC in the absence of clinical signs.

The following defines the occurrence of *Mmm* SC infection:

1. *Mmm* SC has been isolated and identified as such from an *animal*, embryos, oocytes or semen;
- or
2. antibodies to *Mmm* SC antigens which are not the consequence of vaccination, or *Mmm* SC DNA, have been identified in one or more *animals* showing pathological lesions consistent with infection with *Mmm* SC with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible *animals*.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 11.8.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic cattle and water buffalo population of the *exporting country, zone or compartment*.

Article 11.8.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP related conditions, regardless of the CBPP status of the domestic cattle and water buffalo population of the *exporting country, zone or compartment*:

1. *milk* and *milk products*;

2. hides and skins
3. *meat* and *meat products* (excluding lung).

Article 11.8.3.

CBPP free country, zone or compartment

To qualify for inclusion in the existing list of CBPP free countries, a Member should.

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE stating that.
 - a) there has been no *outbreak* of CBPP during the past 24 months;
 - b) no evidence of CBPP infection has been found during the past 24 months;
 - c) no vaccination against CBPP has been carried out during the past 24 months,

and supply documented evidence that *surveillance* for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;

3. not have imported since the cessation of vaccination any *animals* vaccinated against CBPP.

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information 2a), 2b), 2c) and 3 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.8.4.

Recovery of free status

When a CBPP *outbreak* occurs in a CBPP free country, *zone* or *compartment*, one of the following waiting periods is required to regain the status of CBPP free country, *zone* or *compartment*.

1. 12 months after the last *case* where a *stamping-out policy* and serological *surveillance* and strict movement control are applied in accordance with this chapter;
2. if vaccination was used, 12 months after the *slaughter* of the last vaccinated *animal*.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 11.8.3. applies.

Article 11.8.5.

CBPP infected country or zone

When the requirements for acceptance as a CBPP free country or *zone* are not fulfilled, a country or *zone* shall be considered as infected.

Article 11.8.6.

Recommendations for importation from CBPP free countries, zones or compartments for domestic cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of CBPP on the day of shipment.

Article 11.8.7.

Recommendations for importation from CBPP infected countries or zonesfor domestic cattle and water buffaloes for slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of CBPP on the day of shipment;
2. originate from an *establishment* where no *case* of CBPP was officially reported for the past 6 months, and
3. are transported directly to the *slaughterhouse* in sealed *vehicles*.

Article 11.8.8.

Recommendations for importation from CBPP free countries, zones or compartmentsfor bovine semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;
 - b) were kept in a CBPP free country since birth or for at least the past 6 months;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.9.

Recommendations for importation from CBPP infected countries or zonesfor bovine semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) showed no clinical sign of CBPP on the day of collection of the semen;

Annex 23 (contd)

- b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;
 - d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a
CBPP *infected zone*;
 - e) AND EITHER:
 - i) have not been vaccinated against CBPP;
 - OR
 - ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.10.

Recommendations for importation from CBPP free countries, zones or compartmentsfor *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1. the donor *animals*:
 - a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;
 - b) were kept in a CBPP free country since birth or for at least the past 6 months;
- 2. the oocytes were fertilised with semen meeting the conditions of Article 11.8.8.;
- 3. the embryos/oocytes was collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.11.

Recommendations for importation from CBPP infected countries or zonesfor *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

Annex 23 (contd)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;
 - b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
 - c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;
 - d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;
 - e) AND EITHER:
 - i) have not been vaccinated against CBPP;
 - OR
 - ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;
2. the oocytes were fertilised with semen meeting the conditions of Article 11.8.9.;
3. the embryos/oocytes was collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.12.

Surveillance: introduction

Articles 11.8.12. to 11.8.17. define the principles and provides a guide for the *surveillance* of CBPP in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from CBPP. Guidance is provided for Members seeking reestablishment of freedom from CBPP for the entire country or for a *zone* or *compartment*, following an *outbreak* and for the maintenance of CBPP free status.

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence will need to be adapted to the local situation. It is incumbent upon the applicant Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to OIE Members to provide a well-reasoned argument to prove that the absence of CBPP infection is assured at an acceptable level of confidence.

Annex 23 (contd)

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP infection.

Article 11.8.13.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect *cases* of CBPP to a *laboratory* for CBPP diagnoses as described in the *Terrestrial Manual*.
2. The CBPP *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, *meat* inspectors as well as *laboratory* diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) into the *surveillance* system. All suspect *cases* of CBPP should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CBPP diagnosis and control;
 - b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of *animals*, such as those adjacent to a CBPP infected country or *infected zone* (for example, areas of transhumant production systems);
 - c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.

An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP infection should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 11.8.14.

Surveillance strategies1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) within the country, *zone* or *compartment*.

Given the limitations of the diagnostic tools available, the interpretation of *surveillance* results should be at the *herd* level rather than at the individual animal level.

Randomised *surveillance* may not be the preferred approach given the epidemiology of the *disease* (usually uneven distribution and potential for occult foci of *infection* in small populations) and the limited sensitivity and specificity of currently available tests. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on *slaughter* findings, and active clinical *surveillance*) may be the most appropriate strategy. The applicant Member should justify the *surveillance* strategy chosen as adequate to detect the presence of CBPP infection in accordance with Chapter 1.4. and the epidemiological situation.

Targeted *surveillance* may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated.

Irrespective of the *surveillance* system employed, the design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve follow-up with supplementary tests, clinical investigation and post-mortem examination in the original sampling unit as well as *herds* which may be epidemiologically linked to it.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of CBPP in a *herd* by close physical examination of susceptible *animals*. Clinical inspection will be an important component of CBPP *surveillance* contributing to reach the desired level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined.

Annex 23 (contd)

Clinical *surveillance* and laboratory testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. Laboratory testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.

3. Pathological surveillance

Systematic pathological *surveillance* for CBPP is the most effective approach and should be conducted at *slaughterhouses* and other *slaughter* facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for *slaughter* personnel and *meat* inspectors are recommended.

4. Serological testing

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiologic investigations, serological testing may be used.

The limitations of available serological tests for CBPP will make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed-up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP infections and will be usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances should be incorporated in the *surveillance* strategy.

Following the identification of a CBPP infected *herd*, contact *herds* need to be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

5. Agent surveillance

Agent *surveillance* using tests described in the *Terrestrial Manual* should be conducted to follow-up and confirm or exclude suspect *cases*. Isolates should be typed to confirm *MmmSC*.

Article 11.8.15.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in this chapter, an OIE Member applying for recognition of CBPP freedom for the country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of CBPP infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of CBPP infection using methods described in the *Terrestrial Manual*.

Article 11.8.16.

Compartments seeking recognition of freedom from CBPP

The bilateral recognition of CBPP free *compartments* should follow the principles laid in this chapter, Chapter 4.3. and Chapter 4.4.

Article 11.8.17.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this chapter, a Member re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active *surveillance* programme for CBPP, following the recommendations of this chapter.

Two strategies are recognised by the OIE in a programme to eradicate CBPP infection following an *outbreak*:

1. *slaughter* of all clinically affected and in-contact susceptible *animals*;
2. vaccination used without subsequent *slaughter* of vaccinated *animals*.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.8.4.

— text deleted

CHAPTER 11.12.

LUMPY SKIN DISEASE

(caused by group III virus, type
Neethling)

EU position

The EU thanks the OIE TAHC and supports the adoption of this modified chapter.

Article 11.12.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for lumpy skin disease (LSD) shall be 28 days.

For the purpose of this chapter, susceptible animals include cattle (*Bos indicus* and *B. taurus*) and water buffalo (*Bubalus bubalis*).

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the commodities covered in the chapter, with the exception of those listed in Article 11.12.1.bis, Veterinary Authorities should require the conditions prescribed in this chapter relevant to the LSD status of the cattle population of the exporting country.

Article 11.12.1.bis

Safe commodities

When authorising import or transit of the following commodities, Veterinary Authorities should not require any LSD-related conditions regardless of the LSD status of the cattle population of the exporting country or zone:

1. milk and milk products;

2. meat and meat products;

Article 11.12.2.

LSD free country

A country may be considered free from LSD when:

1. LSD is notifiable in the country;
2. no case of LSD has been confirmed for at least the past 3 years;
3. no vaccination against LSD has been performed for at least 3 years;
4. commodities have been are imported in accordance with this chapter.

Article 11.12.3.

Trade in commodities

~~Veterinary Authorities of LSD free countries may prohibit importation or transit through their territory, from countries considered infected with LSD, of the following commodities:~~

- ~~1. domestic and wild animals of the bovine species;~~
- ~~2. semen of animals of the bovine species.~~

Article 11.12.43.

Recommendations for importation from LSD free countries

for domestic cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of LSD on the day of shipment;
2. come from an LSD free country.

Article 11.12.54.

Recommendations for importation from LSD free countries

for wild cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of LSD on the day of shipment;
2. come from an LSD free country;

if the country of origin has a common border with a country considered infected with LSD:

3. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.65.

Recommendations for importation from countries considered infected with LSD

for domestic cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of LSD on the day of shipment;
2. either:
 - a. were not vaccinated against LSD ~~during the 30-~~ and were tested negative using tests according to the *Terrestrial Manual* within 14 days prior to shipment; or
 - b. were vaccinated against LSD ~~not more than 3 months~~ between 30 days and 90 days prior to shipment;

AND

43. either:

- a. were kept since birth, or for the past 28 days, in an *establishment* where no *case* of LSD was officially reported during that period; or
- 5b. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.76.

Recommendations for importation from countries considered infected with LSD

for wild cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of LSD on the day of shipment;
2. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.87.

Recommendations for importation from LSD free countries

for semen of cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a. showed no clinical sign of LSD on the day of collection of the semen;
 - b. were kept for at least 28 days prior to collection in an LSD free country;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.12.98.

Recommendations for importation from countries considered infected with LSD

for semen of cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a. showed no clinical sign of LSD on the day of collection of the semen and for the following 28 days;
 - b. were kept in the *exporting country* for the 28 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of LSD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an LSD *infected zone*.

Annex 24 (contd)

- c. and either:
- i) were vaccinated against LSD between 28 days and 90 days before semen collection and thereafter vaccinated annually; or
 - ii) were tested with negative results using a serum neutralisation test (SNT) or an indirect enzyme-linked immunosorbent assay (ELISA) for LSD on the day of first semen collection or up to 90 days after last collection; or
 - iii) showed stable seropositivity (not more than a two-fold rise in titre) on paired samples (tested side by side) to indirect ELISA or SNT carried out in quarantine, 28-60 days apart, with the first sample taken on the day of first semen collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.12. ~~109~~.

Recommendations for importation from LSD free countries

for embryos/oocytes of cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals* showed no clinical sign of LSD on the day of collection of the embryos/oocytes; and
2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.12. ~~110~~.

Recommendations for importation from countries considered infected with LSD

for embryos/oocytes of cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a. were kept in an *establishment* where no *case* of LSD has been reported during the 28 days prior to collection; and
 - b. showed no clinical sign of LSD on the day of collection;
 - c. and either:
 - i. were vaccinated against LSD between ~~30~~ 28 days and 90 days before first embryo/oocyte collection and thereafter vaccinated annually; or
 - ii. were tested with negative results using a serum neutralisation test (SNT) or an indirect enzyme-linked immunosorbent assay (ELISA) for LSD on the day of embryo/oocyte collection or up to 90 days after last collection according to the *Terrestrial Manual*; or

Annex 24 (contd)

- iii. showed ~~serostability~~ stable seropositivity (not more than a two-fold rise in titre) on paired samples ~~(to indirect ELISA tests, tested side by side, carried out in isolation)~~ to indirect ELISA or SNT carried out in quarantine, 1428–60 days apart with one of the samples taken on the day of embryo/oocyte collection of the embryos/oocytes;
2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.12. ~~1211~~.

Recommendations for importation from LSD free countries

for products of animal origin (from cattle) intended for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in an LSD free country since birth or for at least the past 28 days.

Article 11.12. ~~1312~~.

Recommendations for importation from countries considered infected with LSD

for products of animal origin (from cattle ~~and water buffaloes~~) intended for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the LSD virus.

Article 11.12. ~~1413~~.

Recommendations for importation from countries considered infected with LSD

for raw hides of cattle ~~and water buffaloes~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products were stored for at least 40 days before shipment.

 — text deleted

CHAPTER 12.6.

EQUINE INFLUENZA

EU position

The EU supports the adoption of this modified chapter, but has some comments to be taken into consideration.

In this chapter and throughout the *Terrestrial Code*, by convention and for the sake of clarity, the use of the word "equine(s)" should not be used as a noun, as it can lead to confusion: "equine" should only be used as an adjective that refers to "equids", word that should be used to refer to members of the family Equidae.

Article 12.6.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic horses, donkeys and mules.

EU comment

The words "domestic horses, donkeys and mules" should be replaced by "domestic equids" for clarity reasons and consistency with the rest of the chapter.

~~For the purposes of international trade,~~ This chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of infection with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as 'the separation of domestic equids from domestic equids of a different equine influenza health status, utilising appropriate biosecurity measures, with the purpose of preventing the transmission of *infection*'.

For the purposes of the *Terrestrial Code*, the *infective period* for EI 21 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.7.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country, zone or compartment*.

EU editorial comment

Editorial: in the paragraph above, "12.7.2" should be replaced by "12.6.2".

Article 12.6.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any EIV related conditions, regardless of the EI status of the equine population of the *exporting country, zone or compartment*.

1. semen;

2. *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant (under study).

Article 12.6.3.

Determination of the EI status of a country, a zone or a compartment

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all **potential risk factors for EI occurrence** and their historic **perspective relevance**;
2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, *laboratory* investigations;
3. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic equids.

Article 12.6.4.

EI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from EI provided the *disease* is notifiable in the whole country and it shows evidence, through an effective *surveillance* programme, planned and implemented according to the general principles in Chapter 1.4., that no *case* of EI occurred in the past 2 years.

The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids within and into the country, *zone* or *compartment*, wild equid populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the population of domestic and wild equids during the past 12 months, through *surveillance*, in accordance with Chapter 1.4.

EU comment

The words "domestic and wild" should be replaced by "domestic, feral and wild", in line with the new definitions in the glossary.

In a country in which vaccination is not practised, *surveillance* may be conducted using serological testing alone. In countries where vaccination is practised, the *surveillance* should include agent identification methods described in the *Terrestrial Manual* for evidence of *infection*.

A country, *zone* or *compartment* seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter.

If an *outbreak* of clinical EI occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical *case*, providing that *surveillance* for evidence of *infection* has been carried out during that twelve-month period in accordance with Chapter 1.4.

Article 12.6.5.

Recommendations for the importation of domestic equids for immediate slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids showed no clinical sign of EI on the day of shipment.

Article 12.6.6.

Recommendations for the importation of domestic equids for unrestricted movement

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids:

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its vaccination status should be included in the veterinary certificate;

OR

2. came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and
3. were immunised according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual* between 21 and 90 days before shipment either with a primary course or a booster; information on their vaccination status should be included in the veterinary certificate.

For additional security, countries that are free of EI or undertaking an eradication programme may also request that the domestic equids were tested negative for EIV by an agent identification test for EI described in the *Terrestrial Manual* conducted on samples collected on two occasions at 7 to 14 days and less than 5 days before shipment.

Article 12.6.7.

Recommendations for the importation of domestic equids which will be kept in isolation (see Article 12.6.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids:

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its vaccination status should be included in the veterinary certificate;

OR

2. showed no clinical sign of EI in any premises in which the domestic equids had been resident for the 21 days prior to shipment nor on the day of shipment; and
3. were immunised according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual*; information on their vaccination status should be included in the veterinary certificate.

Article 12.6.8.

Recommendations for the importation of fresh meat of equids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from equids which had been subjected to ante- and post-mortem inspections as described in Chapter 6.2.

CHAPTER 12.9.

EQUINE VIRAL ARTERITIS

EU position

The EU supports the adoption of this modified chapter.

However, in this chapter and throughout the *Terrestrial Code*, by convention and for the sake of clarity, the use of the word "equine(s)" should not be used as a noun, as it can lead to confusion: "equine" should only be used as an adjective that refers to "equids", word that should be used to refer to members of the family Equidae.

Article 12.9.1.

General provisions

For the purposes of the *Terrestrial Code*, equine viral arteritis (EVA) is defined as an *infection* of domestic and feral members of the family, *Equidae*.

EU comment

The words "and feral" should be deleted, as the chapter only deals with domestic equids.

This chapter deals not only with the occurrence of clinical signs caused by equine arteritis virus (EAV), but also with the presence of infection with EAV in the absence of clinical signs. For the purposes of this chapter, isolation is defined as the separation of domestic equids from those of a different EVA health status, utilising appropriate biosecurity measures, with the objective of preventing the transmission of *infection*.

The *infective period* for equine viral arteritis (EVA) shall be 28 days for all categories of equine except sexually mature stallion where the *infective period* may be for the life of the *animal*. Because the *infective period* may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 12.9.2.

Recommendations for the importation of uncastrated male equines

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment and met one of the following requirements:

1. were isolated for the 28 days prior to shipment and were subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a single blood sample collected during the 21 days prior to shipment with negative result; or
2. were subjected between 6 and 9 months of age to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or
3. met the following requirements:
 - a) were isolated; and

- b) not earlier than 7 days of commencing isolation were ~~tested, with negative results, with~~ subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative result; and
 - c) were then immediately vaccinated; and
 - d) were kept separated from other equidae for 21 days following vaccination; and
 - e) were revaccinated regularly according to the manufacturer's instructions; or
4. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a blood sample with positive results and then: either
- a) were subsequently test mated to two mares within 6 months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or
 - b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected during the 6 months prior to shipment; or
 - c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly in accordance with the manufacturer's instructions.

Article 12.9.3.

Recommendations for the importation of equines other than uncastrated males

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of EVA on the day of shipment and were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to shipment; and

EITHER

1. were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to shipment; and

EU comment

The first sentence of point 1 above is redundant with the second part of the first paragraph of the article: one should be deleted, preferably the one in the heading, since if the animal is isolated for 28 days it does not need to come from a free establishment.

For consistency with article 12.9.2, point a) above could read: "a) were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on blood samples collected either once within 21 days prior to shipment with negative result, or on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or".

- a) were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on blood samples collected on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or
- b) were regularly vaccinated according to the manufacturer's instructions;

OR

2. were isolated for the 28 days prior to shipment and during this period the *animals* showed no signs of EVA.

Article 12.9.4.

Recommendations for the importation of equine semen

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the animal donors were kept for the 28 days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of semen collection; and

1. were subjected between 6 and 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* on two blood samples collected at least 14 days apart with a stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or
2. were isolated and not earlier than 7 days of commencing isolation were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or
3. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equidae not of an equivalent EVA status for 14 days prior to blood sampling ~~from the time of the taking of the blood sample~~ until the end of semen collection; or
4. have been subjected to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample with positive results and then: either
 - a) were subsequently test mated to two mares within 6 months prior to semen collection, which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the test mating, or
 - b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months prior to collection of the semen to be exported; or
 - c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly; or
5. were, for frozen semen, were subjected with negative results either:
 - a) to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample taken not earlier than 14 days and not later than 12 months after the collection of the semen for export; or
 - b) to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* carried out on an aliquot of the semen collected immediately prior to processing or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

 — text deleted

CHAPTER 14.5.

CHLAMYDOPHILA ABORTUS INFECTION**(ENZOOTIC ABORTION OF EWES)
(OVINE CHLAMYDIOSIS)****EU position****The EU supports the adoption of this modified chapter.**

Article 14.5.1.

General provisions

For the purposes of the *Terrestrial Code*, enzootic abortion of ewes (EAE), also known as ovine chlamydiosis or ovine enzootic abortion, is an *infection* of domestic sheep and goats by the bacterium *Chlamydophila abortus*.

~~For the purposes of the *Terrestrial Code*, the following information should be considered with regard to the *incubation period* for enzootic abortion of ewes (EAE):~~ Susceptible *animals* become infected through ingestion of infectious materials. In lambs and non-pregnant ewes, the *infection* remains latent until conception. Ewes exposed to *infection* late in pregnancy may not exhibit signs of *infection* until the subsequent pregnancy. Countries should take account of these risk factors.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 14.5.2.

Recommendations for the importation of sheep and/or goats for breeding

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. have remained since birth, or for the previous 2 years, in *establishments* where no EAE has been diagnosed during the past 2 years;
2. showed no clinical sign of EAE on the day of shipment;
3. were subjected to a diagnostic test for EAE with negative results within the 30 days prior to shipment.

Article 14.5.3.

Sheep flocks and/or goat herds free from EAE infection

To qualify as free from EAE *infection*, a sheep *flock* or goat *herd* shall satisfy the following requirements:

1. it is under official veterinary *surveillance*;
2. all sheep and goats showed no clinical evidence of EAE *infection* during the past 2 years;
3. a statistically valid number of sheep and goats over 6 months of age were subjected to a diagnostic test for EAE with negative results within the past 6 months;

4. all sheep or goats are permanently identified;
5. no sheep or goat has been added to the *flock* or *herd* since 30 days prior to the *flock* or *herd* test referred to in point 3 above unless:
 - a) either the additions were isolated from other members of the *flock* or *herd* in the *establishment* of origin for a minimum period of 30 days and then were subjected to a diagnostic test for EAE with negative results, before entry into the new *flock* or *herd*; or
 - b) they originated from an *establishment* of equal health status.

Article 14.5.4.

Recommendations for the importation of semen of sheep

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) have been kept in *establishments* or *artificial insemination centres* free from EAE during the past 2 years, and have not been in contact with *animals* of a lower health status;
 - b) were subjected to a diagnostic test for EAE with negative results 2 to 3 weeks after collection of the semen;
2. an aliquot of the semen to be exported was shown to be free of *Chlamydia psittaci* *Chlamydophila abortus*; by culture techniques.

— text deleted

CHAPTER 14.9.

SCRAPIE

EU position

The EU supports the adoption of this modified chapter, which now should not be revised unless new scientific evidence or obvious trade problem make it necessary.

Article 14.9.1.

General provisions and safe commodities

Scrapie is a neurodegenerative *disease* of sheep and goats. The main mode of transmission is from mother to offspring immediately after birth and to other susceptible neonates exposed to the birth fluids and tissues of an infected *animal*. Transmission occurs at a much lower frequency to adults exposed to the birth fluids and tissues of an infected *animal*. A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the *disease* is variable; however, it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

Scrapie is not considered to pose a risk to human health. The recommendations in this chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The chapter ~~does not cover~~ excludes so-called 'atypical' scrapie ~~which~~ because this condition is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

1. When authorising import or transit of the following *commodities* derived from sheep or goats and any products made from these *commodities* and containing no other tissues from sheep or goats, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*:
 - a) *in vivo* derived sheep embryos handled in accordance with Chapter 4.7. of this *Terrestrial Code*;
 - b) *meat* (excluding materials as referred to in Article 14.9.12.);
 - c) hides and skins;
 - d) gelatine;
 - e) collagen prepared from hides or skins;
 - f) tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
 - g) dicalcium phosphate (with no trace of protein or fat);
 - h) wool or fibre.
2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the scrapie risk status of the sheep and goat populations of the *exporting country, zone or compartment*.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 14.9.2.

Determination of the scrapie status of the sheep and goat populations of a country, zone, compartment or establishment

The scrapie status of the sheep and goat populations of a country, *zone*, *compartment* or *establishment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for scrapie occurrence and their historic perspective, in particular the:
 - a) importation or introduction of sheep and goats or their semen, *in vivo* derived goat embryos or *in vitro* processed sheep and goat embryos/oocytes potentially infected with scrapie;
 - b) extent of knowledge of the population structure and husbandry practices of sheep and goats;
 - c) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;
 - d) importation of *milk* and *milk products* of sheep or goats origin intended for use in feeding of sheep and goats;
2. an on-going awareness programme for *veterinarians*, farmers, and workers involved in transportation, marketing and *slaughter* of sheep and goats to facilitate recognition and encourage reporting of all *animals* with clinical signs compatible with scrapie;
3. a *surveillance* and monitoring system including the following:
 - a) official veterinary *surveillance*, reporting and regulatory control in accordance with the provisions of Chapter 1.4.;
 - b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;
 - c) compulsory notification and clinical investigation of sheep and goats showing clinical signs compatible with scrapie;
 - d) examination, in accordance with the *Terrestrial Manual*, in a *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie;
 - e) maintenance of records including the number and results of all investigations for at least 7 years.

Article 14.9.3.

Scrapie free country or zone

Countries or *zones* may be considered free from scrapie if within the said territory:

1. a *risk assessment*, as described in point 1 of Article 14.9.2., has been conducted, and it has been demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any *risk* identified and points 2 and 3 have been complied with for the preceding 7 years;

Annex 27 (contd)

AND

2. one of the following conditions should be met:
 - a) the country or the *zone* have demonstrated historical freedom as follows:
 - i) scrapie has been notifiable for at least 25 years; and
 - ii) a formal programme of targeted *surveillance* and monitoring, which includes testing of sheep and goats displaying clinical signs compatible with scrapie and those over 18 months of age slaughtered, culled or found dead on farm, can be documented as having been in place for at least 10 years; and
 - iii) appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and
 - either scrapie has never been reported; or
 - no *case* of scrapie has been reported for at least 25 years;
 - b) for at least 7 years, sheep and goats displaying clinical signs compatible with scrapie have been tested. Also a sufficient number of sheep and goats over 18 months of age, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95% level of confidence of detecting scrapie if it is present in that population at a prevalence rate exceeding 0.1% and no *case* of scrapie has been reported during this period; or
 - c) all *establishments* containing sheep or goats have been accredited free as described in Article 14.9.5.;

AND

3. the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;

AND

4. introductions of sheep and goats or their semen, *in vivo* derived goat embryos or *in vitro* processed sheep and goat embryos/oocytes from countries or *zones* not free from scrapie are carried out in accordance with Articles 14.9.6., 14.9.7., 14.9.8. or 14.9.9., as relevant.

Article 14.9.4.

Compartment free from scrapie

To qualify as a *compartment* free from scrapie, all sheep and goats in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

1. all *establishments* within the *compartment* are free from scrapie according to Article 14.9.5.;
2. all *establishments* within the *compartment* are managed under a common *biosecurity plan* protecting them from introduction of scrapie, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.;
3. introductions of sheep and goats are allowed only from ~~accredited~~ free *establishments* or free countries;

Annex 27 (contd)

4. introductions of *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos/oocytes are allowed either from ~~accredited~~ free *establishments* or in accordance with Article 14.9.9.;
5. sheep and goat semen should be introduced into the *compartment* in accordance with Article 14.9.8.;
6. sheep and goats in the *compartment* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* not within the *compartment*.

Article 14.9.5.

Scrapie free establishment

To qualify as free from scrapie, an *establishment* of sheep and goats should satisfy the following requirements:

1. in the country or *zone* where the *establishment* is situated, the following conditions are fulfilled:
 - a) the *disease* is compulsorily notifiable;
 - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are killed and completely destroyed;
 - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;
 - e) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;
2. in the *establishment* the following conditions have been complied with for at least 7 years:
 - a) sheep and goats are permanently identified and records maintained, to enable trace back to their *establishment* of birth;
 - b) records of movements of sheep and goats in and out of the *establishment* are maintained;
 - c) introductions of sheep and goats are allowed only from free *establishments* or *establishment* at an equal or higher stage in the process of accreditation;
 - d) introduction of *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos /oocytes should comply with Article 14.9.9.;
 - e) sheep and goat semen should be introduced into the *establishment* in accordance with Article 14.9.8.;
 - f) an *Official Veterinarian* inspects sheep and goats in the *establishments* and audits the records at least once a year;
 - g) no *case* of scrapie has been reported;
 - h) sheep and goats of the *establishments* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;

Annex 27 (contd)

- i) all culled sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a *laboratory* for scrapie. The selection of the sheep and goats to be tested should be made by the *Official Veterinarian*. Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine *slaughter* should also be tested (including ‘fallen’ stock and those sent for emergency *slaughter*).

Article 14.9.6.

Recommendations for importation from countries or zones not considered free from scrapie

for sheep and goats for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals* come from an *establishment* free from scrapie as described in Article 14.9.5.

Article 14.9.7.

Recommendations for importation from countries or zones not considered free from scrapie

for sheep and goats for slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
 - a) the *disease* is compulsorily notifiable;
 - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are killed and completely destroyed;
2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

Article 14.9.8.

Recommendations for importation from countries or zones not considered free from scrapie

for semen of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) are permanently identified to enable trace back to their *establishment* of origin;
 - b) showed no clinical sign of scrapie at the time of semen collection;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Annex 27 (contd)

Article 14.9.9.

Recommendations for importation from countries or zones not considered free from scrapie
for *in vivo* derived goat embryos and *in vitro* processed sheep and goat embryos/oocytes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. in the country or *zone*:
 - a) the *disease* is compulsorily notifiable;
 - b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - c) affected sheep and goats are killed and completely destroyed;
 - d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country;
2. the donor *animals* either have been kept since birth in a free *establishment*, or meet the following conditions:
 - a) are permanently identified to enable trace back to their *establishment* of origin;
 - b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;
 - c) showed no clinical sign of scrapie at the time of embryo/oocyte collection;
3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 14.9.10.

Recommendations for importation from countries or zones not considered free from scrapie
for milk and milk products of sheep or goat origin intended for use in feeding of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *milk* and *milk products* come from scrapie free *establishments*.

Article 14.9.11.

Recommendations on meat-and-bone meal

Meat-and-bone meal containing any sheep or goat protein, or any feedstuffs containing that type of *meat-and-bone meal*, which originate from countries not considered free of scrapie should not be traded between countries for ruminant feeding.

Article 14.9.12.

Recommendations for importation from countries or zones not considered free from scrapie

for skulls including brains, ganglia and eyes, vertebral column including ganglia and spinal cord, tonsils, thymus, spleen, intestine, adrenal gland, pancreas, or liver, and protein products derived therefrom, from sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* should not be traded for use in ruminant feeds;
2. for purposes other than ruminant feeding, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:
 - a) in the country or *zone*:
 - i) the *disease* is compulsorily notifiable;
 - ii) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
 - iii) affected sheep and goats are killed and completely destroyed;
 - b) the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Article 14.9.13.

Recommendations for the importation of ovine and caprine materials destined for the preparation of biologicals

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from sheep and goats born and raised in a scrapie free country, *zone* or *establishment*.

 — text deleted

CHAPTER 15.2.

CLASSICAL SWINE FEVER

EU position

The EU thanks the OIE TAHSC and would support in general the adoption of this modified chapter, except for the way that the new terms for wild pigs as defined in the draft modified Glossary has been inserted in this chapter, which cannot be accepted as proposed.

Indeed, in the framework of the OIE policy on wildlife/livestock interface, the EU asks the OIE to take into account the EU previous comment regarding the populations of captive wild pigs, which might be kept in zoos but might also be used for the production of meat, and thus play a significant epidemiological role, equivalent to that of free range domestic pigs: the distinction then should be made between domestic pigs and captive wild pigs on the one hand, and wild and feral pigs on the other hand. This is the policy adopted for the draft modified chapter on Aujeszky's disease, with which consistency should be sought. Proposals are inserted in the Article 15.2.1 below, which cannot be adopted as such. Since according to the TAHSC report, the SCAD is supposed to revise it in view of the OIE wildlife policy, it could be an opportunity to address all comments

Article 15.2.1.

General provisions

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between domestic pig and **populations on the one hand, and wild pig, including captive wild, and feral pig populations on the other. (including feral pigs) populations.**

EU comment

The distinction should be made "**between domestic pigs and captive wild pig populations on the one hand, and wild and feral pig populations on the other**".

Alternatively, the words "including captive wild" should be deleted.

For the purposes of ~~international trade~~ the Terrestrial Code, classical swine fever (CSF) is defined as an *infection* of domestic pigs.

EU comment

CSF should be defined as "an *infection* of domestic pigs or captive wild pigs".

Alternatively, CSF could be defined as "an *infection* of domestic pigs or captive wild pigs reared for the production of meat".

Domestic pig is defined as 'all domesticated pigs, permanently captive or farmed free range, used for the production of *meat* for consumption, for the production of other commercial products or for breeding these categories of pigs.

~~The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between domestic pig and wild pig (including feral pigs) populations.~~

Pigs exposed to CSF virus prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of *disease*. Pigs exposed postnatally have an *incubation period* of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic *infections*.

~~For the purposes of *international trade*, a Member should not impose trade bans in response to a notification of infection with classical swine fever virus in wild pigs according to Article 1.2.3. of the *Terrestrial Code* after the Member confirms that Article 15.2.2. is appropriately implemented.~~

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

A Member should not impose trade bans in response to a notification of infection with classical swine fever virus in wild and feral pigs according to Article 1.2.3. of the *Terrestrial Code* after the Member confirms that Article 15.2.2. is appropriately implemented.

Article 15.2.2.

Determination of the CSF status of a country, zone or compartment

The CSF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

1. CSF should be notifiable in the whole territory, and all clinical signs suggestive of CSF should be subjected to appropriate field and/or *laboratory* investigations;
2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;
3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;

EU comment

The *Veterinary Authority* should have current knowledge of, and authority over, all domestic and captive wild pigs in the country, zone or compartment".

4. the *Veterinary Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone*;

EU comment

The *Veterinary Authority* should have current knowledge about the population and habitat of wild and feral pigs in the country or zone".

5. for domestic pigs, appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, and the risk posed by wild pigs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 15.2.23. to 15.2.28.;

EU comment

For domestic and captive wild pigs, appropriate surveillance, etc.

6. for wild pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.2.28., taking into account the presence of natural and artificial boundaries, the ecology of the wild pig population, and an assessment of the risks of *disease* spread.

EU comment

For wild and feral pigs if present in the country or zone, a surveillance programme, etc.

7. Based on the assessed risk of spread within the wild pig population, **and according to Article 15.2.26.**, the domestic pig population should be separated from the wild pig population by appropriate biosecurity measures to prevent transmission of CSF from wild to domestic pigs.

EU comment

The domestic pig and captive wild pig populations should be separated from the wild pig and feral pig populations by appropriate measures to prevent transmission of CSF ~~from wild to domestic pigs~~.

Article 15.2.3.

CSF free country, zone or compartment

A country, *zone* or *compartment* may be considered free from CSF when *surveillance* in accordance with Articles 15.2.23. to 15.2.28. has been in place for at least 12 months, and when:

1. there has been no *outbreak* of CSF in domestic pigs during the past 12 months;
2. no evidence of CSFV infection has been found in domestic pigs during the past 12 months;
3. no vaccination against CSF has been carried out in domestic pigs during the past 12 months unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;
4. imported domestic pigs comply with the requirements in Article 15.2.5. or Article 15.2.6.

Article 15.2.4.

Recovery of free status

Should a CSF *outbreak* occur in a free country, *zone* or *compartment*, the free status may be restored where *surveillance* in accordance with Articles 15.2.23. to 15.2.28. has been carried out with negative results either:

1. 3 months after the last *case* where a *stamping-out policy* without vaccination is practised;

OR

2. where a *stamping-out policy* with emergency vaccination is practised:
 - a) 3 months after the last *case* and the *slaughter* of all vaccinated *animals*, or
 - b) 3 months after the last *case* without the *slaughter* of vaccinated *animals* where there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

OR

3. where a *stamping-out policy* is not practised, the provisions of Article 15.2.3. should be followed.

Article 15.2.5.

Recommendations for importation from countries, zones or compartments free of CSF

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of CSF on the day of shipment;
2. were kept in a country, *zone* or *compartment* free of CSF since birth or for at least the past 3 months;
3. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.2.6.

Recommendations for importation from CSF infected countries or zones

for domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of CSF on the day of shipment;
2. were kept since birth or for the past 3 months in a CSF free *compartment*;
3. have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.2.7.

Recommendations for the importation of wild pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1. showed no clinical sign of CSF on the day of shipment;
2. were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;
3. have not been vaccinated against CSF, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.2.8.

Recommendations for importation from countries, zones or compartments free of CSF

for semen of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) were kept in a country, *zone* or *compartment* free of CSF since birth or for at least 3 months prior to collection;
 - b) showed no clinical sign of CSF on the day of collection of the semen;

2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.2.9.

Recommendations for importation from CSF infected countries or zones

for semen of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor *animals*:
 - a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;
 - b) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;
 - c) met one of the following conditions:
 - i) have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results; or
 - ii) have been vaccinated against CSF and were subjected to a serological test in accordance with the *Terrestrial Manual* performed at least 21 days after collection and it has been conclusively demonstrated that any antibody is due to the vaccine; or
 - iii) have been vaccinated against CSF and were subjected to a virological test performed in accordance with the *Terrestrial Manual* on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;
2. the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.2.10.

Recommendations for importation from countries, zones or compartments free of CSF

for *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females showed no clinical sign of CSF on the day of collection of the embryos;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 15.2.11.

Recommendations for importation from CSF infected countries or zones

for *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

- a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;
 - b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 days;
 - c) and either:
 - i) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or
 - ii) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;
2. the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 15.2.12.

Recommendations for importation from countries, zones or compartments free of CSF

for fresh meat of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *animals* which:

1. have been kept in a country, *zone* or *compartment* free of CSF, or which have been imported in accordance with Article 15.2.5. or Article 15.2.6.;
2. have been slaughtered in an approved *abattoir*, have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of CSF.

Article 15.2.13.

Recommendations for the importation of fresh meat of wild pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that ~~the entire consignment of *fresh meat* comes from *animals*.~~

1. the entire consignment of *fresh meat* comes from *animals* which have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, and have been found free of any sign suggestive of CSF;
2. where the CSF-free status of the wild and feral pig population cannot be assured, the entire consignment of *meat* comes from *animals* from each of which a sample has been collected and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 15.2.14.

Recommendations for the importation of meat and meat products of pigs, or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. have been prepared:
 - a) exclusively from *fresh meat* meeting the conditions laid down in Article 15.2.12.;
 - b) in a processing establishment:
 - i) approved by the *Veterinary Authority* for export purposes;
 - ii) processing only *meat* meeting the conditions laid down in Article 15.2.12.;

OR

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.2.21. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.15.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in accordance with Article 15.2.20. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.16.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for agricultural or industrial use

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.17.

Recommendations for the importation of bristles

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.18.

Recommendations for the importation of litter and manure

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone or compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.19.

Recommendations for the importation of skins and trophies

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the products:

1. originated from domestic pigs in a CSF free country, *zone or compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or
2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.2.22. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.20.

Procedures for the inactivation of the CSF virus in swill

For the inactivation of CSF viruses likely to be present in swill, one of the following procedures should be used:

1. the swill should be maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
2. the swill should be maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar.

Article 15.2.21.

Procedures for the inactivation of the CSF virus in meat

For the inactivation of viruses present in *meat*, one of the following procedures should be used:

1. Heat treatment

Meat shall be subjected to one of the following treatments:

- a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;

- b) heat treatment at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Natural fermentation and maturation

The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

- a) an aw value of not more than 0.93, or
b) a pH value of not more than 6.0.

Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

3. Dry cured pork meat

- a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.
b) Spanish style pork *meat* with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

Article 15.2.21.bis

For the inactivation of CSF virus present in natural casings of pigs, the following procedures should be used: salting for at least 30 days with phosphate supplemented dry salt containing 86.5% NaCl, 10.7% Na₂HPO₄ and 2.8% Na₃PO₄ (weight/weight/weight), and kept at a temperature of greater than 12°C during this entire period.

EU comment

The inactivation procedure above should also allow the use of the same mixture as saturated brine since this is a standard industrial process for the preservation of casings.

Article 15.2.22.

Procedures for the inactivation of the CSF virus in skins and trophies

For the inactivation of CSF viruses ~~likely to be~~ present in skins and trophies, one of the following procedures should be used:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;
2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
3. soaking, with agitation, in a 4% (weight/volume) solution of washing soda (sodium carbonate - Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours;
4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na₂CO₃).

Article 15.2.23.

Surveillance: introduction

Articles 15.2.23. to 15.2.28. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Members seeking to determine their CSF status. This may be for the entire country, ~~or~~ a *zone or a compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of CSF status is also provided.

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific recommendations for all situations. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where wild pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Members to provide a well-reasoned argument to prove that absence of classical swine fever virus (CSFV) infection is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that a population in a country, *zone* or *compartment* is free from CSFV infection or to detect the introduction of CSFV into a population already recognized as free. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on *disease* spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent *infections*, the occurrence of persistent and chronic *infections*, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purposes of this chapter, virus *infection* means presence of CSFV as demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article 15.2.24.

Surveillance: general conditions and methods

1. A *surveillance* system, in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority*, should address the following aspects: A procedure should be in place for the rapid collection and transport of samples to an accredited laboratory as described in the *Terrestrial Manual*.
 - a) formal and ongoing system for detecting and investigating outbreaks of disease or CSFV infection should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of CSF to a laboratory for CSF diagnosis as described in the *Terrestrial Manual*;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
2. The CSF *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of CSF to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological,

and *laboratory* diagnosis. ~~This requires that sampling kits and other equipment are available to those responsible for surveillance.~~ Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;

- b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of *animals* (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected wild pigs are present).

An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is CSFV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Recognitions for freedom from CSFV infection should, as a consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with.

This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement standstill orders, etc.).

Article 15.2.25.

Surveillance strategies

1. Introduction

~~There are two basic strategies that can be employed for CSF surveillance depending on the purpose of the Member for seeking recognition of freedom from CSF. In countries free of CSF, surveillance programmes should be designed to detect the presence introduction of CSFV infection into domestic or wild swine. The optimal strategy to meet this objective is most often targeted surveillance.~~

~~The population covered by surveillance aimed at detecting disease and infection should include domestic and wild pig populations within the country or zone to be recognised as free from CSFV infection. Such surveillance may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted surveillance.~~

Although surveillance may involve opportunistic testing of samples submitted for other purposes, the optimal strategy to meet this objective is usually targeted surveillance. Surveillance is targeted to aimed at the domestic, and wild and feral pig population which presents the highest risk of infection (for example, swill fed farms, pigs reared outdoors, specific wild pig sub-populations or farms in proximity to infected wild pigs). Each Member will need to identify its individual risk factors. Targeted surveillance may include randomized sampling in selected high risk populations, based on the risk factors present. These may include: temporal and spatial distribution of past *outbreaks*, pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent *infections* and difficulties associated with differential diagnosis of other *diseases*, serology is often the most effective and efficient *surveillance* methodology. In some circumstances, which will be discussed later, clinical and virological *surveillance* may also have value.

The surveillance strategy chosen ~~The Member should be justified the surveillance strategy chosen~~ as adequate to detect the presence of CSFV infection in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of passive *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy. ~~If a Member wishes to apply for recognition by other Members of a specific zone within the country as being free from CSFV infection, the design of the surveillance strategy and the basis for any sampling process would need to be aimed at the population within the zone.~~

When applying randomized sampling, either at the level of the entire population or within targeted sub-populations For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalences for the selected populations. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. ~~The sample size and expected disease prevalence determine the level of confidence in the results of the survey.~~ The choice of design prevalence and confidence level ~~The Member should be justified the choice of design prevalence and confidence level~~ based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular, clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design approach selected, the sensitivity and specificity of the diagnostic tests in the target populations employed should be considered are factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.

Irrespective of the testing system employed, the *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

2. Clinical and virological surveillance

~~Beyond their role in targeted surveillance, clinical and virological surveillance for CSF has two aims: a) to shorten the period between introduction of CSF virus into a disease free country or zone and its detection, and b) to confirm that no unnoticed outbreaks have occurred.~~

~~In the past, The value of clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of surveillance alone is limited due to the low virulence of some strains of CSF, as well as the emergence of new diseases (such as post-weaning multisystemic wasting syndrome, and porcine dermatitis and nephropathy syndrome – have made such reliance less effective, and, in countries where such diseases are common, can add significant risk of masking the presence of CSF) which can mask the presence of CSF. Therefore, clinical surveillance should be supplemented, as appropriate, by serological and virological surveillance.~~

~~The spectrum of disease signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a surveillance tool. These factors, along with the compounding effects of concurrent infections and diseases caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring.~~

~~Nevertheless, Clinical and pathological signs presentation should not be ignored as a tool are useful for early detection; in particular, any *cases* where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young *animals*, and adult animals may not show clinical sign. Otherwise close physical examination of susceptible *animals* is useful as a selection criteria for CSF *surveillance*, particularly in diagnostic laboratories or slaughter establishments or when applied to high risk populations such as swill feeding operations.~~

~~The difficulties in detecting chronic disease manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a *herd* investigation, such *animals* are likely~~

to be in a minority and would not confound a diagnosis based on serology. Individually or as part of recently mixed batches, such *animals* may, however, escape detection by this method. A holistic approach to investigation, taking note of *herd* history, pig, personnel and *vehicle* movements and disease status in neighbouring *zones* or countries, can also assist in targeting *surveillance* in order to increase efficiency and enhance the likelihood of early detection.

The labour intensive nature of clinical, pathological and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for *surveillance*. However, *surveillance* based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. *Herds* predominated by adult *animals*, such as nucleus *herds* and artificial insemination studs, are particularly useful groups to monitor, since *infection* by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large scale screening for the presence of virus, at reasonable cost.

Wild **and feral** pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as antibody.

3. Virological surveillance

Virological surveillance should be conducted using tests described in the *Terrestrial Manual*.

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test abnormal daily mortality, to ensure early detection of infection.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of disease. Epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in outbreaks in disease free areas.

Vaccine design and diagnostic methodologies, and in particular methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing *disease*. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in *disease* free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.

3.4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

- a. natural *infection* with CSFV;

- b. ~~legal or illegal~~ vaccination against CSF;
- c. ~~maternal antibodies derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age, but, in some individuals, maternal antibodies can be detected for considerably longer periods;~~
- d. cross-reactions with other pestiviruses;
- e. non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. ~~Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the *herd* level will be high.~~

CSFV may lead to persistently infected, sero-negative young *animals*, which continuously shed virus. CSFV infection may also lead to chronically infected pigs *which* may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these *animals*, such *animals* are likely to be in a minority and would not confound a diagnosis based on serology as part of a *herd* investigation.

It may be possible to use sera collected for other survey purposes for CSF *surveillance*. However, the principles of survey design described in this chapter and the requirement for statistical validity should not be compromised.

~~The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection* by field strains or other pestiviruses. Because clustering may signal field strain *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *animals* is always epidemiologically significant and therefore should be investigated.~~

~~In countries or *zones* that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme. In countries, *zones* or *compartments* that are heading towards freedom from CSF and have recently discontinued the use of vaccination, targeted serosurveillance of young, unvaccinated *animals* stock will indicate whether newly can provide useful information on possible virus circulation circulating virus is present, although the presence of maternal antibody will also need to be considered. Maternal antibodies are usually found up to four and a half months of age and can interfere with the interpretation of serological results. If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated *animals* and after the disappearance of maternal antibody. General usage in such situations may also be used to assess levels of vaccine coverage.~~

~~Marker *v*vaccines also exist which, when used in conjunction with accompanying DIVA tests as described in the *Terrestrial Manual* dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field *natural* *infection*. Such tools, described in the *Terrestrial Manual*, will need to be fully validated. They do not confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental *infections*. Furthermore, However, the interpretation of serosurveillance results using DIVA techniques is only meaningful on a *herd* level such differentiation requires cautious interpretation on a *herd* basis.~~

~~The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV infection is present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.~~

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing freedom, has occurred. Such changes include but are not limited to:

- f. ~~an emergence or an increase in the prevalence of CSF in countries or zones from which live pigs or products are imported;~~
- g. ~~an increase in the volume of imports or a change in their country or zone of origin;~~
- h. ~~an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or zones;~~
- i. ~~an increased entry from, or exposure to, infected wild pig populations of adjacent countries or zones.~~

Article 15.2.26.

Countries, zones or compartments declaring freedom from CSF: additional surveillance procedures

1. Country or zone free of CSF

In addition to the general conditions described above, a Member seeking recognition of CSF freedom for the country or a ~~zone, whether or not vaccination had been practised,~~ should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or ~~zone~~ and will be planned and implemented according to the general conditions and methods described in this chapter. The objective is to demonstrate the absence of CSFV infection in domestic pigs and ascertain the infection status in wild and feral pig populations, as described in Article 15.2.28. This requires the support of a national or other *laboratory* able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.

2. Compartment free of CSF

The objective of *surveillance* is to demonstrate the absence of CSFV infection in the *compartment*. The provisions of Chapters 4.3. and 4.4. should be followed. The frequency and intensity of surveillance should be defined and adapted to the prevailing epidemiological situation in the country or zone. Any deterioration in the epidemiological situation should trigger a review of the biosecurity measures and an intensification of surveillance. The effective separation of the ~~two~~ subpopulations should be demonstrated. To this end, a *biosecurity plan* that includes but is not limited to the following provisions should be implemented:

- a. proper containment of domestic pigs;
- b. control of movement of *vehicles* with cleaning and *disinfection* as appropriate;
- c. control of personnel entering into the *establishments* and awareness of risk of fomite spread;
- d. prohibition of introduction to the *establishments* of wild **and feral** caught *animals* and their products;
- e. record of animal movements into and out of *establishments*;
- f. information and training programmes for farmers, processors, *veterinarians*, etc.

The *biosecurity plan* implemented also requires internal and external monitoring by the *Veterinary Authority*. This monitoring should include:

- g. periodic clinical and serological monitoring of *herds* in the country or *zone*, and adjacent wild pig populations following these recommendations;
- h. *herd* registration;
- i. official accreditation of *biosecurity plans*;
- j. periodic monitoring and review.

Monitoring the CSF status of wild **feral** and domestic pig populations outside the *compartment* will be of value in assessing the degree of risk they pose to the CSF free *compartment*. The design of a monitoring system should follow the provision described in this chapter and in Chapter 1.4. ~~is dependent on several factors such as the size and distribution of the population, the organisation of the *Veterinary Services* and resources available. The occurrence of CSF in wild and domestic pigs may vary considerably among countries. *Surveillance* design should be epidemiologically based, and the Member should justify its choice of design prevalence and level of confidence based on Chapter 1.4.~~

~~The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include government wildlife authorities, wildlife conservation organisations, hunter associations and other available sources. The objective of a *surveillance* programme when the *disease* is already known to exist should be to determine the geographic distribution and the extent of the *infection*.~~

Article 15.2.27.

Recovery of free status: additional surveillance procedures

In addition to the general conditions described in ~~the above mentioned articles~~ this chapter, a Member seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active *surveillance* programme to demonstrate absence of CSFV infection.

Populations under this *surveillance* programme should include:

- a. *establishments* in the proximity of the *outbreak*;
- b. *establishments* epidemiologically linked to the *outbreak*;
- c. *animals* used to re-populate affected *establishments* and any *establishments* where contiguous culling is carried out;
- d. wild **and feral** pig populations in the area of the *outbreak*.

In all circumstances, a Member seeking reestablishment of country or *zone* freedom from CSF ~~with vaccination or without vaccination~~ should report the results of an active and a passive *surveillance* programme, ~~in which~~ the pig population should undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should be based on a statistically representative sample of the populations at risk. To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as demonstrated during the previous declaration of freedom.

Article 15.2.28.

Surveillance for CSFV infection in wild **and feral** pigs

1. The objective of a *surveillance* programme is to determine the CSFV infection status of wild **and feral** pigs, as well as the geographic distribution and prevalence, if present. While the same principles apply, *surveillance* in wild **and feral** pigs presents challenges beyond those encountered in domestic populations in each of the following areas:
 - a) determination of the distribution, size and movement patterns associated with the wild **and feral** pig population;
 - b) assessment of the possible presence of CSF within the population;
 - c) determination of the practicability of establishing a *zone*.

- ~~2.~~ The design of a monitoring system for wild pigs is dependent on several factors such as the organisation of the *Veterinary Services* and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include wildlife conservation organisations, hunter associations ~~and other available sources, etc.~~ The objective of a *surveillance* programme is to determine if a given *disease* is present, and if so, at what prevalence.
- ~~32.~~ Estimates of wild pig populations can be made using ~~advanced~~ a variety of methods (e.g. including radio tracking, linear transect method, capture/recapture) or estimates based on the number of animals hunted ~~traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).~~
- ~~43.~~ For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild and feral pigs range in order to delineate the *epidemiological units* within the monitoring programme. It is often difficult to define *epidemiological units* for wild and feral animals. The most practical approach is based on natural and artificial barriers.
- ~~54.~~ The monitoring programme should also include *animals* found dead, road kills, *animals* showing abnormal behaviour or exhibiting gross lesions during dressing.
- ~~65.~~ There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:
- a. areas with past history of CSF;
 - b. sub-regions with large populations of wild pigs;
 - c. border regions with CSF affected countries or *zones*;
 - d. interface between wild, feral and domestic pig populations;
 - e. ~~picnic and camping areas;~~
 - ~~f.~~ farms with free-ranging pigs;
 - ~~g.~~ ~~garbage dumps;~~
 - ~~h.~~ other risk areas determined by the *Veterinary Authority* such as garbage dumps and picnic and camping areas.
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