UNION EUROPÉENNE

SANCO

01. 07. 2004

Bruxelles, le
D(2004) 521349/HB/vb

Object: **Meeting of the International Terrestrial Animal Health Code Commission – June/July 2004**

Dear Bernard,

Please find attached as an annex to this letter the Community comments firstly on the report of the meeting of the ad hoc group to revise the bluetongue Chapter in the OIE Terrestrial Animal Health Code and secondly on the new Avian Influenza Code Chapter agreed (but under study) at the recent Annual General Session. In order to facilitate the examination of the comments of the Community, they have been incorporated in boxes into the OIE reports. However due to the complexity of the proposed avian influenza Chapter the Community comments are in part in the form of highlighted amendments to the draft. In this context, the Community thanks the OIE for providing the electronic version of the report.

It needs to be highlighted that our comments already submitted to you for the other drafts should also be taken into account, please see my letter to you reference D(2004)520721. Concerns were expressed over the proposed Tuberculosis Chapter in particular over its new construction and in addition a new comment over the need to link the wild life survey to trade in domestic animals should be included; this is not a critical point for trade purposes.

Thank you for the continued excellent collaboration and trust you will find our comments constructive and useful.

Paddy Rogan

Chief Veterinary Officer

Jaana Husu-Kallio

Deputy Director General

Enclosures: 1

Copy: All CVOs Member States, Bulgaria, Iceland, Norway, Romania and Switzerland.

Dr. B. Vallat
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FRANCE

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
SEC(2004)873 Rev1

COMMISSION STAFF WORKING DOCUMENT

Written comments of the Community on (1) a draft report of the meeting of an ad hoc group to revise the bluetongue Chapter in the OIE Terrestrial Animal Health Code and (2) on a review of the new Avian Influenza Code Chapter to be submitted for adoption and consideration in the 73rd General Session to be held in May 2005

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ANNEX 1

Original: English

July 2003

1. COMMUNITY COMMENTS ON THE BLUETONGUE CHAPTER IN THE OIE TERRESTRIAL REPORT OF THE MEETING OF AN AD HOC GROUP TO REVISE THE ANIMAL HEALTH CODE

Organisation Mondiale de la Sante Animale
World Organisation for Animal Health
Organizacion Mundial de Sanidad Animal

2. ORIGINAL: ENGLISH
MARCH 2004

MEETING OF AN AD HOC GROUP TO REVISE THE BLUETONGUE CHAPTER IN THE OIE TERRESTRIAL ANIMAL HEALTH CODE

PARIS 29 MARCH 2004

The *ad hoc* Group met at the OIE Headquarters on 29 March 2004. The list of participants is at Appendix I. The agreed agenda is at Appendix II.

Dr David Wilson welcomed the two participants on behalf of the Director-General Dr Bernard Vallat. He recalled that, during the December meeting of the Code Commission, the Director-General had given a high priority to a review of the bluetongue chapter as a result of the 2003 OIE Bluetongue Conference in Sicily, for discussion at the 2004 OIE General Session. Accordingly, the outcomes of that conference (see report at Appendix III) were used as a basis for discussion of proposed changes to the *Code* chapter. Some comments from Member Countries were also taken into account, including on proposals to protect animals from *Culicoides* attack. The proposed revised chapter is at Appendix IV.

Regarding a surveillance appendix for bluetongue, Dr Caporale confirmed that the OIE *ad hoc* Group on epidemiology would take into account in its work on developing an appendix, the relevant outcomes of the conference and the comments received from Member Countries.

Specific issues discussed and the relevant reference(s) in the report of the 2003 OIE Bluetongue Conference are as follows:

Infective period for bluetongue

> Studies undertaken to follow viraemias in experimentally infected cattle revealed that the virus can be recovered by virus isolation techniques for as long as 45 to 50 days. In contrast, viral RNA can be detected by polymerase chain reaction (PCR) for as long as 220 days after infection. The significance of this observation is that careful consideration of the clinical signs and PCR results is critical for appropriate diagnosis.
>
> In the case of healthy, non-vaccinated animals, animals (whether seropositive from natural infection or seronegative) may move at any time without posing a risk of virus spread provided that an adequate surveillance system has been in place in the source population

for a period of 60 days immediately prior to dispatch without detecting evidence of bluetongue virus circulation.

Global BTV distribution

It was shown that the northern distribution of BTV in Asia and Europe is similar to that in North America, and far beyond the 40° N limit that traditionally was proposed. Specifically, BT recently has occurred to approximately 45° N in Europe, and BTV infection of ruminants has been documented as far as 50° N in Asia. Much remains to be understood about these northern Eurasian BTV episystems, in terms both of their species of insect vector as well as the specific strains of BTV that occur within each. Similarly, the strains of BTV and the relative importance of different potential vector species awaits adequate characterization in variable portions of the extensive BTV episystems that occur in South America, Africa, the Middle East and Asia.

Significant changes in our understanding of BT became evident during the course of the symposium when we learned that the global distribution has changed. As recently as our previous symposium, the distribution was thought to occur between the latitudes of 40 degrees north and 35 degrees south. Since 2000, BT appears to have become established at 45 to 50 degrees north latitude. These new observations of distribution have expanded our perceptions of BT.

Vector competence

The vector competence of Culicoides species and populations should be measured, where possible using field viruses. Candidate species can be prioritised on the basis of epidemiological evidence, feeding preference for hosts and level of abundance. Epidemiological analysis (serosurveys, vector surveys, ecological analysis, study of outbreaks) can provide guidance for the selection of candidate species for vector competence studies, and can be used to assess the likely significance of results.

The OIE should reconsider the broad use of the term "Culicoides" to indicate midges from the genus Culicoides spp. that have been shown or are suspected to be probable vectors of BTV. In other words, be specific as to the species involved.

Surveillance

The extent of a surveillance program in countries adjacent to a country that does not have free status. A distance of 100 km is specified but a lesser distance could be acceptable if there are relevant geographical features that interrupt the transmission of BTV.

Vaccination

In considering the potential movement of BTV seropositive animals from an infected to a free zone or country, the Working Group concludes that animals may move at any time without posing a risk of virus spread if they have been vaccinated with a licensed or authorized attenuated, inactivated, subunit, or genetically manipulated vaccine at least one month prior to movement provided that the vaccine used covers all serotypes which would be expected to be present at origin from adequate surveillance and that the animals are identified as vaccinates.

Animals receiving vaccines produced by culture in embryonated chicken eggs shall not be moved internationally.

Diagnosis

The AGID assay, while easy and cheap to perform, lacks sensitivity and manifests cross reactions with EHDV. The C-ELISA is now standard technology.

... /Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON BLUETONGUE

3.

4. PARIS, 29 MARCH 2004

List of Participants

MEMBERS OF THE OIE AD HOC GROUP

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON BLUETONGUE

5.

6. PARIS 29 MARCH 2004

7. _____

8. AGENDA

1. **Issues arising from the bluetongue conference in Sicily**
2. **Proposed revised Terrestrial Animal Health Code chapter**
3. **Surveillance appendix on bluetongue**
4. **Other issues**

THIRD INTERNATIONAL SYMPOSIUM ON BLUETONGUE: CONCLUSIONS

Introduction

Executive Committee
V. Caporale,
N.J. MacLachlan,
J.E. Pearson
A. Schudel

Introduction

The timely need for a third international symposium on bluetongue (BT) was emphatically emphasized by the unexpected and unprecedented recent occurrence of the disease throughout much of the Mediterranean Basin. Furthermore, international understanding of BT clearly has not kept pace with scientific developments since the last symposium in 1991, and it also now is nearly 10 years since the Uruguay Round of negotiations of the General Agreement on Tariffs and Trade; these negotiations lead to the introduction of the Sanitary and Phytosanitary regulations of the World Trade Organization that now guide international trade of animals and animal products.

Intense international interest in BT and BTV was reflected in the some 300 individuals who attended the symposium, and in the 45 scientific oral presentations and over 90 posters in which relevant information was presented. In conjunction with the symposium, international experts were assigned to various working groups that were charged with providing constructive, transparent and science-based recommendations pertaining to the understanding and international regulation of BT.

Critical conclusions and findings from the symposium

Global occurrence of bluetongue virus episystems: Several researchers elegantly confirmed the original concept pioneered by P. Gibbs, A. Gould and others at the second BT symposium in 1991 that distinct strains of BTV (virus topotypes) vectored by different species of Culicoides vectors occur in specific regions of the world. It was further shown that the topotypes of BTV and the vector species that occur within each episystem are relatively stable, despite extensive and ongoing trade and movement of ruminants between individual episystems. Much remains to be learned about the ecological, climatic and environmental factors that lead to expansion of BTV episystems, as recently occurred in the Mediterranean Basin for example, but it is increasingly evident that an understanding of these factors is prerequisite to defining what limits the boundaries of individual BTV episystems.

It was shown that the northern distribution of BTV in Asia and Europe is similar to that in North America, and far beyond the 40° N limit that traditionally was proposed. Specifically, BT recently has occurred to approximately 45° N in Europe, and BTV infection of ruminants has been documented as far as 50° N in Asia. Much remains to be understood about these northern Eurasian BTV episystems, in terms both of their species of insect vector as well as the specific strains of BTV that occur within each. Similarly, the strains of BTV and the relative importance of different potential vector species awaits adequate characterization in variable portions of the extensive BTV episystems that occur in South America, Africa, the Middle East and Asia.

Although further refinement and sophistication is ongoing, existing diagnostic technology is adequate for comprehensive global surveillance and monitoring of the distribution and activity of BTV. Indeed, there has been remarkable international acceptance and adoption of virus-detection assays based on the polymerase chain reaction (PCR) since the second symposium, and the widespread use of PCR technology also has enhanced our understanding of the global ecology of BTV infection because it has facilitated sequence analysis of the strains of BTV that infect the insect vectors and ruminants that reside within each of the various BTV episystems. A potential disadvantage of the PCR technology is that it is so exquisitely sensitive that it can detect BTV nucleic acid in the tissues of previously infected ruminants in the absence of infectious virus, an issue that is relevant to the regulation of animal movement from BTV-endemic areas. Clearly, however, the available diagnostic technologies specifically and sensitively can identify BTV infection of the insect and animal hosts of the virus. Thus, the global and regional distribution of BTV can now comprehensively be determined using appropriate surveillance and monitoring. Furthermore, the collation of such data should be an issue of the highest priority to the international community given that BTV has been identified on every continent except Antarctica, and that little information currently is available from many areas of the world. An integrated, comprehensive network of surveillance, monitoring and reporting is required to establish the global limits of the distribution of BTV and of competent Culicoides vectors.

Lifecycle of bluetongue virus infection

Several studies confirmed conclusions of the first and second symposia that BTV infection of ruminants is transient, whereas infection of the Culicoides insect vector is persistent. Detailed and elegant studies by Australian workers who evaluated large numbers of naturally infected cattle have unequivocally shown that BTV infection of these animals does not persist more than a few weeks. Thus, international trade policies must increasingly reflect the reality that BTV infection of ruminants is transient and that seropositive animals are resistant to reinfection with the homologous BTV serotype and can be safely moved. Attention should now be focused on the climatic, ecological and environmental factors that determine the range of the insect vectors that persistently harbour BTV within each episystem, because detailed understanding of these factors, and not unwarranted restrictions on animal movement, is prerequisite to the ultimate control of BT.

Vaccines and vaccination

Inactivated, live-attenuated (modified live), and subunit vaccines all have been developed to protectively immunize ruminants against BTV infection. Each of these different vaccines types has perceived inherent advantages and disadvantages, including their ease of production and cost, number of immunizations required, availability, efficacy, duration of immunity, and potential adverse side-effects. However, only live-attenuated BTV vaccines currently are commercially available in the quantities that are required to confront major outbreaks of BT; thus, these vaccines will continue to be utilized until such time as viable substitutes are produced in sufficient quantity. Given the enormous scope of recent outbreaks of BT in the Mediterranean Basin and elsewhere, there is a clear need to develop and evaluate all potential vaccine strategies to both protect animals and to facilitate trade from endemically infected areas. Provocative data also was provided suggesting that strategic vaccination of all susceptible animals reduced virus circulation during the recent incursion of BTV into the European episystem, an observation that clearly warrants further study.

Summary

The third symposium showcased the remarkable progress that has been made on the understanding of BT and BTV since the first and second international symposia that were held in 1984 and 1991. Attention has now shifted from ruminants to Culicoides insects as the primary host of BTV, meaning that animals can safely be moved between and within BTV episystems using transparent, science-based criteria. Current diagnostic technology provides the tools for very accurate surveillance and monitoring within BTV episystems, and to better predict incursion of BTV into previously unaffected areas and to guide the safe movement of animals. Critical deficiencies persist in regard to our understanding of the global ecology of BTV and its episystems, however, including the lack of detailed understanding of the environmental factors that precipitated the recent expansion of the range of competent insect vectors and/or BTV in the Mediterranean Basin for example. Similarly, some global BTV episystems are yet to be defined in any detail at all, including those in South America, portions of Africa and Asia, and at the northern margins of the virus' range in Eurasia. Lastly, viable options (choices) of vaccines that can be produced in the quantities needed to confront an extensive BT outbreak currently are limited to live-attenuated vaccines, meaning that efforts should continue to evaluate all

potential strategies to minimize the economic impact of BTV when it incurs into previously unaffected regions.

Summary of the OIE Third International Symposium on Bluetongue

B. I. Osburn School of Veterinary Medicine University of California, Davis, Ca, USA

Scientists, regulatory officials and livestock producers met at the Third International Symposium on Bluetongue (BT) to discuss current scientific advances, issues and policies as well as to identify areas needing additional research related to policy matters. The symposium addressed:

1) epidemiology and global distribution;
2) monitoring and surveillance;
3) biology of BT and its vectors;
4) diagnostics;
5) vaccines; and
6) strategies for intervention.

Epidemiology and Global Distribution

Significant changes in our understanding of BT became evident during the course of the symposium when we learned that the global distribution has changed. As recently as our previous symposium, the distribution was thought to occur between the latitudes of 40 degrees north and 35 degrees south. Since 2000, BT appears to have become established at 45 to 50 degrees north latitude. These new observations of distribution have expanded our perceptions of BT.

At the Second International Symposium on BT, the epidemiology of BT viruses (BTV) was categorized into zones: endemic, epidemic and incursion zones. The endemic zone lies in tropical climates where competent Culicoides spp. are actively spreading BTVs all year. BT disease is rarely observed in this zone. The epidemic zone is located in temperate climates where competent Culicoides spp. appear during the warm season, and some disease is observed seasonally. The incursion zones are those where BT appears every decade or so, associated with climatic changes. The competent Culicoides spp. appear for one to two years, and outbreaks disease occur as long as competent vectors are in the area.

Maps depicting the distribution of BT are historic records of BT's occurrence. Boundaries move with the vectors, which do not respect political boundaries. Instead, vector distribution is based on climatic and environmental conditions. We realized that we must now approach BT, not as a disease of countries, but one of continents.

Monitoring and surveillance

The symposium highlighted the critical role of vectors as the principal means of spreading BTVs. Not all Culicoides spp. transmit BTV. When seeking to determine

potential distribution of BTVs, regulatory agencies need only consider those Culicoides spp. that are competent for transmission of BTV. In the absence of competent Culicoides spp. vectors, BTV will not survive in an area. There is no evidence that BTV persist in cattle, a clear indication that ruminants are of no importance in the movement of BTV from one geographic region to another.

Symposium participants acknowledged the importance of competent Culicoides spp. vectors in the distribution of BTV in Europe.

Biology of Bluetongue and its Vectors

BTVs are gastrointestinal viruses of Culicoides spp. Domestic and wild ruminants are the amplifying hosts for the insect vectors of BTV. One gene controls BTV competency in Culicoides spp. The phenotypic expression of the gene is influenced by temperature, rainfall, soil pH, and other factors. The role of these vectors in overwintering of BTV in Culicoides spp. appears to be based on temperature. If the environmental temperature is not sufficient for complete viral protein assembly, incomplete virus will remain in the intestinal cells of the vector until the critical temperature for virus assembly is reached.

Identifying the Culicoides spp. vectors in Europe and Central Asia will assist in better understanding the distribution of BTV. The genotyping of viruses based on Non-structural protein 3 (NS-3) has led to the concept of "topotyping" and topotyping makes a significant difference in determining the limitations of the virus serotypes in various locations around the world. For example, BTV 2, 10, 11, 13 and 17 occur in North America.. BTV 2 is only described in Florida and adjacent states in the United States (U.S.). The vector for BTV 2 is Culicoides insignis (C. insignis), whereas the other North American serotypes are transmitted by C. sonorensis. BTV 2 has not adapted to C. sonorensis, even though this vector is in Florida.

Scientists have also made remarkable progress in characterizing the BTV structure and function since the Second International Symposium on BT. Phenomenal advances have taken place with the BTV model, which has helped define serology, virulence, cell biology, and viral assembly.

Topotyping strategies have led to important advances in our understanding of the biology of BTV. The topotyping procedures of BTVs in Australia, Southeast Asia, and South-Central Asia have led to the recognition of regionally distinct viral groupings classified as Australia A, Java A, Java C and Malaysia A. Classifying these viral isolates is important for evaluating whether new groupings will move into defined geographical areas. Experimental evidence was presented to demonstrate that BTV is a quasi-species virus.

Understanding the pathogenesis of BTV infection in ruminants helps define the pathogenic characteristics of these viruses in sheep and cattle. BTV infection is capable of causing hemorraghic lesions. BTV in sheep causes vascular damage resulting in disseminated intravascular coagulopathy with secondary effects include hemorrhage, edema and vascular thrombi leading to skeletal and cardiac muscle necrosis. Endothelial damage does not occur in cattle and therefore clinical disease is rare.

Studies undertaken to follow viremias in experimentally infected cattle revealed that the virus that can be recovered by virus isolation techniques for as long as 45 to 50 days. In contrast, viral RNA can be detected by polymerase chain reaction (PCR) for as long as 220 days after infection. The significance of this observation is that careful consideration of the clinical signs and PCR results is critical for appropriate diagnosis.

Diagnostics

Researchers have also developed improved viral diagnostics by applying molecular techniques to PCR assays for the identification of viral RNA in tissues of infected animals. The potential for application of new sophisticated technologies could greatly enhance diagnostic capabilities for virus identification and differentiation in the near future. Serological tests can be used in a variety of ways to evaluate BTV infections and epidemiology.

Vaccines

Information derived from molecular studies of viral assembly have led to the development of subunit viral proteins that can be recombined to create efficacious and safe vaccines. These newer vaccine types may ultimately replace attenuated and inactivated vaccine products which have been associated with fetal malformation and contamination of semen.

The South African attenuated virus vaccine strategies used on ruminants on Corsica and Italy were described. The sophisticated epidemiological studies will provide the relevant information as to the effectiveness of the vaccines in controlling infection, mortalities and distribution of BTV in Southern Europe. The vaccine strategies used in South Africa were described where 3 different vaccinations containing 5 serotypes of virus are administered over a 3 week period. This strategy has proven to be an effective means of controlling disease in ruminants in South Africa.

Control and Trade Issues

A review of the OIE International Standards for BT set the stage for reports of regulatory procedures in North America, South America and in the European Union. The movement of animals in North America bridges all of the epizones that BT is known to occur. Cattle movement from Mexico with similar and different serotypes of virus found in the U.S. was confined by the vector species. Cattle movement did not influence the distribution of virus beyond the vector boundaries. Similarly, the movement of cattle from the epizootic and incursion zones of the U.S. into the non-BT Northeastern U.S. and Canada has not resulted in the establishment of BTV infection in those zones. Again, C. sonorensis is not present in Northeastern U.S. or Canada thereby limiting the distribution of BTV to those areas. BTV infection was described in Argentina, Brazil and Chile. The virus was confined to the more temperate climates of these South American countries.

Monitoring and Surveillance - Group 1

Working Group Members

P. Kirkland, (Chair) Australia
A. Cameron Australia
C. Gomez-Tejedor Spain
I. Lager, Argentina
L. Melville, Australia
D. Stallknecht, USA
A. Giovannini, (Co-Chair) Italy
D. Dargatz, USA
Y. Goto Japan
J. MacLachlan USA

Committee charge:

Consider what monitoring and surveillance practices might be developed to address all of the animal, vector and virus factors associated with the potential risk of spread of BTV, and how these practices would be interfaced with the current OIE Terrestrial Animal Health Code. Also, consider innovative ways to evaluate risk pertaining to movement of animals from BTV-endemic areas, including the risk associated with the movement of immune versus non-immune animals.

Prior to consideration of a review of the requirements for surveillance and monitoring for BTV, the group was briefed (AC/AG) on a planned OIE Chapter on General Guidelines for Surveillance and Monitoring. The key features of the draft of the proposed General Surveillance and Monitoring Chapter are:

- Compared to the surveillance guidelines in the current Bluetongue Chapter, the proposed chapter on surveillance and monitoring is not prescriptive. If adopted, it would be acceptable to use a number of different sources of data and the merits of each different source could be taken into account. Data sources also could be derived on a random or non-random (structured/planned) basis.

- The analysis of data must be scientifically sound. The proposed chapter recognises the merits of merging data from different sources. Though different data sets may be complex, they may enhance each other.

- The aim of surveillance and monitoring is to generate data for use in risk-based assessments to support trade and usually aims to demonstrate freedom from infection, or the presence of an agent and define areas of low risk. The approach in the proposed chapter is intended to be output oriented, not method oriented.

- The Working Group recommends that OIE convene an ad hoc Group to review the current Bluetongue Chapter. The current BT Chapter is too prescriptive and confusing. In particular, there are a number of issues that require attention. They are listed in the order in which they appear in the Code and not in any order of priority. Those that need to be addressed are:

- The infective period - currently defined as 100 days but there is no data to support a period of longer than 60 days. Consideration could be given to risk assessments based on probabilities determined from the distribution of the duration of viraemias.

- Reference to northern and southern limits in terms of latitude.

- In view of the changing distribution of BTV, specifying actual northern or southern latitude is not appropriate. In the absence of confirmed disease, when a country lies within the latitude of

the current distribution of BTV, or is adjacent to an infected country or region, a surveillance and monitoring program should be conducted.

- Use of the term "Culicoides" on its own is misleading because most countries have one or more species of midges from this genus. The taxonomic term should be clarified to indicate midges from the genus Culicoides that have been shown or are suspected to be vectors of BTV.

- Methods of surveillance and levels of sampling needed to achieve the required degree of confidence need not be specified, rather that surveillance complies with the provisions of the proposed general chapter. Nevertheless, some examples of appropriate surveillance systems that provide guidance to the intensity and frequency of surveillance could be of benefit.

- The extent of a surveillance program in countries adjacent to a country that does not have free status. A distance of 100 km is specified but a lesser distance could be acceptable if there are relevant geographical features that interrupt the transmission of BTV.

- When a country is proven to be free, consideration should be given to less frequent surveillance if the country is not immediately adjacent to a bluetongue zone where the situation is unstable.

- The term "surveillance zone" is confusing because surveillance also occurs within the free zone. The purpose of this zone is to acknowledge a degree of uncertainty in the exact limits of BTV activity and to increase confidence in the status of the free zone. The term "buffer zone" is more appropriate though it is acknowledged that this term is defined in the Code as a zone that is used to prevent spread of a disease or agent into a free zone. Depending on geographical features, this zone may not actually prevent spread of BTV, though it does provide additional assurance for the safety of the free zone. While the width of such a zone has been suggested as 50 km, this may need to be narrower or wider, depending on local circumstances that are relevant to BTV transmission.

- It would be of benefit if the Manual of Diagnostic Tests in future specifies measures of sensitivity and specificity to assist the design of surveillance programs. In the absence of these measures in the Manual or when different tests are used, when a surveillance program is designed the performance characteristics of the test should be described.

- When surveillance is conducted, the species and age of animals needs to be considered to ensure that there is appropriate sensitivity for that surveillance. While cattle are usually more readily infected, other species may be used if they have been shown to be infected at a higher incidence.

- The presence of ecological zones for BTV in different parts of the world warrants recognition. Factors pertaining to vectors and hosts in one system may not be relevant to another.

- In consideration of the movement of live animals and germplasm between countries or zones within a country, it is suggested that a risk-based approach be adopted. Persistent infection with BTV does not occur. Further, the occurrence of virus in semen is rare and confined to the early period of viraemia. Consequently, appropriate strategies can be developed to allow the safe movement of animals (including those that are seropositive either as a result of natural infection or vaccination) and semen from animals in zones where BTV infection may occur. These movement controls should reflect the finite period of viraemia in both natural infections and after vaccination with live vaccines.

Research Needs.

The following research activities would be of benefit to surveillance and monitoring activities:

- For surveillance purposes, tests that distinguish between vaccinated and naturally infected animals will be of value;
- Detailed studies of viruses, vectors and their relationships at the boundaries of continental episystems;
- Improved type-specific serology;
- Enhanced methods for antigenic and genetic analyses of viruses;

The group also endorses the recommendations for research on vectors.

Vectors - Group 2

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Walter Tabachnick (Co-Chair) University of Florida, USA
Alessandra Torina IZS Sicily, Italy
Gert Venter ARC-OVI, South Africa
David White USDA-ARS-ABADRL, USA

Committee charge:
To develop specific recommendations that address issues pertaining to assessment of:
Vector competence
Vector capacity
Vector speciation and systematics
Vector ecology and control

Vector systematics and taxonomy

A clear understanding of Culicoides systematics and taxonomy is crucial to virtually all bluetongue virus (BTV) vector studies. Most important Culicoides vectors exist as species complexes and the members of these complexes may occur together or in different regions. Since individual members may differ widely in vector capacity it is vital that they are able to be distinguished.

Recommendation 1
Better tools to identify and distinguish members of these complexes are urgently required. Tools to be developed should be both morphological and molecular, with the one informing the other.

At least one important Culicoides vector, C. imicola, appears to be spreading rapidly in Europe. The pattern of spread is not known. There is evidence that C. imicola in Europe occurs as several haplotypes.

Recommendation 2
Molecular tools to identify haplotypes and other specific traits should continue to be developed as a priority to enable vector population movement to be identified and monitored.

In many parts of the world, especially Europe, Asia and South America, the systematics and taxonomy of Culicoides are in need of revision. Identification of related species may facilitate the discovery of novel vectors and should significantly improve our ability to assess disease risk.

Recommendation 3
The systematics and taxonomy of Culicoides in Europe, Asia, South America and other parts of the world should be addressed. Phylogenetic analysis of the sequences of multiple genes should be used to identify the relationships between known and novel vector species.

Worldwide, there are few competent Culicoides taxonomists.

Recommendation 4
Consideration should be given to capacity building in the systematics and taxonomy of Culicoides.

Vector Competence

Vector competence is under genetic and environmental control, and varies inter- and intra-specifically. In refractory species or individuals, barriers to infection may occur at several steps in the infection and transmission processes. These barriers are poorly understood, and consequently, no methods currently exist for predicting whether species or populations are competent.

Recommendation 5
Barriers to the infection and dissemination of BTV within individual Culicoides should be characterised, and molecular genetic tools developed that permit prediction of vector competence.

Vector competence is difficult to measure, as field-caught Culicoides do not survive well in captivity and rarely feed. Consequently, transmission from field-caught Culicoides to hosts can rarely be demonstrated. There is some recent preliminary evidence suggesting that vertical transmission of BTV might occur in vector Culicoides species.

Recommendation 6
Methods to improve laboratory survival and feeding of field-caught Culicoides should be investigated. Direct and indirect methods of recording transmission, or transmission potential, should be evaluated. Possible vertical transmission of BTV in vector Culicoides should be further investigated.

Relatively little is known about the competence of Culicoides vectors in many parts of the world, especially Europe, Asia and South America. Work to date indicates complex relationships between vector species and their competence for different orbiviruses and/or viral genotypes as well as intraspecific variability in vector competence.

Recommendation 7
The vector competence of Culicoides species and populations should be measured, where possible using field viruses. Candidate species can be prioritised on the basis of epidemiological evidence, feeding preference for hosts and level of abundance.

Epidemiological analysis (serosurveys, vector surveys, ecological analysis, study of outbreaks) can provide guidance for the selection of candidate species for vector competence studies, and can be used to assess the likely significance of results.

Recommendation 8
Future and historical data sets should be analysed to investigate the possible role played by different vector species in the transmission of BTV.

Vectorial capacity

Vectorial capacity provides a measure of disease risk, incorporating vector competence, abundance, biting rates, survival rates and extrinsic incubation period. Many of these remain to be determined. Methods and tools for measuring some components remain to be developed, particularly in a field context. Interactions of these variables with the environment remain to be characterised.

Recommendation 9
Standard techniques for measuring the variables of vectorial capacity should be developed and adopted, to facilitate comparison of data and data sharing. Trapping methods should be evaluated against a 'gold standard' (e.g. drop-trap over animal, and the Onderstepoort-type light trap). Biases in trapping methods should be measured.
Improved methods for reliably aging Culicoides should be developed.
Improved methods for recording host preferences should be developed.
The effects of the environment, host demography and climate on vectorial capacity should be investigated.
Measures of vectorial capacity should be correlated with other indicators of disease risk, such as host disease status.

Ecology

The ecology of the major and minor Culicoides vectors is poorly understood and their breeding sites are largely uncharacterised. Means and rates of adult dispersal, both local and long distance are unknown. The comparative value of sentinel herds or wild-caught Culicoides as an aid to the early detection of virus activity has not been fully investigated. Adult overwintering in temperate zones has been little studied, but could play a part in the persistence of BT.

Recommendation *10*

Larval microhabitats and diets should be characterised as an aid to colonisation and to the identification of breeding sites. Means and rates of dispersal of adult Culicoides, both local and long distance, need to be defined. Rates and times of virus or viral RNA detection in sentinel herds and vector surveillance systems should be compared. The possibility of adult overwintering in temperate and cool zones needs to be investigated. Development of vector population-simulation models is a long-term goal.

Control

Vector control methods are often used in the event of BT disease outbreaks, but there has been little quantitative work on short and long-term efficacy. Other means of reducing virus transmission that have lower environmental impact (e.g. physical and chemical barriers, husbandry modification), have received little attention.

Recommendation *11*

Specific methods for the long and short-term suppression of Culicoides populations (adults and immatures) should be evaluated and quantified, and clear recommendations given to veterinary authorities. Alternative methods of interrupting the transmission cycle, such as the use of repellents, housing, breeding site destruction or modification, should be investigated. These measures should be evaluated in the context of existing arthropod control efforts. Control success should be judged in terms of disease reduction and/or seroconversion.

Diagnostics working group - Group 3

B. Eaton, (Chair) Australia
T. Gerdes, South Africa
D. Sreenivasulu, India
E. Ostlund, USA
K. Bonneau, USA
S. Mann, UK
W. Wilson, USA
S. Zientara, (Co-chair) France
Z. Nianzu, PRC
H. Yadin, Israel
H. Takamatsu, UK
C. Hamblin, UK
A Samuel, UK
J. Pearson, OIE

Committee charge:

To develop specific recommendations that address issues pertaining to the perceived advantages and disadvantages of existing and new virologic and serologic diagnostic procedures for detection of BTV infection of insects and animals and how these interface with the OIE Manual.

Specifically address the issue of the role of the polymerase chain reaction (PCR) assay in the regulation of animal movement.

Existing procedures in the Manual

Virus isolation

Intravenous inoculation of embryonated chicken eggs (ECE) is the most sensitive technique for isolation of BTV. However, it is a slow procedure, compounded by the need for subsequent virus identification steps. Some ECE-propagated viruses may not readily replicate in cell culture

Virus identification

Serogrouping

A number of techniques such as anti-antigen capture ELISA and immunofluoresence that take advantage of the availability of serogroup-specific monoclonal antibodies work well. The use of serogroup-reactive PCR increases the speed of identification. Precautions must be taken to prevent cross-contamination while doing PCR.

Serotyping

The neutralisation test is biologically relevant and has a number of successful formats such as plaque reduction and microtitre neutralisation. Virus cross-relatedness may make interpretation of results difficult. Maintaining serotyping reagent uniformity is difficult, particularly on a world-wide basis. Such reagents are also costly to make.

'Typing' by PCR-sequencing is a novel and welcome addition to the repertoire of typing tests. It is very rapid and highly information (see new procedures).

Serological tests

The AGID assay while easy and cheap to perform do lacks sensitivity and manifests cross reactions with EHDV. The C-ELISA is now standard technology.

New procedures

Typing instead of serotyping

PCR/sequencing provides information on 'type', genotype and topotype very rapidly. Segments coding for VP2, VP5, VP3, NS1 and NS3 are currently relevant.
Successful identification of BTV around the world depends on availability of relevant sequence data for primer development
Every effort should be made to send viruses or PCR products to all OIE reference labs or other competent laboratories to be sequenced and primer information made available (via the web) to facilitate characterization at the source laboratory
An excellent start has been made in the process of collecting relevant sequence data

http://www.iah.bbsrc.ac.uk/dsRNA_virus_proteins/
http://www.iah.bbsrc.ac.uk/dsRNA_virus_proteins/btv_sequences.htm
provides phylogenetic tree analysis of BTV isolates based on RNA2.

Real time versus nested PCR?

Real time PCR technology is faster and more expensive than traditional PCR methods but is less susceptible to contamination problems. There may be problems attempting to identify new isolates with already-existing 'real time' probes. The technology requires expensive equipment.

IgM ELISA

An IgM ELISA would provide information on recent infection status and offer an opportunity to determine if the presence of IgM antibodies was correlated with the duration of viraemia.

Future trends

Possibilities include multiplexed flat and bead DNA and protein technologies and biosensing technologies

Recommendations

That the AGID test remain in the manual but not be a prescribed test for international trade

That research into novel diagnostic methods continues with tests showing promise being subject to validation by collaborating OIE laboratories and other competent national laboratories.

That the genetic characterisation continues of BTV isolates from diverse regions of the world with the aim of:

- compiling sequence data and identifying new viruses and their genetic relationships. sharing sequence information thereby increasing the size of the data bases
- facilitating establishment of PCR technology and use of appropriate primers in the submitting country
- validating the technology by reference to the 'gold standard' neutralisation test

That, following extensive validation by collaborating laboratories, the current neutralisation-based virus serotyping system be replaced by a genetic typing system.

That an IgM ELISA or similar test be investigated to determine if they would provide a simple test that correlates with viraemia in infected animals and could be used to facilitate trade.

That use of the PCR to differentiate between wild-type and vaccine virus continue.

Vaccines & vaccinations - Group 4

H.Huisman	(Chair)	South	Africa
P.P.C.	**Mertens**	(Co-Chair)	UK
P.Roy			UK
C.Patta			Italy
G.Gerbier			France
M.Vitale			Italy
G.L.	**Autorino**		Italy
M.Papin France			

Specific recommendations in regard to vaccines and vaccination strategy:

- Encourage the development and transfer of complementary and alternative vaccine materials and strategies that provide safe and efficacious inactivated or subunit BTV vaccines, and further encourages that vaccine companies adopt these products and make them available to producers.
- Vaccine strains should be fully sequenced and the data made available to the FAO/OIE Reference database as well as other databases such as the EMBL data base.

- Encourage the development and validation of technologies that will distinguish vaccinated from infected animals, both for current vaccines and the vaccines that are likely to be available in the foreseeable future

- Encourage countries applying current or future vaccine technologies and strategies to make all data on monitoring of vaccination programs, and the surveillance of control programs, available to OIE for addressing future disease outbreaks.

- Animals receiving vaccines produced by culture in embryonated chicken eggs shall not be moved internationally.

- Update and keep current the OIE Manual on research information and data on the efficacy of both subunit and inactivated BT vaccines.

Impact of interventional strategies on virus spread, disease and regulation - Group 5

T.D.	**St.**	**George**	(Chair),	Australia
P.	**Roeder**		(Co-chair)	FAO
V.		**Caporale**		Italy,
P.		**Daniels**		Australia,
R.		**DeHaven**		USA,
J.		**Fevrier**		EU,
S.		**Hammami**		Tunisia
B.		**Jameson**		Canada
E.		**Mmamakgaba**		RSA
G.		**Oliver**		Australia
D.		**Panagiotatos**		Greece
A.		**Schudel**		OIE

B.T. Walton USA

Committee charge:

Address issues pertaining to the impact of interventional strategies on monitoring and surveillance practices and the risk of spread of BTV.

Conclusions:

Considering the potential movement of bluetongue seropositive animals from an infected to a free zone or country:

- animals may move at any time without posing a risk of virus spread if they have been vaccinated with a licensed or authorised attenuated, inactivated, sub-unit or genetically manipulated vaccine at least one month prior to movement, provided that the vaccine used covers all serotypes which would be expected from adequate surveillance to be present at origin and that the animals are identified as vaccinates in the accompanying certification;

- in the case of healthy, non-vaccinated animals, animals (whether seropositive from natural infection or seronegative) may move at any time without posing a risk of virus spread provided that an adequate surveillance system has been in place in the source population for a period of 60 days immediately prior to dispatch without detecting evidence of bluetongue virus circulation.

Pursuant to the above recommendations, the working group invites the OIE to review the relevant chapters of the Terrestrial Animal Health Code to bring them in line.

The working group recommends the OIE to back up safe trade in bluetongue seropositive animals by ensuring the existence of an adequate network of reference laboratories which shall inter alia ensure the archiving of viral strains and derived sequence data to provide a comprehensive database to be made available for research, surveillance and trade purposes.

The working group recommends that animals vaccinated with attenuated vaccines roduced by culture in embryonated eggs shall not be moved.

Control and Trade - Group 6

B.	**I.**	**Osburn**	(Chair)	USA
V.		**Carporale**		Italy
P.		**Daniels**		Australia,
R.		**DeHaven**		USA
J.		**Fevrier**		EU
C.		**Gomez-Tejedor**		Spain
Y.		**Goto**		Japan
G.		**Oliver**		Australia
C.		**Panagiotatos**		Greece
P.		**Roeder**		FAO
T.		**Walton**		USA
A.		**Schudel**		OIE

J. Pearson USA

Committee Charge:

To address the potential impact of issues raised by the other 5 working groups on international trade and movement of animals; specifically, to address issues pertaining to the movement of seropositive as well as potentially viremic animals.

Specific conclusions of the Working Group:

A. In considering the potential movement of BTV seropositive animals from an infected to a free zone or country, the Working Group concludes that animals may move at any time without posing a risk of virus spread if they have been vaccinated with a licensed or authorized attenuated, inactivated, subunit, or genetically manipulated vaccine at least one month prior to movement provided that the vaccine used covers all serotypes which would be expected to be present at origin from adequate surveillance and that the animals are identified as vaccinates.

B. In the case of healthy, non-vaccinated animals, animals (whether seropositive from natural infection or seronegative) may move at any time without posing a risk of virus spread provided that an adequate surveillance system has been in place in the source population for a period of 60 days immediately prior to dispatch without detecting evidence of bluetongue virus circulation.

C. The committee endorses the recommendations of Working Group 5 (Impact of Interventional Strategies on Virus Spread, Disease and Regulation) that the OIE should reevaluate the Terrestrial Animal Health Code in light of conclusions of the 3rd symposium. Further, that the OIE can further ensure the continued safe movement of ruminants that are seropositive to BTV by supporting the network of reference laboratories that will archive BTV strains and derived sequence data to ensure that a comprehensive database is available for research, surveillance and trade purposes.

D. The committee encourages the OIE to ensure that periodic surveillance for BTV occurs in zones with no previous evidence of virus activity; and, that any new evidence of virus activity in these zones be immediately reported to OIE.

E. The committee considers that the agar gel immunodiffusion (AGID) test assay lacks the requisite sensitivity and specificity (because of potential cross reactions with other viruses, particularly EHDV). The C-ELISA is now considered the standard and appropriate technology for serological diagnosis of previous exposure to animals to BTV.

F. The committee endorses the use of polymerase chain reaction (PCR)-based technologies for detection of BTV nucleic acid in animals and insects. The "real time" PCR technology is faster than traditional PCR methods, and is less susceptible to the problems of contamination that compromise nested PCR assays in particular. However, further validation is required as there may be problems in the identification of new strains of BTV with existing "real time" probes.

G. The Working Group recommends that OIE convene an ad hoc Working Group to address the current Bluetongue Chapter and the guidelines for bluetongue surveillance and monitoring, as it is agreed that the current Chapter is both prescriptive and confusing.

H. Issues to be addressed, as detailed by the working group (Working Group 1):

- Infective period based on current scientific information and technologies, i.e., vector capabilities and competence, cell culture and PCR information, etc.
- The recent information on the distribution of BTV makes the current BTV limits based on latitudes obsolete. Consider that BTV distribution is based on continental ecological zones or episystems with associated defined parameters. Adjacent zones should have surveillance and monitoring practices for BTV presence. Evidence of BTV in the adjacent zone should be immediately reported to OIE.
- Reconsider the broad use of the term "Culicoides" to indicate midges from the genus Culicoides spp. that have been shown or are suspected to be probable vectors of BTV. In other words, be specific as to the species involved.
- Consider broad guidelines addressing the intensity and frequency of surveillance, which will compliment the provisions of the general chapter.
- The extent of a surveillance program in countries (zones) adjacent to a country (zone) that does not have free status. (Leave as stands)
- When a surveillance program is designed, the predictive value of the tests used in the program should be described as part of the study.
- When surveillance is conducted, the species and age of animals needs to be considered to ensure that there is appropriate sensitivity for that surveillance.
- The presence of ecological zones for BTV in different parts of the world warrants recognition. Factors pertaining to vectors and hosts in one system may not be relevant to another.
- Tests that distinguish between vaccinated and naturally infected animals will be of value to surveillance programs.

I. Specific recommendations in regard to vaccines and vaccination strategy:

- Encourage the development and transfer of complementary and alternative vaccine materials and strategies providing safe and efficacious inactivated or sub unit vaccines and further encourages that vaccine companies adopted these products and make them available to producers.

- Vaccine strains should be fully sequenced and the data are made available to a reference database(s).
- Encourage the development of technologies, which will distinguish vaccinated from infected animals.
- Encourage countries applying current or future vaccine technologies and strategies to make all data on monitoring and surveillance of control programs available to OIE for addressing future disease outbreaks.
- Animals receiving vaccines produced by culture in embryonated chicken eggs shall not be moved internationally.
- Update and keep current the OIE Manual on research information and data on the efficacy of both subunit and inactivated bluetongue vaccines.

CHAPTER 2.1.9.

BLUETONGUE

Article 2.1.9.1.

Community comments:

The Community is concerned that such a restrictive group had the responsibility for preparing a draft Chapter based on the conclusions of the Taomina conference. Fudamentally significant changes have been made without a total redrafting of the chapter. The Community is concerned with such an approach. It also questions the three main proposed changes as follows:

1. Decrease from 100 to 60 days for the infective period– The Community would need to study the scientific basis for this proposed change as more recent information in particular from France tends to indicate that the proposed decrease is not scientifrically justified. It is not transparent enough to rely solely on the conclusion of the experts at the conference when some documented evidence goes against such a large decrease. It would ask the OIE to further review all the documented scientific work on this and to include the scientific papers used to justify the proposed reduction.

2. Surveillance – This is a crucial part of the whole Chapter and should be adapted to the actual situation and the Community would suggest a separate appendix for surveillance based on proper statistical models taking into account the multiple posible serotypes. With this proposal the territory where the surveillance should be maintained in the northern hemisphere would be huge with little added value.. Surveillance should be targeted at the area most likely to be at risk.

3. Movement of vaccinated animals – The Community is not convinced that this is a practible possibility in all cases. It is still not clarified if such movements represent a risk or not. There are many different serotypes and the situation is continually changing. The Community questions whether it is proven that all vaccines are effective as there are different types of vaccine and is it known if they satisfactory in all species (cattle, sheep and goats etc.). In order to allow trade there must be complete trust in the vaccination. Vaccination status is not taken into account in the proposed draft code which is also also different to other Chapters eg FMD. For a free country how can it be established if a seropositve animal is an imported vaccinated animal or has been infected in the free country e.g. in the case of a sero-positive sheep how can the origin be established.

A number of other comments are included below and in view of all these comments the Community strongly urges the OIE to relook at this Chapter in an enlarged ad hoc group.

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be ~~100~~ 60 days.

The global BTV distribution ~~historically has been shown to be~~ is currently between latitudes of approximately 50~~40~~°N and 35°S but is known to be expanding in the northern hemisphere.

Community comments:

Increasing the global distribution to 50°N with a requirement for surveillance to support freedom is too hard and fast. Much more consideration should be given to the recent history and targeting of the actual disease front based on last 2 years knowledge i.e. need a more flexible and adaptable approach as is referred to below in the text already. The Community proposes that the actual latitudes are deleted. There is still a question of what to do in a country adjacent to a country with historical risk with marked variation in climate etc of these areas. There is also a problem with failure to properly report disease in some countries which needs to be resolved somehow.

The Community proposes the following wording: "The global BTV distribution historically has been shown to be between latitudes of approximately 40°N and 35°S but is known to be expanding in certain parts of the world.

In the absence of clinical disease in a country or zone within this part of the world, its BTV status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) designed in accordance with the epidemiology of the disease, i.e. focusing on climatic and geographical factors, the biology and likely competence of *Culicoides* and/or serology of susceptible animals. 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 Chapter 1.3.6. ~~Random and targeted serological surveillance should provide at least a 95% level of confidence of detecting an annual seroconversion incidence of 2% in cattle (or other ruminant species if sufficient cattle are not available).~~

All countries or zones ~~located outside this part of the world but~~ adjacent to a country or zone not having free status should be subjected to similar surveillance. The surveillance ~~programme~~ 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.

Community comments:

The Community believes a more flexible and adaptable approach is needed as already stated above.

Therefore the Community would propose to discuss the following wording to replace the above "All countries adjacent to an infected or unknown status but at risk zone should carry out surveillance on that part at risk within 100km distance of the known infection front. The front of the disease is the limit of the possible zone where virus could be circulating. It must include those araes where the virus has been thought to be circulatingduring the last 2 years and in any case those areas wherebthe disease is historically present. A number of factors must be taken into account when establishing such a zone such as geography, climate, epidemiology and entomology".

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

Article 2.1.9.2.

BTV free country or zone

A country or a zone may be considered free from BTV when bluetongue is notifiable in the whole country and either:

1) the country or zone lies wholly north of 5040°N or south of 35°S, and is not adjacent to a country or zone not having a free status, or

2) a surveillance and monitoring programme as described in Chapter 1.3.6 ~~Article 2.1.9.1.~~ has demonstrated no evidence of BTV in the country or zone during the past 2 years~~, nor have any ruminants been vaccinated against bluetongue in the country or zone during the past 12 months~~, or

3) a surveillance and monitoring programme has demonstrated no evidence of *Culicoides* likely to be competent BTV vectors in the country or zone.

Community comments:

The Community believes that there is still a problem over what is a competent vector. This still remains unknown just because a competent vector has not been demonstrated does not mean that one is not present. This will only be seen after import of infected viraemic animals and spread of disease.

~~For maintenance of the free status, the provisions of the last paragraph of Article 2.1.9.1. may need to be complied with on a continuous basis according to the geographical location of the country or zone.~~

A BTV free country or zone in which surveillance and monitoring has found no evidence that *Culicoides* likely to be competent BTV vectors 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 zones.

A BTV free country or zone in which surveillance and monitoring has found evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or zones, provided:

Community comment:

It appears that all the text in Paragraph 3 is in fact new text but has not been indicated as such. This is a fundamental change to the code and in addition it is not clear how this would work in practice.

a. the animals have been vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, provided that the vaccine used covers all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6, and that the animals are identified as vaccinates in the accompanying certification; or

Community comments:

30 days appears not long enough as an animal might be infected at the time of vaccination and it has already been proposed that the period for neutralisation of virus by antibodies is at least 60 days. The time period must be at least 60 days and probably longer. The vaccination must also have been carried out within the last 12 months.

b. the animals are not vaccinated, and a surveillance and monitoring programme as described in Chapter 1.3.6 has been in place in the source population for a period of 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected.

Community comments:

60 days appears not long enough for the surveillance based on FR experience. Surveillance is a key aspect and the chapter 1.3.6 is not detailed enough to cover properly this disease. Commission strongly supports the need for a separate and detailed surveillance Appendix.

A BTV free country or zone adjacent to an infected country or zone should include a ~~*surveillance*~~ *zone* in which surveillance is conducted as described in Chapter 1.3.6 ~~Article 2.1.9.1~~. Animals within this ~~the *surveillance*~~ zone must be subjected to continuing surveillance. The boundaries of ~~the *surveillance*~~ this zone must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission ~~infection~~.

Article 2.1.9.3.

BTV seasonally free zone

A BTV seasonally free zone is a part of an infected country or zone for which for part of a year, surveillance and monitoring demonstrate no evidence either of BTV transmission or of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 2.1.9.7., 2.1.9.10. and 2.1.9.14., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the surveillance and monitoring programme), or of the cessation of activity of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 2.1.9.7., 2.1.9.10. and 2.1.9.14., 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 and monitoring programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent BTV vectors.

A BTV seasonally free zone in which surveillance and monitoring has found no evidence that *Culicoides* likely to be competent BTV vectors 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 zones.

Article 2.1.9.4.

BTV infected country or zone

A BTV infected country or zone is a clearly defined area where evidence of BTV has been reported during the past 2 years.

Article 2.1.9.5.

Veterinary Administrations of countries shall consider whether there is a risk with regard to BTV infection in accepting importation or transit through their territory, from other countries, of the following *commodities*:

1) ruminants and other BTV susceptible herbivores;

2) semen of these species;

3) embryos/ova of these species;

4) *pathological material* and biological products (from these species) (see Chapter 1.4.6. and Section 1.5.).

Other *commodities* should be considered as not having the potential to spread BTV when they are the subject of *international trade*.

Article 2.1.9.6.

When importing from BTV free countries or zones, *Veterinary Administrations* should require:

for ruminants and other BTV susceptible herbivores

the presentation of an *international veterinary certificate* attesting that the animals:

1) were kept in a BTV free country or zone since birth or for at least 60~~100~~ days prior to shipment, or

2) 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, ~~such as the BT competition ELISA or the BT AGID test~~, and remained in the BTV free country or zone until shipment; or

3) 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 ~~a BTV isolation test or polymerase chain reaction test on a blood sample~~, and remained in the BTV free country or zone until shipment; or

4) were kept in a BTV free country or zone for at least 7 days, and were vaccinated in accordance with the Terrestrial Manual 30 days before introduction in the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6, were identified as vaccinates and remained in the BTV free country or zone until shipment;

AND

5)4) 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* likely to be competent BTV vectors at all times when transiting through an infected zone; or

c) had been vaccinated in accordance with paragraph 4 above.

Article 2.1.9.7.

When importing from BTV seasonally free zones, *Veterinary Administrations* should require:

for ruminants and other BTV susceptible herbivores

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 for at least 60~~100~~ 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~~such as the BT competition ELISA or the BT AGID test~~, with negative results on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 21 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 an agent identification test according to the Terrestrial Manual ~~to a BTV isolation test or polymerase chain reaction test,~~ with negative results, on blood samples taken on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 7 days after the commencement of the residence period;

4) were kept during the seasonally free period in a BTV seasonally free zone, and were vaccinated in accordance with the Terrestrial Manual 30 days before introduction in the free country or zone against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6, were identified as vaccinates and remained in the BTV free country or zone until shipment;

AND

5)4) 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* likely to be competent BTV vectors at all times when transiting through an infected zone, or

c) were vaccinated in accordance with paragraph 4 above

Article 2.1.9.8.

When importing from BTV infected countries or zones, *Veterinary Administrations* should require:

for ruminants and other BTV susceptible herbivores

the presentation of an *international veterinary certificate* attesting that the animals:

1) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60~~100~~ days prior to shipment, or

2) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 28 days prior to shipment, and were subjected during that period to a serological test according to the Terrestrial Manual to detect antibody to the BTV group, ~~such as the BT competition ELISA or the BT AGID test~~, with negative results on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 21 days after introduction into the *quarantine station*, or

3) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 14 days prior to shipment, and were subjected during that period to an agent identification test according to the Terrestrial Manual ~~a BTV isolation test or polymerase chain reaction test~~, with negative results, on blood samples taken on two occasions, with an interval of not less than 7 days between each test, the first test being carried out at least 7 days after introduction into the *quarantine station*; or

4) were vaccinated in accordance with the Terrestrial Manual at least 30 days before dispatch, against all serotypes whose presence in the source population has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6, and were identified as vaccinates in the accompanying certification;

5) if the animals are non-vaccinated and a surveillance and monitoring programme as described in Chapter 1.3.6, has been in place in the source population for a period of 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected;

and

6) during transportation were protected from attack from Culicoides likely to be competent BTV vectors during transportation to the place of shipment; or

7) were vaccinated 30 days before shipment or had antibodies against all serotypes whose presence in the zones of transit has been demonstrated through a surveillance and monitoring programme as described in Chapter 1.3.6.

Article 2.1.9.9.

When importing from BTV free countries or zones, *Veterinary Administrations* should require:

for semen of ruminants and other BTV susceptible herbivores

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~~100~~ 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, ~~such as the BT competition ELISA or the BT AGID test,~~ between 28 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 ~~a virus isolation test or polymerase chain reaction (PCR)) test~~ 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 either Appendix 3.2.1. or Appendix 3.2.2.

Article 2.1.9.10.

When importing from BTV seasonally free zones, *Veterinary Administrations* should require:

for semen of ruminants and other BTV susceptible herbivores

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~~100~~ 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 ~~such as the BT competition ELISA or the BT AGID test~~, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days after the final collection for this consignment, or

   c) were subjected to an agent identification test according to the Terrestrial Manual ~~a virus isolation test or polymerase chain reaction (PCR)) test~~ 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 either Appendix 3.2.1. or Appendix 3.2.2.

Article 2.1.9.11.

When importing from BTV infected countries or zones, *Veterinary Administrations* should require:

for semen of ruminants and other BTV susceptible herbivores

the presentation of an *international veterinary certificate* attesting that:

1) the donor animals:

   a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60~~100~~ 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 ~~such as the BT competition ELISA or the BT AGID test~~, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days after the final collection for this consignment, or

c) were subjected to an agent identification test according to the Terrestrial Manual ~~a virus isolation test or polymerase chain reaction (PCR) test~~ 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 either Appendix 3.2.1. or Appendix 3.2.2.

Article 2.1.9.12.

Regardless of the bluetongue status of the *exporting country*, *Veterinary Administrations* of *importing countries* should require:

for *in vivo* derived bovine embryos/oocytes

the presentation of an *international veterinary certificate* attesting that the embryos/oocytes were collected, processed and stored in conformity with the provisions of Appendix 3.3.1. or Appendix 3.3.3., as relevant.

Article 2.1.9.13.

When importing from BTV free countries or zones, *Veterinary Administrations* should require:

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores

the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

2. COMMENTS ON THE NEW AVIAN INFLUENZA CHAPTER IN THE OIE TERRESTRIAL ANIMAL HEALTH CODE

CHAPTER 2.1.14.

AVIAN INFLUENZA

Community comments:

The Community welcomes the further development of the chapter. The proposed chapter is to a large extent in line with the recommendations given in the Community Scientific Report on the definition of avian influenza and the use of vaccination against avian influenza of 27 June 2000, where it was made clear that in order to combat highly pathogenic avian influenza (HPAI) low pathogenic avian influenza infections (LPAI) of subtypes H5 and H7 have to be controlled.

The Community appreciates that the approach of differentiating between HPAI and LPAI has been taken on board. However, the establishment of trade requirements for the different commodities proportionate to the risks posed by the two categories of viruses has not fully been followed throughout the chapter. The Community welcomes the creation of an ad hoc group to further develop the risk based approach to requirements for the different commodities with respect to LPNAI and HPNAI.

In addition, the concept of compartmentalisation is introduced to allow trade to continue from infected geographical regions/zones. However if the chapter is adopted without clear rules on how to apply the concept of compartmentalisation to ensure effective bio-security measures, there will be a risk of disease spread via trade in live birds and other high risk commodities.

The Community considers that the proposed surveillance scheme should be further developed and improved, employing a risk based approach to provide guidance which can be adapted to differing geographic and production systems. It welcomes the creation of an ad hoc Group for the further development of surveillance guidelines and considers it essential that the group includes experts in epidemiology and statistics. The Community will be pleased to assist in this work.

The Community requests that the comments and suggested highlighted changes introduced directly into the text below (new text double underlined and text to be deleted is struck through) are taken into account in the further development of the chapter by the OIE.

Article 2.1.14.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for highly pathogenic avian influenza (HPAI) shall be 21 days.

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

Article 2.1.14.2.

HPAI free country

A country may be considered free from HPAI when it has been shown that HPAI 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 HPAI.

Article 2.1.14.3.

HPAI infected zone

A zone shall be considered as infected with HPAI until:

1) at least 21 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 2.1.14.4.

Veterinary Administrations of *importing countries* should require similar arrangements to those provided in Chapter 2.1.15. (Newcastle disease) of the *Terrestrial Code* for the following *commodities*:

1) domestic and wild birds;

2) *day-old birds*;

3) *hatching eggs*;

4) semen of domestic and wild birds;

5) *fresh meat* of domestic and wild birds;

6) *products of animal origin* (from birds) *intended for use in animal feeding* or *for agricultural or industrial use*;

7) *pathological material* and biological products (from birds) which have not been processed to ensure the destruction of the HPAI virus.

Article 2.1.14.5.
(under study)

1. For the purposes of this *Terrestrial Code*, notifiable avian influenza (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 birds reared or kept in captivity 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'.

3. For the purpose of international *trade*, this 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. The following defines the occurrence of NAI virus infection:

   a) HPNAI virus has been isolated and identified as such or specific viral RNA has been detected in poultry or a product derived from poultry, or

   b) LPNAI virus has been isolated and identified as such or specific viral RNA has been detected in poultry or a product derived from poultry, or

c) antibodies to H5 or H7 subtype of NAI virus that are not a consequence of vaccination ~~, nor indicative of a non-specific reaction, have been detected in poultry; in such cases, virus isolation should be attempted to establish whether the serological positivity is due to LPNAI or HPNAI. If appropriate samples are not available or if results are negative, a thorough epidemiological investigation including further sampling and testing should be carried out to identify the type or exclude the presence of NAI infection~~, have been detected in poultry. In the case of isolated serological positive results NAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not indicate further evidence of NAI infection.

Community comments:

The Community believes its new wording is much clearer and reduces the possibility of misinterpretation.

For the purposes of this *Terrestrial Code*, 'NAI-free establishment' means an *establishment* in which there has been no evidence ~~clinical sign~~ of NAI infection for the past 21 days, and which is not situated within 3 km of an *establishment* infected with HPNAI in the past 21 days or ~~and~~ within one km of an *establishment* known to be infected with LPNAI in the past 21 days. If appropriate, precautions should be taken to avoid entering of wild birds.

Community comments:

The Community believes its new wording is much clearer, improves the bio-security measures and better correlates with the incubation period.

For the purposes of this *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

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

Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 2.1.14.6.
(under study)

The NAI status of a country, a zone or compartment can be determined on the basis of the following criteria:

1) the outcome of a risk assessment identifying all potential factors for NAI occurrence and their historic perspective;

2) 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;

3) 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 an NAI surveillance programme in accordance with this Chapter and Chapter 1.3.6.

Article 2.1.14.7.
(under study)

NAI free country or zone/compartment

A country or zone/compartment may be considered free from NAI when it has been shown that NAI infection has not been present for the past 12 months. If infected poultry are slaughtered, this period shall be 3 months after the slaughter of the last infected poultry and *disinfection* of all affected *establishments* and an appropriate surveillance referred to in Article 2.1.14.6 has been carried out. In any case for HPNAI infected poultry stamping out must be applied, whereas LPAI infected poultry may be slaughtered for human consumption.

Community comments:

The Community believes its new wording is much clearer and takes into account the differences in risk posed by HPNAI and LPNAI in respect of trade in meat.

The NAI status should be determined by an ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology. The programme may need to be adapted to target parts of the country or zone/compartment at a higher risk due to historical or geographical factors, population data, or proximity to recent *outbreaks*.

Freedom of infection in a country or zone can be demonstrated with random and/or targeted serological surveillance at a ~~minimum~~ maximum interval of 6 months designed to provide at least a 95% level of confidence of detecting a prevalence of NAI infected establishments ~~enterprises~~ of 1%. Freedom of infection in an compartment can be demonstrated with an ongoing surveillance programme designed to provide at least a 95% level of confidence of detecting a prevalence of NAI ~~infection~~ infected establishments of 10%. Each *establishment* should be sampled to provide a 95% level of confidence of detecting a prevalence of NAI of 25%. For commercial ducks the surveillance programme should be based on virus isolation or detection in the absence of validated serological methods.

In the case of a country or zone in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out on all vaccinated flocks at a ~~minimum~~ maximum interval of 6 months. In each vaccinated flock, the number of birds to be tested should provide at least a 95% level of confidence of detecting a prevalence of NAI infection of 25%. In the case of a compartment in which vaccination is being conducted, the ongoing surveillance and monitoring programme (carried out in conformity with the provisions of Chapter 1.3.6.) based on virus isolation, virus detection or serology should be carried out to provide at least a 95% level of confidence of detecting a prevalence of NAI ~~infection~~ infected establishments of 10%. If a serological test is used, it should be able to distinguish vaccinated birds from infected birds. Additional security should be provided by the use

of identifiable sentinel birds which can be clinically inspected or tested to help identify field infections in vaccinated flocks.

Community comment:
The Community does not agree with the proposals for surveillance outlined above.

If applied without targeting the costs may be disproportionate to the benefit e.g. surveillance of all flocks, regardless of size or type. If targeting is inappropriate the level of assurance required in support of trade may not be achieved. It would highly welcome a further in depth consideration of the statistical basis, the testing requirements for specific species and targeting for poultry populations at specific risk, including compartments located in infected areas.

Factors to be considered in a risk-based surveillance should include:

- History of AI occurrence in the country/zone,

- Geographical and ecological factors,

- Flyways of migratory birds (especially waterfowl),

- Species and categories of poultry e.g. broilers, breeders, ducks, backyard flocks, turkeys etc.,

- Density of poultry,

- Production systems and structure of the poultry industry,

- Movements of poultry nationally including live bird markets and internationally,

- Housing versus free range,

- Bio-security factors,

- Vaccination status.

The Community considers that a basic level of surveillance is a pre-requisite for trade in poultry and poultry products. Guidance on surveillance should be set out in a separate Appendix.

It is not practicably possible to establish a disease free status in relation to LPNAI, unless in well defined compartments.

Article 2.1.14.8.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for live poultry (other than day-old poultry)

the presentation of an *international veterinary certificate* attesting that the poultry were kept in an NAI free establishment and:

1) showed no clinical signs on the day of shipment,

2) were kept in an NAI free ~~country or zone,~~ compartment since ~~they were hatched~~ hatching or for the past 21 days subject to surveillance in accordance with Appendix XXX; or

3) have been tested to give a 95% probability of detecting a 25 % prevalence of NAI infection not more than 7 – 10 days prior to export using virus detection or virus isolation tests and/or serological tests, with negative results in all cases, and

4) either have not been vaccinated against NAI, or have been vaccinated and the date of vaccination and the details of the vaccine are stated.

Community comments:

The concept of free status established by surveillance in support of trade in high risk commodities such as live birds and genetic material would require a very high level of surveillance, which would be impractical in most countries or zones. Effective surveillance may be much easier to apply to well defined compartments and this should be specified in the guidelines for AI surveillance. Alternatively pre-consignment testing could be required to provide the appropriate level of protection. Thus the Community proposes the changes above.

Article 2.1.14.9.
(under study)

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require:

for live birds other than poultry

the presentation of an *international veterinary certificate* attesting that the birds:

1) showed no clinical sign of NAI on the day of shipment;

2) were kept in isolation approved by the *Veterinary Services* since ~~they were hatched~~ hatching or for the 21 days prior to shipment and showed no clinical sign of NAI during the isolation period;

3) were subjected to a diagnostic test 7 to 14 days prior to shipment to demonstrate freedom from NAI.

Article 2.1.14.10.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that the poultry were kept in an NAI free establishment and were derived from parent flocks which:

1) were kept in an NAI free establishment,

2) in an NAI free ~~country or zone/~~compartment since ~~they were hatched~~ hatching or for the 21 days prior to despatch of eggs to the hatchery subject to surveillance in accordance with Appendix XXX; or

3) have been tested to give a 95% probability of detecting a 25 % prevalence of NAI infection not more than 7 – 10 days prior to despatch of eggs to the hatchery using virus detection or virus isolation tests and/or serological tests, with negative results in all cases, and

4) had/had not been vaccinated and, if vaccinated, the date of vaccination and the details of the vaccine are stated.

Community comments:

The concept of free status established by surveillance in support of trade in high risk commodities such as live birds and genetic material would require a very high level of surveillance, which would be impractical in most countries or zones. Surveillance may be much easier to apply to well defined compartments and this should be specified in the guidelines for AI surveillance. Alternatively pre-consignment testing could be required to provide the appropriate level of protection. Thus the Community proposes the changes above.

Article 2.1.14.11.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for *hatching eggs*

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country or zone/compartment and were derived from parent flocks which:

1) have been kept in an NAI free establishment,

2) in an NAI free ~~country or zone/~~compartment since ~~they were hatched~~ hatching or for the past 21 days subject to surveillance in accordance with Appendix XXX; or

3) have been tested to give a 95% probability of detecting a 25 % prevalence of NAI infection not more than 7 – 10 days prior to export using virus detection or virus isolation tests and/or serological tests, with negative results in all cases, and

4) had/had not been vaccinated against NAI, or which had been vaccinated against NAI and the date of vaccination and the details of the vaccine are stated.

Community comments:

The Community welcomes the creation of an ad hoc group to further develop the risk based approach to requirements for the different commodities with respect to LPNAI and HPNAI.

The concept of free status established by surveillance in support of trade in high risk commodities such as live birds and genetic material would require a very high level of surveillance, which would be impractical in most countries or zones. Surveillance may be much easier to apply to well defined compartments and this should be specified in the guidelines for AI surveillance. Alternatively pre-consignment testing could be required to provide the appropriate level of protection. Thus the Community proposes the changes above.

Community comments:

The Community believes that its changes proposed in all the Articles below reflect the risks posed by the different products in relation to HPNAI and LPNAI.

Article 2.1.14.12.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for eggs for consumption

the presentation of an *international veterinary certificate* attesting that the eggs come from an NAI free country or zone/compartment.

Article 2.1.14.13.
(under study)

When importing from a country or zone/compartment not known to be free from ~~HPNAI~~ NAI infection, *Veterinary Administrations* should require:

for eggs for consumption

the presentation of an *international veterinary certificate* attesting that the eggs:

1) come from ~~a country or zone/compartment free from HPNAI infection~~ an establishment not infected with HPNAI; ~~and~~

2) are transported in new disposable packing material; and

3) are not directly dispatched from an establishment or a packing centre that is located on an establishment.

~~Article 2.1.14.14.~~
~~(under study)~~

~~When importing from a country or zone/compartment not known to be free from HPNAI, *Veterinary Administrations* should require:~~

~~for eggs for consumption~~

~~the presentation of an *international veterinary certificate* attesting that the entire consignment of eggs comes from birds:~~

~~1) which have been kept in an NAI free *establishment*;~~

~~2) which have been tested serologically or by virus detection to give a 95% probability of detecting a 5% prevalence of NAI infection, every 21 days, with negative results.~~

Article 2.1.14.15.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in, an NAI free country or zone/compartment.

~~Article 2.1.14.16.~~
~~(under study)~~

~~When importing from a country or zone/compartment free from HPNAI infection, *Veterinary Administrations* should require:~~

~~for egg products~~

~~the presentation of an *international veterinary certificate* attesting that the egg products come from, and were processed in a country or zone/compartment free from HPNAI infection.~~

Article 2.1.14.17.
(under study)

When importing from a country or zone/compartment not known to be free from ~~HPNAI~~ NAI Veterinary *Administrations* should require:

for egg products

the presentation of an *international veterinary certificate* attesting that the egg products:

1) are derived from eggs for consumption which meet the requirements of Articles 2.1.14.12. or 2.1.14.13. ~~or 2.1.14.14~~.; or

2) were processed to ensure the destruction of the NAI virus, and the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

Article 2.1.14.18.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for poultry semen

the presentation of an *international veterinary certificate* attesting that the donor birds:

1) showed no clinical sign of NAI on the day of semen collection;

2) were kept in an NAI free establishment and in an NAI free country or zone/compartment for the 21 days prior to semen collection.

Article 2.1.14.19.
(under study)

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require:

for semen of birds other than poultry

the presentation of an *international veterinary certificate* attesting that the donor birds:

1) were kept in isolation approved by the *Veterinary Services* for the 21 days prior to semen collection;

2) showed no clinical sign of NAI during the isolation period;

3) were tested between 7 and 14 days prior to semen collection and shown to be free of NAI.

Article 2.1.14.20.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for *fresh meat* ~~and *meat products*~~ of poultry~~, and poultry viscera~~

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

1) which have been kept in an NAI free country or zone/compartment since ~~they were hatched~~ hatching or for the past 21 days;

2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.21.
(under study)

When importing from a country or zone/compartment free from HPNAI infection, *Veterinary Administrations* should require:

for *fresh meat* ~~*and meat products*~~ of poultry (other than turkey)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat ~~*or meat product*~~ comes from birds:

1) ~~which have been kept in an *establishment* since they were hatched or for the past 21 days in which there has been no clinical sign of NAI in the past 21 days;~~ which have been kept in an *establishment* not known to be infected with LPNAI since ~~they were hatched~~ hatching or for the past 21 days.

2) which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Community comments:

The Community believes that in order to improve the structure of the Chapter, meat and meat products should be more clearly separated and the viscera should be considered as fresh meat.

Article 2.1.14.22.
(under study)

When importing from a country or zone/compartment not ~~known to be~~ free from HPNAI, *Veterinary Administrations* should require:

for *fresh meat* ~~and *meat products* of~~ poultry ~~and poultry viscera~~ (other than turkey)

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

1) which have been kept in ~~a *free establishment*~~ an establishment not infected with HPNAI since ~~they were hatched~~ hatching or for the past 21 days,

2) which have been tested to give a 95% probability of detecting a ~~5~~ 25 % prevalence of NAI infection not more than 7 – 10 days prior to slaughter using virus detection or virus isolation tests, and/or serological tests, with negative results in all cases, and

3) which have been slaughtered in an *approved abattoir* which has not processed poultry infected with NAI since last cleaned and disinfected, and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.23.
(under study)

When importing from a country or zone/compartment not known to be free from NAI, *Veterinary Administrations* should require:

for *fresh meat* ~~and *viscera*~~ of turkey

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from birds:

1) which have been kept in an establishment not infected with HPNAI since hatching or for the past 21 days ~~a *free establishment*~~;

2) which have been tested to give a 95% probability of detecting a ~~5~~ 25 % prevalence of NAI infection not more than 7 -10 days prior to slaughter using virus detection or virus isolation tests, and/or serological tests, with negative results in all cases; and

3) which have been slaughtered in an approved abattoir which has not processed poultry infected with NAI since ~~last~~ being cleaned and disinfected, and have been subjected to ante-mortem and post-mortem inspections for NAI with favourable results.

Article 2.1.14.24.
(under study)

~~When importing from country or zone/compartment not known to be considered free from NAI, *Veterinary Administrations* should require:~~

Regardless of the NAI status of the country of origin, Veterinary Administrations should require:

~~for *meat products* and *processed viscera*~~ of poultry

the presentation of an *international veterinary certificate* attesting that:

1) the commodity is derived from *fresh meat, meat products* ~~and/or viscera~~ which meet the requirements of Articles 2.1.14.20., 2.1.14.21, 2.1.14.22 or 2.1.14.23.; or

2) the commodity has been processed to ensure the destruction of the NAI virus, and the necessary precautions were taken after processing to avoid contact of the commodity with any source of NAI virus.

Article 2.1.14.25.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use and for meal containing meat and/or feathers and/or bones (from poultry)

the presentation of an *international veterinary certificate* attesting that these products come from birds which have been kept in an NAI free country or zone/compartment since ~~they were hatched~~ hatching or for the past 21 days.

Article 2.1.14.26.
(under study)

When importing from a country or zone/compartment not ~~considered~~ known to be free from NAI, *Veterinary Administrations* should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use and for meal containing meat and/or feathers and/or bones (from poultry)

the presentation of an *international veterinary certificate* attesting that:

1) the commodity has been processed to ensure the destruction of the NAI virus;

2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

Article 2.1.14.27.
(under study)

When importing from an NAI free country or zone/compartment, *Veterinary Administrations* should require:

for feathers and down (from poultry)

the presentation of an *international veterinary certificate* attesting that the entire consignment of feathers or down comes from birds which have been kept in an NAI free country or zone/compartment since ~~they were hatched~~ hatching or for the past 21 days.

Article 2.1.14.28.
(under study)

When importing from a country or zone/compartment not known to be free from NAI, *Veterinary Administrations* should require:

for feathers and down (from poultry)

the presentation of an *international veterinary certificate* attesting that:

1) the *commodity* has been processed to ensure the destruction of the NAI virus;

2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.

Article 2.1.14.29.
(under study)

Regardless of the NAI status of the country of origin, *Veterinary Administrations* should require for the importation of:

meat or other products from birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

1) the *commodity* has been processed to ensure the destruction of the NAI virus;

2) the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of NAI virus.