UNION EUROPEENNE



Bruxelles, le D1 HLB (2008) D/411858

Subject : Next October meeting of the TAHSC

Dear Director General.

Please find attached, an annex indicating the comments of the Community on the annexes XXXI to XXXIV of the report of the Terrestrial Animal Health Standards Commission meeting of March 2008, to be considered in its next meeting in October 2008.

In addition, we would like to express our position with regard to Annex XVII of the report of the March 2008 meeting of OIE Aquatic Animal Health Standard Commission:

- · with regard to the listing of Terebrasabella heterouncinata we can support the OIE's proposal as it complies with the listing criteria;
- with regard to the maintenance on the list of abalone viral mortality (name currently used in chapter 1.2.3, of the Code) we can support QIE's proposal but we would kindly suggest the AAC to consider that this disease is not a syndrome with two manifestations but two different diseases:
- with regard to the proposed case definition for abalone viral mortality complex, we can support OIE's proposal but we would kindly suggest to the AAC to consider that this disease in not a syndrome with two manifestations but two different diseases.

Furthermore, you asked for suggestions on how to improve communications and comments by allowing more time for comments. Firstly we suggest that the initial proposals circulated from the OIE should be those relating to the points intended for a vote in the May Annual General Session. The other proposals could follow later. Secondly the meetings of the Code Commission should be scheduled earlier and a month could be gained for comments after each of the 2 Code meetings. We believe that if these two suggestions were taken on board it would immensely improve the quality of the responses and the number of member countries responding.

These comments come as an addition to the Community positions sent to you before the last General Session of May 2008.

Trusting you will find this useful, we thank you for your continued cooperation.

Yours sincerely,

Monique Eloit CVO of France Paola Testori Coggi Deputy Director General

Annex: 1

Copy:

All Directors/Chief Veterinary Officers of the Community and Croatia, Iceland,

Liechtenstein, Norway, Switzerland and Turkey.

Dr. B. Vallat Directeur général OIE 12 rue de Prony F-75017 Paris

ANNEX

Annex XXXI

APPENDIX 3.8.2.

GUIDELINES FOR <u>ON</u> THE SURVEILLANCE OF <u>FOR</u> RINDERPEST

Community comments

The Community supports the proposed changes.

Article 3.8.2.1.

Purposes of the document Introduction

In order to receive OIE recognition of rinderpest freedom, a country's national authority must present for consideration a dossier of information relating to its livestock production systems, rinderpest vaccination and eradication history and the functioning of its Veterinary Services. The dossier must contain convincing evidence derived from an animal disease surveillance system that sufficient evidence has accrued to demonstrate that the presence of rinderpest virus would have been disclosed were it to be present. Guidelines for the structure and the functioning of Veterinary Services and diagnostic support services are provided in Chapters 1.3.3. and 1.3.4. of the Terrestrial Code. A Member must also be in compliance with its OIE reporting obligations (Chapter 1.1.2. of the Terrestrial Code).

This Appendix defines the principles and provides a guide for the surveillance of rinderpest (RP) in accordance with Appendix 3.8.1. applicable to Members seeking recognition from the OIE for freedom from RP. Guidance for Members seeking reestablishment of freedom from RP, following an *outbreak*, as well as guidelines for the maintenance of RP free status are provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.2.12.

Surveillance strategies employed for demonstrating freedom from RP at an acceptable level of confidence will need to be adapted to the local situation. *Outbreaks* of rinderpest in cattle may be graded as per-acute, acute or sub-acute. Differing clinical presentations reflect variations in levels of innate host resistance (*Bas indicus* breeds being more resistant than *Bas taurus*), and variations in the virulence of the attacking strain. Experience has shown that syndromic surveillance strategies i.e. surveillance based on a predefined set of clinical signs (e.g. searching for "stomatitis-enteritis syndrome") are useful to increase the sensitivity of the system. It is generally accepted that unvaccinated populations of cattle are likely to promote the emergence of virulent strains and associated epidemics while partially vaccinated populations favour the emergence of mild strains associated with endemic situations. In the case of per-acute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect.

In certain areas there are some key wildlife populations, especially African buffaloes, which act as sentinels for rinderpest infection. These subpopulations should be included in the design of the surveillance strategy.

Surveillance for RP should be in the form of a continuing programme designed to establish that the whole country is free from RP virus (RPV) infection.

Definitions General conditions and methods

1. Rinderpest

For the purpose of this Appendix, rinderpest is defined as an *infection* of large ruminants (cattle, buffaloes, yaks, etc.), small ruminants, pigs and various wildlife species within the order Artiodactyla, caused by rinderpest virus. In small ruminants and various species of wildlife, particularly antelopes, *infection* generally passes without the development of frank clinical signs. Characteristic clinical signs and pathological lesions are described in Chapter 2.1.4. of the *Terrestrial Manual*

Outbreaks of rinderpest in cattle may be graded as per-acute, acute or sub-acute. Differing clinical presentations reflect variations in levels of innate host resistance (Bos indicus breeds being more resistant than Bos taurus), and variations in the virulence of the attacking strain. It is generally accepted that unvaccinated populations of cattle are likely to promote the emergence of virulent strains and associated epidemics while partially vaccinated populations favour the emergence of mild strains associated with endemic situations. In the case of per-acute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect.

Freedom from rinderpest means freedom from rinderpest virus infection.

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the Veterinary Authority. A procedure should be in place for the rapid collection and transport of samples from suspect cases of RP to a laboratory for RP diagnoses as described in the Terrestrial Manual.

2. Rinderpest vaccines

For the purpose of this Appendix and the *Terrestrial Code*, OIE-recognised rinderpest vaccines currently in use, or likely to become so in the forseeable future, are considered to be commercial modified live vaccines produced from attenuated rinderpest virus (referred to as 'rinderpest vaccine') produced in accordance with Chapter 2.1.4. of the *Terrestrial Manual*

2. The RP surveillance programme should:

- a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of RP. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government information programmes and the Veterinary Authority. All significant epidemiological events consistent with "stomatitis-enteritis syndrome" should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a laboratory. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in RP diagnosis and control:
- b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an RP infected country.

An effective surveillance system will periodically identify suspicious cases compatible with the "stomatitis-enteritis syndrome" that require follow-up and investigation to confirm or exclude that the cause of the condition is RPV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from RPV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory

testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 3.8.2.3.

Rinderpest surveillance Surveillance strategies

General guidelines on animal disease surveillance are outlined in Appendix 3.8.1. of the Terrestrial Code.

Rinderpest must be a *notifiable disease* i.e. notification of *outbreaks* of rinderpest as soon as detected or suspected must be brought to the attention of the *Veterinary Authority*.

The precise surveillance information required for establishing freedom will differ from country to country depending on factors such as the former rinderpest status of the country, the regional rinderpest situation and accreditation status, the time clapsing since the last occurrence of rinderpest, livestock husbandry systems (e.g. extensive pastoralism, nomadism and transhumance versus sedentary agropastoralism) and trading patterns.

Evidence of efficiency of the surveillance system can be provided by the use of performance indicators.

Surveillance results presented will be expected to have accrued from a combination of surveillance activities including some or all of the following:

1. A routine national animal disease reporting system supported by evidence of its efficiency and followup – an on-going, statutory, centrally organised system of reporting

Ideally disease reports should be expressed in a Geographical Information System environment and analysed for clustering of observations and followed up.

1. Introduction

The target population for surveillance aimed at identifying *disease* and *infection* should cover all significant populations of susceptible species within the country to be recognised as free from RPV infection.

The strategy employed can be based on randomised sampling requiring surveillance consistent with demonstrating the absence of RPV infection at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species) can be an appropriate strategy. The applicant Member should justify the surveillance strategy chosen as adequate to detect the presence of RPV infection in accordance with Appendix 3.8.1. and the epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular subpopulations likely to exhibit clear clinical signs. For targeted surveillance consideration should be given to the following:

- i) historical disease patterns (risk mapping) clinical, participatory and laboratory-based;
- ii) critical population size, structure and density;
- iii) livestock husbandry and farming systems;
- iv) movement and contact patterns markets and other trade-related movements;
- v) transmission parameters (e.g. virulence of the strain, animal movements);

vi) wildlife and other species demography.

For random surveys, the design of the sampling strategy will need to take into account the expected disease prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the expected prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained.

Irrespective of the testing system employed, surveillance design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as herds which may be epidemiologically linked to it.

The principles involved in surveillance for *disease/infection* are technically well defined in Appendix 3.8.1. The design of surveillance programmes to prove the absence of RPV infection needs to be carefully followed to ensure the reliability of results. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Emergency disease reporting systems and investigation of epidemiologically significant events (*stomatitis-enteritis syndrome*)

Emergency reporting systems can be devised to short-circuit normal passive reporting systems to bring suspicious events to the fore and lead to rapid investigation and tracing. All such investigations should be well documented for presentation as an outcome of the surveillance system.

2. Clinical surveillance

Clinical surveillance aims at detecting clinical signs of "stomatitis-enteritis syndrome" by close physical examination of susceptible animals. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of disease if sufficiently large numbers of clinically susceptible animals are examined. It is essential that clinical cases detected be followed by the collection of appropriate samples such as ocular and nasal swabs, blood or other tissues for virus isolation. Clinical surveillance and laboratory testing should always be applied in series to clarify the status of RP suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.

Active search for clinical disease can include participatory disease searching, tracing backwards and forwards, and follow-up investigations. Participatory disease surveillance is a form of targeted active surveillance based upon methods to capture livestock owners perceptions on the prevalence and patterns of disease.

The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

It is essential that all RPV isolates are sent to thean OIE reference laboratory to determine the biological characteristics of the causative virus as well as its genetic and antigenic characterization.

3. <u>Detection and thorough investigation of epidemiologically significant events (*stomatitis-enteritis syndrome</u>) which raise suspicion of rinderpest supported by evidence of efficiency of the system

Laboratory examination undertaken to confirm or rule out rinderpest is given extra credibility if it is accompanied by the results of differential diagnostic examinations.

3. <u>Virological surveillance</u>

Given that rinderpestRP is an acute infection with no known carrier state, virological surveillance using tests described in the *Terrestrial Manual* should be conducted to confirm clinically suspect cases. Applying virological methods in seropositive animals is not regarded as an efficient approach.

4. Searching for evidence of clinical rinderpest

Active search for *disease* might include participatory *disease* searching combined with village *disease* searching, tracing backwards and forwards, follow-up and investigation.

5<u>4</u>. <u>Serosurveillance</u> Serological surveillance

Serological surveillance aims at detecting antibodies against RPV. Positive RPV antibody test results can have four possible causes:

- a) natural infection with RPV;
- b) vaccination against RP;
- <u>maternal antibodies derived from an immune dam (maternal antibodies in cattle can be found only up to 12 months of age);</u>
- d) heterophile (cross) and other non-specific reactions.
- a) Randomised serosurveys

Statistically selected samples from relevant strata within the host populations are examined to detect serological evidence of possible virus circulation.

A sampling unit for the purposes of *disease* investigation and surveillance is defined as a group of animals in sufficiently close contact that individuals within the group are at approximately equal risk of coming in contact with the virus if there should be an infectious animal within the group. In most circumstances, the sampling unit will be a herd which is managed as a unit by an individual or a community, but it may also be other epidemiologically appropriate groupings which are subject to regular mixing, such as all animals belonging to residents of a village. In the areas where nomadic or transhumant movements exist, the sampling unit can be the permanent bore holes, wells or water points. Sampling units should normally be defined so that their size is generally between 50 and 1,000 animals.

i) Criteria for stratification of host populations

Strata are homogeneously mixing sub-populations of livestock. Any disease surveillance activities must be conducted on populations stratified according to the management system, and by herd size where this is variable. Herds, or other sampling units, should be selected by proper random statistical selection procedures from each stratum.

ii) Field procedures and sample sizes

Annual sample sizes shall be sufficient to provide 95% probability of detecting evidence of rinderpest if present at a prevalence of 1% of herds or other sampling units and 5% within herds or other sampling units. This can typically be achieved by examining 300 herds per stratum per year, but procedures for sampling should be in accordance with the "Guide to Epidemiological Surveillance for Rinderpest", or another procedure that would achieve the same probability of detection.

Where the sampling frame of herds is known, herds shall be selected for examination by the use of random number tables. Otherwise, samples of herds can be selected by taking the nearest herd to a randomly selected map reference, provided that the herds are evenly distributed. Failing this, any herd(s) within a fixed radius of randomly selected map references should be sampled. It must be compulsory for any selected herd to be examined or tested as required.

In carrying out clinical surveillance for evidence of rinderpest, all animals in selected herds or sampling units will be examined by a reterinarian for signs of the disease, especially mouth lesions. Any positive result shall be evaluated using epidemiological and laboratory methods to confirm or refute the suspicion of rinderpest virus activity. All animals born after the cessation of vaccination and more than one year old will be eligible for serological testing.

Where operational considerations require it, the number of eligible animals tested within each sampled herd may be reduced. This will reduce the probability of within-herd detection and there must be at least a compensatory increase in the number of herds sampled, so that the required 95% probability of detecting 1% between-herd prevalence is maintained.

b) Risk-focussed serosurveillance

Risk-focussed serosurveillance differs from randomised serosurveillance in that it increases detection sensitivity by obtaining samples from areas/populations determined to be at higher risk of *infection*, so as to detect serological evidence of possible virus circulation. The operational modalities for risk-based focussing of surveillance require definition (randomisation within defined focus, high risk animals, etc.). The extent to which randomisation needs to be retained in the generation of risk-focussed serosurveillance data needs to be established.

Focussing can be achieved by reference to some or all of the following:

- i) Historical disease patterns (prior probability mapping)—clinical, participatory and laboratory—based
- ii) Critical population size, structure and density
- iii) Livestock husbandry and farming systems
- iv) Movement and contact patterns markets and other trade related movements
- v) Transmission parameters (e.g. virulence of the strain, animal movements)
- vi) Wildlife and other species demography.

Article 3.8.2.4.

Selection of cattle and buffaloes for serosurveillance

Ageing cattle and Asian buffaloes for the purpose of serosurveillance:

Mis-ageing of cattle selected for serosurveillance is the most common source of error. Colostral immunity can persist almost up to one year of age when measured by the H c-ELISA. Thus, it is essential to exclude

from sampling buffaloes and cattle less than one year of age. In addition, it is frequently necessary to be able to exclude those which are older than a certain age, for example, to select only those born after cessation of vaccination.

Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed.

Pragmatically, and solely for the purposes of serosurveillance, it can be accepted that:

- a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffaloes 24.48 months);
- b) cattle having only two pairs of crupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffaloes 48-60 months).

Thus selecting a cohort of cattle possessing only one pair of permanent incisors will preclude any interference from maternal immunity derived from earlier vaccination or *infection* and ensure that vaccinated cattle are not included if vaccination ceased 3 years or more previously (for Asian buffaloes 4 years or more).

It is important to select a cohort of cattle possessing only one pair of permanent incisors to preclude any interference from maternal immunity derived from earlier vaccination or infection and ensure that vaccinated cattle are not included.

Although it is stressed here that animals with milk teeth only are not suitable for surveillance based on serology, they are of particular interest and importance in surveillance for clinical *disease*. After the loss of colostral immunity, by about one year of age, these are the animals which are most likely to suffer the more severe *disease* form and in which to look for lesions indicative of rinderpest.

It may be possible to use serum collected for other survey purposes for RP surveillance. However, the principles of survey design described in this Appendix and the requirement for a statistically valid survey for the presence of RPV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain infection. As clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design.

The results of random or targeted serological surveys are important in providing reliable evidence that RPV infection is not present in a country. It is therefore essential that the survey be adequately thoroughly documented.

Article 3.8.2.5.

Wildlife surveillance where a significant susceptible wildlife population exists

There are some key wildlife populations, especially African buffaloes, which act as sentinels for rinderpest infection. Where a significant population of a susceptible wildlife species exists, serosurveillance data are required should be collected to support absence of infection. These populations should be monitored purposively to support the dossiers to be submitted for freedom from rinderpest virus infection. Detection of virus circulation in wildlife can be undertaken indirectly by sampling contiguous livestock populations.

Obtaining meaningful data from wildlife surveillance can be enhanced by close coordination of activities in the regions and countries. Both purposive and opportunistic samplings are used to obtain material for analysis in national and reference laboratories. The latter are required because most many countries are unable do not have adequate facilities to perform the full testing protocol for detecting rinderpest RP antibodies in wildlife sera.

Purposive <u>Targeted</u> sampling is the preferred method to provide wildlife data to evaluate the status of rinderpest *infection*. In reality, the capacity to perform purposive work targeted surveillance in the majority of countries remains minimal. Opportunistic sampling (hunting) is feasible and it provides useful background information.

Wildlife form transboundary populations; therefore, any data from the population could be used to represent the result for the ecosystem and be submitted by more than one country Member in a dossier an application to the OIE (even if the sampling was not obtained in the country Member submitting the application). It is therefore recommended therefore that the countries Members represented in a particular ecosystem should coordinate their sampling programmes.

The standards for serosurveillance are different from that set for cattle because the serological tests are not fully validated for wildlife species and financial and logistic constraints of sampling prevent collection of large numbers of samples.

Where the serological history of the herd is known from previous work (as might be the case for a sentinel herd), repeat sampling need only focus on the untested age groups, born since the last known infection. The sample needs to be taken according to the known epidemiology of the disease in a given species. Opportunistic samples, which are positive, should not be interpreted without a targeted survey to confirm the validity of these results. Opportunistic sampling cannot follow a defined protocol and therefore can only provide background information.

From the collective experience of the laboratories and experts over the years, an appropriate test protocol is based on the high expected sero-prevalence in a previously infected buffalo herd (99% seroconversion of eligible animals within a herd), which is detected using a test, which is 100% sensitive. No single test can achieve this; however, combining H c-ELISA to VNT raises sensitivity close to 100%.

In the order of 1-2% of a herd of African buffaloes must be sampled to ensure that no positive case is missed. For example in a herd of 300 buffaloes, five animals should be sampled and the above multiple test protocol followed. Where the serological history of the herd is known from previous work (as might be the case for a sentinel herd), repeat sampling need only focus on the untested age groups, born since the last known infection. Appropriate sampling fraction for other wildlife species are less well defined, as social organization (herd structure, likely contact rates, etc.) vary. The sample needs to be taken according to the known epidemiology of the disease in a given species. Opportunistic samples, which are positive, should not be interpreted without a purposive survey to confirm the validity of these results. Opportunistic sampling cannot follow a defined protocol and therefore can only provide background information.

Article 3.8.2.6.

Evaluation of applications for accreditation of Members applying for recognition of freedom from rinderpest RP

Evaluation of applications for the status of freedom from rinderpest will be the responsibility of the OIE Scientific Commission for Animal Diseases which can request the Director General if the OIE to appoint an ad hoc group in order to assist in reaching an informed decision to present to the OIE International Committee for approval.

The composition and method of selection of the *ad bot* group shall be such as to ensure both a high level of expertise in evaluating the evidence and total independence of the group in reaching conclusions concerning the *disease* status of a particular country.

In addition to the general conditions described in Chapter 2.2.12., a Member applying for recognition of RP freedom for the country should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Appendix, to demonstrate absence of RPV infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of RPV infection through virus/antigen/genome detection and antibody tests described in the Terrestrial Manual.

Article 3.8.2.7.

Steps to be taken to declare a country to be free from rinderpest

Recognition of the status 'free from rinderpest' is given to a Member. Where traditionally managed livestock move freely across international borders, groups of Members may usefully associate themselves into a group for the purposes of obtaining data to be used for mutually supportive applications for individual country accreditation.

For the purpose of this Appendix, the following assumptions are made:

- that within most previously infected countries, rinderpest vaccine will have been used to control the rate of infection;
- b) that within an endemically infected population there will be a large number of immune hosts (both vaccines and recovered animals);
- c) that the presence of a proportion of immune hosts within a vaccinated population could have led to a slowing of the rate of virus transmission and possibly the concomitant emergence of strains of reduced virulence, difficult to detect clinically;
- d) that the virulence of the virus (and therefore the ease of clinical detection) may or may not increase as the herd immunity declines following withdrawal of vaccination; however, continuing transmission will generate serological evidence of their persistence.

Before accreditation can be considered, countries which have controlled the disease by the use of rinderpest vaccine must wait until an unvaccinated cohort is available to allow meaningful serological surveillance to be conducted.

The OIE has concluded that the majority of countries have stopped vaccinating for a sufficient length of time for it now to be feasible that a single submission of evidence gained over 2 years of appropriate surveillance shall be sufficient to gain rinderpest free accreditation.

A Member accredited as free from rinderpest must thereafter submit annual statements to the Director General of the OIE indicating that surveillance has failed to disclose the presence of rinderpest, and that all other criteria continue to be met.

A country previously infected with rinderpest which has not employed rinderpest vaccine for at least 25 years and has throughout that period detected no evidence of rinderpest virus *disease* or *infection* may be accredited as free from rinderpest by the OIE based on historical grounds, provided that the country:

- has had throughout at least the last 10 years and maintains permanently an adequate animal *disease* surveillance system along with the other requirements outlined in Article 3.8.1.6.;
- is in compliance with OIE reporting obligations (Chapter 1.1.2.).

The Veterinary Authorities of the Member must submit a dossier containing evidence supporting their claim to be free from rinderpest on a historical basis to the Director General of the OIE for evaluation by the OIE Scientific Commission for Animal Diseases and accreditation by the OIE International Committee. The dossier should contain at least the following information:

- a description of livestock populations, including wildlife;
- the history of rinderpest occurrence in the country and its control;
- an affirmation that rinderpest has not occurred for 25 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*;

- evidence that in the last 10 years the disease situation throughout the Member has been constantly
 monitored by a competent and effective veterinary infrastructure that has operated a national animal
 disease reporting system submitting regular (monthly) disease occurrence reports to the Veterinary
 Authority;
- the structure and functioning of the Veterinary Services;
- the Member operates a reliable system of *risk analysis* based importation of livestock and livestock products.

Evidence in support of these criteria must accompany the Member's accreditation application dossier. In the event that satisfactory evidence is not forthcoming, the OIE may seek clarification or refer the dossier back to the originators, giving its reasons for so doing. Under such circumstances a fresh dossier would be entertained in due course.

OR

A Member having eradicated rinderpest within the last 25 years, wishing to be accredited free from rinderpest and having ended rinderpest vaccination must initiate a two-year surveillance programme to demonstrate freedom from rinderpest whilst banning further use of rinderpest vaccine. The step of accreditation as free from rinderpest is subject to meeting stringent criteria with international verification under the auspices of the OIE.

A country historically infected with rinderpest but which has convincing evidence that the *disease* has been excluded for at least two years and is not likely to return, may apply to OIE to be accredited as free from rinderpest. The conditions which apply include that an adequate animal *disease* surveillance system has been maintained throughout at least that period.

The Veterinary Authority of the Member must submit a dossier containing evidence supporting their claim to be free from rinderpest to the Director General of the OIE for evaluation by the OIE Scientific Commission for Animal Diseases and accreditation by the OIE International Committee showing that they comply with:

- the provisions outlined in Chapter 2.2.12. of the Terrestrial Code;
- OIE reporting obligations outlined in Chapter 1.1.2. of the *Terrestrial Code*.

Other conditions that apply are:

- The Member affirms that rinderpest has not occurred for at least 2 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*.
- The Veterinary Authority has issued orders curtailing the distribution and use of rinderpest vaccine in livestock.
- The Veterinary Authority has issued orders for the recall and destruction of rinderpest vaccine already issued.
- The Veterinary Authority has issued orders restricting the importation of rinderpest vaccine into, or the further manufacture of rinderpest vaccine within, the territory under his jurisdiction. An exception can be made for establishing a safeguarded rinderpest emergency vaccine bank under the control of

the Chief Veterinary Officer who can demonstrate that no calls have been made on that vaccine bank.

- The Veterinary Authority has set in place a rinderpest contingency plan.
- Over the previous 2 years at least, the *disease* situation throughout the Member has been constantly monitored by a competent and effective infrastructure that has operated a national animal *disease* reporting system submitting regular (monthly) *disease* occurrence reports to the *Veterinary Authority*.
- All outbreaks of disease with a clinical resemblance to rinderpest have been thoroughly investigated and
 routinely subjected to laboratory testing by an OIE recognised rinderpest specific test within the
 national rinderpest laboratory or at a recognised reference laboratory.

The dossier shall contain:

- the results of a continuous surveillance programme, including appropriate serological surveys
 conducted during at least the last 24 months, providing convincing evidence for the absence of
 rinderpest virus circulation;
- a description of livestock populations including wildlife;
- the history of rinderpest occurrence in the country and its control;
- an affirmation that rinderpest has not occurred for at least 2 years, that vaccine has not been used during that time, and that rinderpest is a *notifiable disease*;
- evidence that in the last 2 years the disease situation throughout the Member has been constantly
 monitored by a competent and effective veterinary infrastructure that has operated a national animal
 disease reporting system submitting regular (monthly) disease occurrence reports to the Veterinary
 Anthority;
- the structure and functioning of the Veterinary Services;
- the Member operates a reliable system of *risk analysis* based importation of livestock and livestock products.

In the event that satisfactory evidence in support of the application is not forthcoming, the OIE may seek clarification or refer the dossier back to the originators, giving its reasons for so doing. Under such circumstances a fresh dossier would be entertained in due course.

Article 3.8.2.8<u>7</u>.

Rinderpest outbreaks after the accreditation process and recovery of rinderpest free status Members re-applying for recognition of freedom from RP following an outbreak

Should there be an *outbreak*, or *outbreaks*, of rinderpest in a Member at any time after recognition of rinderpest freedom, the origin of the virus strain must be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of *infection*. The virus must be isolated and compared with historical strains from the same area as well as those representatives of other possible sources. The *outbreak* itself must be contained with the utmost rapidity using the resources and methods outlined in the Contingency Plan.

Following an *outbreak*, or *outbreaks*, of rinderpest in a Member at any time after recognition of rinderpest freedom, the origin of the virus strain should be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of infection. Ideally, the virus should be isolated and compared with historical strains from the same area as well as those representatives of other possible sources.

After elimination of the *outbreak*, a Member wishing to regain the status 'free from rinderpest' must should undertake serosurveillance according to this Appendix to determine the extent of virus spread. In addition to the general conditions described in Chapter 2.2.12., a Member re-applying for recognition of country freedom from RP should show evidence of an active surveillance programme for RP as well as absence of RPV infection.

If investigations show the *outbreak* virus originated from outside the country, provided the *outbreak* was localised, rapidly contained and speedily eliminated, and provided there was no serological evidence of virus spread outside the index infected area, accreditation of freedom could proceed rapidly. The **country** Member must satisfy the OIE Scientific Commission for Animal Diseases that the *outbreaks* were contained, eliminated and did not represent endemic *infection*.

An application to regain the status free from rinderpest shall not generally be accepted until both clinical and serological evidence shows that there has been no virus transmission for at least 3 or 6 months, depending on whether or not stamping-out or vaccination respectively has been applied.

Article 3.8.2.8.

The use and interpretation of serological tests for serosurveillance of RP

Serological testing is an appropriate tool to use for RP surveillance. The prescribed serological tests which should be used for RP surveillance are described in the *Terrestrial Manual*; these are of high diagnostic specificity and minimise the proportion of false positive reactions. Antibodies to virulent strains and the Kabete O vaccine strain of RPV can be detected in cattle from about 10 days post infection (approximately 7 days after the appearance of fever) and peak around 30 to 40 days post infection. Antibodies then persist for many years, possibly for life, although titres decline with time. In the case of less virulent strains the detection of the antibody response by ELISA may be delayed by as much as three weeks. There is only one serotype of virus and the tests will detect antibodies elicited by infection with all RP viruses but the tests cannot discriminate between antibodies to field infection and those from vaccination with attenuated vaccines. This fact compromises serosurveillance in vaccinated populations and realistically meaningful serosurveillance can only commence once vaccination has ceased for several years. In these circumstances, dental ageing of cattle and buffaloes is of great value to minimise the inclusion of animals seropositive by virtue of colostral immunity and historic vaccination or infection. The cohort of cattle with one single set of central incisors is the most appropriate to sample².

The test most amenable to the mass testing of sera as required to demonstrate freedom from infection is the H c-ELISA. Practical experience from well-controlled serological surveillance in non-vaccinated populations in Africa and Asia demonstrate that one can expect false positive reactions in 0.05% or less of sera tested. The sensitivity of the test approaches 100% (relative to the VNT) in Kabete O vaccinated cattle and infection with highly virulent viruses but is lower in the case of low virulence strains. Experience supported by experimental studies indicates that in all cases sensitivity exceeds 70%.

Only tests approved by OIE as indicated in the *Terrestrial Manual* should be used to generate data presented in support of applications for accreditation of RP freedom. It is necessary to demonstrate that apparently positive serological results have been adequately investigated. The follow-up studies should use appropriate clinical, epidemiological, serological and virological investigations. By this means the investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the survey were not due to virus circulation.

The prescribed serological tests have not been fully validated for use in all wild species. From the collective experience of the reference laboratories and experts over the years, an appropriate test protocol

for wildlife is based on the high expected sero-prevalence in a previously infected buffalo herd which is 99 % seroconversion of eligible animals within a herd as detected by use of a 100% sensitive test. No single test can achieve this but combining the H c-ELISA with the VNT raises sensitivity close to 100%.

- 1. JAMES A.D. (1998). Guide to epidemiological surveillance for rinderpest. Rev. Sci. Tech. 17 (3), 796-824.
- 2. Pragmatically and solely for the purposes of serosurveillance, it can be accepted that:
 - a) Cattle having one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffaloes 24 to 48 months);
 - b) Cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffaloes 48-60 months).

text deleted

CHAPTER 2.3.15.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

Community comments

The Community supports the proposed changes.

Article 2.3.15.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be 6 months.

For the purpose of this chapter, a case of CBPP means an animal infected with Mycoplasma mycoides subsp. mycoides SC (MmmSC), and freedom from CBPP means freedom from MmmSC infection.

For the purpose of this chapter, susceptible animals include domestic cattle (*Bos indicus* and *B. taurus*) and water buffalo (*Bubalus bubalis*).

For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by *MmmSC*, but also with the presence of infection with *MmmSC* in the absence of clinical signs.

The following defines the occurrence of MmmSC infection:

- 1. MmmSC has been isolated and identified as such from an animal, embryos, oocytes or semen; or
- antibodies to MmmSC antigens which are not the consequence of vaccination, or MmmSC DNA, have been identified in one or more animals showing pathological lesions consistent with infection with MmmSC with or without clinical signs, and epidemiological links to a confirmed outbreak of CBPP in susceptible animals.

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

Article 2.3.15.2.

CBPP free country, zone or compartment

To qualify for inclusion in the existing list of CBPP free countries, a country Member should:

- 1. have a record of regular and prompt animal disease reporting;
- 2. send a declaration to the OIE stating that:
 - a) there has been no outbreak of CBPP during the past 24 months;
 - b) no evidence of CBPP infection has been found during the past 24 months;
 - c) no vaccination against CBPP has been carried out during the past 24 months,

and supply documented evidence that surveillance for CBPP in accordance with Appendix 3.8.3. is in operation and that regulatory measures for the prevention and control of CBPP have been

implemented;

3. not have imported since the cessation of vaccination any animals vaccinated against CBPP.

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information 2a), 2b), 2c) and 3 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.2.

Article 2.3.15.3.

Recovery of free status

When a CBPP *outbreak* occurs in a CBPP free country, *zone* or *compartment*, one of the following waiting periods is required to regain the status of CBPP free country, *zone* or *compartment*:

- 1. 12 months after the last *case* where a *stamping-out policy* and serological surveillance and strict movement control are applied in accordance with Appendix 3.8.3.;
- 2. if vaccination was used, 12 months after the slaughter of the last vaccinated animal.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 2.3.15.2. applies.

Article 2.3.15.4.

Infected country

When the requirements for acceptance as a CBPP free country, *zone* or *compartment* are not fulfilled, a country shall be considered as CBPP infected.

Article 2.3.15.5.

Veterinary Authorities of CBPP free countries, zones or compartments may prohibit importation or transit through their territory of domestic cattle and water buffalo, from countries and zones_considered infected with CBPP.

Article 2.3.15.6.

When importing from CBPP free countries, zones or compartments, Veterinary Authorities should require:

for domestic cattle and water buffaloes

the presentation of an *international veterinary vertificate* attesting that the animals showed no clinical sign of CBPP on the day of shipment.

Article 2.3.15.7.

When importing from CBPP infected countries or zones, Veterinary Authorities should require:

for domestic cattle and water buffaloes for slaughter

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

- 1. showed no clinical sign of CBPP on the day of shipment;
- 2. originate from an establishment where no case of CBPP was officially reported for the past 6 months, and

3. are transported directly to the *slaughterhouse* in sealed *vehicles*.

Article 2.3.15.8.

When importing from CBPP infected countries, Veterinary Authorities should require:

for fresh meat of bovidae

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

- 1. which showed no lesion of CBPP;
- 2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections to rule out the presence of CBPP with favourable results.

Annex XXXII (contd)

APPENDIX 3.8.3.

GUIDELINES ON SURVEILLANCE FOR CONTAGIOUS BOVINE PLEUROPNEUMONIA

Community comments

The Community supports the proposed changes.

Article 3.8.3.1.

Introduction

This Appendix defines the principles and provides a guide for the surveillance of contagious bovine pleuropneumonia (CBPP) in accordance with Appendix 3.8.1. applicable to **countries Members** seeking recognition from the OIE for freedom from CBPP. This may be for the entire country, *zone* or *compartment* within the country. Guidance for **countries Members** seeking reestablishment of freedom from CBPP for the whole country, *zone* or *compartment* within the country, following an *outbreak*, as well as guidelines for the maintenance of CBPP status are provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.3.15. Applications to the OIE for recognition of freedom should follow the format and answer all the questions posed by the "Questionnaire on CBPP" available from the OIE *Central Bureau*.

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence will need to be adapted to the local situation. It is incumbent upon the applicant country Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to OIE Members to provide a well-reasoned argument to prove that the absence of CBPP infection is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP infection.

Article 3.8.3.2.

General conditions and methods

- 1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of CBPP to a laboratory for CBPP diagnoses as described in the *Terrestrial Manual*.
- 2. The CBPP surveillance programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, meat inspectors as well as laboratory diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) into the surveillance system. All

suspect cases of CBPP should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an *laboratory*. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CBPP diagnosis and control;

- b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of animals, such as those adjacent to a CBPP infected country or *zone* (for example, areas of transhumant production systems);
- c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.

An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 3.8.3.3.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) within the country, *zone* or *compartment* to be recognised as free from CBPP infection.

Given the limitations of the diagnostic tools available, the interpretation of surveillance results should be at the herd level rather than at the individual animal level.

Randomised surveillance may not be the preferred approach given the epidemiology of the disease (usually uneven distribution and potential for occult foci of infection in small populations) and the limited sensitivity and specificity of currently available tests. Targeted surveillance (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on slaughter findings, and active clinical surveillance) may be the most appropriate strategy. The applicant country should justify the surveillance strategy chosen as adequate to detect the presence of CBPP infection in accordance with Appendix 3.8.1. and the epidemiological situation.

Targeted surveillance may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country Member must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated.

Irrespective of the surveillance system employed, the design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve follow-up with supplementary tests, clinical investigation and post-mortem examination in the original sampling unit as well as herds which may be epidemiologically linked to it.

2. <u>Clinical surveillance</u>

Clinical surveillance aims at detecting clinical signs of CBPP in a herd by close physical examination of susceptible animals. Clinical inspection will be an important component of CBPP surveillance contributing to reach the desired level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible animals is examined.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. Laboratory testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.

3. Pathological surveillance

Systematic pathological surveillance for CBPP is the most effective approach and should be conducted at *slaughterhouses* and other slaughter facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for slaughter personnel and meat inspectors are recommended.

4. Serological testing

Serological surveillance is not the preferred strategy for CBPP. However, in the framework of epidemiologic investigations, serological testing may be used.

The limitations of available serological tests for CBPP will make the interpretation of results difficult and useful only at the herd level. Positive findings should be followed-up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP infections and will be usually accompanied by clinical signs. As clustering may signal field strain infection, the investigation of all instances must be incorporated in the surveillance strategy.

Following the identification of a CBPP infected herd, contact herds need to be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in herd classification.

5. Agent surveillance

Agent surveillance using tests described in the *Terrestrial Manual* should be conducted to follow-up and confirm or exclude suspect cases. Isolates should be typed to confirm *Mmm*SC.

Article 3.8.3.4.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in Chapter 2.3.15., an OIE Member applying for recognition of CBPP freedom for the country or a zone should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general

conditions and methods in this Appendix, to demonstrate absence of CBPP infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of CBPP infection using methods described in the *Terrestrial Manual*.

Article 3.8.3.5

Compartments seeking recognition of freedom from CBPP

The bilateral recognition of CBPP free *compartments* should follow the principles laid in Chapter 2.3.15, Chapter 1.3.5, Appendix 3.x.x.x (Guidelines for compartmentalization) and this Appendix.

Article 3.8.3.6.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in Chapter 2.3.15., a **country** Member re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active surveillance programme for CBPP, following the recommendations of this Appendix.

Two strategies are recognised by the OIE in a programme to eradicate CBPP infection following an *outbreak*:

- 1. slaughter of all clinically affected and in-contact susceptible animals;
- 2. vaccination used without subsequent slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 2.3.15.3.

CHAPTER 2.4.8.

SCRAPIE

Community comments

The Community would like to thank the OIE for revising Chapter 2.4.8 on scrapie which is an improvement compared to the old Chapter.

The Community notes that due to the specific epidemiology of scrapie and its wide distribution, it might prove difficult for countries or zones to achieve negligible scrapie risk status. Trade in breeding and rearing animals will therefore predominantly be restricted to negligible scrapie risk establishments or compartments within controlled risk countries.

To avoid disproportionate restrictions on trade in those animals, the Community suggests some relaxations to the rules on controlled risk countries, zones or compartments in order to ensure the possibility for trade from negligible scrapie risk establishments and compartments within those countries, zones or compartments.

A further way to avoid disproportionate trade restrictions in trade with breeding or rearing animals could be introducing the possibility of establishing compartments with negligible scrapie risk in countries with undetermined scrapie risk.

This chapter aims at providing safeguards at a national, regional or herd level. It should be recognized however that genetic resistance to scrapie can also provide sufficient safeguard on the level of individual ovine animals.

It should be acknowledged that ovine animals of the ARR/ARR genotype can be considered of the same risk level as ovine animals originating from an establishment with negligible risk as referred to in article 2.4.8.6.

Article 2.4.8.1.

The recommendations in this Chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in cattle, sheep and goats. Scrapie is not considered to pose a risk to human health. In the context of this Chapter, 'scrapie' includes all transmissible spongiform encephalopathies in small ruminants except bovine spongiform encephalopathy. That is, the Chapter covers 'classical' scrapie, which is known to be contagious, as well as 'atypical' scrapie which may not be contagious or may be only poorly transmissible.

Community comments

Under natural circumstances scrapie has never been diagnosed in cattle. Therefore the Community proposes to delete the reference to the presence of the scrapie agent in cattle.

Scientific evidence shows that the characteristics of atypical scrapie are distinct from those of classical scrapie. The Community would like to point that if more evidence becomes available there might be the need to introduce certain derogations or alternative measures linked to countries where only atypical scrapie has been diagnosed. In addition due to the uncertainties linked to atypical scrapie, it might therefore be difficult to "control" this risk.

The recommendations in the present chapter are not intended, or sufficient, to manage the risks associated with the potential presence of the bovine spongiform encephalopathy agent in small ruminants.

Standards for diagnostic tests are described in the Terrestrial Manual.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from small ruminants, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the small ruminant populations of the *exporting country*, *zone* or *compartment*:

Community comments

The terms "milk and milk products" have been removed from the list of commodities for which Veterinary Authorities should not require any scrapic related-conditions regardless of the scrapic risk status of the exporting country, zone or compartment.

However, there is no other provision for trade of these products in the proposal. Therefore it is fundamental to provide for condition for trade of milk and milk products.

- a) meat and meat products;
- b) semen and *in vivo* derived embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

Community comments

The Community wants to reserve its position on the inclusion of semen and in vivo derived embryos to the list of products which do not require any scrapie-related measures.

- c) hides and skins;
- d) gelatine;
- e) collagen prepared from hides or skins;
- f) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
- g) dicalcium phosphate (with no trace of protein or fat);
- h) wool or fibre.

2. When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the scrapie risk status of the small ruminant populations of the *exporting country*, *zone* or *compartment*.

Article 2.4.8.2.

The scrapie risk status of the sheep and goat populations of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

the outcome of a *risk assessment* identifying potential factors for scrapie occurrence and their historic perspective. In situations where a country *risk assessment* cannot be conducted because of insufficient information, consideration should be given to conducting *risk assessments* on individual *establishments* or *compartments*. The diverse routes of transmission of the agent, including from long-lasting environmental contamination, and long *incubation periods*, may also make compartmentalisation a more practicable option than whole of country assessments.

1. Members should review the *risk assessment* periodically to determine whether the situation has changed.

a) Release assessment

Release assessment consists of assessing, through consideration of the following, the likelihood that the scrapie agent has either been introduced into the country, zone or compartment via commodities potentially contaminated with it, or is already present in the country, zone or compartment:

- i) the presence or absence of the scrapie agent in the indigenous small ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;
- ii) production of meat-and-bone meal from the indigenous small ruminant population;
- iii) imported meat-and-bone meal;
- iv) imported sheep and goats;
- v) imported animal feed and feed ingredients.

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

b) Exposure assessment

If the release assessment identifies a risk factor, an exposure assessment should be conducted, consisting of assessing the likelihood of small ruminants being exposed to the scrapie agent, through a consideration of the following:

i) the eradication measures which are applied following the detection of scrapie in sheep and goat flocks;

Community comments

The presence of a breeding program in sheep which will contribute to the eradication measures should be taken into account in the exposure assessment. In addition due to the protective effect associated with the ARR allele, its frequency in the sheep population of a given country, zone or compartment might represent a useful factor for assessing the risk of scrapie.

Therefore the Community proposes the following wording:

"i) the eradication measures which are applied following the detection of scrapie in sheep and goat flocks (including breeding program if appropriate and information on the distribution of PrP alleles in sheep population within the country)"

- ii) distribution and fate of imported sheep and goats;
- iii) recycling and amplification of the scrapie agent through consumption by small ruminants of *meat-and-bone meal* of ruminant origin, or other feed or feed ingredients contaminated with these;
- iv) the use of ovine and caprine carcasses (including from fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- v) the feeding or not of ruminants with *meat-and-bone meal* derived from ruminants, including measures to prevent cross-contamination of animal feed;
- vi) the level of surveillance for scrapie conducted on the sheep and goat populations up to that time, the tests used, and the results of that surveillance;
- 2. the compulsory notification and investigation of all small ruminants showing clinical signs consistent with scrapie;
- 3. the examination carried out in accordance with the *Terrestrial Manual* in a *laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system;
- 4. an on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of small ruminants to encourage reporting of *cases* showing clinical signs consistent with scrapie.

Article 2.4.8.3.

Negligible scrapie risk

Commodities from the small ruminant populations of a country or zone pose a negligible risk of transmitting the scrapie agent if the following conditions are met:

- 1. a risk assessment, as described in point 1 of Article 2.4.8.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
- 2. the Member has in place a surveillance programme, based on a combination of testing all small ruminants showing clinical signs consistent with scrapie, and appropriate samples of fallen stock, dead-in-transit stock and culled-for-age stock, and capable of detecting *infection* at an annual period prevalence of 0.1% of animals over 18 months of age with 95% confidence and which has failed to detect scrapie for 7 consecutive years;

Community comments

The requirement for sheep surveillance with a small ovine and caprine population will be very difficult to be met.

The OIE requirement for surveillance streams in negligible risk countries or zones poses certain practical problems as:

- Combining results from different surveillance streams is epidemiologically complex.
- Analysing the results from each stream is also epidemiologically complex and depends upon the test sensitivity and the age-dependent detectable prevalence of infection, which is itself genotype-dependent. The latter two variables are country specific.

We suggest that the OIE provides tables with the number of samples to be analysed in different surveillance streams depending on the population size. Specific requirements should be used for small populations, which cannot reach the required sample size.

3. EITHER:

a) all *establishments* containing sheep or goats have been accredited as negligible scrapie risk as described in Article 2.4.8.6.;

OR

- b) there has been no case of scrapie and
 - i) the criteria in points 2 and 3 of Article 2.4.8.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated through an appropriate level of control and audit that for at least 7 years no *meat-and-bone meal* derived from ruminants has been fed to ruminants;

OR

c) if there has been a case of scrapie, every case was born more than 9 years ago; and

Community comments

Due to the horizontal transmission of scrapie, the year of birth of the case is less relevant. Taken into account an incubation period of two years, the Community suggest the following wording:

"c) if there has been a case of scrapie, every case was detected more than 7 years ago."

- i) the criteria in points 2 and 3 of Article 2.4.8.2. have been complied with for at least 7 years; and
- ii) it has been demonstrated through an appropriate level of control and audit that for at least 7 years no *meat-and-bone meal* derived from ruminants has been fed to ruminants;
- iii) and

- in the case of classical scrapie, all cases have been culled, as well as all sheep (except rams of the genotype ARR/ARR and ewes of genotypes ARR/xxx with no VRQ) and all goats, or
- in the case of atypical scrapie, all *cases* have been culled, as well as all sheep carrying the AF¹⁴¹RQ allele;

Community comments

The Community would like the OIE to clarify if the culling requirement is restricted to the culling of affected herds/ flocks or concerns the whole country. This comment also applies to Article 2.4.8.4, point 3),b),ii). In addition the culling requirement of all sheep based on the genotypes in infected flocks in the case of atypical scrapie is disproportionate.

Indeed, in the case of atypical scrapie, AFRQ is 14 times more sensitive as ALRQ or ARR (Moreno et al, 2007 Arch Vir). However in the case of classical scrapie, VRQ animals are 177 times more sensitive as ARR animals. In addition the culling measures might be limited to rams carrying the AF141RQ and/or the AHQ allele which represent the main genetic risk factors for "atypical" scrapie. Based on this limited genetic predisposition in case of atypical scrapie compared to classical scrapie, a culling strategy based on genotypes might be less suitable.

This comment also applies to Articles 2.4.8.4, point 3), b), ii) and 2.4.8.6, point 3), b). The same comment applies to Article 2.4.8.4, point 3) b) ii) and Article 2.4.8.6, 3)b).

4. introductions of sheep and goats for breeding are made only from a country, zone or compartment of negligible scrapie risk or an establishment or compartment free from scrapie as described in Article 2.4.8.6.

Community comments

The wording "compartment free from scrapie should refer to "compartment of negligible scrapie risk". The same comment applies for Article 2.4.8.4., point 4.a). and Article 2.4.8.12., point 1).

Article 2.4.8.4.

Controlled scrapie risk

Commodities from the small ruminant populations of a country, zone or compartment pose a controlled risk of transmitting the scrapie agent if the following conditions are met:

- 1. a *risk assessment*, as described in point 1 of Article 2.4.8.2., has been conducted in order to identify the historical and existing risk factors and the Member has demonstrated that appropriate measures are being taken to manage all identified risks;
- 2. the Member has in place a surveillance programme, based on a combination of testing all small ruminants showing clinical signs consistent with scrapie, and appropriate samples of fallen stock, dead-in-transit stock and culled-for-age stock, and capable of detecting *infection* at an annual period prevalence of 0.1% of animals over 18 months of age with 95% confidence;

Community comments

Surveillance in countries, zones or compartments should be less onerous than in negligible risk status. Such countries can only export breeding or rearing animals from negligible risk establishments or compartments, so there is no need having such onerous surveillance in the rest of the country or zone. Furthermore, achieving negligible risk status in the short or medium term may not be realistic if the disease is widespread in the country.

The Community propose pragmatic sample sizes along the lines presently used in the Community.

3. EITHER:

- a) there has been no *case* of scrapie, the criteria in points 2 to 4 of Article 2.4.8.2. are complied with and it can be demonstrated through an appropriate level of control and audit that no *meat-and-bone meal* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:
 - i) the criteria in points 2 and 3 of Article 2.4.8.2. have not been complied with for 5 years;
 - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* derived from ruminants to ruminants have been in place for 5 years;

Community comments

In order to take into account the situation where countries not complying for seven years period for the points i) and ii) in order to be eligible for recognition as a negligible scrapie risk country status but comply with the points i) and ii) for more than 5 years, the Community propose the following:

- "i) the criteria in points 2 and 3 of Article 2.4.8.2. have not been complied with for 7 years;
- ii) it cannot be demonstrated that controls over the feeding of meat-and-bone meal derived from ruminants to ruminants have been in place for 7 years"

OR

b) there has been a *case* of scrapie, the criteria in points 2 and 3 of Article 2.4.8.2. are complied with, and it can be demonstrated that controls over the feeding of *meat-and-bone meal* derived from ruminants to ruminants have been in place for 5 years and;

Community comments

The Community suggest the following wording:

"b) if there has been a case of scrapie,"

- i) in the case of classical scrapie, all *cases* have been culled, as well as all sheep except rams of the genotype ARR/ARR and ewes of genotypes ARR/xxx with no VRQ, and all goats, or
- ii) in the case of atypical scrapie, all *cases* have been culled, as well as all sheep carrying the AF141RQ allele.

Community comments

The culling requirements are disproportionate taking into account that export of breeding or rearing animals is only allowed from negligible risk establishments or compartments. Countries were scrapie is widespread must have the possibility to use alternative culling measures.

4. EITHER:

a) introductions of sheep and goats for breeding are made only from a country, zone or compartment of negligible scrapie risk or an establishment or compartment free from scrapie as described in Article 2.4.8.6., or

OR

b) introductions of sheep for breeding are restricted to rams of the genotype ARR/ARR and ewes of genotypes ARR/xxx with no VRQ.

Article 2.4.8.5.

Undetermined scrapie risk

The small ruminant populations of a country, *zone* or *compartment* poses an undetermined scrapie risk if it cannot be demonstrated that it meets the requirements of another category.

Article 2.4.8.6.

Negligible scrapie risk establishment or compartment

An establishment or compartment can be considered eligible for accreditation as negligible scrapic risk if:

- 1. the *establishment* or *compartment* is situated within a country that meets the requirements for negligible scrapie risk according to Article 2.4.8.3., or
- 2. the *establishment* or *compartment* is situated within a country that meets the requirements for controlled scrapie risk according to Article 2.4.8.4., and
 - a) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;
 - b) in the establishment the following conditions have been complied with for at least 7 years:
 - i) sheep and goats should be permanently identified and records maintained, to enable trace back to their *establishment* of birth and to any other *establishment* on which they may have resided since birth;
 - ii) records of movements of sheep and goats in and out of the *establishment* or *compartment* are established and maintained;
 - c) introductions of animals are allowed only from establishments of an equal or higher stage in the

process of accreditation; however, rams of the ARR/ARR genotype may also be introduced;

- d) an official veterinarian inspects sheep and goats in the establishment or compartment and audits the records at least once a year;
- e) no case of scrapie has been reported;
- f) sheep and goats of the establishment or compartment should have no direct or indirect contact with sheep or goats from establishments of a lower status;

Community comments

The Community would like the OIE to clarify what is meant by "indirect" contacts with sheep or goats from establishments of a lower status.

g) all culled animals over 18 months of age are inspected by an *official veterinarian*, and all animals exhibiting neurological or wasting signs are tested in a *laboratory* for scrapie; all animals over 18 months of age that have died or have been killed for reasons other than routine slaughter should also be tested (including fallen stock, dead-in-transit stock and animals sent for emergency slaughter);

Community comments

The Community propose an editorial change and propose to add the word "and" at the end of point g).

h) intermediate stages of accreditation may be considered where compliance for the full time frames prescribed is not yet possible, but where a level of control sufficient to reduce the risk to other small ruminants is shown to in place;

Community comments

The Community propose editorial changes:

- To include the word "be" in the last part of this point i.e. to other small ruminants is shown to "be" in place, and
- To propose the word "or" at the end of point h).
- 3. if there has been a case of scrapie on the establishment:
 - a) in the case of classical scrapie, all cases have been culled and destroyed, as well as all sheep (except rams of the genotype ARR/ARR and ewes of genotypes ARR/xxx with no VRQ) and all goats, or
 - b) in the case of atypical scrapie, all *cases* have been culled and destroyed, as well as all sheep carrying the AF¹⁴¹RQ allele.

Article 2.4.8.7.

When importing from a country, zone or compartment posing a negligible scrapie risk, Veterinary Authorities should require:

for commodities from sheep and goats not listed in Article 2.4.8.1.

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.8.3.

Community comments

The correct reference is Article 2.4.8.3. instead of Article 2.3.8.3.

In order to be consistent with article 2.4.8.6, it should read in the title and the paragraph above: country, zone, establishment or compartment.

This applies to all the articles relating to certification.

Article 2.4.8.8.

When importing from a country, zone or compartment posing a negligible scrapie risk, Veterinary Authorities should require:

for sheep and goats for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals come from a country, *zone* or *compartment* which complies with the conditions in Article 2.4.8.3.

Article 2.4.8.9.

When importing from a country, *zone* or *compartment* posing a negligible scrapie risk, but in which there has been an indigenous *case*, *Veterinary Authorities* should require:

for sheep and goats for breeding or rearing

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

1. are identified by a permanent identification system in such a way as to demonstrate that, regardless of genotype, they have never been present in the same flock as a *case*;

Community comments

The current wording might be confusing which is the targeted flock or herd. The Community propose the wording as follows:

- "1. are identified by a permanent identification system in such a way as to demonstrate that, regardless of genotype, they have not been present in any flock where a case has been kept during the last 7 years,"
- 2. were born after the date from which the ban on the feeding of small ruminants with *meat-and-bone meal* derived from small ruminants had been effectively enforced.

Community comments

The feed ban requiremenst refer to the MBM derived from ruminants. Therefore the Community propose the following correction:

"2. were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from small ruminants had been effectively enforced."

Article 2.4.8.10.

When importing from a country, *zone* or *compartment* not complying with the conditions in Article 2.4.8.3., *Veterinary Authorities* should require:

for sheep and goats for breeding or rearing

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

- 1. come from an *establishment* or *compartment* posing a negligible scrapie risk as described in Article 2.4.8.6.
- 2. are identified by a permanent identification system in such a way as to demonstrate that, regardless of genotype, they have never been present in the same flock as a *case*;
- 3. were born after the date from which the ban on the feeding of small ruminants with *meat-and-bone meal* derived from small ruminants had been effectively enforced.

Article 2.4.8.11.

When importing sheep and goats for immediate slaughter, Veterinary Authorities should require:

the presentation of an international veterinary certificate attesting that:

- 1. in the country or zone:
 - a) the disease is compulsorily notifiable;
 - b) affected sheep and goats are slaughtered and completely destroyed;

Community comments

For consistency reasons, the Community propose to replace "slaughtered" by "culled".

2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

Article 2.4.8.12.

Veterinary Authorities of importing countries should require:

for ovine and caprine materials destined for the preparation of biologicals intended for administration to small ruminants

the presentation of an international veterinary certificate attesting that:

- 1. the products originate from sheep or goats born and raised in a country, zone or compartment of negligible scrapie risk or an establishment or compartment free from scrapie as described in Article 2.4.8.6.; or
- 2. the products originate from a country or *zone* posing a controlled scrapie risk, are derived from sheep and goats which passed ante- and post-mortem inspections, and have not been prepared using the tissues listed in Article 2.4.8.15.

Article 2.4.8.13.

1. Small ruminant-derived *meat-and-bone meal* or any *commodities* containing it, which originate from a country, *zone* or *compartment* defined in Article 2.4.8.3., but in which there has been an indigenous *case*

of scrapie, should not be traded if such products were derived from animals born before the date from which the ban on the feeding of small ruminants with *meat-and-bone meal* derived from small ruminants had been effectively enforced.

2. Small ruminant-derived *meat-and-bone meal* or any *commodities* containing it, which originate from a country, *zone* or *compartment* not complying with the conditions referred to in Article 2.4.8.3 should not be traded between countries.

Article 2.4.8.14.

- 1. Small ruminant-derived *meat-and-bone meal* or any *commodities* containing it, which originate from a country, *zone* or *compartment* defined in Article 2.4.8.3., but in which there has been an indigenous *case* of scrapie, should not be traded if such products were derived from animals born before the date from which the ban on the feeding of small ruminants with *meat-and-bone meal* derived from small ruminants had been effectively enforced.
- 2. Small ruminant-derived *meat-and-bone meal* or any *commodities* containing it, which originate from a country, *zone* or *compartment* not complying with the conditions referred to in Article 2.4.8.3 should be certified as being derived from sheep and goats which passed ante- and post-mortem inspections, and was not been prepared using the tissues listed in Article 2.4.8.15.

Community comments

The Community supports the wording used in Article 2.4.8.14, point 2) related to trade of MBM from countries, zones or compartments with a non-negligible scrapie risk.

Trade should be possible under the conditions specified. The Community propose to delete Article 2.4.8.13.

In addition the Community propose an editorial change to the last part of point 2: "has not been prepared using the tissues listed in Article 2.4.8.15."

Article 2.4.8.15.

- 1. From small ruminants of any age originating from a country, zone or compartment not complying with the conditions referred to in Article 2.4.8.3., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of feed, fertilisers, or veterinary pharmaceuticals including biologicals: spleen and ileum. Protein products intended for animal use, feed, fertilisers or veterinary pharmaceuticals prepared using these commodities (unless covered by other Articles in this Chapter) should also not be traded.
- 2. From small ruminants that were at the time of *slaughter* over 12 months of age or which have a permanent incisor erupted through the gum originating from a country, *zone* or *compartment* not complying with the conditions referred to in Article 2.4.8.3., the following *commodities*, and any *commodity* contaminated by them, should not be traded for the preparation of feed, fertilisers, or veterinary pharmaceuticals including biologicals: skull, brain, eyes, spinal cord. Protein products intended for animal use, feed, fertilisers or veterinary pharmaceuticals prepared using these *commodities* (unless covered by other Articles in this Chapter) should also not be traded.

Community comments

Based on the opinion of the Scientific Steering Committee (SSC, 7-8 November 2002) on TSE infectivity distribution in ruminant tissues, tonsils should be added to the list of commodities referred to under point 2.

CHAPTER X.X.X.

GUIDELINES ON THE DETECTION, CONTROL AND PREVENTION OF SALMONELLA SPP. IN POULTRY

Community comments

The Community thanks the OIE for its important work, but has several comments that should be taken into account.

Article X.X.X.1.

Introduction

The aim of the *Code* is to assist Members in the management and control of significant animal diseases, including diseases with zoonotic potential, and in developing animal health measures applicable to trade in terrestrial animals and their products. These guidelines provide recommendations on the detection, control and prevention of *Salmonella* spp. in poultry.

In most food animal species, *Salmonella* spp. can establish a clinically inapparent infection of variable duration, which is significant as a potential zoonosis. Such animals may be important in relation to the spread of infection between flocks and as causes of human foodborne infection. In the latter case, this can occur when meat, eggs, or their products, enter the food chain thus producing contaminated food products.

Salmonellosis is one of the most common foodborne bacterial diseases in the world. It is estimated that over 90% of *Salmonella* infections in humans are foodborne with *Salmonella* Enteritidis and *Salmonella* Typhimurium accounting for a major part of the problem.

In the development and implementation of programs to achieve control of *S*. Enteritidis and *S*. Typhimurium, an improvement in flock status for other *Salmonella* serotypes can be expected.

Article X.X.X.2.

Purpose and scope

These guidelines deal with methods for on farm detection, control and prevention of *Salmonella* spp. in poultry. These guidelines complements the Codex Alimentarius Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 Revision 2007). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in producing eggs and meat that are safe to eat.

All hygiene and biosecurity procedures to be implemented in poultry flocks and hatcheries are described in Appendix 3.4.1. on Hygiene and Biosecurity Procedures in Poultry Production.

The scope covers breeding flocks, chickens and other domesticated birds used for the production of eggs and meat for human consumption. The recommendations presented in these guidelines are relevant to the control of all non-typhoid *Salmonella* spp. with special attention to *S*. Enteritidis and *S*. Typhimurium.

Article X.X.X.3.

Definitions (for this chapter only)

Broilers

birds of the species Gallus gallus selectively bred and reared for their meat rather than eggs.

Community comments

The following words should be added to the above definition: "(independent of the production system)".

Rationale: It might be useful to clarify the definition by adding this words because in other international texts (e.g. Codex alimentarius), broilers seem to be limited to industrial production and exclude e.g. organic farming.

Broken/leaker egg

means an egg showing breaks of both the shell and the membrane, resulting in the exposure of its contents.

Competitive exclusion

means the administration of defined or undefined bacterial flora to poultry to prevent gut colonisation by enteropathogens, including *Salmonella*.

Cracked egg

means an egg with a damaged shell, but with intact membrane.

Culling

means the depopulation of a flock before the end of its normal production period.

Dirty egg

means an egg with foreign matter on the shell surface, including egg yolk, manure or soil.

Layer or laying flock

means a flock of poultry during the period of laying eggs for human consumption.

Peak of lay

means the period of time in the laying cycle (normally expressed as age in weeks) when the production of the flock is highest.

Poultry

means members of the class Aves that are kept for the purpose of breeding or for the production of meat or eggs.

Pullet flock

means a flock of poultry prior to the period of laying eggs for human consumption or hatching.

Article X.X.X.4.

Surveillance of poultry flocks for Salmonella spp.

Where justified by risk assessment, surveillance should be performed to identify infected flocks in order to take measures that will reduce the prevalence in poultry and the risk of transmission of *Salmonella* spp. to humans. Microbiological testing is preferred to serological testing because of its higher sensitivity in broilers and higher specificity in breeders and layers. In the framework of regulatory programmes for the control of *Salmonella* spp., confirmatory testing may be appropriate to ensure that decisions are soundly based.

Results of surveillance will allow control measures to be implemented to reduce the risk of transmission of *Salmonella* spp. to humans:

Community comments

The words "will allow" should be replaced by "may result in", as the measures are directly dependant of the results and the results may show that there is no need for specific measures.

- a) In breeders control measures taken will prevent the transmission of *Salmonella* spp. to the next generation.
- b) In layers control measures will reduce or eliminate *Salmonella* spp. contamination of eggs for human consumption.

Community comments

The word "or" should be replaced by "and may", as total elimination is difficult.

c) In broilers this will permit measures to be taken at slaughter and further down the food chain (logistic slaughter and channelling).

Sampling

1. Available methods for sampling

Drag swabs: sampling is done by dragging swabs around the poultry building.

Boot swabs: sampling is done by walking around the poultry building with absorbent material placed over the footwear of the sampler.

Faecal samples: multiple samples of fresh faeces collected from different areas in the poultry building.

Meconium, dead in shell and culled chicks at the hatchery.

Additional sampling of equipment and surfaces may be performed to increase sensitivity.

2. Number of samples to be taken according to the chosen method

Recommendation is five pairs of boot swabs or 10 drag swabs. These swabs may be pooled into no less than two samples.

Community comments

The paragraph above should be deleted and replaced by the following:

"Recommendation is a number of pairs of boot swabs or drag swabs, sampled so as to guarantee that 100% of the floor surface of a house is represented. These swabs may be pooled."

Rationale: This refers to all poultry populations and therefore more flexibility is needed for practical reasons. In addition, scientific evidences shows that not the number of boot swabs is important for sensitivity but the fact the whole floor surface is covered.

The total number of faecal samples to be taken on each occasion is shown in Table I and is based on the random statistical sample required to give a probability of 95% to detect at least one positive sample given that infection is present in the population at a level of 5% or greater.

Table I

Number of birds in the flock	Number of faecal samples to be taken on each occasion
25-29	20
30-39	25
40-49	30
50-59	35
60-89	40
90-199	50
200-499	55
500 or more	60

3. <u>Laboratory methods</u>

Refer to the Terrestrial Manual.

4. Time, frequency and type of samples to be tested

Time, frequency and type of sample for each poultry category listed below are based on risk assessment and production methods:

- a) Breeders and hatcheries
 - i) Breeder pullet flock
 - At the end of the first week of life.

Community comments

In the point above, the word "At" should be replaced by "Before", so as to be applicable.

In the point below, "four" should be replaced by "two", in order for the results to be more accurate.

- Within the four weeks before being moved to another house, or before going into production if the animals will remain in the same house for the production period.
- One or more times during the growing period if there is a culling policy in place. The frequency would be determined on commercial considerations.
- ii) Breeding flocks in lay
 - At least at monthly intervals during the laying period.

Community comments

The word "monthly" should be replaced by "two weeks".

Rationale: The sampling should be frequent enough to be more accurate and to be able to take fast and effective measures.

- The minimal frequency would be determined by the Veterinary Services.
- iii) Hatcheries
 - Testing in hatcheries complements on farm testing.

Community comments

The above paragraph should read: "Testing in hatcheries may replace or complement on farm testing. If infection is detected in a hatchery, on farm testing should be carried out to find the origin of infection."

Rationale: there is no reason to implement both testing simultaneously.

- The minimal frequency would be determined by the Veterinary Services.
- b) Poultry for the production of eggs for human consumption
 - i) Layer pullet flocks
 - At the end of the first week of life when the status of the breeding farm and the hatchery is not known or does not comply with these guidelines.

Community comments

In the point above, the word "At" should be replaced by "Before", so as to be applicable.

In the point below, "four" should be replaced by "two", in order for the results to be more accurate.

- Within the four weeks before being moved to another house, or before going into production if the animals will remain in the same house for the production period.
- One or more times during the growing period if there is a culling policy in place. The frequency would be determined on commercial considerations.
- ii) Layer or laying flocks
 - At expected *peak of lay* for each production cycle.
 - One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency would be determined by the *Veterinary Services*.
- c) Broilers

Community comments

Limiting the testing to broilers seems in contradiction with the scope of the chapter (other domestic birds for the production of meat). Either the scope should be modified or this point extended to other poultry.

- i) Flocks should be sampled at least once. On farms where there is a long period (2 weeks or more) between thinning and final depopulation further testing should be considered.
- ii) Flocks should be sampled as late as possible before the first birds are transported to the slaughter house. However, this must be done at a time that ensures the results are available before slaughter.
- d) Empty building testing
 - i) Bacteriological monitoring of the efficacy of disinfection procedures is recommended when *Salmonella* spp. have been detected in the previous flock.
 - ii) Sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty building after depopulation, cleaning and *disinfection*.

Article X.X.X.5.

Control measures

Salmonella control can be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP) in combination with the following measures. No single measure used alone will achieve effective Salmonella control.

Additional control measures currently available include: vaccination, *competitive exclusion*, flock culling and product diversion to processing.

Antimicrobials should not be used to control *Salmonella* spp. in poultry for human consumption because the effectiveness of the therapy is limited; it has the potential to produce residues in meat and eggs and can contribute to the development of antimicrobial resistance. Antimicrobials may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella* spp. In special circumstances antimicrobials may be used to salvage animals with high genetic value.

Community comments

The words "for human consumption" should be deleted, as poultry used may not be for human consumption but have a role in occurrence of antimicrobial resistance.

The last sentence should read: "In special circumstances antimicrobials may be used <u>e.g.</u> to salvage animals with high genetic value <u>or in case of undue suffering</u>." This takes into account the animal welfare too.

- 1. Day old chicks used to stock a poultry house should be obtained from breeding flocks and hatcheries that are certified as free from at least *S*. Enteritidis and *S*. Typhimurium and have been monitored according to these guidelines.
- 2. Layer or laying flocks or breeder flocks should be stocked from pullet flocks that are certified as free from at least S. Enteritidis and S. Typhimurium and have been monitored according to these guidelines.

- 3. Feed may be contaminated with *Salmonella*. Therefore, it is recommended to monitor the *Salmonella* status of poultry feed, and if found positive take corrective measures. The use of pelletised feeds or feeds subjected to other bactericidal treatment is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.
- 4. Competitive exclusion can be used in day old chicks to reduce colonisation by Salmonella spp.
- 5. As far as vaccination is concerned, many vaccines are used against *Salmonella* infections caused by different serovars in various poultry species, including single or combined vaccines against *S.* Enteritidis and *S.* Typhimurium. Vaccines produced according to the *Terrestrial Manual* should be used.

If live vaccines are used it is important that field and vaccine strains can easily be differentiated in the laboratory. If serology is used as the surveillance method, it may not be possible to distinguish between vaccination or infection with a field strain.

Vaccination can be used as part of an overall *Salmonella* control programme. Vaccination should never be used as the sole control measure.

Community comments

The second sentence of the paragraph above should read: "It is recommended not to use vaccination as the sole control measure."

Rationale: Too strict a statement could be discouraging; vaccination as a sole measure is better than doing nothing at all.

When the status of the breeding farm and the hatchery from which the *pullet flock* originates is not known or does not comply with these guidelines, vaccination of *pullet flocks*, starting with day-old chicks, against *S*. Enteritidis or *S*. Enteritidis/*S*. Typhimurium should be considered.

Vaccination should be considered when moving day-old chicks to a previously contaminated shed so as to minimize the risk of the birds contracting infection with *S*. Enteritidis and *S*. Typhimurium.

When used, vaccination should be performed according to the instructions provided by the manufacturer and in accordance with the instructions of the *Veterinary Services*.

Vaccination against S. Enteritidis can cause positive reaction in Salmonella Pullorum-Gallinarum serological tests and needs to be considered when implementing measures for these pathogens.

6. Depending on animal health, risk assessment, and public health policies, culling is an option to manage infected breeder and layer flocks. Infected flocks should be destroyed or slaughtered and processed in a manner that minimises human exposure to *Salmonella* spp.

Community comments

In order to be clearer, the word "manage" in the first sentence of point 6 above should be replaced by the words "directly reduce the risk from".

If poultry are not culled, eggs for human consumption should be diverted for processing for inactivation of *Salmonella* spp.

7. As far as the veterinary involvement is concerned, the responsible veterinarian should monitor the results of surveillance testing for *Salmonella* spp. This information should be available to the

veterinarian before marketing in order to certify the flock for slaughter. This veterinarian should notify the *Veterinary Authority* if the presence of *Salmonella* spp. is confirmed.

Community comments

The last sentence of the paragraph above should read: "This veterinarian should notify the *Veterinary Authority* if the presence of *Salmonella* spp., which are subjected to control measures, is confirmed.

Rationale: When certification is concerned, one should be clear and precise. Not all *Salmonella spp* may be subject to specific regulations or control programmes.

Article X.X.X.6.

Prevention of Salmonella spread

If a *flock* is found infected with *Salmonella* spp. the following actions should be taken in addition to general measures detailed in the Appendix 3.4.1. on Hygiene and Biosecurity Procedures in Poultry Production:

1. Epidemiological investigations should be carried out to determine the origin of the infection as appropriate to the epidemiological situation.

Community comments

The end of the sentence is unclear. An alternative would be: "<u>According</u> to the epidemiological situation, epidemiological investigations should be carried out to determine the origin of the infection."

2. Movement of broilers, culled poultry or layers at the end of the production cycle should only be allowed for slaughter or destruction. Special precautions should be taken in the transport, slaughter and processing of the birds, e.g. they could be sent to a separate slaughter house or processed at the end of a shift before cleaning and disinfection of the equipment.

Community comments

The words "broilers, culled poultry or layers at the end of the production cycle" should be replaced by the word "poultry", to include all possible cases.

- 3. Litter should not be reused. Poultry litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the spread of infections with *Salmonella* spp. Particular care needs to be taken in regard to poultry litter/faeces used to fertilise plants intended for human consumption.
- 4. Before restocking bacteriological examination should be carried out as detailed in these guidelines.

Article X.X.X.7.

Special considerations for broiler flocks

Community comments

The scope should not be limited to "broilers" unless the word means "domestic birds/poultry for the production of meat".

- 1. The grow out phase of broiler production is short and therefore it is important to emphasize the *Salmonella* status of the source flock.
- 2. Broilers are susceptible to colonisation with *Salmonella* spp. because they are young and are grown at high stocking rates.

Community comments

Prevalence data are as high in flocks of layers, turkeys, ducks, geese, ...

- 3. To reduce *Salmonella* spp. contamination in the abattoir it is helpful to reduce the amount of feed in the bird's gut at the time of slaughter. Feed transits the gut in about four hours therefore it is recommended to withdraw feed to the birds at an appropriate period before slaughter (8-10 hours).
- 4. Slaughter processing should be conducted in accordance with Appendix 3.10.1.

APPENDIX 3.4.1.

HYGIENE AND BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

Community comments

The Community supports the OIE work, but have various comments, inserted below.

Article 3.4.1.1.

Recommendations applicable to poultry, establishments (including hatcheries) and flocks

This Appendix refers to poultry as defined in Chapter X.X.X.

- 1. Access to the *establishment* should be controlled to ensure only authorized persons and conveyances enter the site. This may require that the *establishment* be surrounded by a security fence. A suitably isolated geographical location is recommended, taking into account the direction of the prevailing winds and location of other poultry establishments. A sign indicating restricted entry should be posted at the entrance.
- 2. *Establishments*, or flocks, should be single purpose single species enterprises, and ideally an all in all out single age group principle should be adopted whenever possible.
- 3. Where several flocks are maintained on one *establishment*, each flock should be managed as a separate epidemiological unit.
- 4. Poultry houses and buildings used to store feed or eggs should be constructed and maintained to prevent the entry of wild birds, rodents and insects.
- 5. Poultry houses should be designed and constructed so that cleaning and *disinfection* can be carried out adequately and preferably of smooth impervious materials.
- 6. *Establishments* should be free from unwanted vegetation and debris. The area immediately surrounding the poultry houses should ideally consist of concrete or other material to facilitate cleaning.
- 7. Animals, other than poultry of the resident species and age, should not be permitted access to poultry houses, and buildings used to store feed or eggs.

Community comments

No animals, including local poultry should have access to buildings used to store feed or eggs.

Thus the point should read: "Animals, other than poultry of the resident species and age, should not be permitted access to poultry houses. Animals should not have access to buildings used to store feed or eggs."

8. Clean outer garments (coveralls or overalls, hats and footwear) should be provided for all personnel and visitors before entering the poultry house. A physical hygiene facility and/or a disinfectant footbath should be provided, and the disinfectant solution should be changed regularly as recommended

by the manufacturer. Personnel and visitors should wash their hands with soap and water or in a disinfectant solution before entering and after leaving the poultry house. Personnel and visitors should not recently have had contact with other poultry, raw poultry products, or poultry waste.

Community comments

The last sentence should be reworded or deleted: what about veterinarians, and farmers or workers who have prepared, cooked and eaten chicken?

9. When a poultry house is depopulated, it is recommended that all faeces and litter be removed from the houses and disposed of in a manner approved by the *Veterinary Services*. After removal of faeces and litter cleaning and *disinfection* of the building and equipment should be applied in accordance with Appendix 3.6.1. If litter is not removed and replaced between flocks then the litter should be treated in a manner to inactivate infectious agents, to prevent the spread from one flock to the next.

Microbiological monitoring of the efficacy of *disinfection* procedures is recommended when pathogenic agents have been detected in the previous flock.

Community comments

The words "when pathogenic agents have been detected in the previous flock" should be deleted: monitoring of disinfection is recommended in any case after depopulation.

Routine procedures for the prevention of entry of wild birds, and the control of rodents and insects should be carried out at this time.

- 10. Birds used to stock a poultry house should preferably be obtained from breeding flocks and hatcheries that are certified as free from vertically transmitted poultry pathogens.
- 11. The use of pelletised feeds or feeds subjected to other bactericidal treatment is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds, rodents and insects.
- 12. The water supply to poultry houses should be potable according to the World Health Organization or to the relevant national standard, and microbiological quality should be monitored if there is any reason to suspect contamination. The water delivery system should be disinfected between flocks when the poultry house is empty.
- 13. Sick and dead birds and dead in shell embryos should be removed from poultry houses and hatcheries as soon as possible or at least daily. These should be disposed of in a safe and effective manner (Appendix 3.6.6.).
- 14. Records of production/performance and flock history, including mortality, surveillance, treatment and vaccinations should be maintained on an individual flock basis within the *establishment*. Such records should be readily available for inspection.
- 15. There should be good communication and interaction between all involved in the food chain so that control can be maintained from breeding to production and consumption. Farmers should have access to basic training on hygiene and biosecurity measures relevant to poultry production and food safety. On-farm personnel should be trained to understand their responsibility in upholding the biosecurity guidelines in place on the premises.
- 16. For poultry flocks that are allowed to range outdoors, attractants to wild birds should be minimised (e.g. commercial feed and watering points should be kept inside the poultry house if possible).

Poultry should not be allowed access to sources of contamination (e.g. household waste, other farm animals, surface water and manure storage areas). The nesting area should be inside the poultry house.

17. During the production cycle a veterinarian should be responsible for monitoring flock health on the farm.

Article 3.4.1.2.

Recommendations applicable to hatching egg hygiene and transport

- 1. The litter in the poultry house should be kept dry and in good condition. The nest box litter should be kept clean and an adequate quantity maintained. Cages should be maintained in good condition and kept clean.
- 2. Eggs or their conveyances should be marked to assist traceability and veterinary investigations.
- 3. Eggs should be collected at frequent intervals and placed in new or clean and disinfected packing materials.
- 4. Grossly dirty, broken, cracked, or leaking eggs should be collected separately and should not be used as hatching or table eggs. If eggs are cleaned on the farm, this should be done in accordance with the requirements of the *Veterinary Authority*.
- 5. Table eggs should be stored in a cool and dry room used only for this purpose. Storage conditions should minimise the potential for microbial contamination and growth. The room should be well ventilated, kept clean, and regularly disinfected. Cooling should be undertaken as soon as possible after collection. If available, refrigeration is recommended.

Community comments

Table eggs are not in the scope of this article. The point should be deleted or the title of the article modified to include table eggs, or another article introduced.

6. Refer to Article 3.4.1.7. regarding the specific requirements for the sanitization of hatching eggs and hatchery equipment.

Article 3.4.1.3

Recommendations applicable to catching and transportation of poultry

- 1. Personnel involved in the catching of the birds need to be adequately trained in bird handling and basic hygiene procedures.
- 2. Poultry should not be unduly stressed during the catching and transportation process. Reducing the light intensity or using blue light can help to calm the birds and reduce stress.
- 3. Poultry should be transported to the slaughter house or to markets in well ventilated *containers*, and not be over crowded.
- 4. Containers and vehicles need to be cleaned and sanitized between each use.
- 5. Poultry should not be exposed to extreme temperatures.

Article 3.4.1.4.

Recommendations applicable to hatchery buildings

- 1 The design of the hatchery should be based on suitable work flow and air circulation principles. It should be constructed so that there is a one way flow for the movement of eggs and chicks, and the air flow also follows this same one way direction.
- 2. The hatchery buildings should include physical separation of all work areas. If possible, separate ventilation should be provided for these work areas, namely, the rooms for:
 - a) egg receiving and egg storage;
 - b) egg traying;
 - c) fumigation;
 - d) setting or initial incubation;
 - e) hatching;
 - f) sorting, sexing and placing chicks in boxes;
 - g) material storage, including egg and chick boxes, egg flats, box pads, chemicals and other items;
 - h) facilities for washing equipment and disposal of waste;
 - i) room for employees to have meals;
 - j) office.
- 3. The hatchery area should be maintained free from all hatchery waste, garbage of all kinds and discarded equipment.
- 4. Approved disposal methods and adequate drainage must be available.
- 5. All hatchery equipment, tables and horizontal surfaces in rooms must be promptly and thoroughly vacuumed, cleaned, washed, scrubbed, rinsed with clean water and finally disinfected with an approved disinfectant.

Article 3.4.1.5.

Hygiene measures during the handling of eggs and day-old chicks

- 1. Egg handlers in the hatchery should wash their hands with soap and water and change into clean outer garments before handling *hatching eggs* received from the poultry farm.
- 2. Chick sexers and chick handlers should wash and disinfect their hands and change into clean outer garments before commencing work and between different batches of chicks.
- 3. Day-old chicks or other poultry should be delivered or distributed in new chick boxes; or in used boxes made of suitable material which have been thoroughly cleaned and disinfected or fumigated.
- 4. The chicks should be delivered directly from the hatchery by personnel wearing clean, disinfected outer garments, which should be changed or disinfected between each delivery.
- 5. The delivery truck must be cleaned, and disinfected before loading each consignment of chicks.

Article 3.4.1.6.

Sanitization of hatching eggs and hatchery equipment

- 1. The clean eggs should be sanitized as soon as possible after collection. The methods of sanitization are described below.
- 2. The sanitized eggs should be stored in a clean, dust free room used exclusively for this purpose and kept at a temperature of 13-15°C (55°-60°F) and at a relative humidity of 70-80%.
- 3. The eggs should be transported to the hatchery in new or clean packing material which have been furnigated or sanitized with a liquid disinfectant (see Table *I*). The cleaning and *disinfection* of *vehicles* must be a regular part of the hatchery routine.

4. Sanitization means:

- a) fumigation with formaldehyde, or
- b) spraying with or immersion in an eggshell disinfectant in accordance with the manufacturers instructions, or
- c) made hygienic by another method approved by the Veterinary Authority.

Formaldehyde gas has been used for many years for the *disinfection* of *hatching eggs* and hatchery equipment. As a fumigant, formaldehyde gas has proved to be a very effective means of destroying micro-organisms on eggs, egg packing material, chick boxes, hatching machines and other hatchery equipment, provided these items have been subjected to preliminary cleaning. When the correct mixture of formalin and potassium permanganate is used, a dry brown powder will remain after the reaction is completed.

At the present time, there is lack of uniform opinion on the optimum concentration of formaldehyde required for the sanitization of eggs and hatchery equipment. In general, three levels of concentration have been used. Also, two methods of use have been adopted.

Method 1

a) Concentration A

53 ml formalin (37.5%) and 35 g potassium permanganate per m³ of space.

This can be expressed as:

5.25 oz by volume (148.5 ml) formalin (37.5%) and 3.5 oz by weight (98 g) potassium permanganate per 100 ft³ (2.8 m³) of space.

b) Concentration B

43 ml formalin (37.5%) and 21 g potassium permanganate per m³ of space.

This can be expressed as:

4 oz by volume (120 ml) formalin (37.5%) and 2 oz (60 g) potassium permanganate per 100 ft³ (2.8 m³) of space.

c) Concentration C

45 ml formalin (40%) and 30 g potassium permanganate per m³ of space.

This can be expressed as:

4.5 oz by volume (135 ml) formalin and 3 oz (90 g) potassium permanganate per 100 ft³ (2.8 m³) of space.

d) Procedure

Fumigation of *hatching eggs* and equipment should be carried out in a special chamber or in a room or building constructed of impermeable material which can be made as airtight as possible. A fan is necessary to circulate the gas during fumigation and to expel it after fumigation is completed.

The total volume of the room is determined accurately from the internal measurements. The space occupied by trays, or eggs, or articles to be fumigated, is to be disregarded. The quantities of materials required are based on the total volume.

Place in the centre of the floor, one or preferably several large metal basins, metal trays or containers of earthenware, enamelware, asbestos or other non-inflammable material.

Plastic or polyethylene containers are not to be used due to the heat generated by the chemical reaction. To avoid possible fire hazards, the containers should slope outwards. Also, the containers must be large enough so that the two chemicals occupy no more than one quarter of the volume of the container. Preferably, the container should have a capacity of at least 10 times the volume of the total ingredients.

The eggs should be placed on wire racks, in wire baskets or on cup-type egg flats stacked in a manner that will permit air circulation and exposure to the formaldehyde gas.

An electric or hot water heater should be available in the chamber to maintain the temperature at 75°-100°F (24°-38°C). Water pans or other equipment should be available to provide a relative humidity of 60-80%.

Place required amount of potassium permanganate into the containers before adding the formalin.

Pour the required amount of formalin onto the potassium permanganate in the containers.

Leave the chamber as quickly as possible and close the door. Some operators may wish to use a gas mask when pouring the formalin into the containers.

The door of the chamber should be securely closed and permanently labelled to prevent accidental opening.

The fans should be operated to circulate the formaldehyde and the fumigation time should be 20 minutes.

After 20 minutes, the gas should be expelled through a controlled vent leading to the outside of the building.

The door may be opened to facilitate expelling the formaldehyde to the outside.

Method 2

An alternative method to the above is to use formaldehyde gas produced by the evaporation of paraformaldehyde. Proprietary preparations are available and the operation is carried out by placing the requisite amount of powder on a pre-heated hot plate.

In this method it is necessary to ensure that the relative humidity of the chamber is sufficiently high (60-80%).

10 g paraformaldehyde powder or pellet is used per m³ of space.

Warning

In carrying out fumigation, the following points should be borne in mind:

- a) Caution is necessary when formalin and potassium permanganate are mixed together in large amounts because of the risk of personal injury and fire through careless use. Formaldehyde gas causes irritation to the eyes and nose of the operator and the use of a gas mask is advised.
- b) Effective fumigation depends on optimum conditions of temperature and humidity. Formaldehyde gas rapidly loses its efficiency at low temperatures or in a very dry atmosphere.

Article 3.4.1.7.

Fumigation procedures at the hatchery

1. <u>Fumigation of eggs in setting machines</u>

Eggs should be fumigated within 12 hours after setting and after the temperature and humidity has returned to normal operating levels. The temperature of the machines must remain at the operating level.

The setting machine doors and ventilators should be closed, but the circulation fan should be kept operating.

After fumigation for 20 minutes, the ventilators should be opened to the normal operating position in order to release the gas.

Warning

Do not fumigate eggs that have been incubated for 24 to 96 hours, as this can result in embryo mortality.

2. Fumigation of eggs in hatching machines

This is a common practice in certain areas and under certain conditions. The eggs should be fumigated after being transferred from the setting machine to the hatching machine and before 10% of the chicks have begun to break the shell. After transfer of the eggs, the hatching machines are permitted to return to normal operating temperatures and humidity. The ventilators are closed and fumigation is conducted with the fans running. In some countries, the standard amounts of formalin (53 ml) and potassium permanganate (35 g) per m³ are used. Fumigation time is 20 minutes. In other countries, 0.8 cc formalin (37.5%) is added to 0.4 g potassium permanganate for each ft³ (0.02832 m³) of space; or 25 ml formalin to 12.5 g potassium permanganate per m³. Fumigation time is 20 minutes.

3. Fumigation of empty setting and hatching machines

Following removal of all the eggs or the chicks and the subsequent cleaning and *disinfection* of the empty machine, the disinfected egg trays are replaced and the machine prepared for the next batch of incubating eggs.

The doors and ventilators should be closed and the temperature and humidity returned to normal operating levels. Fumigation time should be at least 3 hours or preferably overnight, using the standard amounts of formalin and potassium permanganate (Concentration A).

The machines should be well ventilated before use to remove any residual fumigant.

Warning

The above fumigation procedure applies to a machine in which there are no *hatching eggs*. Eggs and chicks cannot be fumigated using the above fumigation time.

4. Neutralisation of formaldehyde gas

This can be achieved with a 25% solution of ammonium hydroxide using an amount not more than one half the volume of formalin used. The ammonia can be spread on the floor of the machine and the doors closed quickly.

Table 1. Properties and uses of disinfectants

Properties	Chlorine	lodine	Phenol	Quats	Formaldehyde
Bactericidal	+	+	+	+	+
Bacteriostatic	-	-	+	+	+
Fungicidal	-	+	+	±	+
Virucidal	±	+	+	±	+
Toxicity	+	-	+	-	+
Activity with organic matter*	++++	++	+	+++	+
Use area					
Hatchery equipment	+	+	+	+	±
Water equipment	+	+	-	+	-
Personnel	+	+	-	+	-
Egg washing	+	-	-	+	+
Floor	-	-	+	+	+
Foot baths	-	-	+	+	-
Rooms	±	+	±	+	+

- Quats = Quaternary ammonium compounds
 - Number of + indicates degree of affinity for organic material and the corresponding loss of disinfecting action
- + = Positive property
- = Negative property
- ± = Limited activity for specific property

Article 3.4.1.8.

General disease prevention and control measures

Recommendations in specific disease chapters should be followed as appropriate.

Disease prevention and control should be based on the adoption of Good Agricultural Practice and Hazard Analysis Critical Control Point (HACCP). No single measure used alone will achieve effective and efficient disease control. The biosecurity measures recommended in Article 3.4.1.1. should be applied.

- 1. The first week of life is important to develop immunocompetence in the birds and increase resistance to infections. It is important to have a good brooding system including appropriate temperature and humidity.
- 2. If the use of antimicrobials is indicated to control a poultry disease or infection, consideration should be given to the fact that it has the potential to produce residues in the eggs and meat, and may lead to the development of antimicrobial resistance. Antimicrobials should be used according to the instructions provided by the manufacturer and in accordance with Section 3.9. and the directions of the *Veterinary Services*.
- 3. Vaccination should be performed according to the instructions provided by the manufacturer and in accordance with the directions of the *Veterinary Services*. Recommendations in the *Terrestrial Manual* should be followed as appropriate.
- 4. Depending on the epidemiology of a disease, risk assessment, and public and animal health policies, culling is an option to manage infected flocks. Infected flocks should be destroyed or slaughtered and

processed in a manner that minimises subsequent exposure to pathogens. Before restocking, the poultry house should be cleaned, disinfected and tested to verify that the cleaning has been effective. Special attention should be paid to feed equipment and water systems

Article 3.4.1.9.

Prevention of further spread of poultry diseases

When a flock is found to be infected, in addition to the general control measures described previously, management procedures should be adjusted to effectively isolate the infected flock from other flocks on the establishment, adjacent establishments and from other establishments under common management. The following measures are recommended:

- Farmers should be educated on how to handle infected flocks in order to prevent spread to adjacent
 establishments and/or human exposure. Personnel should observe standard disease control
 procedures (e.g. handle infected flock separately/last in sequence and use of dedicated personnel and
 clothing and, if possible equipment).
- 2. Control measures for wild birds, rodents and insects should be observed stringently.
- 3. Epidemiological investigations should be carried out to determine the origin of infections as appropriate to the epidemiological situation.
- 4. Movement of culled poultry should only be allowed for slaughter or destruction.
- 5. Poultry litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the spread of infections.
- 6. After depopulation of an infected flock the poultry house should be thoroughly cleaned and disinfected, with special attention to feed equipment and water systems.
- 7. Before restocking microbiological examination should be carried out, as appropriate, to verify that the cleaning has been effective.

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