Annex XXXI

APPENDIX 3.8.2.

GUIDELINES ~~FOR~~ ON ~~THE~~ SURVEILLANCE ~~OF~~ FOR RINDERPEST

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 (*Bos indicus* breeds being more resistant than *Bos 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.

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Article 3.8.2.2.

~~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 elapsing 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 follow-up – 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:

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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 ~~the~~an OIE reference laboratory to determine the biological characteristics of the causative virus as well as its genetic and antigenic characterization.

~~3. Detection and thorough investigation of epidemiologically significant events ('stomatitis-enteritis syndrome') 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. Virological surveillance

Given that ~~rinderpest~~RP 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~~4. ~~Serosurveillance~~ 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;

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c) maternal antibodies derived from an immune dam (maternal antibodies in cattle can be found only up to 12 months of age);

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"[1], 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 *veterinarian* 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 erupted 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~~ Targeted 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 hoc* 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.~~

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

a) 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.

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- 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 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.

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~~7.

~~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 sample[2].

Annex XXXI (contd)

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%.

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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).

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Annex XXXII

CHAPTER 2.3.15.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

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 (*Mmm*SC), and freedom from CBPP means freedom from *Mmm*SC 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 *Mmm*SC, but also with the presence of infection with *Mmm*SC in the absence of clinical signs.

The following defines the occurrence of *Mmm*SC infection:

1. *Mmm*SC has been isolated and identified as such from an animal, embryos, oocytes or semen; or

2. antibodies to *Mmm*SC antigens which are not the consequence of vaccination, or *Mmm*SC DNA, have been identified in one or more animals showing pathological lesions consistent with infection with *Mmm*SC with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible animals.

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

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.

Annex XXXII (contd)

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 certificate* 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.

APPENDIX 3.8.3.

GUIDELINES ON SURVEILLANCE FOR CONTAGIOUS BOVINE PLEUROPNEUMONIA

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~~ Member 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. Clinical surveillance

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

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.

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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.

Annex XXXIII

CHAPTER 2.4.8.

SCRAPIE

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.

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*:

    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;

    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*.

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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;

      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;

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

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;

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.

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;

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;

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;

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 AF^{141}RQ allele.

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 scrapie risk if:

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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;

   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);

   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;

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 $AF^{141}RQ$ 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.

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*;

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.

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.

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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;

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.

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.

Annex XXXIV

CHAPTER X.X.X.

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

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.

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:

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.

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.

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. Laboratory methods

Refer to the *Terrestrial Manual.*

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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.
- 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.
- The minimal frequency would be determined by the *Veterinary Services*.

iii) Hatcheries

- Testing in hatcheries complements on farm testing.
- 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.
- 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

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.

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.

   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.

   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.

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.

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.

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

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.

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

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.

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 foot-bath 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.

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.

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.

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 fumigated 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 m^3 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 ft^3 (2.8 m^3) of space.

   b) Concentration B

      43 ml formalin (37.5%) and 21 g potassium permanganate per m^3 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 ft^3 (2.8 m^3) of space.

   c) Concentration C

      45 ml formalin (40%) and 30 g potassium permanganate per m^3 of space.

      This can be expressed as:

      4.5 oz by volume (135 ml) formalin and 3 oz (90 g) potassium permanganate per 100 ft^3 (2.8 m^3) 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 m^3 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. Fumigation of eggs in setting machines

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 m^3 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 ft^3 (0.02832 m^3) of space; or 25 ml formalin to 12.5 g potassium permanganate per m^3. 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 3hours 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**	**Iodine**	**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:

1. 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.

Annex XXXIV (contd)

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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Annex XXXV

EXPLANATION FOR RESTRUCTURING THE OIE *TERRESTRIAL ANIMAL HEALTH CODE*

OIE Members are aware of the importance and legal dimension of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) with reference to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO). In the OIE 4th Strategic Plan (2006-2010) the expansion of the OIE Mandate has continued and the OIE has developed and continues to initiate new texts on veterinary public health and animal welfare. The OIE started to consider restructuring the *Terrestrial Code* when it became clear that the number of pages had increased to the point that it was becoming difficult to bind as a single book using the established techniques.

Having accepted that the Code could be divided into two volumes, the OIE decided to take this opportunity to update and improve the structure and format, while maintaining the text. The intent is to make it easier for Members and interested parties to understand and use the OIE *Terrestrial Code*.

The OIE considers that the 2008 edition contains many improvements, including the following examples:

1. All 'horizontal' texts (i.e. those that apply to a range of species, production sectors and/or diseases) are grouped in volume 1 and all 'vertical' texts (i.e. recommendations on specific diseases) are grouped in volume 2. The new vertical texts incorporate the previous 'disease chapter' and the previous appendices dealing with pathogen inactivation, disease surveillance and risk assessment, for the relevant diseases (including BSE, FMD, avian influenza, scrapie, bluetongue, contagious bovine pleuropneumonia and rinderpest).

2. The term 'appendix' has been removed and the 'chapter' is used as the basic unit of text. This is to make it clear that all the provisions, guidelines and recommendations in the Terrestrial Code have the same legal standing.

3. To facilitate understanding of terms and expressions routinely used in the Terrestrial Code, the definitions previously found in Chapter 1.1.1. have been transferred to a 'Glossary of terms', which will be included in both volumes.

4. The numbering of the sections and chapters has been modified and simplified to allow for easier cross-referencing between articles. The term 'parts' is no longer used as the separation into volumes renders 'parts' redundant.

5. Texts in the *Terrestrial Code* and the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *'Terrestrial Manual'*) have been harmonised, e.g. texts on the international transfer and laboratory containment of animal pathogens and on risk analysis for biologicals for veterinary use. Decisions to move pertinent texts between the *Terrestrial Code* and the *Terrestrial Manual* will be made by relevant OIE Specialist Commissions and submitted to OIE Delegates for adoption.

6. It is important to note that the texts contained in the *Terrestrial Code* have not been significantly changed. However, it is clear that more work will be needed in future to harmonise approaches to diseases and horizontal issues and, in some cases, to update older texts. This work will be carried out according to the established OIE procedures, with all proposals submitted for consideration of OIE Members before adoption, in the normal way.

A table illustrating the new structure and contents of the *Terrestrial Code*, including modified numbering, follows.

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DIVISION OF THE OIE *TERRESTRIAL ANIMAL HEALTH CODE* INTO TWO VOLUMES

VOLUME I - GENERAL PROVISIONS		
OLD NUMBERING	**NEW NUMBERING**	**CHAPTER AND SECTION NEW NAME**
		Foreword
		User's guide
Chapter 1.1.1.		Glossary of terms
	SECTION 1	**ANIMAL DISEASE DIAGNOSIS, SURVEILLANCE AND NOTIFICATION**
Chapter 1.1.2.	Chapter 1.1.	Notification of diseases and epidemiological information
Chapter 2.1.1.	Chapter 1.2.	Criteria for listing diseases
Appendix 3.1.1.	Chapter 1.3.	Prescribed and alternative diagnostic tests for OIE listed diseases
Appendix 3.8.1.	Chapter 1.4.	General guidelines for animal health surveillance
	SECTION 2	**RISK ANALYSIS**
Chapter 1.3.1.	Chapter 2.1.	General considerations (excluding Articles 1.3.1.2. and 1.3.1.3. which have been moved to Chapter 5.3.)
Chapter 1.3.2.	Chapter 2.2.	Guidelines for import risk analysis
	SECTION 3	**QUALITY OF VETERINARY SERVICES**
Chapter 1.3.3.	Chapter 3.1.	Evaluation of Veterinary Services
Chapter 1.3.4.	Chapter 3.2.	Guidelines for the evaluation of Veterinary Services
	SECTION 4	**GENERAL RECOMMENDATIONS: DISEASE PREVENTION AND CONTROL**
Appendix 3.5.1.	Chapter 4.1.	General principles on identification and traceability of live animals
Chapter 1.3.5.	Chapter 4.2.	Zoning and compartmentalisation (excluding Article 1.3.5.4. which has been moved to Chapter 5.3.)
Appendix 3.2.1.	Chapter 4.3.	Collection and processing of bovine and small ruminant semen
Appendix 3.2.2.	Chapter 4.4.	Collection and processing of porcine semen
Appendix 3.3.1.	Chapter 4.5.	Collection and processing of *in vivo* derived embryos
Appendix 3.3.2.	Chapter 4.6.	Collection and processing of *in vitro* fertilised bovine embryos/*in vitro* maturing oocytes
Appendix 3.3.3.	Chapter 4.7.	Collection and processing of micromanipulated bovine embryos
Appendix 3.3.4.	Chapter 4.8.	Collection and processing of laboratory rodent and rabbit embryos/ova
Appendix 3.3.5.	Chapter 4.9.	Categorisation of diseases and pathogenic agents by the International Embryo Transfer Society
Appendix 3.6.6.	Chapter 4.10.	General guidelines for the disposal of dead animals
Appendix 3.6.1.	Chapter 4.11.	General recommendations on disinfection and disinsectisation
Appendix 3.4.2.	Chapter 4.12.	Hygiene and disease security procedures in apiaries
Appendix 3.4.3.	Chapter 4.13.	Hygiene precautions, identification, blood sampling and vaccination
	SECTION 5	**TRADE MEASURES, IMPORT/EXPORT PROCEDURES AND VETERINARY CERTIFICATION**
Chapter 1.2.1.	Chapter 5.1.	General obligations
Chapter 1.2.2.	Chapter 5.2.	Certification procedures
Article 1.3.1.2. Chapter 1.3.6. Article 1.3.5.4. Article 1.3.1.3.	Chapter 5.3.	OIE procedures relevant to the Sanitary and Phytosanitary Agreement of the World Trade Organization
Chapter 1.4.1.	Chapter 5.4.	Animal health measures applicable before and at departure
Chapter 1.4.2.	Chapter 5.5.	Animal health measures applicable during transit from the place of departure in the exporting country to the place of arrival in the importing country
Chapter 1.4.3.	Chapter 5.6.	Border posts and quarantine stations in the importing country
Chapter 1.4.4.	Chapter 5.7.	Animal health measures applicable on arrival
Chapter 1.4.5.	Chapter 5.8.	International transfer and laboratory containment of animal pathogens
Chapter 1.4.6.	Chapter 5.9.	Quarantine measures applicable to non-human primates
Appendix 4.1.1.	Chapter 5.10.	Model international veterinary certificate for dogs and cats originating from rabies infected countries
Appendix 4.1.2.	Chapter 5.11.	Model international veterinary certificate for domestic or wild animals of the bovine, bubaline, ovine, caprine or porcine species

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VOLUME I - GENERAL PROVISIONS (CONTD)		
OLD NUMBERING	**NEW NUMBERING**	**CHAPTER AND SECTION NEW NAME**
Appendix 4.1.3.	Chapter 5.12.	Model international veterinary certificate for semen of animals of the bovine, bubaline, equine, ovine, caprine or porcine species
Appendix 4.1.4.	Chapter 5.13.	Model international veterinary certificate for equines
Appendix 4.1.5.	Chapter 5.14.	Model passport for international movement of competition horses
Appendix 4.1.6.	Chapter 5.15.	Model international veterinary certificate for birds
Appendix 4.1.7.	Chapter 5.16.	Model international veterinary certificate for day-old birds and hatching eggs
Appendix 4.1.8.	Chapter 5.17.	Model international veterinary certificate for rabbits
Appendix 4.1.9.	Chapter 5.18.	Model international veterinary certificate for bees and brood-combs
Appendix 4.2.1.	Chapter 5.19.	Model international veterinary certificate for meat of domestic animals of the bovine, bubaline, equine, ovine, caprine or porcine species or of poultry
Appendix 4.2.2.	Chapter 5.20.	Model international veterinary certificate for products of animal origin destined for use in animal feeding, or for agricultural or industrial or pharmaceutical or surgical use
	SECTION 6	**VETERINARY PUBLIC HEALTH**
Appendix 3.10.1.	Chapter 6.1.	Guidelines for the control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection
Appendix 3.4.1.	Chapter 6.2.	Hygiene and disease security procedures in poultry breeding flocks and hatcheries
Chapter 2.10.2.	Chapter 6.3.	Infection with *Salmonella* Enteritidis and *Salmonella* Typhimurium in poultry
Appendix 3.9.1.	Chapter 6.4.	Guidelines for the harmonisation of national antimicrobial resistance surveillance and monitoring programmes
Appendix 3.9.2.	Chapter 6.5.	Guidelines for the monitoring of the quantities of antimicrobials used in animal husbandry
Appendix 3.9.3.	Chapter 6.6.	Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine
Appendix 3.9.4.	Chapter 6.7.	Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals
Chapter 2.10.1.	Chapter 6.8.	Zoonoses transmissible from non-human primates
SECTION 3.7.	**SECTION 7**	**ANIMAL WELFARE**
Appendix 3.7.1.	Chapter 7.1.	Introduction to the guidelines for animal welfare
Appendix 3.7.2.	Chapter 7.2.	Guidelines for the transport of animals by sea
Appendix 3.7.3.	Chapter 7.3.	Guidelines for the transport of animals by land
Appendix 3.7.4.	Chapter 7.4.	Guidelines for the transport of animals by air
Appendix 3.7.5.	Chapter 7.5.	Guidelines for the slaughter of animals
Appendix 3.7.5.	Chapter 7.6.	Guidelines for the killing of animals for disease control purposes
VOLUME 2 - RECOMMENDATIONS APPLICABLE TO OIE LISTED DISEASES AND OTHER DISEASES OF IMPORTANCE FOR INTERNATIONAL TRADE		
OLD NUMBERING	**NEW NUMBERING**	**CHAPTER AND SECTION NEW NAME**
		Foreword
		User's guide
Chapter 1.1.1.		Glossary of terms
SECTION 2.2.	**SECTION 8**	**MULTIPLE SPECIES**
Chapter 2.2.1.	Chapter 8.1.	Anthrax
Chapter 2.2.2.	Chapter 8.2.	Aujeszky's disease
Chapter 2.2.13. Appendix 3.8.10.	Chapter 8.3.	Bluetongue (Sub-chapters: General considerations and surveillance)
Chapter 2.2.3.	Chapter 8.4.	Echinococcosis/hydatidosis
Chapter 2.2.10. Appendix 3.6.2. Appendix 3.8.7.	Chapter 8.5.	Foot and mouth disease (Sub-chapters: General considerations, inactivation and surveillance)

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VOLUME 2 - RECOMMENDATIONS APPLICABLE TO OIE LISTED DISEASES AND OTHER DISEASES OF IMPORTANCE FOR INTERNATIONAL TRADE		
OLD NUMBERING	**NEW NUMBERING**	**CHAPTER AND SECTION NEW NAME**
Chapter 2.2.7.	Chapter 8.6.	Heartwater
Chapter 2.2.15.	Chapter 8.7.	Japanese encephalitis
Chapter 2.2.4.	Chapter 8.8.	Leptospirosis
Chapter 2.2.8.	Chapter 8.9.	New world screwworm (*Cochliomyia hominivorax*) and old world screwworm (*Chrysomya bezziana*)
Chapter 2.2.6.	Chapter 8.10.	Paratuberculosis
Chapter 2.2.5.	Chapter 8.11.	Rabies
Chapter 2.2.14.	Chapter 8.12.	Rift Valley fever
Chapter 2.2.12. Appendix 3.8.2.	Chapter 8.13.	Rinderpest (Sub-chapters: General considerations and surveillance)
Chapter 2.2.9.	Chapter 8.14.	Trichinellosis
Chapter 2.2.16.	Chapter 8.15.	Tularemia
Chapter 2.2.11.	Chapter 8.16.	Vesicular stomatitis
SECTION 2.9.	**SECTION 9**	**APIDAE**
Chapter 2.9.1.	Chapter 9.1.	Acarapisosis of honey bees
Chapter 2.9.2.	Chapter 9.2.	American foulbrood of honey bees
Chapter 2.9.3.	Chapter 9.3.	European foulbrood of honey bees
Chapter 2.9.5.	Chapter 9.4.	*Tropilaelaps* infestation of honey bees
Chapter 2.9.4.	Chapter 9.5.	Varroosis of honey bees
SECTION 2.7.	**SECTION 10**	**AVES**
Chapter 2.7.4.	Chapter 10.1.	Avian chlamydiosis
Chapter 2.7.6.	Chapter 10.2.	Avian infectious bronchitis
Chapter 2.7.7.	Chapter 10.3.	Avian infectious laryngotracheitis
Chapter 2.7.12. Appendix 3.6.5. Appendix 3.8.9.	Chapter 10.4.	Avian influenza (Sub-chapters: General considerations, inactivation and surveillance)
Chapter 2.7.3.	Chapter 10.5.	Avian mycoplasmosis (*Mycoplasma gallisepticum*)
Chapter 2.7.8.	Chapter 10.6.	Avian tuberculosis
Chapter 2.7.10.	Chapter 10.7.	Duck virus enteritis
Chapter 2.7.9.	Chapter 10.8.	Duck virus hepatitis
Chapter 2.7.11.	Chapter 10.9.	Fowl cholera
Chapter 2.7.5.	Chapter 10.10.	Fowl typhoid and pullorum disease
Chapter 2.7.1.	Chapter 10.11.	Infectious bursal disease (Gumboro disease)
Chapter 2.7.2.	Chapter 10.12.	Marek's disease
Chapter 2.7.13.	Chapter 10.13.	Newcastle disease
SECTION 2.3.	**SECTION 11**	**BOVIDAE**
Chapter 2.3.7.	Chapter 11.1.	Bovine anaplasmosis
Chapter 2.3.8.	Chapter 11.2.	Bovine babesiosis
Chapter 2.3.1.	Chapter 11.3.	Bovine brucellosis
Chapter 2.3.9.	Chapter 11.4.	Bovine cysticercosis
Chapter 2.3.2.	Chapter 11.5.	Bovine genital campylobacteriosis
Chapter 2.3.13. Appendix 3.6.3. Appendix 3.8.4. Appendix 3.8.5.	Chapter 11.6.	Bovine spongiform encephalopathy (Sub-chapters: General considerations, reduction of infectivity of transmissible spongiform agents, surveillance and risk analysis)
Chapter 2.3.3.	Chapter 11.7.	Bovine tuberculosis
Chapter 2.3.15. Appendix 3.8.3.	Chapter 11.8.	Contagious bovine pleuropneumonia (Sub-chapters: General considerations and surveillance)
Chapter 2.3.10.	Chapter 11.9.	Dermatophilosis
Chapter 2.3.4.	Chapter 11.10.	Enzootic bovine leukosis
Chapter 2.3.12.	Chapter 11.11.	Haemorrhagic septicaemia (*Pasteurella multocida* serotypes 6:b and 6:e)
Chapter 2.3.5.	Chapter 11.12.	Infectious bovine rhinotracheitis / infectious pustular vulvovaginitis
Chapter 2.3.14.	Chapter 11.13.	Lumpy skin disease (caused by group III virus, type Neethling)

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VOLUME 2 - RECOMMENDATIONS APPLICABLE TO OIE LISTED DISEASES AND OTHER DISEASES OF IMPORTANCE FOR INTERNATIONAL TRADE		
OLD NUMBERING	**NEW NUMBERING**	**CHAPTER AND SECTION NEW NAME**
Chapter 2.3.11.	Chapter 11.14.	Theileriosis
Chapter 2.3.6.	Chapter 11.15.	Trichomonosis
SECTION 2.5.	**SECTION 12**	**EQUIDAE**
Chapter 2.5.14.	Chapter 12.1.	African horse sickness
Chapter 2.5.1.	Chapter 12.2.	Contagious equine metritis
Chapter 2.5.2.	Chapter 12.3.	Dourine
Chapter 2.5.13.	Chapter 12.4.	Epizootic lymphangitis
Chapter 2.5.3.	Chapter 12.5.	Equine encephalomyelitis (Eastern and Western)
Chapter 2.5.4.	Chapter 12.6.	Equine infectious anaemia
Chapter 2.5.5.	Chapter 12.7.	Equine influenza
Chapter 2.5.6.	Chapter 12.8.	Equine piroplasmosis
Chapter 2.5.7.	Chapter 12.9.	Equine rhinopneumonitis (Equine herpes virus type 1 infection)
Chapter 2.5.10.	Chapter 12.10.	Equine viral arteritis
Chapter 2.5.8.	Chapter 12.11.	Glanders
Chapter 2.5.11.	Chapter 12.12.	Horse mange
Chapter 2.5.9.	Chapter 12.13.	Horse pox
Chapter 2.5.12.	Chapter 12.14.	Venezuelan equine encephalomyelitis
SECTION 2.8.	**SECTION 13**	**LAGOMORPHA**
Chapter 2.8.1.	Chapter 13.1.	Myxomatosis
Chapter 2.8.2.	Chapter 13.2.	Rabbit haemorrhagic disease
SECTION 2.4.	**SECTION 14**	**OVIDAE AND CAPRIDAE**
Chapter 2.4.2.	Chapter 14.1.	Caprine and ovine brucellosis (excluding *Brucella ovis*)
Chapter 2.4.4.	Chapter 14.2.	Caprine arthritis/encephalitis
Chapter 2.4.3.	Chapter 14.3.	Contagious agalactia
Chapter 2.4.6.	Chapter 14.4.	Contagious caprine pleuropneumonia
Chapter 2.4.7.	Chapter 14.5.	Enzootic abortion of ewes (Ovine chlamydiosis)
Chapter 2.4.5.	Chapter 14.6.	Maedi-visna
Chapter 2.4.1.	Chapter 14.7.	Ovine epididymitis (*Brucella ovis*)
Chapter 2.4.9.	Chapter 14.8.	Peste des petits ruminants
Chapter 2.4.8. Appendix 3.8.6.	Chapter 14.9.	Scrapie (General considerations and principles for recognising a historically free status)
Chapter 2.4.10.	Chapter 14.10.	Sheep pox and goat pox
SECTION 2.6.	**SECTION 15**	**SUIDAE**
Chapter 2.6.6.	Chapter 15.1.	African swine fever
Chapter 2.6.1.	Chapter 15.2.	Atrophic rhinitis of swine
Chapter 2.6.7. Appendix 3.6.4. Appendix 3.8.8.	Chapter 15.3.	Classical swine fever (Sub-chapters: General considerations, inactivation and surveillance)
Chapter 2.6.2.	Chapter 15.4.	Porcine brucellosis
Chapter 2.6.5.	Chapter 15.5.	Swine vesicular disease
Chapter 2.6.3.	Chapter 15.6.	Teschovirus encephalomyelitis (previously enterovirus encephalomyelitis or Teschen/Talfan disease)
Chapter 2.6.4.	Chapter 15.7.	Transmissible gastroenteritis

Annex XXXVI

Original: English
November 2007

REPORT OF THE SEVENTH MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY

Paris, 6–8 November 2007

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The OIE Working Group on Animal Production Food Safety (hereinafter referred to as the Working Group) met for the seventh time at the OIE Headquarters from 6 to 8 November 2007.

The members of the Working Group and other participants are listed at Annex A. The Agenda adopted is provided at Annex B.

The Director General of the OIE, Dr B. Vallat, welcomed the members of the Working Group and Dr Claude Mosha, Chairperson of the Codex Alimentarius Commission, to the seventh meeting of the Working Group. He emphasised the importance of this Working Group for furthering the important collaboration between the OIE and Codex, and for the OIE's coordination with other international organisations, and noted the excellent progress that has been achieved since the creation of the Working Group. Dr Vallat made reference to several important food safety issues on the Working Group's agenda, in particular the issue of antimicrobial resistance and encouraged the Working Group to maintain its focus on these issues. Dr Vallat commented on the interest of the OIE in developing a closer formal relationship with Codex and mentioned the discussion at the 29th Session of the Codex Alimentarius Commission, where it was agreed that the OIE, FAO and WHO would explore the possibilities of making a formal agreement allowing to build a stronger basis for the establishment of OIE/Codex joint standards.

Dr Vallat also joined the Working Group on the final day of the meeting for a discussion of the Working Group's conclusions. Dr Vallat outlined the ongoing concerns of the OIE about international policies on the use of antimicrobials. In particular, an extreme position opposing the use in livestock of all antimicrobials used in humans would have a very harmful effect on animal production and food security, animal proteins being a relevant input for public health. On the topic of genetically modified vaccines, Dr Vallat indicated that the use of these vaccines is of critical importance to the OIE's work on the control of animal diseases, food security and international trade and is also important to animal welfare and the reduction of use of antimicrobial products. The Working Group will continue to closely monitor subsequent developments relating to these issues.

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Agenda Item 1. Report of the Sixth Working Group Meeting (November 2006)

The Working Group reviewed the report of the sixth meeting. In regard to item 10: Use of the term 'risk based', it was noted that Codex had deferred further work on this topic until 2009 and it was agreed the Working Group would continue to monitor developments in this area. The report of the sixth meeting of the Working Group was adopted unchanged.

Agenda Item 2. Update on OIE, Codex, FAO and WHO activities

Dr K. Miyagishima provided an outline of some recent and ongoing work by the Codex Alimentarius Commission and its subsidiary bodies that was relevant to the OIE.

The 30th Session of the Codex Alimentarius Commission, in July 2007, adopted a number of documents including the food safety risk analysis principles for application by governments as well as several other guidance documents addressing specific categories of food of animal origin. The Commission also adopted its Strategic Plan for 2008-2013 which recognises the importance of cooperation and coordination with the OIE.

Dr Miyagishima also reported on ongoing or completed work regarding the Guidelines for food safety assessment of recombinant-DNA animals; a Model Export Certificate for Milk and Milk Products; revision of the Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals; the Guidelines for the Control of Campylobacter and Salmonella spp. in Chicken Meat. New work was being contemplated for: further guidance on traceability/product tracing; a generic template for health certificates; guidance on risk assessment and risk management of antimicrobial resistance in foodborne pathogens; and a Code of Hygienic Practice for Vibrio spp. in seafood.

Dr Miyagishima expressed his appreciation for the active participation of the OIE in the Codex process and its positive contribution to Codex work. He looked forward to further collaboration between Codex and the OIE in areas of common interest, in order to avoid duplication of work and ensure consistency between international standards set by these bodies.

More details of relevant Codex work were provided under specific Agenda Items.

Dr J. Schlundt provided the following update on relevant WHO activities.

In a recent revision of the structure at HQ WHO, the Department of Food Safety, Zoonoses and Foodborne Diseases has been moved into a new Cluster of Health Security and the Environment.

As a follow-up to the WHO meeting on critically important antimicrobials held in Canberra (Australia) in 2005, WHO convened the second WHO Expert Meeting on Critically Important Antimicrobials for Human Medicine in Copenhagen (Denmark) from 29 to 31 May 2007. The meeting was intended to prioritise agents within the critically important category, to enable the allocation of resources for agents, for which management of the risks from antimicrobial resistance are needed most urgently. A more detailed application of the two original criteria was used for this process than that used to develop the Canberra list. Participants considered drugs of greatest priority for which comprehensive risk management strategies are needed most urgently to be: quinolones, 3rd/4th generation cephalosporins and macrolides.

It was noted that for the first time a microbiological risk assessment model has been released on the web. The model enables comparison of different preparation and testing schemes with respect to how they influence the final reduction of the risk of *Enterobacter sakazakii* in powdered infant formula. This is the first example of such use of international risk assessments, enabling full use of this work at country level. FAO and WHO intend to continue this development for other pathogen/product combinations. The model is available at: www.mramodels.org/esak

Dr J. Domenech provided the following update on relevant FAO activities.

Due to restriction of budgets in FAO, the replacement of officers who left AGAH and AGAP Services was delayed. The veterinary public health group dealing with zoonotic diseases and food safety at the production level has been reactivated and the new leader, Dr Katinka DeBalogh, is in place. A new programme on food safety along the food chain, from farm to fork, is being prepared with the assistance of an expert consultant and in strong partnership between the FAO Animal Production and Health Division and the Nutrition and Consumer Protection Division. FAO has the unique opportunity to put together the live animal level (production and health), the products level and socio-economic and environmental group of experts. This will allow FAO to address the food safety issue with a multidisciplinary and holistic approach and to bring together its partners OIE, WHO and Codex. This is a new programme and its activities will be reported to the Working Group next year.

Dr A. Thiermann provided an update on activities of the OIE Terrestrial Animal Health Standards Commission (hereinafter referred to as the Terrestrial Code Commission) meeting held in September 2007.

On paratuberculosis, the Terrestrial Code Commission agreed that no further work could be done on the chapter until effective diagnostic methods are available.

On bovine tuberculosis, the Biological Standards Commission undertook to examine alternatives to tuberculin testing and draft appropriate text for inclusion in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. An article was added to the tuberculosis chapter providing measures in regard to the importation of antler velvet of farmed deer.

The Terrestrial Code Commission has forwarded the amended draft guidelines on the design and implementation of identification system to achieve animal traceability, to the Working Group for their consideration.

The Terrestrial Code Commission modified the scope of the guidelines on the control of hazards of animal health and public health importance in animal feed to include all terrestrial animals, not just food producing animals. The Terrestrial Code Commission has forwarded the amended text to the Working Group for their consideration in view of the changed scope.

The Terrestrial Code Commission has forwarded the Members' comments on the Guidelines on the detection, control and prevention of *Salmonella* Enteritidis and *S.* Typhimurium in poultry producing eggs for human consumption to the Working Group for their consideration. The Terrestrial Code Commission has recommended that the *ad hoc* Group should commence drafting guidelines on the detection, control and prevention of *Salmonella* in broilers.

Agenda Item 3. Role of Veterinary Services in Food Safety

The Chair introduced this paper, noting that it had been reviewed and endorsed by the Terrestrial Code Commission at its meeting held from 17 to 29 September 2007. Dr Kahn explained that the OIE's intention is to include this text in the OIE *Terrestrial Animal Health Code* (hereinafter referred to as the *Terrestrial Code*), in the context of providing guidance to OIE Member Countries and Territories.

In the background section of the paper some Members queried whether the term 'uniquely equipped' was too exclusive in relation to the role of other professionals in food safety. Concerns were raised that the paper may send a message that only veterinarians are qualified to work in food safety. Several members made comments in support of the original text in relation to the uniqueness of the veterinary qualification.

The Members agreed to modify this section to clarify the role of other professionals and to make some minor changes to improve the clarity of the text. The amended text is shown in Annex C.

Annex XXXVI (contd)

Agenda Item 4. Guide to Good Farming Practices

The Working Group discussed the document prepared by the *ad hoc* Group in detail. Dr Domenech commended the *ad hoc* Group on the Guide to Good Farming Practices and made some comments on behalf of the FAO which had been represented in the *ad hoc* Group by Dr D. Battaglia. The Working Group agreed that the Guide should address the issue of cost-effectiveness, and consideration to the socio-economic and cultural contexts of the farming systems in developing countries and to the particular health situation in the section on Implementation.

The Working Group agreed to delete 'all' and replace utilise with use, in the sentence 'Farmers and farm managers should actively seek and use relevant training opportunities…' (Section 1.5 Training).

Some members recommended that more guidance be provided on compliance of practices (such as the use of antimicrobials and the prevention of chemical residues) with relevant international standards and guidelines.

The Working Group agreed to amend the section on Hazards to recognise that some of the listed hazards had impacts on food safety only indirectly. It also recommended that radionuclides be grouped together with chemical hazards, for the purpose of this document.

The Working Group agreed that there was some redundancy and duplication in the document and recommended that it be restructured as follows. In sections 2, 3, 4, 5 and 6, the first sub-point should be 'Common Measures', followed by sub-points entitled 'Measures to address biohazards', 'Measures to address chemical hazards' and 'Measures to address physical hazards'. The same measures are recommended for several risks and grouping these measures together under the heading 'Common Measures' will help to reduce duplication.

The Working Group noted that risks associated with animal manure and other wastes had not been adequately addressed and proposed the following text for consideration:

'While the use of animal manure, animal slurry and human sewage sludge for fertiliser purposes is becoming increasingly common, enabling higher crop yields as well as sensible waste management, these processes may facilitate the transmission of food safety related diseases within or between herds or directly to humans. Therefore systems for animal or human waste usage for fertiliser purposes should take into consideration relevant treatment methods as well as specific holding times before animals are allowed onto treated pastures. Suggested holding times are directly related to climatic conditions in the region in question (die-off of pathogens is faster at higher temperatures). As a general rule neither animal nor human waste, which has not been appropriately treated, should be used on plants intended for direct human consumption.'

The Working Group recommended that the OIE and FAO support developing countries in their efforts to raise awareness and provide training to farmers and other stakeholders to assist them in complying with the Guide to Good Farming Practices. In particular, resources should be made available through international projects directed to developing countries with the goal of improving the infrastructure of the food production sectors and the performance of the Veterinary Services.

The Working Group also proposed a number of other changes. The amended text is shown in Annex D. The Working Group recommended that the OIE/FAO *ad hoc* Group revisit this document electronically taking into account the Working Group's recommendations. In order to expedite the finalisation of the document, a revised version should be circulated electronically to the Working Group.

The Working Group noted that the GGFP will serve as a guide for Members and as such it does not contain detailed technical recommendations. More specific guidelines will be developed, in particular for developing countries, e.g. specific species or farming systems. These will be prepared by technical agencies such as FAO with the objective of making applicable the implementation of good farming practices in these socio-economic and cultural contexts.

Agenda Item 5. Animal Identification and Traceability

The Working Group noted the work completed by the *ad hoc* Group on Animal Identification and Traceability and did not propose any additional amendments to the proposed text. The Working Group expressed its wish to be involved in further developments on this topic.

Bearing in mind potential future standard-setting work of Codex on product traceability, the Working Group recommended that OIE and Codex maintain close collaboration on this topic.

Dr Kahn advised members of the OIE's intention to hold an International Conference on Animal Identification and Traceability in early 2009, in technical collaboration with Codex, as a mechanism to provide countries with technical information on systems for identification and traceability. The Working Group recommended that the OIE Director General accept collaboration with the FAO.

Agenda Item 6. Terrestrial Animal Feed

The Working Group reviewed the revised draft document entitled "Guidelines for the Control of Hazards of Animal Health and Public Health Importance in Animal Feed", which contained the comments of OIE Members and the Terrestrial Code Commission meeting held from 17 to 29 September 2007. The Working Group addressed the revised Guidelines from a food safety perspective, bearing in mind the need to maintain consistency with the Codex Code of Practice on Good Animal Feeding. Therefore, the Working Group did not address all of the Member comments made on the draft.

The Working Group noted the Terrestrial Code Commission's proposed modification of the scope and suggested that the intention be clarified as the new text could generate some confusion as to whether terrestrial animals other than livestock (e.g. pet animals) were covered. In addition, the reference to 'food' in the sentence 'These guidelines deal with *food* or feed for terrestrial animals (i.e. livestock and poultry)' was felt to be confusing and the Working Group recommended to delete the word *food*.

The Working Group then reviewed the Definitions section and proposed a number of modifications, as follows. An alternative to the definition of 'hazard', was proposed, based on an amendment that had been proposed by an OIE Member. It was of the opinion that the wording 'or a condition of' (as found in the Codex definition of hazard) was not relevant to animal feed. The revised definition supported by the Working Group was:

> ***Hazard**: means a biological, chemical or physical agent in feed or a feed ingredient with the potential to cause an adverse effect on animal or public health.*

The Working Group recommended to delete the definition of 'undesirable substance' as this term is not used in the Guidelines.

The Working Group noted that the term 'feed additive' (in the definition of 'contamination') should be replaced by the term 'feed ingredient'.

Under the section on General Principles, the Working Group recommended changing the placement of the text on contingency plans and the addition of text to clarify the intent. The proposed revised text is as follows:

'Appropriate contingency plans should be in place to enable tracing and recall of non-compliant products.'

The Working Group reviewed the revised text on labeling, in light of Codex recommendations on this point. In relation to contamination, the Working Group recommended that attention should be focused on contamination in general with reference to cross contamination only where necessary. For this reason the Working Group supported the change in the definition of contamination and amended the relevant text as follows:

to remove the word 'cross' from the expression 'cross contamination' and from the first sentence of this text (but to maintain the reference to cross contamination in the final sentence under this title).

Annex XXXVI (contd)

The Working Group also made some other minor amendments to the text. The amendments are shown in Annex E. Amendments made by the Terrestrial Code Commission are shown in the usual manner as double underline and ~~strikeout~~. Amendments made at this meeting (November 2007) are shown with a coloured background to distinguish them from those made previously by the Terrestrial Code Commission.

Agenda Item 7. Aquatic Animal Feed

The Working Group discussed this item in light of its discussion on Agenda Item 6. Members considered that the food safety issues associated with feeding aquatic animals should be addressed and agreed that it would review any further text covering food safety that might be produced through the OIE procedure.

The Working Group recommended that the two guidelines (on terrestrial and aquatic animal feed) should be as closely aligned as possible, for example in relation to contamination and cross-contamination.

The Working Group recommended that OIE expert(s) further review the Guidelines on Feeding Terrestrial Animals, in addition to Codex guidance on animal feeding and FAO publications on aquaculture, with a view to developing text on the food safety implications of aquatic animal feed. In addition to the Codex and FAO publications referenced in the draft Guidelines for the Control of Aquatic Animal Health Hazards in Aquatic Animal Feed, the expert(s) should examine recommendations relevant to feed in texts recently developed by the Codex Committee on Residues of Veterinary Drugs in Foods and the Codex Committee on Fish and Fishery Products (section on aquaculture feed).

The Working Group recommended the OIE should continue to closely monitor developments on aquatic animal feed in Codex.

Agenda Item 8. Revision of OIE Model Veterinary Certificates

The Working Group discussed the report of the *ad hoc* Group on Model Veterinary Certificates, the comments of OIE Members and the text modifications proposed by the Terrestrial Code Commission at its meeting held from 17 to 29 September 2007.

The Working Group recommended that the amendment of Article 1.2.1.1. proposed by the Terrestrial Code Commission be modified to read : 'Safe *international trade*…', which seemed to be the normal OIE usage.

The Working Group recommended that the order of Article 1.2.2.3. and Article 1.2.2.4. be swapped.

The Working Group recommended that the OIE ensure that their recommendations on international veterinary certification are as closely aligned as possible with relevant recommendations of Codex (specifically those developed by the Codex Committee on Food Import and Export Inspection and Certification Systems).

The Working Group also recommended that the OIE take steps to encourage the use of electronic certification, where possible, and other systems helpful in preventing fraud which is a key consideration for safe international trade. With this in mind, the *ad hoc* Group on Model Veterinary Certificates should, at its February 2008 meeting, review the Codex Guidelines for Design, Production, Issuance and Use of Generic Official Certificates (CAC/GL 38-2001), as revised in 2007.

The Working Group noted the good collaboration between OIE and Codex on matters relating to international health certification and encouraged both organisations to continue their efforts to harmonise approaches.

Agenda Item 9. Salmonellosis

The Working Group discussed the draft Guidelines on the Detection, Control and Prevention of *Salmonella* Enteritidis and *S*. Typhimurium in Poultry Producing Eggs for Human Consumption, which had been prepared by an OIE *ad hoc* Group, and the comments of OIE Members on this draft document. The Working Group noted that the *ad hoc* Group will meet again from 4 to 7 February 2008 and recommended that the Group should review Codex recommendations on this topic (CAC/RCP 15-1976), as revised in 2007.

The Working Group noted that the OIE recommendations provided specific advice on measures to be taken on farm (including in relation to hygienic collection, handling and storage of eggs) which complement the Codex recommendations that address the entire food chain including the measures to be taken post-farm (including hygienic handling, transport and storage of eggs). Therefore, the Working Group urged the OIE and Codex to ensure that recommendations are consistent wherever possible and that any unnecessary duplication is eliminated.

The Working Group recommended that the *ad hoc* Group clarify what is meant by environmental sampling in Article 3.10.2.7 and review Article 3.10.2.8. to make the recommendations more operational and clearly differentiate between what is common practice and what are clear recommendations, in particular the section on Vaccination.

The Working Group recommended that the OIE develop a definition for 'pest' – either for use in this Appendix or for use generally in the *Terrestrial Code*.

The Working Group provided comment on some of the general food safety related issues raised by Members and made a number of recommendations to modify the text, including the addition of certain definitions from the Codex Code of Practice, as shown in Annex F.

The Working Group reviewed the terms of reference for the *ad hoc* Group that will be convened to develop recommendations on *Salmonella* detection, prevention and control in broiler chickens and made several recommendations, which are shown in Annex G.

Agenda Item 10. Tuberculosis

The Working Group discussed the report of the Terrestrial Code Commission and noted the amendments proposed by the Commission, most of which were not directly relevant to food safety.

Agenda Item 11. Brucellosis

The Working Group noted the status report on this item.

Agenda Item 12. Antimicrobial Resistance

Dr T. Ishibashi, Deputy Director of the OIE Scientific and Technical Department, joined the Working Group meeting for this item. Dr Ishibashi reported on progress in the area of antimicrobial resistance over the last year. She explained that the OIE has finalised its list of Critically Important Antimicrobials which will be made available on the OIE website. The fourth joint FAO/WHO/OIE Meeting on Critically Important Antimicrobials, to be held on 26 November 2007, will be an important forum to discuss the appropriate balance between animal health needs and public health concerns in the use of antimicrobial products. There will also be an associated stakeholders meeting. The Chair thanked Dr Ishibashi for this update.

The Working Group also noted that, in addition to the work being undertaken by FAO/WHO/OIE and FAO/OIE meetings, the Codex Task Force has started work in 3 areas: risk assessment policy, risk management measures and risk profiling. The new Codex work would have due regard to the existing work by the OIE/FAO/WHO.

Annex XXXVI (contd)

The Working Group will continue to follow this important issue with interest.

Agenda Item 13. Biotechnology

The Working Group noted the status of work in Codex regarding biotechnology. As mentioned in the report of the 7th Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (ALINORM 08/31/34), the Codex Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals is at Step 5/8 of the Codex procedure. This guideline identifies the health status of the recombinant animal as one of the factors that is relevant to the safety assessment of recombinant-DNA animals. It was understood that the assessment of animal health status fell within the OIE mandate and was not covered by the Codex guideline.

The Working Group noted the report of the 12-14 June 2007 meeting of the OIE Biotechnology *ad hoc* Group and noted that this Group will next meet on 26-29 November 2007. In response to the recommendations of an FAO/WHO expert group, the status of food derived from animals treated with recombinant DNA vaccines will be addressed. The Working Group accepted the invitation for Dr Slorach to be present at this meeting and he will report back to the next Working Group meeting.

Agenda Item 14. Work Programme for 2008

The Working Group reviewed the work programme for 2007 and updated it, based on the progression of relevant texts in the past 12 months and the discussion at this meeting.

Priorities for 2008 include:

- Biotechnology:
  - identification and tracing of animals and animal products that have resulted from biotechnological intervention;
  - food safety implications of the use in food producing animals of vaccines derived from recombinant biotechnology.
- Animal feed:
  - food safety implications of feed for aquatic animals.
- Identification and traceability:
  - OIE International Conference on the Identification and Traceability of Animals and Animal Products to be held in technical collaboration with Codex in Buenos Aires in early 2009.
- Disease specific texts:
  - Salmonellosis in broilers
  - Campylobacteriosis in broilers – on work programme for 2009 pending progress in Codex
  - Cysticercosis.

The Work Programme for 2008 is at Annex H.

Agenda Item 15. Revised version of WHO publication' Terrorist Threats to Food'

Dr Schlundt briefly summarised the amendments made to the publication. He indicated that WHO's intention is to publish the revised publication as soon as possible. The Working Group noted the publication.

Agenda Item 16. Date of Next Meeting

4-6th or 11-13th November 2008

.../Annexes

Annex A

REPORT OF THE SEVENTH MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY

Paris, 6–8 November 2007

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Annex XXXVI (contd)

Annex A (contd)

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Annex XXXVI (contd)

Annex B

REPORT OF THE SEVENTH MEETING OF THE OIE WORKING GROUP ON ANIMAL PRODUCTION FOOD SAFETY

Paris, 6–8 November 2007

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Adopted agenda

Welcome from the OIE Director General

Adoption of the Agenda

1. Report of the previous Working Group Meeting – November 2006

2. Update on OIE / Codex / FAO / WHO activities

2.1. OIE Contribution to 30th Session of Codex

2.2. Codex

3. Role of Veterinary Services in Food Safety

4. Guide to Good Farming Practices

4.1. Extract from the report of the Terrestrial Code Commission

4.2. Report of the *ad hoc* Group meeting

4.3. Future work

5. Animal Identification and Traceability

5.1. Report of the *ad hoc* Group meeting

5.2. Extract from the report of the Terrestrial Code Commission

5.3. Comments received from Members

5.4. Future work and international conference

6. Terrestrial Animal Feed

6.1. Extract from the report of the Terrestrial Code Commission

6.2. Comments received from Members

6.3. Future work

Annex XXXVI (contd)

Annex B (contd)

7. Aquatic Animal Feed

7.1. Extract fromthe report of the Terrestrial Code Commission

7.2. Report of the meeting of the *ad hoc* Group on Aquatic Animal Feed

7.3. Future work

8. Revision of OIE Model Veterinary Certificates

8.1. Extract from the report of the Terrestrial Code Commission

8.2. Comments received from Members

8.3. Future work

9. Salmonellosis

9.1. Extract from the report of the Terrestrial Code Commission

9.2. Comments received from Members

9.3. Future work on salmonellosis and campylobacteriosis

10. Tuberculosis

10.1. Extract from Draft Report of the Terrestrial Code Commission

10.2. Comments received from Members'

10.3. Future work

11. Brucellosis

11.1. Extract from the report of the Terrestrial Code Commission

12. Antimicrobial resistance – status report

12.1. VICH press release

13. Biotechnology

13.1. Report of the *ad hoc* Group meeting

13.2. Future Work

14. Work Programme for 2008

15. Any other business

15.1. Revised version of WHO publication 'Terrorist Threats to Food'

16. Next meeting

Annex XXXVI (contd)

Annex C

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY

The purpose of this paper is to provide guidance to OIE Members in regard to the role and responsibilities of *Veterinary Services* in food safety, to assist them in meeting the food safety objectives laid down in national legislation and the requirements of importing countries.

Definitions

The following definitions, from the *Terrestrial Animal Health Code* (the *Terrestrial Code*) (1), are relevant to this paper. Throughout the paper, terms that are defined in the *Code* appear in italics.

Veterinarian means a person registered or licensed by the relevant *veterinary statutory body* to practice veterinary medicine/science in that country.

Veterinary Services means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and guidelines in the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) and *Aquatic Animal Health Code* (*Aquatic Code*) in the country. The *Veterinary Services* are under the overall control and direction of the *Veterinary Authority*. Private veterinary organisations are normally accredited or approved to deliver functions by the *Veterinary Authority*.

Veterinary Authority means the governmental authority of a Member Country, comprising *veterinarians*, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and guidelines in the *Terrestrial Code* in the whole country.

The *Veterinary Statutory Body* is an autonomous authority regulating *veterinarians* and veterinary para-professionals.

Zoonosis means any disease or infection that is naturally transmissible from animals to man.

Background

Historically, the *Veterinary Services* were set up to control livestock diseases at the farm level. There was an emphasis on prevention and control of the major epizootic diseases of livestock and of diseases that could affect man (zoonotic diseases). As countries begin to bring the serious diseases under control, the scope of official animal health services normally increases to address production diseases of livestock, where control leads to more efficient production and/or better quality animal products.

The role of the *Veterinary Services* has traditionally extended from the farm to the slaughterhouse, where *veterinarians* have a dual responsibility – epidemiological surveillance of animal diseases and ensuring the safety and suitability of meat. The education and training of *veterinarians*, which includes both animal health (including zoonoses) and food hygiene components, makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of food of animal origin. As described below, in addition to *veterinarians*, several other professional groups are involved in ensuring integrated food safety approaches throughout the food chain. ~~For this reason, i~~In many countries the role of the *Veterinary Services* has been ~~further~~ extended to include ~~also later~~ subsequent stages of the food chain ~~from~~ in the "farm to fork" continuum (2, 3).

Annex XXXVI (contd)

Annex C (contd)

Approaches to food safety

The concept of the food production continuum

Food safety and quality are best assured by an integrated, multidisciplinary approach, considering the whole of the food chain. Eliminating or controlling food hazards at source, i.e. a preventive approach, is more effective in reducing or eliminating the risk of unwanted health effects than relying on control of the final product, traditionally applied via a final 'quality check' approach. Approaches to food safety have evolved in recent decades, from traditional controls based on good practices (Good Agricultural Practice, Good Hygienic Practice, etc.), via more targeted food safety systems based on hazard analysis and critical control points (HACCP) to risk-based approaches using food safety risk analysis (4).

Risk-based management systems

The development of risk-based systems has been heavily influenced by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"). This Agreement stipulates that signatories shall ensure that their sanitary and phytosanitary measures are based on an assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organizations. Risk assessment, the scientific component of risk analysis, should be functionally separated from risk management to avoid interference from economic, political or other interests. The SPS Agreement specifically recognises as the international benchmarks the standards developed by the OIE for animal health and zoonoses and by the Codex Alimentarius Commission for food safety. In recent decades there has also been a trend towards a redefinition of responsibilities. The traditional approach, whereby food operators were primarily held responsible for food quality while regulatory agencies were charged with assuring food safety, has been replaced by more sophisticated systems that give food operators primary responsibility for both the quality and the safety of the food they place on the market. The role of the supervisory authorities is to analyse scientific information as a basis to develop appropriate food safety standards (both processing and end product standards) and monitoring to ensure that the control systems used by food operators are appropriate, validated and operated in such a way that the standards are met. In the event of non-compliance, regulatory agencies are responsible to ensure that appropriate sanctions are applied.

The *Veterinary Services* play an essential role in the application of the risk analysis process and the implementation of risk based recommendations for regulatory systems, including the extent and nature of veterinary involvement in food safety activities throughout the food chain, as outlined below. Each country should establish its health protection objectives, for animal health and public health, through consultation with stakeholders (especially livestock producers, processors and consumers) in accordance with the social, economic, cultural, religious and political contexts of the country. These objectives should be put into effect through national legislation and steps taken to raise awareness of them both within the country and to trading partners.

Functions of Veterinary Services

The *Veterinary Services* contribute to the achievement of these objectives through the direct performance of some veterinary tasks and through the auditing of animal and public health activities conducted by other government agencies, private sector *veterinarians* and other stakeholders. In addition to *veterinarians*, several other professional groups are involved in ensuring food safety throughout the food chain, including analysts, epidemiologists, food technologists, human and environmental health professionals, microbiologists and toxicologists. Irrespective of the roles assigned to the different professional groups and stakeholders by the administrative system in the country, close cooperation and effective communication between all involved is imperative to achieve the best results from the combined resources. Where veterinary or other professional tasks are delegated to individuals or enterprises outside the *Veterinary Authority*, clear information on regulatory requirements and a system of checks should be established to monitor and verify performance of the delegated activities. The *Veterinary Authority* retains the final responsibility for satisfactory performance of delegated activities.

At the farm level

Through their presence on farms and appropriate collaboration with farmers, the *Veterinary Services* play a key role in ensuring that animals are kept under hygienic conditions and in the early detection, surveillance and treatment of animal diseases, including conditions of public health significance. The *Veterinary Services* may also provide livestock producers with information, advice and training on how to avoid, eliminate or control food safety hazards (e.g. drug and pesticide residues, mycotoxins and environmental contaminants) in primary production, including through animal feed. Producers' organisations, particularly those with veterinary advisors, are in a good position to provide awareness and training as they are regularly in contact with farmers and are well placed to understand their priorities. Technical support from the *Veterinary Services* is important and both private *veterinarians* and employees of the *Veterinary Authority* can assist. The *Veterinary Services* play a central role in ensuring the responsible and prudent use of biological products and veterinary drugs, including antimicrobials, in animal husbandry. This helps to minimise the risk of developing antimicrobial resistance and unsafe levels of veterinary drug residues in food of animal origin. Appendix 3.9.3. of the OIE *Terrestrial Code* contains guidelines on the use of antimicrobials.

Meat inspection

Slaughterhouse inspection of live animals (*ante-mortem*) and the carcase (*post-mortem*) plays a key role in both the surveillance network for animal diseases and zoonoses and ensuring the safety and suitability of meat and by-products for their intended uses. Control and/or reduction of biological hazards of animal and public health importance by *ante-* and *post-mortem* meat inspection is a core responsibility of the *Veterinary Services* and they should have primary responsibility for the development of relevant inspection programmes.

Wherever practicable, inspection procedures should be risk-based. Management systems should reflect international norms and address the significant hazards to both human and animal health in the livestock being slaughtered. The Codex Alimentarius Code of Hygienic Practice for Meat (CHPM) (5) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to application of sanitary measures throughout the meat production chain. Section 3.10 of the *Terrestrial Code* contains guidelines for the control of biological hazards of animal health and public health importance through *ante-*mortem and *post-mortem* meat inspection, which complement the CHPM.

Traditionally, the primary focus of the OIE Codes was on global animal health protection and transparency. Under its current mandate, the OIE also addresses animal production food safety risks. The Code includes several standards and guidelines aimed at protecting public health (such as Appendix 3.10.1. on the Control of Biological Hazards of Animal Health and Public Health Importance through Ante- and Post-Mortem Meat Inspection) and work is underway developing new standards to prevent the contamination of animal products by *Salmonella* spp. and *Campylobacter* spp. The OIE and Codex collaborate closely in the development of standards to ensure seamless coverage of the entire food production continuum. The recommendations of the OIE and the Codex Alimentarius Commission on the production and safety of animal commodities should be read in conjunction.

The *Veterinary Authority* should provide for flexibility in the delivery of meat inspection service. Countries may adopt different administrative models, involving degrees of delegation to officially recognised competent bodies operating under the supervision and control of the *Veterinary Authority*. If personnel from the private sector are used to carry out *ante-* and *post-mortem* inspection activities under the overall supervision and responsibility of the *Veterinary Authority*, the *Veterinary Authority* should specify the competency requirements for all such persons and verify their performance. To ensure the effective implementation of *ante-* and *post-mortem* inspection procedures, the *Veterinary Authority* should have in place systems for the monitoring of these procedures and the exchange of information gained. Animal identification and animal traceability systems should be integrated in order to be able to trace slaughtered animals back to their place of origin, and products derived from them forward in the meat production chain.

Annex XXXVI (contd)

Annex C (contd)

Certification of animal products for international trade

Another important role of the *Veterinary Services* is to provide health certification to international trading partners attesting that exported products meet both animal health and food safety standards. Certification in relation to animal diseases, including zoonoses, and meat hygiene should be the responsibility of the *Veterinary Authority*. Certification may be provided by other professions (a sanitary certificate) in connection with food processing and hygiene (e.g. pasteurisation of dairy products) and conformance with product quality standards.

Other roles of the *Veterinary Services*

Most reported outbreaks of foodborne disease are due to contamination of food with zoonotic agents, often during primary production. The *Veterinary Services* play a key role in the investigation of such outbreaks all the way back to the farm and in formulating and implementing remedial measures once the source of the outbreak has been identified. This work should be carried out in close collaboration with human and environmental health professionals, analysts, epidemiologists, food producers, processors and traders and others involved.

In addition to the roles mentioned above, *veterinarians* are well equipped to assume important roles in ensuring food safety in other parts of the food chain, for example through the application of HACCP-based controls and other quality assurance systems during food processing and distribution. The *Veterinary Services* also play an important role in raising the awareness of food producers, processors and other stakeholders of the measures required to assure food safety.

Optimising the contribution of the *Veterinary Services* to food safety

In order for *Veterinary Services* to make the best possible contribution to food safety, it is important that the education and training of *veterinarians* in the roles outlined in this paper meets high standards and that there are national programmes for ongoing professional development. The *Veterinary Services* should comply with the OIE fundamental principles of quality given in Chapter 1.3.3. of the OIE *Terrestrial Code.* Guidelines for the evaluation of *Veterinary Services* are provided in Chapter 1.3.4. of the OIE *Terrestrial Code* and in the OIE *Tool for the Evaluation of Performance of Veterinary Services* (the OIE *PVS Tool*).

There should be a clear and well documented assignment of responsibilities and chain of command within the *Veterinary Services*. The national *Competent Authority* should provide an appropriate institutional environment to allow the *Veterinary Services* to develop and implement the necessary policies and standards and adequate resources for them to carry out their tasks in a sustainable manner. In developing and implementing policies and programmes for food safety the *Veterinary Authority* should collaborate with other responsible agencies to ensure that food safety risks are addressed in a coordinated manner.

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Annex XXXVI (contd)

Annex D

OIE-FAO GUIDE TO GOOD FARMING PRACTICES FOR ANIMAL PRODUCTION FOOD SAFETY

Introduction

Food safety is universally recognised as a public health priority. It requires a holistic approach, from production to consumption.

These guidelines are intended to help competent authorities to assist stakeholders, including farmers, to fully assume their responsibilities at the first stages of the food chain to produce safe food of animal origin. Good farming practices should also address socio-economic, animal health and environmental issues in a coherent manner.

The recommendations in these guidelines complement the responsibilities of the competent authorities at the farm level, and in particular of the Veterinary Services. These guidelines are intended to assist in developing on-farm quality assurance systems for animal product food safety. This document also complements existing works from OIE, FAO and Codex Alimentarius aimed at addressing animal health and welfare, socio-economic and environmental issues related to farming practices. The bibliography lists the most relevant documents and publications.

To support the competent authorities an indication is given at the end of this document on the steps to be taken to implement these guidelines.

Hazards

Many aspects of primary production are at risk of biological, chemical (including radionuclide), and physical ~~and radionuclide~~ agents. These may enter the animal, and thus the food chain, and may have impacts on the safety of animal feed and food for human consumption, through a large variety of exposure points. It will not be possible to exhaustively list all hazards here, but the intention of these guidelines is to describe, in very broad terms, a set of generic good farming practices intended to minimise these hazards.

The measures to address the listed hazards will be considered under the following headings:

1. General farm management
2. Animal health management
3. Veterinary medicines and biologicals
4. Animal feeding and watering
5. Environment and infrastructure
6. Animal and product handling.

The approach adopted will be to briefly outline, in tabular form, the hazards inherent in each of these, and then to address each heading in turn to describe a set of good practices to manage these hazards.

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Hazard Tabulation

Hazards	Control Points
Biohazards	
Introduction of pathogens and contaminants	• Sources of animals (horizontal and vertical transmission) • Sourcing of breeding stock • Breeding procedures • Semen and embryo quality • Bedding • Feed[1] and water • Records of acquisitions and animal movements • Health and hygiene of visitors and personnel • Contact with other animals (including wild life/rodents/insects, etc.) • Vehicles/clothing/instruments/equipment • Infected/contaminated carcases, tissues or secretions
Transmission of pathogens and contaminants	• Animal housing and population density • Disease diagnosis (horizontal and vertical transmission) • Health and hygiene of visitors and personnel • Vehicles/clothing/instruments/equipment • Infected/contaminated carcases, tissues or secretions • Bedding management • Insect or pest vectors
Microbial and parasitic infections on pastures and paddocks	• Pasture management • Microbial/parasite diagnosis
Microbial load on skins	• Environment of animals • Waste management • Bedding management • Population density
Airborne infections and contaminations	• Farm location • Animal housing and ventilation • Population density
Carrier animals shedding pathogens	• Animal management • Diagnosis • Population density
Increased susceptibility to pathogens	• Animal management (incl. transport) • Diagnosis • Population density
Antimicrobial and parasiticide resistance	• Diagnosis • Therapeutic regimes • Record-keeping

[1] In this document, 'feed' includes all animal feedstuff, ingredients, additives and supplements as defined in the Codex Alimentarius Code of Practice on Good Animal Feeding (CAC/RCP54 -2004).

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Annex D (contd)

Hazards	Control Points
Biohazards (contd)	
Feed borne infections and contaminations	• Production, transport and storage • Feed quality • Feed equipment • Record keeping
Water-borne infections and infestations	• Water quality • Effluent management • Watering equipment
Livestock not well adapted to conditions	• Breeding selection • Record-keeping
Chemical hazards	
Chemical contamination of environment, feed/water	• Farm location • Animal movement • Use of agricultural chemicals • Feed and water quality • Equipment and building materials • Hygiene practices
Toxins of biological origin (plants, fungi, algae).	• Feed, pasture and water quality • Farm location • Animal movements • Feed production, storage and transport
Residues of veterinary medicines and biologicals (incl. medicated feed and water)	• Treatment of animals • Sales and prescription control • Record-keeping • Residue control • Quality of feed and water
Radionuclide pollution	• Farm location • Sources of feed and water
Physical hazards	
Broken needles and other penetrating bodies.	• Treatment of animals
Injuries	• Farm location • Infrastructure • Population density • Animal handling • Construction and equipment
Ingestion of dangerous/harmful objects	• Farm location • Source of feed and water • Record-keeping • Construction and equipment • Infrastructure
~~**Radionuclides**~~	
~~Radionuclide pollution~~	~~• Farm location~~ ~~• Sources of feeds and water~~

Annex XXXVI (contd)

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Recommended Good Practices

1. General farm management

A number of common threads run through all levels of farm management and recur often in the principles elaborated below. They are:

1.1 Legal obligations

Farmers should be aware of, and comply with all legal obligations relevant to livestock production e.g. disease reporting, record keeping, animal identification, carcase disposal.

1.2 Record keeping

When any form of problem arises in an enterprise, be it a disease, a chemical hazard issue or a physical safety matter, record-keeping is central to any effort to trace the problem and eliminate it. Hence, as far as is practicable, farmer should keep records of:

- Animal populations on the farm (groups or individuals as relevant)
- Movements of animals around the enterprise, changes to feeding or health regimes, and any other management changes that may occur
- Origin and use of all feed, drugs, disinfectants, herbicides and other consumable items used on the farm
- Origin and destination of all animal movements to and from the farm
- Known diseases and deaths on the farm.

1.3 Animal identification

Animal identification and the ability to trace animals have become more important as tools to ensure food safety and improve management. Identification of animals may be on an individual or group basis, and connections between properties as a result of animal movements should be able to be deduced from good record keeping and animal identification.

Where a food safety incident occurs, it should be possible to determine the source and to take appropriate action.

The ability to trace animals at least one step forward and one step back from the current holding is recommended.

1.4 Hygiene and disease prevention

Measures aimed at preserving cleanliness, preventing pathogen build-up and breaking possible pathways of transmission are essential in the management of any modern farming enterprise, regardless of species, and whether intensive or extensive.

Precautions should aim at:

- Reducing contact between potentially infected and healthy animals
- Maintaining hygiene and safety of all facilities
- Ensuring overall health of livestock through good nutrition and reducing stress
- Maintain an appropriate population density for the species and age group in question, following either locally enforceable measures, or obtaining appropriate advice from recognised experts
- Keep records of populations in facilities/on farms under his/her control

1.5 Training

Husbandry measures and techniques are ever-changing. Farmers, farm managers and farm personnel should have their knowledge and skills updated regularly through continuing education.

Competent authorities are encouraged to assess training needs amongst stakeholders and to promote necessary training. This would contribute to commitment to and effective execution of all practices described in this guide.

Farmers and farm managers should:

- Actively seek and use ~~utilise all~~ relevant training opportunities for themselves and their workers
- Be aware of any training courses that may be compulsory in their countries and regions
- Keep records of all training undergone.

2. Animal health management

2.1 Addressing biohazards

Owners or managers of livestock should:

- Establish a working relationship with a veterinarian to ensure that animal health and welfare, and disease notification issues are addressed
- Seek veterinary assistance to immediately investigate suspicion of serious disease
- Keep records of all diseases, diseased animals and mortalities as far as possible, giving details such as dates, diagnosis (where known), animals affected and treatments

Annex XXXVI (contd)

Annex D (contd)

- Acquire animals (including breeding stock) only from sources with a known and safe health status, where possible with supporting health certificates from veterinarians

- Ensure that movements of incoming animals are traceable to source and that animals are appropriately identified to ensure this.

- Keep records of all breeding stock, semen or embryos used on their premises, the animals upon which they were used, the breeding dates and outcomes.

- Keep records of all arrivals, including their identification marks or devices, origin and date of arrival.

- Comply with regulations concerning restrictions on animal movements

- Keep new arrivals separate from resident stock for an appropriate period in order to monitor them for diseases and infestations in order to prevent transmission of such conditions

- Ensure that after arrival, animals are where necessary given time to adapt to new feeding regimes, are not overcrowded, and that their health is monitored

- Source fresh or frozen semen, ova and embryos from safe sources, accredited by the competent authority of the country of origin, with appropriate health certification

- Minimise contact between resident animals and professional or other visitors, and take all hygienic measures necessary to reduce possible introduction of pathogens and contaminants

- Take all appropriate measures to prevent contamination by vehicles entering and traversing the property

- Ensure the health of all workers on the farm and implementation of hygienic working procedures

- Practice breeding and selection such that animals well suited to local conditions are raised and keep detailed breeding records

- Separate diseased from healthy animals such that transmission of infection does not occur, and where necessary, cull diseased animals

- Ensure that equipment and instruments used in animal husbandry are suitably cleaned and disinfected between uses

- Effectively remove or dispose of dead and fallen stock where possible so that other animals cannot come in contact with carcases and that carcases do not contaminate the pasture or drinking water, and keep records of all such disposals.

As a general principle, closed farming systems and all-in all-out systems are recommended from a food safety and ~~recognised as the safest from a biosafety~~ biosecurity point of view.

2.2 Addressing physical hazards

Owners or managers of livestock should apply animal welfare practices in accordance with regulatory requirements, and in particular:

- Ensure that people working with animals are properly experienced and trained for the tasks they should perform
- Ensure that facilities and equipment are properly designed and maintained to prevent physical injury
- Ensure that animals are handled and transported appropriately.

3. Veterinary medicines and biologicals

3.1 Addressing biohazards

Owners or managers of livestock should:

- Use veterinary medicines and biologicals strictly in accordance with manufacturer's instructions or veterinary prescription, as appropriate
- Use antimicrobials only in accordance with regulatory requirements and other veterinary and public health guidance
- Keep detailed records of the origin and use of all medicines and biologicals, including batch numbers, dates of administration, doses, individuals or groups treated and withdrawal times. Treated individuals or groups should be clearly identified
- Maintain required storage conditions for veterinary medicines and biologicals
- Keep all treated animals on the farm until the relevant withdrawal times have expired (unless animals should leave the farm for veterinary treatment)
- ~~Ensure that products from treated animals are not used for human consumption until the withdrawal periods have elapsed~~.
- Use clean, sterilised or disposable instruments, syringes and needles for the treatment of animals
- Dispose of used instruments (incl. needles) in a biosecure manner
- Use only appropriate and correctly calibrated instruments for the administration of veterinary medicines and biologicals.

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3.2 Addressing chemical hazards

Owners or managers of livestock should:

- Be aware of and comply with restrictions on medicines or biologicals for use in livestock
- Correctly observe all recommended dosage regimes ~~and withdrawal times~~ as specified by the manufacturer or attending veterinarian
- Ensure that products from treated animals are not used for human consumption until the withdrawal periods have elapsed.

3.3 Addressing physical hazards

Owners or managers of livestock should:

- Ensure that all treatments or procedures are carried out using instruments that are fit for purpose, and that animals are correctly and calmly handled and restrained
- Ensure that all handling or treatments facilities are safe and appropriate to the species in question and that their construction is such that the likelihood of injury is minimised.

4 – Animal feeding and watering

4.1 Addressing biohazards

Owners or managers of livestock should:

- Acquire feed from suppliers ~~manufacturers~~ who follow recognised good manufacturing practices such that feed contamination is minimised
- Ensure that antibiotics are not be used in feed for growth promoting purposes in the absence of a public health safety assessment
- Ensure that ruminant protein is not fed to ruminants
- Where on-farm manufacture of feed is practised, procedures designed to minimise contamination and prevent the inclusion of undesirable feed components are followed. Where necessary, expert assistance should be sought
- Manage the feed chain (transport, storage and feeding) in such a way as to protect feed from contamination and minimise deterioration. Feed should be used as soon as possible and, if applicable, in accordance with labelling instructions
- Keep records of all feed and dates of acquisition and feeding; where possible the animals/groups of animals fed should be clearly recorded. Self-mixed feed should have their ingredients and mixes recorded, as well as dates of feeding and animals fed as specified above
- Ensure that nutritional levels promote animal health, growth and production

- Where appropriate, manage pastures by stocking rate and rotation to maintain healthy and productive livestock and reduce parasite burdens. Keep records of pasture rotation and other on-farm animal movements between pens, sheds, etc.

- Ensure that changes to feeding regimes are, where possible, gradual, and that the regimes are safe and nutritious by following acceptable feeding practices

- Ensure that only water of known and acceptable biological quality (fit for animal consumption) is used for watering stock

- Ensure that effluents are managed in such a way that drinking water sources are not contaminated

- Regularly inspect and, when necessary, clean and disinfect feeding and watering facilities such as drinkers and troughs

- Prevent animal access to places where feed are stored.

4.2 Addressing chemical hazards

Owners or managers of livestock should:

- Acquire feed from manufacturers who follow recognised good manufacturing practices such that the likelihood of undesirable chemical substances in the feed is minimised

- Use herbicides and pesticides judiciously and according to manufacturer's instructions and applicable legislation such that animal exposure to these chemicals is minimised. Records of usage, including date and location of application, should be kept

- Ensure that only water of known and acceptable mineralogical quality (dissolved/suspended solids levels fit for animal consumption) is used for watering stock

- Ensure that when feed additives are used, that manufacturer's instructions as to dosage levels and withdrawal periods are followed, and that records of usage of such feed additives are kept

- Prevent animal access to places where hazardous chemicals are stored.

4.3 Addressing physical hazards

Owners or managers of livestock should:

- Ensure that feed originate from trustworthy sources following good production practices

- Ensure that animals are not kept in sheds, pens or pastures where they are likely to ingest foreign objects and that all facilities are kept clean and free from metal objects, pieces of wire, plastic bags, etc.

- Manage the feed chain (transport, storage and feeding) in such a way as to protect feed from contamination with foreign objects.

5. Environment and infrastructure

5.1 Addressing biohazards

Owners or managers of livestock should:

- Locate farms in areas free from industrial and other pollution and sources of contamination and infection
- Ensure that farm layout minimises livestock contact with visitors, vehicles and other potential sources of contamination and infection
- Maintain adequate separation between clean and contaminated materials (e.g. feed and manure)
- Ensure that where animals are confined, the housing or corrals are constructed such that the basic needs of the animals are fulfilled especially with regard to ventilation, drainage and manure removal. Walking surfaces should be non-slippery and easily cleaned and all surfaces should ideally be washable
- Ensure that effluent disposal is effective and that facilities where animals are kept are an appropriate distance from any disposal points
- Apply appropriate pest and vermin control measures, which may include the use of barriers such as nets or fencing, or the use of pest/vermin population control measures
- Ensure that where used, bedding or litter is regularly renewed and used bedding or litter safely disposed of
- Ensure that buildings and perimeter fences are so constructed that contact with other livestock and wild animals is minimised
- Ensure that farm layout and building construction provides for adequate separation of animals by production group as necessary.

5.2 Addressing chemical hazards

Owners or managers of livestock should:

- Use chemical disinfectants and cleansers strictly in accordance with proper instructions, ensuring that disinfected or cleaned surfaces and facilities are properly rinsed if necessary
- Seek professional advice with regard to the use of disinfectants or cleansers.

5.3 Addressing physical hazards

Owners or managers of livestock should:

- Ensure that animal housing facilities do not bear any features likely to cause injury to animals, that flooring is non-slippery and that where possible surfaces are not uneven and/or poorly drained
- Manage pastures such that livestock are not exposed to dangerous and impassable areas.

6 – Animal and product handling

6.1 Addressing biohazards

Owners or managers of livestock should:

- Ensure that all animals destined for slaughter are clean, healthy and fit to travel and have not had recent contact with diseased stock or infectious material
- Apply short duration feeding regimes aimed to reduce the shedding of harmful bacteria in animals destined for slaughter
- Ensure that contamination of animal products from animal and environmental sources during primary production and storage are minimised
- Ensure that storage conditions maintain the quality of the products
- Keep records of animals and animal products leaving the farm as well as the destination and the date of dispatch.

6.2 Addressing chemical hazards

Owners or managers of livestock should:

- Ensure full compliance with existing legislation such that applicable maximum residue levels are not exceeded
- Ensure that all animals destined for slaughter have not been subjected to treatment for which the withdrawal period has not elapsed.

6.3 Addressing physical hazards

Owners or managers of livestock should:

- Ensure that mustering or catching and handling prior to loading is carried out in a safe and humane manner
- Ensure that loading facilities are appropriately constructed
- Take the necessary care during animal loading so as to minimise injury
- Handle products in such a way as to prevent damage.

Annex XXXVI (contd)

Annex D (contd)

Implementation

It is desirable that the competent authorities and relevant stakeholders agree on acceptable farm management measures (which may include codes of practice) for the various livestock industries in their countries, based on the principles elaborated in these guidelines.

Ideally, farmers should implement all measures recommended in this guide. In order to achieve this, these measures need to be adapted to specific production and farming systems from the subsistence small holder systems found in many developing countries to large industrial farm units.

Diagram 1 proposes a methodology for such implementation.

The OIE and FAO encourage member countries to develop their own measures or codes of practice based on these guidelines. Competent authorities should consult with the appropriate stakeholders to establish the cost effectiveness and the applicability of the measures recommended in this Guide. Competent authorities should take account of the particular health, socio-economic and cultural situations in their countries as they proceed to apply this Guide.

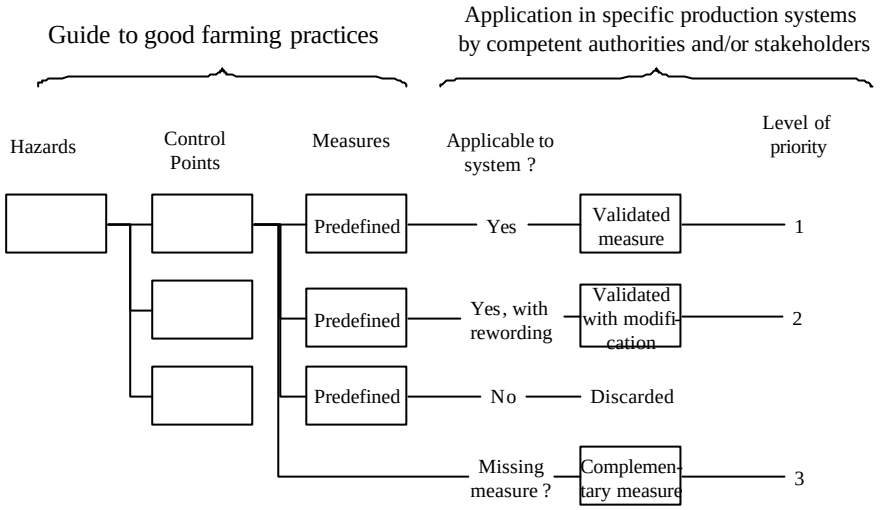
Some measures could be adopted without change, while others will have to be adapted and their wording modified before being validated and integrated into a specific code of practice. Non relevant measures might even be discarded. Some complementary measures might have to be added to specific codes of practice in order to correctly address specific hazards.

Countries could decide what level of priority to assign to each of the measures in this guide in developing their own frameworks. Measures with the highest priority should be the minimum requirement for farmers, while measures of lower priority could be applied as circumstances dictate.

On-farm quality assurance should be supported by policies and programmes, including raising awareness and training of stakeholders. These activities are deemed essential to obtaining stakeholder commitment to the quality assurance process.

The Competent authorities in consultation with stakeholders should develop mechanisms to monitor the implementation of this Guide.

Diagram 1: ***Implementation methodology for specific production and farming systems***



Priority levels :
1. Critical measure
2. Higly advisable measure
3. Recommended measure

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Annex E

GUIDELINES FOR THE CONTROL OF HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED

Article 1

Introduction

Animal feed is a critical component of the food-chain that has a direct impact on animal health and welfare and also on food safety and public health.

Historically, the OIE primarily addressed animal feed as an important pathway for the entry and spread of contagious epidemic *diseases*, such as foot and mouth disease, swine vesicular disease and avian influenza. In recent years, the role of feed as a vector for *disease* agents, including zoonotic organisms, was a focus of standards development in regards to bovine spongiform encephalopathy. Animal feed and feed ingredients are widely traded internationally and trade disruptions have the potential to impact economies in both developed and developing countries. Since 2002 the OIE has expanded its zoonotic disease mandate to encompass animal production food safety, working in collaboration with the Codex Alimentarius Commission (CAC) and other international organisations. In 2006 the International Committee resolved that the OIE should develop guidance on foodborne zoonoses and animal feeding, complementing relevant CAC texts.

Article 2

~~PURPOSE~~ Objective and scope

The ~~purpose~~ objective of this OIE guideline is to provide guidance on animal feeding in relation to animal health and to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety.

This guideline aims at ensuring the control of animal and public health hazards through adherence to recommended practices during the production (procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced animal feed and feed ingredients for food producing animals.

~~SCOPE~~

This guideline applies to the production and use of all products destined for animal feed and feed ingredients at all levels whether produced commercially or on farm. It also includes grazing or free-range feeding, forage crop production and water for drinking. Swill feeding is a particular aspect of on-farm practice that is specifically addressed because of its recognised role in *disease* transmission.

~~This~~ These ~~g~~Guidelines deal~~s~~ with ~~food or~~ feed for terrestrial ~~food-producing~~ animals ~~other than aquatic animals~~ (i.e. livestock and poultry).

Annex XXXVI (contd)

Annex E (contd)

Article 3

Definitions

Hazard

means a biological, chemical or physical agent in~~, or a condition of~~, feed or a feed ingredient ~~an *animal* or animal product~~ with the potential to cause an adverse effect on animal or public health.

Feed

means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial ~~food producing~~ animals (except bees).

Feed additives~~*~~

means any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed, ~~or~~ health of the animal or ~~and~~ the characteristics of products. Microorganisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration. This excludes veterinary drugs.

Medicated feed

means any feed which contains a veterinary drug administered to food producing animals, for therapeutic or prophylactic purposes or for modification of physiological functions.

Feed ingredient

means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant~~,~~ or animal ~~or aquatic~~ origin, or other organic or inorganic substances.

~~***Undesirable substance***~~

~~means a contaminant or other substance material which is present in and/or on feed and feed ingredients and which constitute a risk whose presence is potentially harmful to animal or public health and/or is restricted under current regulations.~~

Commercial feed

means all materials that are sold and distributed as feed, or to be mixed with feed, for animals except: unmixed seed, whole, processed, or unprocessed; straw, stover, silage, cobs, husks, and hulls; or individual chemical compounds not mixed with other ingredients.

~~Cross~~ contamination

means ~~contamination~~ the presence of a material or product ~~with another material or product containing a component that~~ in a feed or feed ingredient ~~additive and~~ whose presence in that feed or feed ingredient ~~additive~~ is potentially harmful for animal or public health or is restricted under ~~the regulatory framework~~ current regulations.

Article 4

General principles

1. Roles and responsibilities

The Competent Authority has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The Competent Authority may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 1.3.3. and 1.3.4. of the OIE *Terrestrial Code*.

Those involved in the production and use of animal feed and feed ingredients have the responsibility to ensure that these products meet regulatory requirements. Appropriate contingency plans should be in place to enable tracing and recall of non-compliant products. All personnel involved in the manufacture, storage and handling of feed and feed ingredients should be adequately trained and aware of their role and responsibility in preventing the spread of ~~animal health and public health~~ hazards. ~~Appropriate contingency plans should be developed.~~ Equipment should be maintained in good working order and in a sanitary condition.

It is a particular responsibility of Veterinary Services to set and enforce the regulatory requirements pertaining to the use of veterinary drugs, animal *disease* control and the food safety aspects that relate to the management of live animals on farm.

Those providing specialist services to producers and to the feed industry (e.g. private veterinarians and laboratories) may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. *disease* reporting, quality standards, transparency).

2. Regulatory safety standards

All feed and feed ingredients should meet regulatory safety standards. In defining limits and tolerances for hazards, scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account.

3. Risk analysis (risk assessment, risk management and risk communication)

Internationally accepted principles and practices on risk analysis (Section 1.3. of the OIE *Terrestrial Code*; and relevant Codex texts) should be used in developing and applying the regulatory framework.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while recognising the different risk assessment methodologies used in animal and public health.

4. Good practices

Where national guidelines exist, good agricultural practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them.

Where appropriate, Hazard Analysis and Critical Control Point[2] (HACCP) principles should be followed to control hazards that may occur in the manufacture of feed and feed additives.

[2] Hazard Analysis and Critical Control Point, as defined in the Annex to the Recommended International Code of

Annex XXXVI (contd)

Annex E (contd)

5. Geographic and environmental considerations

Land and facilities used for production of animal feed and feed ingredients and water sources should not be located in close proximity to sources of hazards for animal health or food safety. Animal health considerations include factors such as *disease* status, location of quarantined premises and existence of *zones/compartments* of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

6. Zoning and compartmentalisation

Feed is an important component of biosecurity and needs to be considered when defining a compartment or zone in accordance with Chapter 1.3.5. of the OIE *Terrestrial Code*.

7. Sampling and analysis

Sampling and analytical protocols should be based on scientifically recognized principles and procedures.

8. Labelling

Labelling on how the feed or feed ingredients should be handled, stored and used should be ~~clear and~~ informative ~~as to how the feed and feed ingredients should be handled, stored and used~~ unambiguous, legible and conspicuously placed on the package if sold in package ~~bagged~~ form and on the waybill and other sales documents if sold in bulk, un-packaged ~~bagged~~ form, and should comply with regulatory requirements.

See Codex Code of ~~P~~practice on ~~G~~good ~~A~~animal ~~F~~feeding (CAC/RCP 54-2004).

9. Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, Competent Authorities contribute through the direct performance of some tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Feed and feed ingredients business operators and other relevant parts of industry should practice self-regulation to secure compliance with required standards for procurement, handling, storage, processing, distribution and use. Operators have the primary responsibility for implementing systems for process control. ~~Where such systems are applied~~, The Competent Authority should verify that they achieve all regulatory requirements.

10. Assurance and certification

Competent Authorities are responsible for providing assurances domestically and to trading partners that regulatory ~~requirements~~ safety standards have been met. For international trade in animal product based feed, *Veterinary Services* are required to provide international veterinary certificates.

Practice ~~on~~ - General Principles of Food Hygiene (CAC/RCP 1-1969).

11. Hazards associated with animal feed

a) Biological hazards

Biological hazards that may occur in feed and feed ingredients include agents such as bacteria, viruses, prions, fungi and parasites.

b) Chemical hazards

Chemical hazards that may occur in feed and feed ingredients include naturally occurring chemicals (such as mycotoxins and gossypol), industrial and environmental contaminants (such as dioxins and PCBs), residues of veterinary drugs and pesticides and also radionuclides.

c) Physical hazards

Physical hazards that may occur in feed and feed ingredients include foreign objects (such as pieces of glass, metal, plastic or wood).

12. ~~*Cross c*~~Contamination

It is important to avoid ~~cross-~~contamination during the manufacture, storage, distribution (including transport) and use of feed and feed ingredients and relevant provisions should be included in the regulatory framework. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Procedures, such as flushing, sequencing and physical clean-out, should be used to avoid cross-contamination between batches of feed or feed ingredients.

13. Antimicrobial resistance

Concerning the use of antimicrobials in animal feed refer to Section 3.9. of the OIE *Terrestrial Code*.

14. Management of information

The Competent Authority should establish clear requirements for the provision of information by the private sector as this relates to regulatory requirements.

Records should be maintained in a readily accessible form regarding the production, distribution and use of feed and feed ingredients. These records are required to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source, and trace-forward to the next subsequent recipients, to address identified animal health or public health concerns.

Animal identification and *animal traceability* are tools for addressing animal health (including zoonoses), and food safety risks arising from animal feed (see Section 3.5. of the OIE *Terrestrial Code*; Section 4.3. of CAC/RCP 54-2004).

– text deleted

APPENDIX 3.10.2.

GUIDELINES ON THE DETECTION, CONTROL AND PREVENTION OF *SALMONELLA* ENTERITIDIS AND *S.* TYPHIMURIUM IN POULTRY PRODUCING EGGS FOR HUMAN CONSUMPTION

Article 3.10.2.1.

Introduction

The aim of the *Terrestrial Code* is to assist OIE 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. This guideline provides recommendations on the detection, control and prevention of *Salmonella* Enteritidis and *S.* Typhimurium in poultry producing eggs for human consumption. These considerations equally apply to other paratyphoid *Salmonella* serovars.

S. Enteritidis and *S.* Typhimurium belong to the species of *S.* Enterica. In most food animal species, *S.* Enteritidis and *S.* Typhimurium can establish a clinically unapparent infection in poultry, 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 food poisoning. In the latter case, this can occur when these animals, or their products, enter the food chain thus producing contaminated food products.

Salmonellosis is one of the most common food-borne bacterial diseases in the world. It is estimated that over 90% of *Salmonella* infections in humans are food-borne with *S.* Enteritidis and *S.* Typhimurium accounting for major part of the problem. Egg-associated salmonellosis, particularly *S.* Enteritidis, is an important public health problem worldwide.

Article 3.10.2.2.

Purpose and scope

This guideline deals with methods for on farm detection, control and prevention of *S.* Enteritidis and *S.* Typhimurium in poultry producing eggs for human consumption. This guideline complements the Codex Alimentarius ~~draft~~ Code of H~~h~~ygienic P~~p~~ractice for E~~e~~ggs and E~~e~~gg P~~p~~roducts (CAC/RCP 15-1976 Revision 2007~~ALINORM 07/28/13, appendix II~~). It covers the preharvest part of the production chain from elite flock to the commercial layer farm. ~~The objective is to control *Salmonella* in poultry with the goal of producing *Salmonella* free eggs.~~ A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in producing eggs that are safe to eat.

The scope covers chickens and other domesticated birds used for the production of eggs for human consumption. The recommendations presented in this guideline are also relevant to the control of other *Salmonella* serotypes.

Annex XXXVI (contd)

Annex F (contd)

Article 3.10.2.3.

Definitions (for this chapter only)

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

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

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

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.

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

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

Competitive exclusion
means the administration of bacterial flora to poultry to prevent gut colonisation by enteropathogens, including Salmonellae.

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

Article 3.10.2.4.

Hazards in poultry breeding flocks, hatcheries and poultry producing eggs for human consumption

All measures to be implemented in breeding flocks and hatcheries are described in Chapter 2.10.2. on *Salmonella* Enteritidis and *Salmonella* Typhimurium in Poultry and in Appendix 3.4.1. on hygiene and disease security procedures in poultry breeding flocks and hatcheries.

This guideline addresses ~~deals with~~ poultry that produc~~e~~ing eggs for human consumption. The rest of the food chain is addressed by the Codex Alimentarius ~~draft c~~Code of H~~h~~ygienic P~~p~~ractice for E~~e~~ggs and E~~e~~gg P~~p~~roducts.

Article 3.10.2.5.

Biosecurity recommendations applicable to pullet and layer or laying flocks

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. The choice of a suitably isolated geographical location, taking into account the direction of the prevailing winds, facilitates hygiene and disease control. A sign indicating restricted entry should be posted at the entrance.

~~2. *Establishments* should operate on an 'all in – all out' single age group whenever possible.~~

2. An 'all in - all out' step should be followed for each poultry house, where feasible, taking into consideration multi-aged poultry houses.

3. Where several flocks are maintained on one *establishment*, each flock should be managed as separate entities.

4. Poultry houses and buildings used to store feed or eggs should be pest proof and not accessible to wild birds.

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 ideally should consist of concrete or other material to facilitate cleaning. ~~An exception to this would be trees for heat control, with the exception of fruit trees which could be attractive to birds.~~

7. Domestic animals, other than poultry, should not be permitted access to poultry houses and buildings used to store feed or eggs.

8. Clean coveralls or overalls, hats and footwear should be provided for all personnel and visitors entering the poultry house. A physical hygiene barrier or a ~~A~~ disinfectant foot-bath 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 and after entering the layer house.

9. When a poultry house is depopulated, all faeces and litter should be removed from the house 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.

   Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when *S.* Enteritidis and/or *S.* Typhimurium have been detected in the flock. Routine pest control procedures should also be carried out at this time.

10. Birds used to stock a pullet house should be obtained from breeding flocks that are certified as free from *S.* Enteritidis and *S.* Typhimurium and have been monitored according to Article 3.4.1.9.

11. *Layer or laying flocks* ~~Layer flocks~~ should be stocked from pullet flocks that are certified as free from *S.* Enteritidis and *S.* Typhimurium and have been monitored according to this guideline.

12. ~~While *S.* Enteritidis and *S.* Typhimurium are not normally found as a contaminant in feed~~, Because *Salmonella* organisms may contaminate feed, it is ~~nonetheless~~ recommended to monitor the salmonella status of feed used in poultry houses. The use of pelletised feed or feed subjected to other bactericidal treatment is recommended. Feed should be stored in clean closed containers to prevent access by birds and pests. Spilled feed should be cleaned up regularly to remove attractants for wild birds and pests.

Annex XXXVI (contd)

Annex F (contd)

13. 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.

14. Sick or dead birds should be removed from poultry houses as soon as possible and at least daily, and effective and safe disposal procedures implemented.

15. Records of flock history ~~and performance~~, including mortality, as well as surveillance, treatment and vaccinations in regard to *Salmonella* should be maintained on an individual flock basis within the establishment. Such records should be readily available for inspection.

16. There should be good communication and interaction between all involved in the food chain so that control can be maintained from breeding to egg production and consumption. Farmers should have access to basic training on hygiene and biosecurity measures relevant to egg production and food safety.

17. For poultry flocks that are allowed to range outdoors, the following provisions apply:

    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 rubbish, other farm animals, surface water and manure storage areas). The nesting area should be inside the poultry house.

Article 3.10.2.6.

Recommendations applicable to egg hygiene and collection

1. Cages should be maintained in good condition and kept clean. 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.

2. Eggs should be collected at frequent intervals, e.g. not less than twice per day, and placed in new or clean and disinfected trays.

3. Dirty, broken, cracked, leaking or dented eggs should be collected separately and should not be used as table eggs.

4. 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 kept clean and regularly sanitised.

5. Records of egg production should be kept to assist traceability and veterinary investigations.

6. If eggs are cleaned on the farm, this should be done in accordance with the requirements of the Competent Authority.

Article 3.10.2.7.

Surveillance of pullet and layer or laying flocks for *S.* Enteritidis and *S.* Typhimurium

Surveillance should be performed to identify infected flocks in order to take measures that will reduce transmission of *S.* Enteritidis and *S.* Typhimurium to humans and to reduce the prevalence in poultry. Microbiological testing is preferred to serological testing because of its higher sensitivity and specificity. In the framework of regulatory programmes for the control of *S.* Enteritidis and *S.* Typhimurium, confirmatory testing may be appropriate to ensure that decisions are soundly based.

Sampling

2. Time and frequency of testing

a) Pullet flock testing

i) 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.

ii) At the end of the first week of life when the status of breeding farm and hatchery is not known or does not comply with Chapter 2.10.2.

iii) One or more times during the growing period if there is a *culling* policy in place. The frequency would be determined on commercial considerations.

b) *Layer or laying flock* ~~Layer flock~~ testing

i) At expected *peak of lay* for each production cycle.

ii) 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) Empty building testing

Environmental sampling of the empty building after depopulation, cleaning and *disinfection*, following a *S*. Enteritidis and *S*. Typhimurium positive flock.

3. 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.

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

Recommendation is 5 pair of boot swabs or 10 drag swabs. These swabs may be pooled into no less than 2 samples. 5 Pair of boot swabs correspond to 300 faeces samples.

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 one positive sample given that infection is present in the population at a level of 5% or greater.

Annex XXXVI (contd)

Annex F (contd)

Table I

Number of birds in the flock	Number of 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

Table 2

Number of birds in the commercial flock	Number of faecal samples to be taken on each occasion	Number of drag swabs	Number of boot swabs
25-29	20	1	1
30-39	25	1	1
40-49	30	1	1
50-59	35	2	2
60-89	40	2	2
90-199	50	2	2
200-499	55	2	2
500 or more	60	2	2

Laboratory methods

Refer to the *Terrestrial Manual*.

Article 3.10.2.8.

Control measures

Salmonella control can be achieved by adopting the management practices mentioned above in combination with the following measures. No single measure used alone will achieve effective *S*. Enteritidis and *S*. Typhimurium control.

Currently available control measures are: vaccination, *competitive exclusion*, flock *culling* and product diversion to processing. Antimicrobials, *competitive exclusion* and live vaccination are used in elite flocks.

Antimicrobials should not be used ~~are not recommended~~ to control *S*. Enteritidis and *S*. Typhimurium in poultry producing eggs for human consumption because the effectiveness of the therapy is limited; it has the potential to produce residues in the eggs and can contribute to the development of antimicrobial resistance.

1. Vaccination

Many inactivated vaccines are used against *Salmonella* infections caused by different serovars in various poultry species, including a single or combined vaccine against *S*. Enteritidis and *S*. Typhimurium.

Live vaccines are also used in a number of countries to prevent *Salmonella* infections in poultry. It is important that field and vaccine strains can easily be differentiated in the laboratory. Vaccines produced according to the *Terrestrial Manual* should be used.

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

When the status of breeding farm and hatchery from which the *pullet flock* originates is not known or does not comply with Chapter 2.10.2., 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 directions of the *Veterinary Services*.

2. Competitive exclusion

Competitive exclusion can be used in day old chicks to reduce colonisation by *S*. Enteritidis and *S*. Typhimurium.

3. Culling

Depending on animal health and public health policies, culling is an option to manage infected flocks. If poultry are not culled, eggs should be sent for processing for inactivation of pathogens. Infected flocks should be destroyed or slaughtered and processed in a manner that minimises human exposure to pathogens.

Before restocking, the poultry house should be cleaned, disinfected and tested to verify that the cleaning has been effective (see above).

~~Farmers should be educated on how to handle *Salmonella* infected flocks in order to prevent spread to adjacent farms and human exposure.~~

Article 3.10.2.9.

Prevention of Salmonella spread

When a *layer or laying flock* or *pullet flock* is found infected with *S*. Enteritidis and *S*. Typhimurium, management procedures should be implemented.

Annex XXXVI (contd)

Annex F (contd)

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 farm, adjacent farms and from other farms under common management.

1. 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. Pest control measures should be observed stringently

3. Epidemiological investigations should be carried out to determine the origin of new infections as appropriate to the epidemiological situation.

4. Movement of *culled* poultry or layers at the end of the production cycle should only be allowed for slaughter or destruction.

5. Farmers should be educated on how to handle *Salmonella* infected flocks in order to prevent spread to adjacent farms and human exposure.

~~5~~6. Poultry litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the spread of infections with *S*. Enteritidis and *S*. Typhimurium. Particular care needs to be taken in regard to poultry litter/faeces used to fertilise plants intended for human consumption.

~~6~~7. 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~~8. Before restocking bacteriological examination should be carried out, if possible, to verify that the cleaning has been effective.

– text deleted

Annex XXXVI (contd)

Annex G

TERMS OF REFERENCE FOR THE

OIE *AD HOC* GROUP ON SALMONELLOSIS

(as amended by the Working Group on Animal Production Food Safety in November 2007)

1. Review Members' comments and Animal Production Food Safety Working Group's comments on the draft Guidelines on the detection, control and prevention of *Salmonella* Enteritidis and *S.* Typhimurium in poultry producing eggs for human consumption.

2. Review the Appendix of the OIE *Terrestrial Animal Health Code* on hygiene and disease security procedures in poultry breeding flocks and hatcheries to assure consistency between this text and the (draft) texts on *Salmonella* in laying hens and future texts on *Salmonella* in broilers.

3. Using up to date scientific information, draft a Chapter for the OIE *Terrestrial Animal Health Code* that addresses on farm methods for the detection, control and prevention of *Salmonella* spp. in broilers.

4. Take into account risk assessments carried out by the Joint FAO/WHO Meetings on Microbial Risk Assessment (JEMR) and other expert groups.

5. Take into account standards developed and under development by relevant international organisations, in particular the CAC, seeking complementarity.

6. Provide scientific justification and risk basis for all recommendations.

Annex XXXVI (contd)

Annex H

WORK PROGRAMME FOR 2008

The Working Group on Animal Production Food Safety (APFSWG) discussed issues that had been identified at its previous meeting and that still needed to be addressed at some stage. The following priorities for 2007/2008 were agreed:

1. Horizontal issues

   a) Animal identification and traceability (including animals and animal products derived from biotechnological interventions)

      – OIE *Terrestrial Animal Health Code* chapters - underway through the OIE *ad hoc* Group

      – Animal Identification and Traceability Conference 2009 – contribute to scientific programme

   b) Certification – Terrestrial Code Commission to update the current OIE model certificates – underway with Working Group to follow up

   c) Antimicrobial resistance – Working Group to monitor Codex (Task Force on Antimicrobial Resistance), FAO, WHO and OIE developments

   d) Alternative approaches in risk management of zoonoses – listing (*ad hoc* Group on disease notification) or alternative approaches (*ad hoc* Group on emerging zoonoses, tripartite FAO/OIE/WHO GLEWS mechanism)

   e) Good farming practices – *ad hoc* Group jointly with the FAO to advance the document including the use of veterinary drugs and animal feeding

      Subtopic: reduction of chemical hazards of public and animal health significance at the farm level

   f) Guidelines for animal feeding addressing the animal health issues and complementing the existing CAC international standards – underway through an OIE *ad hoc* Group

   g) Guidelines for aquatic animal feeding - underway through an OIE *ad hoc* Group reporting to the APFSWG and to the Terrestrial Code Commission.

   h) Biotechnology – animals and animal products derived from biotechnological interventions

   i) Monitoring developments on the use of the term 'risk based.'

2. Disease-specific OIE texts

   a) Chapters of the OIE *Terrestrial Animal Health Code* on brucellosis. A further *ad hoc* Group meeting is to be held in 2008.

   b) Foodborne zoonoses

      – salmonellosis in eggs for human consumption

      – salmonellosis in broilers

      – campylobacteriosis in broilers – on work programme for 2009 pending progress in Codex

      – cysticercosis.

Annex XXXVI (contd)

Annex H (contd)

3. Continue to strengthen relationship between OIE and Codex by:

a) Encouraging enhanced OIE input into Codex texts

b) Developing a method for the most effective utilisation of Codex expertise in the work of OIE *ad hoc* Groups.

Annex XXXVII

Original: English
January 2008

REPORT OF THE FIFTH MEETING OF THE OIE *AD HOC* GROUP ON IDENTIFICATION AND TRACEABILITY OF LIVE ANIMALS
Paris, 22–24 January 2008

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The OIE *ad hoc* Group on Identification and Traceability of Live Animals (hereafter referred as *ad hoc* Group) met at the OIE Headquarters from 22 to 24 January 2008.

The members of the *ad hoc* Group and other participants are listed at Appendix I. The Agenda adopted is given at Appendix II.

Dr Bernard Vallat, Director General of the OIE, welcomed the group members and thanked the entire group for its efforts in the very important topic of identification and traceability. He commented that identification and traceability are of paramount importance to the control of animal diseases and complement the OIE objective of improving animal health worldwide. An additional emphasis of the OIE in collaboration with Codex Alimentarius is food safety and the ultimate goal is to establish a continuum of standards and recommendations relating to identification and traceability from the animal to the point of food consumption.

Dr Vallat mentioned that it could be good to put further reference in the OIE text to the Codex text in order to link live animal traceability and food traceability. The Group agreed on the necessity for both Codex and the OIE to make appropriate cross references.

It is important for the OIE to encourage all countries to implement adequate systems for identification and traceability to meet their requirements according to individual circumstances. The demand from consumers to make personal choices in food selection is growing and animal identification and traceability enhances the ability to make these choices. Dr Vallat emphasized the importance of the group to the OIE and the OIE will consider very seriously the recommendations of this *ad hoc* Group for standards on animal identification and traceability in the OIE *Terrestrial Animal Health Code* (hereafter referred as *Terrestrial Code*).

Annex XXXVII (contd)

The *ad hoc* Group discussed the planned First International OIE Conference on Identification and Traceability to be held in Argentina in March 2009 and Dr Vallat responded that the conference is important to stimulate the implementation of animal identification and traceability systems worldwide and also to underline the cooperation with Codex Large private companies tend to implement standards that are often "zero risk" and are addressed to their clients in rich countries. These private standards are often difficult for developing countries to achieve and therefore hampering trade. The OIE seeks to create standards that are sufficiently generic to be applicable by all countries. The conference will create an opportunity for the exchange of knowledge on experiences and relevant technologies. The OIE uses the twinning concept to match established OIE reference laboratories to laboratories in developing countries. The idea might be extended to Collaborating Centres and perhaps a centre for identification and traceability might be feasible in the future. Dr Vallat also highlighted the possible use of the OIE PVS Tool for the evaluation of identification and traceability systems as part of the overall evaluation of performance of a country's veterinary service, if accepted by Members.

The Chair, Dr Luis Barcos, OIE Regional Representative for the Americas, said that the *ad hoc* Group should revise the draft guidelines taking into account the comments from Members and from the OIE Terrestrial Animal Health Standards Commission (hereafter referred as "Terrestrial Code Commission") and the Animal Production Food Safety Working Group (APFSWG). He also brought the groups attention to the importance of the planning for the Conference in 2009 as an avenue to communicate the spectrum of methods and implementation strategies available to support the introduction of identification and traceability systems.

The *ad hoc* Group reviewed the report from the 75th General Session, the reports from the Terrestrial Code Commissions and the report of the APFSWG. The *ad hoc* Group noted that the OIE Members requested that the guidelines not be prescriptive and to limit them to generic guidelines. Dr Thiermann, President of the Terrestrial Code Commission, explained that the proposed "Guidelines on the Design and Implementation of Identification Systems to Achieve Animal Traceability" will be an integral part of the *Terrestrial Code*. The *ad hoc* Group addressed the concern of the member from India that costs of programs and developing countries should be kept in mind while developing the guidelines. Members of the Group were in consensus that there are many different systems of identification and traceability and that as long as the chosen system accomplishes the desired objectives, it can be as simple or as complex as is desired by the implementing country. Members of the group acknowledged that some member countries are interested in more specific information about identification systems and how to accomplish the implementation of these new systems. Some relevant information is already available in "Traceability of animals and animal products - *Scientific and Technical Review*, Vol. 20 (2), August 2001" and "Identificación animal y trazabilidad [Animal identification and traceability]. Technical Item II. *In* Proc. 72nd OIE General Session, 23-28 May, Paris. Document 72 SG/10. World Organisation for Animal Health, Paris". The International Conference will be an excellent forum for the presentation for such information and the proceedings will be available to participants and others.

Dr Annamaria Bruno, Food Standards Officer of the Codex Alimentarius Secretariat, informed the *ad hoc* Group about discussions at the 16th Session of the Codex Committee on Food Import and Export Inspection and Certification (CCFICS). She recalled that the Delegation of Norway had prepared "Discussion Paper on the Need for Further Guidance on Traceability/Product tracing (CX-FICS07/16/7)". However, CCFICS felt that the discussion paper was too limited and agreed to revise the document. Therefore CCFICS has established an electronic working group and Dr Bruno extended an invitation to the OIE to join the electronic working group to ensure a continuum of information between Codex and the OIE.

The *ad hoc* Group reviewed and addressed the Members' comments on the draft Guidelines for Implementation and revised the guidelines accordingly (Appendix III). In Appendix III, amendments made at this meeting are shown with a coloured background to distinguish them from those made previously by the Terrestrial Code Commission.

The *ad hoc* Group first reviewed the definitions and recommended that the definition for transhumance be included in the General Definitions of the *Terrestrial Code* as it also appears in the chapter on Rinderpest Surveillance.

A Member commented that group identifier cannot be unique. The *ad hoc* Group discussed the comment and concluded that group identifiers are unique to a specific group of animals.

The *ad hoc* Group discussed the suggested addition of three additional sub headings under the section describing the design of an identification and traceability programme. The topics covered included commercial arrangements, transition planning and use of incentives. The *ad hoc* Group agreed that these items did not materially add to the text and in the case of transition planning duplicated information included in the section on preliminary studies. The group recommended to not to include these additional items.

The *ad hoc* Group recommended that clearer linkages should be established between "Guidelines on the Design and Implementation of Identification Systems to Achieve Animal Traceability" and the International Model Certificates described in Part 4 of the *Terrestrial Code*.

The Chair welcomed Dr Harpreet Kochhar as a representative from the OIE *ad hoc* Group on Biotechnology. Dr Kochhar presented information on the current status of identification and traceability as it applies to animals derived through advanced techniques such as cloning and genetic modification. The group recognised the importance of the issues surrounding biotech derived animals and the challenges that may be associated with individual identification of such animals. However, the general principles of identification and traceability are still relevant to all animals. Dr Kochhar and the members of the *ad hoc* Group agreed that there is a continued need for close collaboration between the two *ad hoc* Groups.

The *ad hoc* Group discussed the plans for the First OIE International Conference on Identification and Traceability. The objectives of the conference were reviewed and agreed upon by the group. The members of the *ad hoc* Group will compose the Scientific Committee chaired by Dr Kahn. Dr Vallat will chair the Steering committee. Dr Barcos will participate in all committees for coordination purposes.

The *ad hoc* Group concluded that the mandate given to this group has been accomplished. Future work of the OIE in this subject area may include evaluation and verification of the implementation of these guidelines. Also the group recognized that additional guidelines may need to be developed to address some specificities relevant to the issue of biotechnology derived animals.

…/ Appendices

Annex XXXVII (contd)

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON IDENTIFICATION AND TRACEABILITY OF LIVE ANIMALS

Paris, 22–24 January 2008

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List of participants

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON IDENTIFICATION AND TRACEABILITY OF LIVE ANIMALS

Paris, 22–24 January 2008

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Adopted agenda

1. Introduction

OIE update: the 75th General Session, activities of the OIE Terrestrial Animal Health Standards Commission and Animal Production and Food Safety Working Group.

Update on relevant work of the Codex Alimentarius Commission.

2. Draft guidelines for the design and implementation of animal traceability

Address comments of OIE Member Countries and Territories; Animal Production and Food Safety Working Group and Terrestrial Animal Health Standards Commission.

Prepare revised text for consideration by the OIE Terrestrial Animal Health Standards Commission in March 2008.

Consider the development of additional text for possible inclusion in the OIE *Terrestrial Animal Health Code* regarding the establishment of linkages between the identification and traceability of animals and their products at the primary processing level (e.g. the abattoir).

3. Discussion of draft program for OIE International Conference on Animal Identification and Traceability in collaboration with the Codex Alimentarius

4. Consider future work on Traceability for **Food Animals developed through biotechnology applications** (draft paper provided by OIE *ad hoc* Group on Biotechnology)

5. Conclusions

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Appendix III

DRAFT GUIDELINES ON THE DESIGN AND IMPLEMENTATION OF IDENTIFICATION SYSTEMS TO ACHIEVE ANIMAL TRACEABILITY

Article 1

Introduction and objectives

These guidelines are based on the general principles presented in Article 3.5.1.1. The Guidelines outline for Member Countries the basic elements that need to be taken into account in the design and implementation of an *animal identification system* to achieve *animal traceability*. Whatever *animal identification system* the country adopts, it should comply with relevant OIE standards, including Part 4 for animals and animal products intended for export. Each country should design a program in accordance with the scope and relevant performance criteria to ensure that the desired *animal traceability* outcomes can be achieved.

Article 2

Definitions

These following definitions apply for the purpose of this Appendix.

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

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

Reporting: means advising the *Veterinary ~~Administration~~ Authority* in accordance with the procedures listed in the programme.

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

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

Article 3

Key elements of the animal identification system

1. Desired outcomes

   Desired outcomes should be defined through consultation between the *Veterinary ~~Administration~~ Authority* and other parties, which should include (depending on scope) animal producers and food processors, private sector veterinarians, scientific research organisations and other government agencies. Desired outcomes may be defined in terms of any or all of the following:

   a) animal health (e.g. *disease* surveillance and notification; detection and control of *disease*; vaccination programmes);

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Appendix III (contd)

b) public health (e.g. surveillance and control of zoonotic diseases and food safety);

c) management of emergencies e.g. natural catastrophies or man-made events;

d) trade (support for inspection and certification activities of *Veterinary Services*, as described in Part 4 Model International Veterinary Certificates);

e) animal husbandry aspects (e.g. animal performance, genetic data).

2. Scope

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

3. Performance criteria

Performance criteria are also designed in consultation with other parties, as discussed above. The performance criteria depend on the desired outcomes and scope of the program. They are usually described in quantitative terms according to the epidemiology of the disease. For example, some countries consider it necessary to trace susceptible animals within 24-48 hours when dealing with highly contagious *diseases* such as FMD and avian influenza. For food safety, animal tracing to support investigation of incidents may also be urgent. For chronic animal *diseases* that are not a zoonosis, ~~such as bovine paratuberculosis~~ it may be considered appropriate that animals can be traced over a longer period ~~30 days~~.

4. Preliminary studies

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

a) animal populations, species, distribution, herd management,

b) farming and industry structures, production and location,

c) animal health,

d) public health,

e) trade issues,

f) animal husbandry,

~~f~~g) zoning and compartmentalisation,

~~g~~h) animal movement patterns (including transhumance),

~~h~~i) information management and communication,

~~i~~j) availability of resources (human and financial),

~~j~~k) social and cultural aspects,

~~k~~l) stakeholder knowledge of the issues and expectations,

~~l~~m) gaps between current enabling legislation and what is needed long term,

~~m~~n) international experience,

~~n~~o) national experience,

~~o~~p) available technology options,

q) existing identification system(s),

r) expected b~~B~~enefits from the *animal identification systems* and *animal traceability* ~~scheme~~ and to whom they accrue.

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

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

5. Design of the programme

a) General provisions

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

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

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

b) Means of animal identification

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

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

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

i) the time period within which an animal born on an *establishment* should be identified;

ii) when a~~A~~nimals are ~~imported~~ introduced into an *establishment*;

iii) when an animal loses its identification or the identifier becomes unusable;

iv) arrangements and rules for the destruction and/or reuse of identifiers.

Where group identification without a physical identifier is adequate, documentation should be created specifying at least the number of animals in the group, the species, the date of identification, the person legally responsible for the animals and/or establishment. This documentation constitutes a unique group identifier.

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

c) Registration

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

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

i) Establishments/owners or responsible keeper

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

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

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

ii) Animals

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

iii) Movements

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

Some countries classify birth, *slaughter* and *death* of the animal as movements.

The information registered should include the date of the movement, the *establishment* from which the animal or group of animals was dispatched, the number of animals moved, the destination *establishment*, and any *establishment* used in transit ~~*establishment*~~.

When *establishments* are not registered as part of the *animal identification system*, ownership and location changes constitute a movement record. Movement recording may also include means of *transport* and the *vehicle* identifier.

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

iv) Events other than movements

The following events may also be *registered*:

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

d) Documentation

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

e) Reporting

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

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Appendix III (contd)

f) Information system

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

- have the potential for linkage to traceability in the other parts of the food chain;
- minimise duplication;
- relevant components, including databases, should be compatible;
- confidentiality of data ;
- appropriate safeguards to avoid loss of data, including backup systems.

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

g) Laboratories

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

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

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

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

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

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

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

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

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

i) Penalties

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

~~j) Commercial arrangements~~

~~An animal identification system requires producers, processors and others (depending on the design of the system) to purchase equipment. There are many possible commercial arrangements that will have a variety of implications for the uptake of the animal identification system.~~

~~k) Transition planning~~

~~Any transition from an existing animal identification system needs to be designed to ensure it is easy for users of the existing system to make the change and to insure that data integrity is maintained during the transition and integrated into the new animal identification system.~~

~~l) Use of incentives~~

~~Depending on the drivers for participation in the animal identification scheme, incentives may be useful to encourage early adoption of the system or to fill capability, capacity or technology gaps.~~

6. Legal framework

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

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

This legal framework should address:

i) desired outcomes and scope;

ii) obligations of the *Veterinary ~~Administration~~ Authority* and other parties;

iii) organisational arrangements, including the choice of technologies and methods used for the *animal identification system* and *animal traceability*;

iv) management of animal movement;

v) confidentiality of data;

vi) data access / accessibility;

vii) checking, verification, inspection and penalties;

viii) where relevant, funding mechanisms;

ix) where relevant, arrangements to support a pilot project.

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7. Implementation

a) Action plan

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

The following activities should be addressed in the action plan:

i) Communication

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

Communication strategies need to be targeted to the audience, taking into account elements such as the level of literacy (including technology literacy) and spoken languages.

ii) Training programmes

It is desirable to implement training programmes to assist the *Veterinary Services* and other parties.

iii) Technical support

Technical support should be provided to address practical problems.

b) Checking and verification

Checking activities should start at the beginning of the implementation to detect, prevent and correct errors and to provide feedback on programme design.

Verification should begin after a preliminary period as determined by the *Veterinary ~~Administration~~ Authority* in order to determine compliance with the legal framework and operational requirements.

c) Auditing

Auditing should be carried out under the authority of the *Veterinary ~~Administration~~ Authority* to detect any problems with the *animal identification system* and *animal traceability* and to identify possible improvements.

d) Review

The programme should be subject to periodic review, taking into account the results of checking, verification and auditing activities.

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Annex XXXVIII

Original: English
January 2008

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE REVISION OF THE OIE MODEL CERTIFICATES

Paris, 28–30 January 2008

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The OIE *ad hoc* Group on the Revision of the OIE Model Certificates (hereinafter referred to as the *ad hoc* Group) met at the OIE Headquarters from 28 to 30 January 2008.

The members of the *ad hoc* Group and other participants are listed at Appendix I. The Agenda adopted is given at Appendix II.

On behalf of the Director General of the OIE, Dr Sarah Kahn, Head of the International Trade Department, welcomed all members and thanked them for their work on this very important topic. She emphasized the importance of these model certificates in the facilitation of international trade amongst OIE Members. She called the group's attention to the comments from Members, the Terrestrial Animal Health Standards Commission (hereinafter referred to as the Code Commission), and the Animal Production Food Safety Working Group (APFSWG). She encouraged the group to carefully review these comments and create a revised text for the Code Commission to review in March and submit to the General Session for adoption this May.

Dr Kahn recalled the mandate of the OIE in animal production food safety and the need for continued good cooperation between the OIE and the Codex Alimentarius Commission (CAC) to address food safety issues related to the on-farm stage of food production. She mentioned that the revision of the certification principles by the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) should be considered by this *ad hoc* Group while revising the OIE model certificates. On this point she said that there were several similarities between the OIE and the CAC approach to certification for international trade. However, there may be some valid differences in relation to the different nature of the products (i.e. live animals/genetic material or transformed food products) that need to be addressed by the two organisations and that the certificates need to reflect these differences.

Dr Valder then took over as Chair of the meeting and presented the draft agenda and terms of reference (Appendix III). He acknowledged the importance of the work of the *ad hoc* Group and the need to consider the work presently being done by other international organisations (notably the CAC) and the comments from Members, the Code Commission and APFSWGas well as 75th General Session.

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Dr Tom Heilandt, Senior Food Standards Officer, CAC Secretariat, updated the group on work done by the CAC.

The 30th Session of the CAC in July 2007 adopted the revised *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001) which could now be taken into account in the work of the *ad hoc* Group.

The 16th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems in November 2007 following a proposal by the European Community agreed to start new work on a generic model health certificate as an annex to CAC/GL 38-2001. The relevant project document will be forwarded for approval to the 61st Session of the Executive Committee of the Codex Alimentarius Commission (CCEXEC) and the 31st Session of the CAC.

A physical working group (Brussels, 8-9 July 2008) will develop proposed draft guidelines for discussion at the 17th Session of the CCFICS in November 2008. Taking into account the standards development process of the CAC, this work could be adopted earliest by the 32nd Session of the Commission in 2009 (assuming that the frequencies of the meetings do not change). While developing the model certificate the working group and the CCFICS will take into account work already done in other international organizations such as UN/CEFACT and the OIE which should result in a harmonized layout.

The 16th Session of the CCFICS also sent comments to the Codex Committee on Milk and Milk Products (CCMMP) on the draft certificate developed by that committee. After finalization of the model certificate under development in the CCFICS the milk certificate and the already adopted certificate for fishery products may have to be reviewed.

The *ad hoc* Group recommends the OIE should participate in the forthcoming CAC working group in July 2008.

The *ad hoc* Group reviewed the report from the 75th General Session, the reports from the Code Commission and the report of the APFSWG. The *ad hoc* Group reviewed and addressed the comments from Australia, European Union, Japan, New Zealand, Switzerland and an OIE expert on the Model Veterinary Certificates and adjusted the text accordingly (Appendix IV).

In Appendix IV amendments made at this meeting are shown with a coloured background to distinguish them from those made previously by the Code Commission.

The group reviewed the certificates presently in the Terrestrial Animal Health Code (the *Code*) and agreed that the four Model Veterinary Certificates developed should replace the certificates currently in the *Code* except for the Dog and Cat Model Veterinary Certificate and the Competition Horse Passport which should remain unchanged in the *Code*.

The *ad hoc* Group discussed the Member comment to revise the last sentence of the last paragraph in Article 1.2.1.2. They concluded that the standardization of the use of *Veterinary Authority* clarifies the sentence and the suggested revision is not necessary.

The *ad hoc* Group discussed the Member comment regarding Article 1.2.1.3 and the addition of "and *Veterinary Authority*" after *Veterinary Services*. *Veterinary Services* is defined in the general definitions section of the *Code*. Therefore, in order to maintain harmonisation with the rest of the *Code Veterinary Services* should be left as is.

The *ad hoc* Group discussed the Member comments that suggest an emphasis should be placed on the adoption of a standardized format for the Model Veterinary Certificates. There was concern expressed by other Members that the format of the certificate should not be restrictive and the emphasis should be placed on the content of certificate instead. The group thoroughly discussed these comments and reached the conclusion that the certificates are intended to be models and the OIE is hopeful that the use of these certificates will facilitate the exchange of information as required. The conclusion of the group was not to include any stronger language in the current text to ensure that the use of certificates in a different layout will not become a blockage to trade.

The *ad hoc* Group found the Member comment concerning situations which may arise after the issuance of the certificate resulting in changes to some of the information in the certificate very insightful. The group reviewed this comment and determined that there were a few instances (consignee, identification of means of transport, and border post) on the certificate where information might change after the issuance of the certificate, without a resulting change in the animal or public health status of the consignment. The *ad hoc* Group recommended the addition of a fifth paragraph in Article 1.2.1.2. under General Obligations, Responsibilities of Importing Countries. Hopefully this text will prevent shipments being blocked at the port of entry due to changes in circumstances arising after the certificate was issued.

The *ad hoc* Group considered the Member comment that the option "Other" should be deleted from Box I.23 on the Model Veterinary Certificate for Products of Animals Origin. The group concluded that "Other" should remain as an option because it can be used in situations of limited import, such as samples.

The *ad hoc* Group discussed the Member comment that in general animal feed may contain both animal and plant matter. It was noted that these certificates are intended for products of animal origin only and therefore the definition of animal feed as outlined in the notes is sufficient.

The *ad hoc* Group considered the recommendation from the APFSWG to change the order of the articles in Chapter 1.2.2. In response to this comment the group moved the original Article 1.2.2.2. to become the new Article 1.2.2.3. and the original Article 1.2.2.3. to become the new Article 1.2.2.2.

The *ad hoc* Group, to ensure harmonisation with the Codex *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001), reviewed and compared items present in the Codex texts and in the *Code*. As the *Code* does not provide for replacement certificates in the event of loss or damage to the original certificate, a new point eight, based on the Codex text, was added to original Article 1.2.2.2. (new Article 1.2.2.3.) outlining measures to take to issue replacement certificates.

The *ad hoc* Group discussed the use of technology and electronic certification as a means to improve the security of safe international trade in live animals and animal products. The group reviewed the current text in Article 1.2.2.4 and found it to be sufficient for the current world situation. However the group recognized that electronic certification will become an increasingly important area for continued review and potential future expansion. Currently electronic certification is in limited use or in the trial phase between few developed countries. It is important that these countries are encouraged to share the lessons learned from the testing and use of electronic certification. These systems should also be continuously evaluated for potential increases in efficiency or effectiveness. The OIE should take into account the status of infrastructure and capabilities in developing countries when drafting standards for electronic certification. The OIE should continue to actively support worldwide efforts at capacity building in these countries. Another important issue associated with electronic certification that was highlighted in the Codex text was the need to include a contingency plan to ensure minimal disruption to trade in the event of a system failure. This is an important issue to address in the drafting of any additional text. In summary, the recommendation of this group is to wait for conclusions from the current phase of testing and use of electronic certification before developing further guidance on this subject.

.../Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON THE REVISION OF THE OIE MODEL CERTIFICATES

Paris, 28–30 January 2008

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON THE REVISION OF THE OIE MODEL CERTIFICATES

Paris, 28–30 January 2008

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Adopted agenda

Welcome from the Director General

Adoption of the agenda

1. Report of the *ad hoc* group on the revision of OIE model certificates, January 2007

2. Terms of Reference

3. Update on the activities of OIE/CAC

3.1. Update on relevant OIE activities

3.2. Relevant work in the Codex Alimentarius Commission

Report of the 16th session of the Codex Committee on Food Import and Export Inspection and Certification

Discussion Paper on the Development of a Generic Template for Health Certificates (prepared by the European Community)

Guidelines for Design, Production, Issuance and use of Generic Official Certificates (CAC/GL 38-2001)

4. Model veterinary certificates

4.1. Consider Members' comments, those made by an OIE expert, recommendations of the Terrestrial Animal Health Standards Commission (Code Commission) (September 2007 meeting) and the Animal Production Food Safety Working Group (November 2007 meeting) and prepare a revised text for consideration by the Code Commission (March 2008 meeting).

5. Other issues

5.1. The use of electronic certification systems

5.2. Steps the OIE could take with the objective of helping to prevent fraudulent certification in international trade

Annex XXXVIII (contd)

Appendix III

MEETING OF THE OIE *AD HOC* GROUP ON THE REVISION OF THE OIE MODEL CERTIFICATES

Paris, 28–30 January 2008

TERMS OF REFERENCE

1. Consider Members' comments and those made by an OIE expert and prepare a revised text for consideration by the Terrestrial Animal Health Standards Commission (the Code Commission).

2. Address Code Commission's recommendations (see report of September 2007 meeting).

3. Address the recommendations of the Animal Production Food Safety Working Group (see report of November 2007 meeting).

4. If time allows, develop recommendations on

   a) the use of electronic certification systems, and

   b) steps the OIE could take with the objective of helping to prevent fraudulent certification in international trade.

CHAPTER 1.2.1.

GENERAL OBLIGATIONS

Article 1.2.1.1.

Safety of ~~I~~*international trade* in *animals* and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade, without incurring unacceptable risks to human and animal health.

Because of differences between countries in their ~~the likely variations in~~ animal health situations, various options are offered by the *Terrestrial Code*. The animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements ~~which have to be met~~ for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Veterinary Authorities* of Members ~~Countries~~ should base their import requirements on the OIE standards~~,~~ and guidelines ~~and recommendations~~.

These requirements should be included in the model certificates approved by the OIE which ~~form~~ are included in Part 4 of the *Terrestrial Code*.

Certification requirements should be exact and concise, and should clearly convey the wishes of the *importing country*. For this purpose, prior consultation between *Veterinary Authorities* of *importing* and *exporting countries* ~~is useful and~~ may be necessary. It enables the setting out of the exact requirements so that the signing *veterinarian* can, if necessary, be given a note of guidance explaining the understanding between the *Veterinary Authorities* involved.

When ~~Members~~ officials of a *Veterinary Authority* wish to visit another country for matters of professional interest to the *Veterinary Authority* of the other country, the latter should be informed.

Article 1.2.1.2.

Responsibilities of the importing country

1. The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the national level of protection ~~that it has~~ chosen for animal and human health. *Importing countries* should restrict their requirements to those justified for such level of protection. If these are stricter than the OIE standards, they should be based on an import *risk analysis*.

2. The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal *diseases* which are present ~~within the territory of~~ in the *importing country* and are not subject to any *official control programme*. ~~The requirements applying to pathogens or *diseases* subject to *official control programmes* in a country or *zone* should not provide a higher level of protection on imports than that provided for the same pathogens or *diseases* by the measures applied within that country or *zone*.~~ The measures imposed on imports to manage the *risks* posed by a specific pathogen or *disease* should not require a higher level of protection than that provided by measures applied as part of the *official control programme* operating within the *importing country*.

Annex XXXVIII (contd)

Appendix IV (contd)

3. The *international veterinary certificate* should not include ~~requirements for disease agents~~ measures against pathogens or *diseases* which are not OIE listed, unless the *importing country* has ~~identified the disease agent as presenting a significant risk for that country, after conducting a scientifically based import risk analysis according o the guidelines in Section 1.3~~ demonstrated through import *risk analysis*, carried out in accordance with Section 1.3., that the pathogen or *disease* poses a significant *risk* to the *importing country*.

4. The transmission by the *Veterinary Authority* of certificates or the communication of import requirements to persons other than the *Veterinary Authority* of another country, necessitates that copies of these documents are also sent to the *Veterinary Authority*. This important procedure avoids delays and difficulties which may arise between traders and *Veterinary Authorities* when the authenticity of the certificates or permits is not established.

   This information is ~~usually~~ the responsibility of *Veterinary Authorities*. However, it can be issued by private sector *veterinarians* at the place of origin of the ~~*animals*~~ *commodities* when this practice is the subject of appropriate approval and authentication by the *Veterinary Authority*.

5. Situations may arise which result in changes to the consignee, identification of the means of transportation, or border post after a certificate is issued. Because these do not change the animal or public health status of the consignment, they should not prevent the acceptance of the certificate.

Article 1.2.1.3.

Responsibilities of the exporting country

1. An *exporting country* should, on request, ~~be prepared to~~ supply the following ~~information~~ to *importing countries* ~~on request~~:

   a) information on the animal health situation and national animal health information systems to determine whether that country is free or has *free zones* of *listed diseases*, including the regulations and procedures in force to maintain its free status;

   b) regular and prompt information on the occurrence of ~~transmissible~~ notifiable *diseases*;

   c) details of the country's ability to apply measures to control and prevent the relevant *listed diseases*;

   d) information on the structure of the *Veterinary Services* and the authority which they exercise;

   ~~e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.~~

2. *Veterinary Authorities* of *exporting countries* should:

   a) have official procedures for authorisation of certifying *veterinarians*, defining their functions and duties as well as conditions covering possible suspension and termination of the appointment;

   b) ensure that the relevant instructions and training are provided to certifying *veterinarians*;

   c) monitor the activities of the certifying *veterinarians* to verify their integrity and impartiality.

3. The Head of the *Veterinary Service* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

Article 1.2.1.4.

Responsibilities in case of an incident ~~occurring after~~ related to importation

1. *International trade* involves a continuing ethical responsibility. Therefore, if within the recognised *incubation periods* of the various *diseases* subsequent to an export taking place, the *Veterinary Authority* becomes aware of the appearance or reappearance of a *disease* which has been specifically included in the *international veterinary certificate*, there is an obligation for the Administration to notify the *importing country*, so that the imported stock may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.

2. Equally, if a *disease* condition appears in imported stock within a time period after importation consistent with the recognised *incubation period* of the *disease*, the *Veterinary Authority* of the *exporting country* should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the *disease* in a previously free herd. The *Veterinary Authority* of the *importing country* should be informed of the result of the investigation since the source of *infection* may not be in the *exporting country*.

3. In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the *Veterinary Authority* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The *Veterinary Authorities* of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

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Annex XXXVIII (contd)

Appendix IV

CHAPTER 1.2.2.

CERTIFICATION PROCEDURE

Article 1.2.2.1.

Protection of the professional integrity of the certifying veterinarian

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the certifying veterinarian must be respected and safeguarded.

It is essential not to include in the requirements additional specific matters which cannot be accurately and honestly signed by a veterinarian. For example, these requirements should not include certification of an area as being free from non-notifiable diseases the occurrence of which the signing veterinarian is not necessarily informed about. Equally, to ask certification for events which will take place after the document is signed is unacceptable when these events are not under the direct control and supervision of the signing veterinarian.

Certification of freedom from diseases based on purely clinical freedom and herd history is of limited value. This is also true of diseases for which there is no specific diagnostic test, or the value of the test as a diagnostic aid is limited.

The note of guidance referred to in Article 1.2.1.1. is not only to inform the signing veterinarian but also to safeguard professional integrity.

Article 1.2.2.2.

Certifying veterinarians

Certifying veterinarians should:

1. be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;

2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;

3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying veterinarian should be in possession of that documentation before signing;

4. have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.

Article 1.2.2.3.

Preparation of international veterinary certificates

Certificates should be drawn up in accordance with the following principles:

Annex XXXVIII (contd)

Appendix IV (contd)

1. Certificates should be designed so as to minimize the potential for fraud including use of a unique identification number, or other appropriate means to ensure security.Paper certificates should ~~be pre-printed, if possible on one sheet of paper, serially numbered, and issued by the Veterinary Authority on officially headed notepaper and, if possible, printed using techniques which prevent forgery.~~ bear the official identifier of the issuing *Veterinary Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.

2. They should be written in terms that are as simple, unambiguous and easy to understand as possible, without losing their legal meaning.

3. If so required, they should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the certifying veterinarian.

4. They should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).

5. They should not require a veterinarian to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.

6. Where appropriate, they should be accompanied, when presented to the certifying veterinarian, by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.

7. Their text should not be amended except by deletions which must be signed and stamped by the certifying veterinarian. The signature and stamp must be in a colour different to that of the printing of the certificate.

8. Replacement certificates may be issued by a *Veterinary Authority* to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These must be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.

~~8~~9. Only original certificates are acceptable.

~~Article 1.2.2.3.~~

~~**Certifying veterinarians**~~

~~Certifying veterinarians should:~~

~~1. be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;~~

~~2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;~~

~~3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying veterinarian should be in possession of that documentation before signing;~~

~~4. have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.~~

Article 1.2.2.4.

Electronic certification

1. Certification may be provided by electronic documentation sent directly from the *Veterinary Authority* of the *exporting country* to the *Veterinary Authority* of the *importing country*. Such systems also normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The certifying veterinarian must have access to all information such as laboratory results and animal identification data.

2. Electronic certificates should carry the same information as conventional certificates.

3. The *Veterinary Authority* must have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.

4. The certifying veterinarian must be officially responsible for the secure use of his/her electronic signature.

- text deleted

Annex XXXVIII (contd)

Appendix IV (contd)

Model Veterinary Certificate for International Trade in Live Animals and Hatching Eggs

COUNTRY:

Part I: Details of dispatched consignment

I.1. Consignor
Name

Address

I.2. Certificate reference number

~~I.3. Veterinary Administration~~

I.~~4~~3. Veterinary Authority

I.~~5~~4. Consignee
Name

Address

I.~~6~~5. Country of origin | ISO code~~*~~ | I.~~7~~6. Zone or compartment of origin~~**~~

I.~~8~~7. Country of destination | ISO code* | I.~~9~~8. Zone or compartment of destination~~**~~

I.~~10~~9. Place of origin

Name

Address

I.~~11~~10. Place of shipment
~~Address~~

I.~~12~~11. Date of departure

I.~~13~~12. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:

I.~~14~~13. Expected border post

I.~~15~~14. CITES permit No(s). ~~**~~

I.~~16~~15. Description of commodity

I.~~17~~16. Commodity code (HS code)

I.~~18~~17. Total qQuantity

I.~~19~~18.

I.~~20~~19. Total nNumber of packages

I.~~21~~20. Identification of container/seal number

I.~~22~~21.

I.~~23~~22. Commodities intended for use as:
Breeding/rearing Competition Slaughter Game restocking
Pets Circus/exhibition Other

I.~~24~~23. For import or admission
Definitive import Re-entry Temporary admission

I.~~25~~24. Identification of the commodities

~~Species (Scientific name)~~ ~~Breed / Category~~ ~~Identification system~~ ~~Identification number/details~~
~~Age~~ ~~Sex~~ ~~Quantity~~

Species (Scientific name)	Breed* / Category*	Identification system	Identification number/details	Age*	Sex*	Quantity

~~*: optional~~
~~**: if referenced in Part II~~

Annex XXXVIII (contd)

Appendix IV (contd)

COUNTRY:

Part II: Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the animal(s)/hatching eggs described above satisfy(ies) the following requirements:

Official Veterinarian

Name and address (in capital letters):

~~Qualification and title~~ Official position

Date:

Signature:

Stamp

Annex XXXVIII (contd)

Appendix IV (contd)

Model Veterinary Certificate for International Trade in Embryos, Ova and Semen

COUNTRY:

Part I: Details of dispatched consignment

I.1. Consignor
Name

Address

I.2. Certificate reference number

~~I.3. Veterinary Administration~~

I.~~3~~4. Veterinary Authority

I.~~4~~5. Consignee
Name

Address

I.~~5~~6. Country of origin ISO code* I.~~6~~7. Zone or compartment of origin**

I.~~7~~8. Country of destination ISO code* I.~~8~~9. Zone or compartment of destination**

I.~~9~~10. Place of origin

Name

Address

I.~~10~~11. Place of shipment
~~Address~~

I.~~11~~12. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification: ☐

I.~~12~~13. Expected border post

I.~~13~~14. CITES permit No(s).**

I.~~14~~15. Description of commodity

I.~~15~~16. Commodity code (HS code)

I.~~16~~17. Total qQuantity

I.~~17~~18.

I.~~18~~19. Total nNumber of packages

I.~~19~~20. Identification of container/seal number

I.~~20~~21.

I.~~21~~22. Commodities intended for use as:
Artificial reproduction ☐ Other ☐

I.~~22~~23.

I.~~23~~24. Identification of the commodities

~~Species (Scientific name)~~ ~~Breed /Category~~ ~~Donor identity~~ ~~Date of collection~~

~~Approval number of the centre/team~~ ~~Identification mark~~ ~~Quantity~~

Species (Scientific name)	Breed*	Donor identity	Date of collection	Approval number of the centre/team	Identification mark	Quantity

*: optional
**: if referenced in Part II

Annex XXXVIII (contd)

Appendix IV (contd)

COUNTRY:

Part II: Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the embryos/ova/semen described above satisfy(ies) the following requirements:

Official Veterinarian

Name and address (in capital letters):

~~Qualification and title~~ Official position

Date:

Signature:

Stamp

Annex XXXVIII (contd)

Appendix IV (contd)

Model Veterinary Certificate for International Trade in Products of Animal Origin

COUNTRY:

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address

I.2. Certificate reference number

~~I.3. Veterinary Administration~~

I.43. Veterinary Authority

I.54. Consignee
Name
Address

I.65. Country of origin ISO code* I.76. Zone or compartment of origin**

I.87. Country of destination ISO code* I.98. Zone or compartment of destination**

I.109. Place of origin
Name
Address

I.1110. Place of shipment
~~Address~~

I.1211. Date of departure

I.1312. Means of transport
Aeroplane Ship Railway wagon
Road vehicle Other
Identification:

I.1413. Expected border post

I.1514. CITES permit No(s).**

I.1615. Description of commodity

I.1716. Commodity code (HS code)

I.1817. Total qQuantity

I.1918. Temperature of product
Ambient Chilled Frozen

I.2019. Total nNumber of package

I.2120. Identification of container/se number

I.2221.Type of packaging

I.2322. Commodities intended for use as:
Human consumption Animal feed Further processing Technical use
Other

I.2423.

I.2524. Identification of the commodities

~~Species (Scientific name)~~ ~~Nature of commodity~~ ~~Treatment type~~

~~Approval number of establishments~~
~~Abattoir~~ ~~Cutting plant/~~ ~~Processing plant~~ ~~Cold store/~~

~~Number of packages~~ ~~Net weight~~ ~~Lot identification/date code~~

~~Species (Scientific name)~~	~~Nature of commodity~~	~~Treatment type~~	~~Approval number of establishments~~	~~Number of packages~~	~~Net weight~~	~~Lot ID/date code~~

~~*: optional~~
~~**: if referenced in Part II~~

Annex XXXVIII (contd)

Appendix IV (contd)

COUNTRY:

Part II: Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the product(s) of animal origin described above satisfy(ies) the following requirements:

Official Veterinarian

Name and address (in capital letters):

~~Qualification and title~~ Official position

Date:

Signature:

Stamp

Annex XXXVIII (contd)

Appendix IV (contd)

Model Veterinary Certificate for International Trade in Bees and Brood Combs

COUNTRY:

Part I: Details of dispatched consignment

I.1. Consignor
Name

Address

I.2. Certificate reference number

~~I.3. Veterinary Administration~~

I.43. Veterinary Authority

I.54. Consignee
Name

Address

I.65. Country of origin | ISO code* | I.76. Zone ~~or compartment~~ of origin**

I.87. Country of destination | ISO code* | I.98. Zone ~~or compartment~~ of destination**

I.109. Place of origin

Name

Address

I.1110. Place of shipment
~~Address~~

I.1211. Date of departure

I.1312. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:

I.1413. Expected border post

I.1514. CITES permit No(s).**

I.1615. Description of commodity

I.1716. Commodity code (HS code)

I.1817. Total qQuantity

I.1918.

I.2019. Total nNumber of packages

I.2120. Identification of container/seal number

I.2221.

I.2322. Commodities intended for use as:
Breeding/rearing ☐ Other ☐

I.2423.

I.2524. Identification of the commodities

Category	Breed* / Variety*	Quantity	Identification details

*: optional
**: if referenced in Part II

Annex XXXVIII (contd)

Appendix IV (contd)

COUNTRY:

Part II: Zoosanitary information

II.a. Certificate reference number

II. The undersigned Official Veterinarian certifies that the bees/brood comb(s) described above satisfy(ies) the following requirements:

Official Veterinarian

Name and address (in capital letters):

~~Qualification and title~~ Official position

Date:

Signature:

Stamp

APPENDIX X.X.X

NOTES FOR GUIDANCE ON THE VETERINARY CERTIFICATES FOR INTERNATIONAL TRADE IN LIVE ANIMALS, HATCHING EGGS AND PRODUCTS OF ANIMAL ORIGIN

General: Please complete the certificate in capitals. To confirm an option, mark the box with a cross (X). Ensure that no portion of certificate is left blank in a manner that would allow it to be amended. Non-applicable fields may be crossed out.

PART I. DETAILS OF DISPATCHED CONSIGNMENT

Country: Name of the country that issues the certificate.

Box I.1. Name and full address of the natural or legal person dispatching the consignment. Information on telephone and fax numbers or e-mail address is recommended.

Box I.2. The certificate reference number is the number used by the Veterinary Authority of the country to identify the certificate.

~~Box I.3.~~ ~~Name of the *Veterinary Administration*.~~

Box I.~~4~~3. Name of the *Veterinary Authority*.

Box I.~~5~~4. Name and full address of the natural or legal person to whom the consignment is destined at the time the certificate is issued.

Box I.~~6~~5. Name of the country from which the *animals*, *hatching eggs*, embryos, semen, ova or brood combs are being exported. For products, name the country(ies) where the finished products were produced, manufactured or packed.

"ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.

Box I.~~7~~6. Name of the zone or compartment of origin, if relevant, in part II of the certificate.

Box I.~~8~~7. Name of the country of destination.

"ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.

Box I.~~9~~8. Name of the zone or compartment of destination, if relevant, in part II of the certificate.

Box I.~~10~~9. Name and full address of the place(s) from which the *animals* or products are being exported; and official approval or registration number when required.

Annex XXXVIII (contd)

Appendix IV (contd)

For *animals* and *hatching eggs*: the *establishment(s)*, wildlife or hunting reserves.

For semen: the *artificial insemination centre.*

For embryos and ova: the name, address and official approval number of the collection team (not the premises of storage).

For products of animal origin: the premises from which the products are to be dispatched.

Box I.~~11~~10. Name ~~and full address~~ of the place from which the *animals* or products are being shipped (this will be a land, sea or airport).

Box I.~~12~~11. Date of departure. For *animals* include the expected time of departure.

Box I.~~13~~12. Details of the means of transport.

Identification of the means of transport at the time the certificate is issued: for air transport, the flight number; for maritime transport, the name of the vessel; for rail transport, the number of the train and the wagon and for road transport, the registration number of the road vehicle and the number of the trailer where used.

Box I.~~14~~13. Name of expected *border post* and, if available, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).

Box I.~~15~~14. CITES permit number(s) if the *commodity* concerns species listed in Convention on International Trade in Endangered Species of Wild Fauna and Flora ~~the Washington Convention~~.

Box I.~~16~~15. Describe the *commodity* or use the titles as they appear in the Harmonised System of the World Customs Organization.

Box I.~~17~~16. Heading or HS Code of the Harmonized System set up by the World Customs Organization.

Box I.~~18~~17. Total q~~Q~~uantity of the *commodity*.

For *animals*, *hatching eggs* and animal products (semen, ova, embryos) give the total count of *animals*, eggs or straws.

For products give the gross weight and the net weight in kg of the whole consignment.

Box I.~~19~~18. Temperature of products for transport and storage.

Box I.~~20~~19. Total n~~N~~umber of boxes, cages or stalls in which the *animals* or *hatching eggs* are being transported. Total n~~N~~umber of cryogenic containers for semen, ova, embryos. Total n~~N~~umber of packages for products.

Box I.~~21~~20. Identify the containers/seal numbers where required.

Box I.~~22~~21. Identify the type of packaging of products as defined in Recommendation No. 21 – Code of Passengers, Type of Cargo, Package and Packaging Materials of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business) ~~(e.g. cans, boxes)~~.

Box I.~~23~~22. Intended use of the imported *animals* or products.

Breeding/rearing: applies to *animal for breeding or rearing* and *hatching eggs*.

Slaughter: applies to *animal for slaughter*.

Game restocking: applies to game for the purpose of rebuilding stocks.

Pet: applies to *animals* kept for companionship or enjoyment. This excludes livestock species.

Circus/exhibition: applies to *animals* used in a circus, show or exhibition.

Human consumption: applies to products intended for human consumption.

Animal feed: means any product of animal origin (single or multiple), whether processed, semi-processed or raw, which is intended to be fed to *animals*.

Further processing: applies to products of animal origin which have to be further processed before being suitable for end use.

Technical use: applies to products not intended for human or animal consumption. These include animal products that are intended for use in the pharmaceutical, medical, cosmetic and other industries. Such products may be subjected to extensive further processing.

Other: intended for purposes not listed elsewhere in this classification.

Box I.~~24~~23. Mark, if appropriate.

Box I.~~25~~24. Details on the nature of the *commodity* sufficient to identify it.

For *animals* and *hatching eggs*: Species (scientific name); ~~Breed/Category;~~ Identification system; Identification number or other identification details; ~~Age; Sex;~~ Quantity and if required, Breed / Category (e.g. heifer, steer, layer, broiler); Age; Sex. For animals holding an official passport, the international animal passport number should be provided, and a copy of the details on the passport attached to the certificate.

For embryos, ova and semen: Species (Scientific name); ~~Breed/Category;~~ Identification mark according to the International Embryo Transfer Society (IETS) or the International Committee for Animal Recording (ICAR); Collection date; Approval number of the centre/team; Identification of the donor animal; Quantity. If required, Breed.

Annex XXXVIII (contd)

Appendix IV (contd)

For bees and brood combs: Category means hive with bees, swarm, consignment of bees (worker bees, drones), queen bees, brood-combs, royal cells, etc. Identification details include peculiarities (e.g. Marks or age or weight or surface). Breed / Variety if required.

For products of animal origin: Species (Scientific name); Nature of commodity; Treatment type; approval number of establishment(s) (~~e.g. dairy farm,~~ abattoir; cutting plant; processing plant; cold store); Lot identification/date code; Quantity; Number of packages; Net weight.

PART II. ZOOSANITARY INFORMATION

Box II. Complete this part in accordance with the requirements agreed between the *Veterinary ~~Administrations~~ Authorities* of the importing and exporting countries in accordance with the recommendations in the *Terrestrial Code*.

Box II.a. Reference number: see box I.2.

Official veterinarian: Name, address, ~~qualification and title~~ official position, date of signature and official stamp of the *Veterinary Services*.

– text deleted

Annex XXXIX

Original: English
February 2008

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON SALMONELLOSIS
Paris, 4-7 February 2008

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The OIE *ad hoc* Group on Salmonellosis (hereinafter referred to as the *ad hoc* Group") met at the OIE Headquarters from 4 to 7 February 2008.

The members of the *ad hoc* Group and other participants are listed at Annex I, and the adopted Agenda is given at Annex II.

On behalf of the Director General of the OIE, Dr Sarah Kahn, Head of the OIE International Trade Department, welcomed the group and emphasised the importance of this work. Dr Kahn noted that the Terrestrial Animal Health Standards Commission (hereinafter referred to as the "Terrestrial Code Commission") was generally satisfied with the draft text produced last year and had presented it to the General Session with the possibility of adoption. The draft text was not adopted and has been returned to the *ad hoc* Group with Member comments for review. She advised that the results of the *ad hoc* Group's work will be reviewed by the Terrestrial Code Commission at its meeting in March 2008.

The OIE Animal Production Food Safety Working Group (APFSWG), at its November 2007 meeting, reviewed the draft Guidelines on the Detection, Control and Prevention of *Salmonella* Enteritidis and *S.* Typhimurium in Poultry Producing Eggs for Human Consumption and made recommendations which should be reviewed by the *ad hoc* Group.

The *ad hoc* Group noted that the OIE is working jointly with FAO to develop Guidelines on Good Farming Practice. These guidelines are not intended for inclusion in the OIE *Terrestrial Animal Health Code* (hereinafter referred to as the "*Terrestrial Code*").

The Codex Alimentarius Commission (CAC) has been working on the issue of Salmonella and adopted a Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976) in July 2007. The *ad hoc* Group reviewed this document to ensure that the draft OIE guidelines are harmonised with the Codex document. The *ad hoc* Group also noted that the CAC has started drafting guidelines for the control of *Salmonella* spp. in broilers and a physical working group will meet in May 2008.

Annex XXXIX (contd)

Dr Ignacio Sánchez Esteban then took over as Chair of the meeting, introduced the members of the *ad hoc* Group and presented the draft agenda and terms of reference (refer to Annex III). He re-emphasised the need to consider the work already done by other international organisations, notably the CAC.

1. Draft Guidelines on the Detection, Control and Prevention of *Salmonella* Enteritidis and *S.* Typhimurium in Poultry Producing Eggs for Human Consumption

The *ad hoc* Group reviewed the report of the 75th OIE General Session and the reports of the Terrestrial Code Commission and the APFSWG. The *ad hoc* Group reviewed and addressed comments received from Australia, Canada, the European Union, Japan, South Africa and the United States of America and amended the text accordingly (refer to Annex IV).

The *ad hoc* Group considered Members' comments on the need to use a standard nomenclature for Salmonella in the text and decided that the correct way to refer to *Salmonella* spp. in print is to capitalise and italicise *Salmonella* and capitalise, without italics, the serovar, e.g. *Salmonella* Enteritidis (LE MINOR L. & POPOFF M.Y. 1987 "Designation of *Salmonella enterica* sp. Nov., nom Rev., as the type and only species of the genus *Salmonella*." International Journal of Systematic Bacteriology, **37**, 465-468). The text was modified to reflect this decision.

The *ad hoc* Group considered comments from several Members as to whether the text should address *S.* Typhimurium and/or *S.* Enteritidis or *Salmonella* spp. as a group. There was general agreement that *S.* Enteritidis warrants special treatment because this pathogen is transmitted in ovo. The members of the *ad hoc* Group also agreed that *S.* Enteritidis and *S.* Typhimurium are the most important serovars from a food safety perspective. It was agreed that the implementation of measures to address the Typhimurium serovar would have a beneficial effect in controlling other Salmonella serovars of importance in food borne infections. An additional sentence was added at the end of the introductory paragraph to reflect this.

The *ad hoc* Group responded to a Member's comment by recommending that the applicable chapter in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereinafter referred to as the "*Terrestrial Manual*") be updated to include current approaches to diagnostic testing.

The *ad hoc* Group carefully considered the recommendation of the APFSWG that the OIE should ensure a clear delineation between common practices and OIE recommendations, specifically with regards to the use of vaccination. The *ad hoc* Group reviewed the draft text and provided additional clarity where possible, but concluded that it is important to list a number of control options that should be used in combination. It is not possible to recommend one measure as more important than others.

The *ad hoc* Group considered a Member's comment that the location of signs indicating "restricted access" should be clearly specified. However, the *ad hoc* Group felt that the text adequately conveys the intent. A requirement for signs at multiple and specific locations was considered to be too prescriptive.

The *ad hoc* Group considered a Member's comment on the use of guard dogs for free ranging poultry and concluded that, if guard dogs are used, they should not have access to the interior of poultry houses and feed storage areas.

2. Draft Guidelines on the Detection, Control and Prevention of *Salmonella* spp. in Broilers

As requested in the terms of reference, the *ad hoc* Group drafted a new text: Guidelines on the Detection, Control and Prevention of *Salmonella* spp. in Broilers (refer to Annex V).

The *ad hoc* Group agreed that the scope of its work would cover members of the class Aves that are kept for the purpose of breeding or for the production of meat or eggs. However, broilers are defined as birds of the species *Gallus gallus* selectively bred and reared for their meat rather than eggs.

3. Review of Code Appendix 3.4.1. Hygiene and Disease Security Procedures in Poultry Breeding Flocks and Hatcheries

The *ad hoc* Group reviewed Appendix 3.4.1. and noted that Article 3.4.1.7. contained highly specific information on the use of formaldehyde. The *ad hoc* Group noted that there are additional methods available and recommended that the OIE ask an expert to review this section in detail, including whether it is appropriate to include such detailed information in a horizontal text and, if so, whether detailed information on other methods should be provided.

4. Conclusions and Further Recommendations

During the course of this meeting the *ad hoc* Group was advised by the OIE of the proposed reorganisation of the information in the *Terrestrial Code*, i.e. horizontal texts in Volume I and disease specific ('vertical texts') in Volume II. The text on Salmonella is proposed to be included in Volume I, in the section on Veterinary Public Health. Therefore, the members felt that it would be appropriate to align the format and the presentation of the Salmonella text with those of other horizontal texts. The *ad hoc* Group discussed the best way to do this and noted that the existing text on Hygiene and Disease Security Procedures in Poultry Breeding Flocks and Hatcheries (Appendix 3.4.1.) contains both horizontal and disease-specific elements.

With the goal of eliminating duplication, the group reviewed the text in the draft Guidelines on the Detection, Control and Prevention of *Salmonella* Enteritidis and *S.* Typhimurium in Poultry Producing Eggs for Human Consumption, the current Appendix 3.4.1. and the new draft text on broilers and produced two texts: Hygiene and Biosecurity Procedures in Poultry Production (refer to Annex VI) and Guidelines on the Detection, Control and Prevention of *Salmonella* spp. in Poultry (refer to Annex VII). The Guidelines on the Detection Control and Prevention of *Salmonella* spp. in Poultry was developed by combining the revised text in the Guidelines on the Detection, Control and Prevention of *Salmonella* Enteritidis and *S.* Typhimurium in Poultry Producing Eggs for Human Consumption, the newly developed text on broilers, and the part of the existing Appendix 3.4.1. that is specific to Salmonella. The revised Appendix 3.4.1. was renamed "Hygiene and Biosecurity Procedures in Poultry Production". It now covers general practices for the prevention and control of infectious agents in poultry production, including hatcheries. The *ad hoc* Group felt that this was the best way to address the APFSWG's recommendations.

The *ad hoc* Group recommended that the Terrestrial Code Commission consider for inclusion in Volume I of the *Terrestrial Code* two texts, as follows:

a) Hygiene and Biosecurity Procedures in Poultry Production in Section 4 - General Recommendations on Disease Prevention and Control (refer to Annex VI);

b) Guidelines on the Detection Control and Prevention of *Salmonella* spp. in Poultry in Section 6 - Veterinary Public Health (refer to Annex VII).

The *ad hoc* Group had a brief discussion on future needs and work, and recommended consideration of the following issues: Salmonella in livestock species, meat of spent hens, meat of other avian species (turkeys, ducks, ratites), and duck eggs for human consumption.

Dr Kahn presented closing remarks on behalf of Dr Vallat, who was unable to join the *ad hoc* Group due to mission travel. Dr Kahn congratulated the *ad hoc* Group on its hard work and noted that the results were testimony to the excellent contributions of all members throughout the discussions. In response, Dr Sanchez, on behalf of all members, thanked the OIE for the support provided during the meeting.

.../Annexes

MEETING OF THE OIE *AD HOC* GROUP ON SALMONELLOSIS

Paris, 4-7 February 2008

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Annex I (contd)

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Annex II

MEETING OF THE OIE *AD HOC* GROUP ON SALMONELLOSIS

Paris, 4-7 February 2008

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Adopted agenda

Welcome from the Director General

Adoption of the Agenda

Terms of Reference

1. Update on OIE / Codex activities

1.1. Terrestrial Animal Health Standards Commission

1.2. Animal Production Food Safety Working Group

1.3. Codex Alimentarius

2. Draft guidelines on the detection, control and prevention of *Salmonella* Enteritidis and *S. Typhimurium* in poultry producing eggs for human consumption (Article 3.10.2.)

2.1. Review comments made by Members, Terrestrial Animal Health Standards Commission (Terrestrial Code Commission) and Animal Production Food Safety Working Group.

2.2. Revise the *Terrestrial Code* chapter for the Terrestrial Code Commission March 2008 meeting.

3. Draft a chapter for the OIE *Terrestrial Animal Health Code* that addresses on farm methods for the detection, control and prevention of Salmonella spp. in broilers

Where appropriate, take into account comments received on the chapter for poultry producing eggs.

4. Hygiene and disease security procedures in poultry breeding flocks and hatcheries (Appendix 3.4.1.)

Review *Code* Appendix 3.4.1. to ensure consistency and eliminate duplication between this text and the draft text on Salmonella in poultry producing eggs and future texts on Salmonella in broilers.

5. Any other business

Annex XXXIX (contd)

Annex III

TERMS OF REFERENCE FOR THE

OIE *AD HOC* GROUP ON SALMONELLOSIS

1. Review Members' comments and APFSWG comments on the draft Guidelines on the detection, control and prevention of *Salmonella* Enteritidis and *S.* Typhimurium in poultry producing eggs for human consumption.

2. Review the Code Chapter on hygiene and disease security procedures in poultry breeding flocks and hatcheries to assure consistency between this text and the (draft) texts on Salmonella in laying hens and future texts on Salmonella in broilers.

3. Using up to date scientific information, draft a Chapter for the OIE *Terrestrial* Animal Health Code that addresses on farm methods for the detection, control and prevention of Salmonella spp. in broilers.

4. Take into account risk assessments carried out by the Joint FAO/WHO Meetings on Microbial Risk Assessment (JEMR) and other expert groups.

5. Take into account standards developed and under development by relevant international organisations, in particular the CAC, seeking complementarity.

6. Provide scientific justification and risk basis for all recommendations.

APPENDIX 3.10.2.

GUIDELINES ON THE DETECTION, CONTROL AND PREVENTION OF *SALMONELLA* ENTERITIDIS AND *S.* TYPHIMURIUM IN POULTRY PRODUCING EGGS FOR HUMAN CONSUMPTION

Article 3.10.2.1.

Introduction

The aim of the *Terrestrial Code* is to assist Member Countries 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. This guideline provides recommendations on the detection, control and prevention of *Salmonella* Enteritidis and *S.* Typhimurium in poultry producing eggs for human consumption. This chapter primarily focuses on layer hens and other poultry systems are covered where appropriate. These considerations may equally apply to other non-typhoid Salmonella serovars.

S. Enteritidis and *S.* Typhimurium belong to the species of *S. enterica*. In most food animal species, *S.* Enteritidis and *S.* Typhimurium can establish a clinically unapparent infection ~~in poultry,~~ 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 food borne infection ~~poisoning~~. In the latter case, this can occur when these animals, or their products, enter the food chain thus producing contaminated food products.

Salmonellosis is one of the most common food-borne bacterial diseases in the world. It is estimated that over 90% of Salmonella infections in humans are food-borne with *S.* Enteritidis and S Typhimurium accounting for major part of the problem. Egg-associated salmonellosis, particularly caused by *S.* Enteritidis, is an important public health problem worldwide.

Article 3.10.2.2.

Purpose and scope

This guideline deals with methods for on farm detection, control and prevention of *S.* Enteritidis and *S.* Typhimurium in poultry producing eggs for human consumption. This guideline complements the Codex Alimentarius ~~draft~~ Code of Hhygienic Ppractice for Eeggs and Eegg Pproducts (CAC/RCP 15-1976 Revision 2007 ~~ALINORM 07/28/13, appendix II~~). It covers the preharvest part of the production chain from elite flock to the commercial layer farm. ~~The objective is to control Salmonella in poultry with the goal of producing Salmonella free eggs.~~ A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in producing eggs that are safe to eat.

The scope covers chickens and other domesticated birds used for the production of eggs for human consumption. The recommendations presented in this guideline are also relevant to the control of other Salmonella serotypes.

Annex XXXIX (contd)

Annex IV (contd)

Article 3.10.2.3.

Definitions (for this chapter only)

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

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

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

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.

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

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

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

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

Article 3.10.2.4.

Hazards in poultry breeding flocks, hatcheries and poultry producing eggs for human consumption

All measures to be implemented in breeding flocks and hatcheries are described in Chapter 2.10.2. on *S. Enteritidis* Enteritidis and *S. Typhimurium* Typhimurium in Poultry and in Appendix 3.4.1. on hygiene and disease security procedures in poultry breeding flocks and hatcheries.

This guideline addresses deals with poultry that producing eggs for human consumption. The rest of the food chain is addressed by the Codex Alimentarius draft Code of Hygienic Practice for Eggs and Egg Products.

Article 3.10.2.5.

Biosecurity recommendations applicable to pullet and layer flocks

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. The choice of a suitably isolated geographical location, taking into account the direction of the prevailing winds, facilitates hygiene and disease control. A sign indicating restricted entry should be posted at the entrance.

2. *Establishments*, or flocks, should operate on an 'all in - all out' single age group whenever possible.

3. Where several flocks are maintained on one *establishment*, each flock should be managed as a separate epidemiological unit ~~separate entities~~.

4. Poultry houses and buildings used to store feed or eggs should prevent the entry of ~~be pest-proof and not accessible to~~ 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 ideally should consist of concrete or other material to facilitate cleaning. ~~An exception to this would be trees for heat control, with the exception of fruit trees which could be attractive to birds.~~

7. ~~Domestic a~~Animals, other than pullets and laying hens ~~poultry~~, should not be permitted access to poultry houses and buildings used to store feed or eggs.

8. Clean 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 ~~A~~ disinfectant foot-bath 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 and after entering the layer house.

9. When a poultry house is depopulated, all faeces and litter should be removed from the house 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.

   Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when *S.* Enteritidis and/or *S.* Typhimurium have been detected in the previous flock.

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

10. Birds used to stock a pullet house should be obtained from breeding flocks and hatcheries that are certified as free from *S.* Enteritidis and *S.* Typhimurium and have been monitored according to Article 3.4.1.9.

11. *Layer or laying flocks* ~~Layer flocks~~ should be stocked from pullet flocks that are certified as free from *S.* Enteritidis and *S.* Typhimurium and have been monitored according to this guideline.

12. ~~Because~~ Feed may be contaminated with *Ssalmonella* spp. ~~organisms may contaminate feed. While S. Enteritidis and S. Typhimurium are not normally found as a contaminant in feed,~~ Therefore, it is ~~nonetheless~~ recommended to monitor the salmonella status of layer feed, ~~used in poultry houses~~ 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 ~~pests~~. Spilled feed should be cleaned up immediately ~~regularly~~ to remove attractants for wild birds and rodents ~~pests~~.

Annex XXXIX (contd)

Annex IV (contd)

13. 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.

14. Sick or dead birds should be removed from poultry houses as soon as possible and at least daily, and effective and safe disposal procedures implemented.

15. Records of production and flock history ~~and performance~~, including mortality, surveillance, treatment and vaccinations ~~in regard to Salmonella~~ should be maintained on an individual flock basis within the establishment. Such records should be readily available for inspection.

16. There should be good communication and interaction between all involved in the food chain so that control can be maintained from breeding to egg production and consumption. Farmers should have access to basic training on hygiene and biosecurity measures relevant to egg production and food safety.

17. For poultry flocks that are allowed to range outdoors, the following provisions apply:

    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 rubbish, other farm animals, surface water and manure storage areas). The nesting area should be inside the poultry house.

18. On each layer farm a person with overall responsibility for on-farm salmonella preventive controls should be identified and appropriately trained. Other on-farm personnel should be trained to understand the principles of biosecurity and their responsibility in upholding the biosecurity guidelines in place on the premises.

Article 3.10.2.6.

Recommendations applicable to egg hygiene and collection

1. Cages should be maintained in good condition and kept clean. 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.

2. Eggs should be collected at frequent intervals, ~~not less than twice per day,~~ and placed in new or clean and disinfected trays.

3. Grossly ~~D~~dirty, broken, cracked~~,~~ or leaking ~~or dented~~ eggs should be collected separately and should not be used as table eggs.

4. 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 ~~sanitised~~. If available, refrigeration of shell eggs is recommended. Cooling of eggs should be undertaken as soon as possible after collection.

5. Eggs or their conveyances should be marked ~~Records of egg production should be kept~~ to assist traceability and veterinary investigations.

6. If eggs are cleaned on the farm, this should be done in accordance with the requirements of the *Competent Authority*.

Article 3.10.2.7.

Surveillance of pullet and layer or laying flocks for *S.* Enteritidis and *S.* Typhimurium

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

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.

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

5. 2. Time and frequency of testing

a) Pullet flock testing

~~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.~~

~~ii)~~i) At the end of the first week of life when the status of breeding farm and hatchery is not known or does not comply with Chapter 2.10.2.

ii) Within the f~~F~~our 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.

iii) One or more times during the growing period if there is a *culling* policy in place. The frequency would be determined on commercial considerations.

b) *Layer* or *laying flock* ~~Layer flock~~ testing

i) At expected *peak of lay* for each production cycle.

ii) 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*.

Annex XXXIX (contd)

Annex IV (contd)

c) Empty building testing

Bacteriological monitoring of the efficacy of disinfection procedures is recommended when *S.* Enteritidis and/or *S.* Typhimurium have been detected in the previous flock.

~~Environmental s~~Sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty building after depopulation, cleaning and *disinfection*. ~~following a *S.* Enteritidis and *S.* Typhimurium positive flock.~~

~~2. 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.~~

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

Recommendation is 5 pair of boot swabs or 10 drag swabs. These swabs may be pooled into no less than 2 samples. 5 Pair of boot swabs correspond to 300 faeces samples.

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 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

6. Laboratory methods

Refer to the *Terrestrial Manual.*

Article 3.10.2.8.

Control measures

Salmonella control can be achieved by adopting Good Agricultural Practice and Hazard Analysis Critical Control Point (HACCP) ~~the management practices mentioned above~~ in combination with the following measures. No single measure used alone will achieve effective *S.* Enteritidis and *S.* Typhimurium control.

Additional ~~Currently available~~ control measures currently available include ~~are~~: vaccination, *competitive exclusion*, flock *culling* and product diversion to processing. ~~Antimicrobials, *competitive exclusion* and live vaccination are used in elite flocks.~~

In breeding flocks *competitive exclusion* and vaccination may be used at the outset of a salmonella control programme if the infection rate is at a very high level. In certain circumstances antimicrobials may be used to salvage animals with high genetic value.

Antimicrobials should not be used ~~are not recommended~~ to control *S.* Enteritidis and *S.* Typhimurium in poultry producing eggs for human consumption because the effectiveness of the therapy is limited; it has the potential to produce residues in the eggs and can contribute to the development of antimicrobial resistance.

1. Vaccination

   Many inactivated vaccines are used against Salmonella infections caused by different serovars in various poultry species, including a single or combined vaccine against *S.* Enteritidis and *S.* Typhimurium.

   Live vaccines are also used in a number of countries to prevent Salmonella infections in poultry. It is important that field and vaccine strains can easily be differentiated in the laboratory. Vaccines produced according to the *Terrestrial Manual* should be used.

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

   When the status of breeding farm and hatchery from which the *pullet flock* originates is not known or does not comply with Chapter 2.10.2., 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.

   If serology is used as the surveillance method, it may not be possible to distinguish between vaccination or infection with a field strain.

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

2. Competitive exclusion

   Competitive exclusion can be used in day old chicks to reduce colonisation by *S.* Enteritidis and *S.* Typhimurium.

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Annex IV (contd)

3. Culling

Depending on animal health, risk assessment, and public health policies, culling is an option to manage infected flocks. ~~If poultry are not culled, eggs should be sent for processing for inactivation of pathogens.~~ Infected flocks should be destroyed or slaughtered and processed in a manner that minimises human exposure to pathogens.

If poultry are not culled, eggs should be diverted for processing for inactivation of pathogens.

Before restocking, the poultry house should be cleaned, disinfected and tested to verify that the cleaning has been effective (see above).

~~Farmers should be educated on how to handle Salmonella infected flocks in order to prevent spread to adjacent farms and human exposure.~~

Article 3.10.2.9.

Prevention of Salmonella spread

When a *layer or laying flock* or *pullet flock* is found infected with *S*. Enteritidis and *S*. Typhimurium, *Good Agricultural Practice and Hazard Analysis Critical Control Point* (HACCP) ~~management procedures~~ should be implemented.

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 farm, adjacent farms and from other farms under common management.

1. Farmers should be educated on how to handle *Salmonella* spp infected flocks in order to prevent spread to adjacent farms and 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. ~~Pest c~~Control measures for wild birds, rodents and insects should be observed stringently.

3. Epidemiological investigations should be carried out to determine the origin of new infections as appropriate to the epidemiological situation.

4. Movement of *culled* poultry or layers at the end of the production cycle 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 with *S*. Enteritidis and *S*. Typhimurium. Particular care needs to be taken in regard to poultry litter/faeces used to fertilise plants intended for human consumption.

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 bacteriological examination should be carried out, if possible, to verify that the cleaning has been effective.

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Annex XXXIX (contd)

Annex V

APPENDIX X.X.X.

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

Article X.X.X.1.

Introduction

The aim of the *Terrestrial Code* is to assist Member Countries 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. This guideline provides recommendations on the detection, control and prevention of *Salmonella* spp. in broilers.

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 food borne infection. In the latter case, this can occur when broiler meat, or their products, enter the food chain thus producing contaminated food products.

Salmonellosis is one of the most common food-borne bacterial diseases in the world. It is one of the major public health problems and economic concerns.

Article X.X.X.2.

Purpose and scope

This guideline deals with methods for on farm detection, control and prevention of *Salmonella* spp. in broilers. It covers the preharvest part of the production chain of broilers. A pathogen reduction and elimination strategy at the farm level is seen as another step that will assist in producing broiler meat that is safe.

The scope covers the control of *Salmonella* spp. in broiler meat for human consumption.

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.

Article X.X.X.4.

Hazards in broiler breeding flocks, hatcheries and broilers for human consumption

All measures to be implemented in breeding flocks and hatcheries are described in Chapter 2.10.2. on *Salmonella* Enteritidis and *Salmonella* Typhimurium in poultry and in Appendix 3.4.1. on hygiene and disease security procedures in poultry breeding flocks and hatcheries.

This guideline addresses Salmonella infection control in broiler production.

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Article X.X.X.5.

Biosecurity recommendations applicable to broiler production

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. The choice of a suitably isolated geographical location, taking into account the direction of the prevailing winds, facilitates hygiene and disease control. A sign indicating restricted entry should be posted at the entrance.

2. *Establishments*, or flocks, should operate on an 'all in - all out' single age group 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 should 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 ideally should consist of concrete or other material to facilitate cleaning.

7. Animals, other than broilers, should not be permitted access to poultry houses and buildings used to store feed.

8. Clean 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 foot-bath 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 and after entering the broiler house.

9. When a broiler house is depopulated, it is recommended that all faeces and litter be removed from the house 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.

   Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when *Salmonella* spp. have been detected in the previous flock.

   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 broiler house should preferably be obtained from broiler breeding flocks and hatcheries that are certified as free from *Salmonella* spp., and have been monitored according to Article 3.4.1.9.

11. Feed may be contaminated with *Salmonella* spp. Therefore, it is recommended to monitor the salmonella status of broiler 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 pests.

12. The water supply to broiler 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 broiler house is empty.

13. Sick or dead birds should be removed from broiler houses as soon as possible and at least daily, and effective and safe disposal procedures implemented.

14. Records of performance and flock history, including mortality, surveillance, treatment and vaccination 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 broiler production and consumption. Farmers should have access to basic training on hygiene and biosecurity measures relevant to broiler production and food safety.

16. For broiler flocks that are allowed to range outdoors, the following provisions apply:

    Attractants to wild birds should be minimised (e.g. commercial feed and watering points should be kept inside the broiler house if possible). Broilers should not be allowed access to sources of contamination (e.g. household rubbish, other farm animals, surface water and manure storage areas).

17. On each broiler farm a person with overall responsibility for on-farm salmonella preventive controls should be identified and appropriately trained. Other on-farm personnel should be trained to understand the principles of biosecurity and their responsibility in upholding the biosecurity guidelines in place on the premises.

Article X.X.X.6.

Surveillance of broiler flocks for *Salmonella* spp.

Where justified by risk assessment, surveillance should be performed to identify infected flocks and to prevent infection of subsequent flocks. Microbiological testing is preferred to serological testing because of its higher sensitivity.

To reduce the risk of transmission of *Salmonella* spp. to humans, results of surveillance will allow precautionary measures to be taken at slaughter and further down the 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.

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Annex V (contd)

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

2. Frequency and time of flock testing

a) 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.

b) 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.

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

Five (5) pair of boot swabs or 10 drag swabs should be sampled per flock. These swabs may be pooled into no less than 2 samples.

In flocks where boot or drag swab sampling is not feasible, the total number of faecal samples to be taken on each occasion is shown in Table I. This is based on the random statistical sample required to give a probability of 95% to detect 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

4. Empty building testing

Bacteriological monitoring of the efficacy of disinfection procedures is recommended when *Salmonella* spp. have been detected in the previous flock.

Sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty building after depopulation, cleaning and *disinfection*.

5. Laboratory methods

Refer to the *Terrestrial Manual*.

Article X.X.X.7.

Recommendations applicable to catching and transportation of broilers

1. Personnel involved in the catching of the birds need to be adequately trained in bird handling and basic hygiene procedures.

2. Broilers 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. Broilers 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 sanitised between each use.

5. Broilers should not be exposed to extreme temperatures.

Article X.X.X.8.

Control measures

The grow out phase of broiler production is short and therefore it is important to emphasize the salmonella status of the source flock.

Broilers are susceptible to colonisation with *Salmonella* spp. because they are young and are grown at high stocking rates.

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. Competitive exclusion, the administration of defined or undefined bacterial flora to prevent gut colonisation by enteropathogens, including Salmonella, can be used but is often cost prohibitive.

Antimicrobials should not be used to control *Salmonella* spp. because the effectiveness of the therapy is limited; it has the potential to produce residues in the meat 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.

1. On farm procedures

   a) First week of life

      The first week of life is important to develop immunocompetence in the birds and increase resistance to *Salmonella* spp. It is important to have a good brooding system including appropriate temperature and humidity.

   b) Veterinary involvement

      During the production cycle a veterinarian should be responsible to monitor flock health on the farm.

      This 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.

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Annex V (contd)

2. Slaughtering Broilers

   a) Preparation of the broilers

      To reduce Salmonella spp. contamination in the abattoir it is helpful to reduce the amount of feed in the birds gut at the time of slaughter. Feed transits the gut in about four hours therefore it is recommended to withdrawal feed to the birds at an appropriate period before slaughter (8-10 hours).

   b) Processing

      Slaughter processing should be conducted in accordance with the Appendix 3.10.1. and Codex Alimentarius Code of Hygienic Practice for Meat.

   c) Salmonella infected flocks

      Where flocks are known to be infected with *Salmonella* spp., they should be processed separately from flocks not known to be infected with *Salmonella* spp. They could be sent to a separate slaughter house or processed at the end of a shift before cleaning and disinfection of the equipment.

Article X.X.X.9.

Prevention of Salmonella spread

If a broiler *flock* is found infected with *Salmonella* spp., the following actions should be taken:

1. Farmers should be educated on how to handle *Salmonella* spp. infected flocks in order to prevent spread within the establishment, to adjacent farms and prevention of 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 new infections as appropriate to the epidemiological situation.

4. 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.

5. After depopulation of an infected flock the poultry house should be thoroughly cleaned and disinfected, with special attention to feed equipment and water systems.

6. Before restocking bacteriological examination should be carried out as detailed in this Guideline.

7. Special precautions should be taken in the transport, slaughter and processing of the birds.

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Annex VI

APPENDIX 3.4.1.

HYGIENE AND ~~DISEASE~~ BIOSECURITY PROCEDURES IN POULTRY PRODUCTION ~~BREEDING FLOCKS AND HATCHERIES~~

Article 3.4.1.1.

Recommendations applicable to ~~breeding~~ poultry (as defined in Chapter X.X.X.: Guidelines on the Detection, Control, and Prevention of *Salmonella* spp. in Poultry), establishments (including hatcheries) and flocks

1. Access to the *establishment* should be controlled to ensure only authorized persons and conveyances enter the site. This may require that t~~T~~he *establishment* ~~should~~ be surrounded by a security fence ~~and a gateway to control traffic and access to the site~~.~~The choice of a~~A suitably isolated geographical location is recommended, taking into account the direction of the prevailing winds and location of other poultry establishments~~, facilitates hygiene and disease control~~. A sign indicating restricted entry should be posted at the entrance.

2. ~~Poultry breeding~~ e*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*, ~~the individual~~ each flock~~s~~ should be managed as a separate epidemiological unit ~~entities~~.

4. ~~Buildings housing p~~Poultry houses and buildings ~~or those~~ used to store feed or eggs should be constructed and maintained to prevent the entry of ~~free of vermin and not accessible to~~ wild birds, rodents and insects.

5. Poultry houses should be designed and constructed so that ~~all surfaces inside the buildings are of an impervious smooth material so that~~ cleaning and *disinfection* can be carried out adequately and prefereably of smooth impervious materials.

6. *Establishments* should be free from unwanted vegetation and debris. *The* area immediately surrounding the poultry houses should ~~be free from vegetation and debris and~~ ideally ~~this should~~ consist of ~~an area of~~ concrete or other ~~similar~~ material to facilitate cleaning. ~~An exception to this would be trees for heat control, with the exception of fruit trees which could be attractive to birds.~~

7. ~~Domestic a~~ 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.

8. Clean 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 foot-bath 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 and after entering the broiler house. Personnel and visitors should not recently have had contact with other poultry, raw poultry products, or poultry waste.

   ~~Appropriate disease security precautions, which could include showering and changing facilities, should be adopted for all visitors to the *establishment* and for all staff entering individual poultry houses.~~

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Annex VI (contd)

9. When a poultry house ~~or *establishment*~~ is depopulated, it is recommended that all faeces and litter ~~manure should~~ be removed from the house~~s~~ and disposed of in a manner approved by the *Veterinary Services*. After removal of faeces and litter ~~effective~~ cleaning and *disinfection* of the building and equipment should be ~~procedures~~ 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 ~~Bacteriological~~ monitoring of the efficacy of *disinfection* procedures is recommended when pathogenic agents have been detected in the previous flock.

   Routine ~~When necessary, rodent and insect control~~ procedures for the prevention of entry of wild birds, and the control of rodents and insects should ~~also~~ be carried out at this time.

10. Birds used to stock a ~~Repopulation of~~ poultry house~~s or *establishments*~~ should preferably ~~only~~ be obtained from breeding ~~made from poultry~~ flocks and hatcheries that are certified as free from vertically transmitted ~~of known high health status and which are regularly monitored for salmonella and other~~ poultry pathogens.

11. ~~All feed used in poultry houses and *establishments* should be monitored for salmonella prior to use~~. The use of pelletised feeds or feeds subjected to other bactericidal treatment ~~salmonella decontamination procedures~~ 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 removes attractants for wild birds rodents and insects.

12. The water supply to poultry houses should be ~~of a satisfactory~~ potable ~~status~~ according to the World Health Organisation 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. ~~and safe disposal procedures implemented~~.

14. ~~Full records relating to~~ Records of production/performance and flock history, including mortality, surveillance ~~disease diagnosis~~, treatment~~s~~ 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 rubbish, 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 to monitor flock health on the farm.

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Annex VI (contd)

Article 3.4.1.2.

Recommendations applicable to hatching egg hygiene and transport

1. The litter in the ~~laying~~ poultry house should be kept dry and in good condition. The nest box litter should be kept clean and an adequate ~~in~~ 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.

~~2~~3. Eggs should be collected at frequent intervals ~~of not less than twice per day~~ and placed in new or clean and disinfected containers.

~~3~~4. Grossly ~~D~~dirty, broken, cracked, or leaking ~~and dented~~ eggs should be collected ~~in a~~ separately ~~container~~ and should not be used ~~for~~ as hatching or table eggs ~~purposes~~. 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.

~~4~~6. ~~The clean eggs should be sanitised as soon as possible after collection. The methods of sanitisation are described in~~ Refer to Article 3.4.1.7. regarding the specific requirements for the sanitisation of hatching eggs and hatchery equipment.

~~5. The sanitised 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%.~~

~~6. The eggs should be transported to the hatchery in new or clean cases which have been fumigated or sanitised with a liquid disinfectant (see Table I). The cleaning and *disinfection* of *vehicles* must be a regular part of the hatchery routine.~~

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 sanitised between each use.

5. Poultry should not be exposed to extreme temperatures.

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Annex VI (contd)

Article 3.4.1.~~3.~~4.

Recommendations applicable to hatchery buildings

~~1. The choice of a suitably isolated geographical location facilitates hygiene and disease control. The building should be located as far as possible from other buildings housing livestock and poultry in particular, and the direction of the prevailing winds should be taken into consideration.~~

~~2.~~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.

~~3~~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.

~~4. Openable windows, ventilators and other open areas should be screened against insects and vermin.~~

~~Article 3.4.1.4.~~

~~Recommendations applicable to hatchery building hygiene~~

~~1. The area adjacent to the hatchery buildings should be surrounded by a security fence and a gateway to control all traffic.~~

~~2. Wild birds, domestic and wild animals must be excluded from the hatchery area. When necessary, a specific programme for fly control should be implemented.~~

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.~~

~~Requirements applicable to personnel and visitors~~

~~1. Clean coveralls or overalls, hats and footwear must be provided for all personnel and visitors entering the *establishment* or the hatchery.~~

~~2. A disinfectant foot bath for footwear is necessary and the disinfectant solution should be changed frequently. Washing the hands in disinfectant solution or with soap and water should be required.~~

~~3. Personnel and visitors should have no direct contact with other poultry or poultry products.~~

Article 3.4.1.~~6~~5.

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

1. Egg handlers in the hatchery should wash their hands with soap and water and change to clean outer garments before handling *hatching eggs* received from the poultry farm.

2. Chick sexers and chick handlers should ~~must~~ wash and disinfect their hands and change into clean protective clothing and boots before commencing work and between different ~~lots~~ batches of chicks.

3. Day-old chicks or other poultry should ~~must~~ 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 clothing. Outer clothing 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.~~7~~6.

Sanitisation of hatching eggs and hatchery equipment

1. The clean eggs should be sanitised as soon as possible after collection. The methods of sanitisation are described below.

2. The sanitised 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 cases which have been fumigated 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. Sanitisation means:

   a) fumigation with formaldehyde, or

   b) spraying with or immersion in an egg shell disinfectant in accordance with the manufacturers instructions, or

   c) made hygienic by another method approved by the *Veterinary Authority*.

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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 cases, 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 sanitisation of eggs and hatchery equipment. In general, three levels of concentration have been used. Also, two methods of use have been adopted.

1. Method 1

   a) Concentration A

      53 ml formalin (37.5%) and 35 g potassium permanganate per m^3 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 ft^3 (2.8 m^3) of space.

   b) Concentration B

      43 ml formalin (37.5%) and 21 g potassium permanganate per m^3 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 ft^3 (2.8 m^3) of space.

   c) Concentration C

      45 ml formalin (40%) and 30 g potassium permanganate per m^3 of space.

      This can be expressed as:

      4.5 oz by volume formalin and 3 oz potassium permanganate per 100 ft^3.

   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 POLYETHYLEN 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.

2. 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%).

Ten g paraformaldehyde powder or pellet is used per m^3 of space.

3. 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.

Annex XXXIX (contd)

Annex VI (contd)

Article 3.4.1.~~8.~~7.

Fumigation procedures at the hatchery

1. Fumigation of eggs in setting machines

   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 m^3 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 ft^3 of space; or 25 ml formalin to 12.5 g potassium permanganate per m^3. 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 3hours 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.

Annex XXXIX (contd)

Annex VI (contd)

Table 1. ***Properties and uses of disinfectants***

Properties	**Chlorine**	**Iodine**	**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 *OIE 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

Annex XXXIX (contd)

Annex VI (contd)

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:

1. 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.

~~Article 3.4.1.9.~~

~~**Monitoring of poultry breeding flocks and hatcheries for salmonella**~~

~~1. At the present time the only method for monitoring poultry breeding flocks and hatcheries for salmonella is by means of bacteriological examination of samples obtained from these *establishments*.~~

~~2. Samples for bacteriological monitoring of *poultry flocks* are obtained in the case of rearing flocks from the premises in which the birds are housed or in the case of adult laying birds either from the premises in which the birds are housed or from the hatchery to which the *hatching eggs* from that flock are consigned.~~

~~3. The samples to be taken are:~~

~~a) on the premises in which birds are housed – fresh faeces (each sample at least 1 gram), dead or culled birds, or in the case of *day old birds* the chick box liners;~~

~~b) at the hatchery – meconium, dead in shell and culled chicks.~~

~~Additionally, it is recommended that environmental samples such as drag swabs, litter, feather, down and dust, are also taken in both the premises and the hatchery at a similar frequency. Where the laying flock is sampled only on the premises, environmental sampling of the hatchery is required.~~

Annex XXXIX (contd)

Annex VI (contd)

4. The total number of samples to be taken on each occasion is shown in Table 2 and is based on the random statistical sample required to give a probability of 95% to detect one positive sample given that infection is present in the population at a level of 5% or greater.

Table II

Number of birds in the flock	**Number of 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

5. All samples should be selected at random to represent the house or in the case of samples taken at the hatchery to represent the *hatching eggs* from that poultry flock.

6. The following minimum frequency of sampling is recommended:

   a) Rearing flocks

      At day old and 3 weeks before moving to laying accomodation.

      Where birds are moved from the rearing premises other than direct to laying accomodation, a further sample should be taken 3 weeks before such movement.

   b) Breeding flocks in lay

      The laying flocks should be sampled at least at monthly intervals during the laying period.

7. All samples should be fully marked and identified as to the date of sampling and the flock to which the samples relate.

8. Samples should be stored in a refrigerator at between 1°C and 4°C until they are dispatched to the laboratory (not more than 5 days).

9. All samples should be examined in a laboratory authorised for that purpose by the *Veterinary* Authority.

— deleted text

Annex XXXIX (contd)

Annex VII

APPENDIX X.X.X.

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

Article X.X.X.1.

Introduction

The aim of the *Terrestrial Code* is to assist Member Countries 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. This guideline provides 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 food borne 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 food-borne bacterial diseases in the world. It is estimated that over 90% of Salmonella infections in humans are food-borne with *S.* Enteritidis and S. Typhimurium accounting for 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

This guideline deals with methods for on farm detection, control and prevention of *Salmonella* spp. in poultry. This guideline 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 Hygiene and Biosecurity Procedures in Poultry Production Chapter X.X.X.

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 this guideline are relevant to the control of all non-typhoid *Salmonella* spp. with special attention to *Salmonella* Enteritidis and *Salmonella* 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.

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Annex VII (contd)

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

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

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

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.

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

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

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

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

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

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.

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

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.

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 5 pair of boot swabs or 10 drag swabs. These swabs may be pooled into no less than 2 samples.

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. Laboratory methods

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 is based on risk assessment and production methods

Annex XXXIX (contd)

Annex VII (contd)

a) Breeders and Hatcheries

i) Breeder pullet flock

- At the end of the first week of life.
- 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.
- The minimal frequency would be determined by the *Veterinary Services*.

iii) Hatcheries

- Testing in hatcheries complements on farm testing.
- 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 breeding farm and hatchery is not known or does not comply with these guidelines.
- 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

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.

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 this guideline.

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 this guideline.

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.

Annex XXXIX (contd)

Annex VII (contd)

When the status of breeding farm and hatchery from which the *pullet flock* originates is not known or does not comply with this guideline, 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 directions 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.

   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.

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 Chapter X.X. 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.

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.

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 this guideline.

Article X.X.X.7.

Special considerations for broiler flocks

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.

3. To reduce *Salmonella* spp. contamination in the abattoir it is helpful to reduce the amount of feed in the birds gut at the time of slaughter. Feed transits the gut in about four hours therefore it is recommended to withdrawal 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. and the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

Annex XXXX

Original: English
December 2007

REPORT OF THE FIRST MEETING OF THE OIE *AD HOC* GROUP ON LABORATORY ANIMAL- WELFARE

Paris, 5–7 December 2007

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The OIE *ad hoc* Group on Laboratory Animals Welfare (hereinafter referred to as the *ad hoc* Group) met at the OIE Headquarters from 5 to 7 December 2007.

The members of the *ad hoc* Group and other participants at the meeting are listed at Appendix I. The adopted Agenda is at Appendix II.

Agenda Item 1

On behalf of Dr Vallat, Director General of the OIE, the Deputy Director General of the OIE, Dr Jean-Luc Angot, welcomed all members and thanked them for their agreement to work with the OIE on this important topic. He indicated how the work done in animal welfare had been addressed by the OIE through its permanent Animal Welfare Working Group (AWWG), which provides advice and draft texts to the Terrestrial Animal Health Standards Commission (the Code Commission) and, for aquatic animals, to the Aquatic Animal Health Standards Commission. Draft texts are provided by the Code Commission to OIE Members for comment and consideration, with a view to final adoption in the Terrestrial Animal Health Code (the Code). Dr Angot also discussed the overall animal welfare work programme and expectations of OIE Members.

An extract from the report of the fourth meeting of the AWWG is presented in Appendix III.

Agenda Item 2

Dr Bayvel referred to the inclusion of animal welfare in the OIE's third and fourth strategic plans and the progress made to date in developing the four adopted sets of guidelines and working closely with international organisations representing the industry and animal welfare NGO interests. The 2004 first Global Conference on Animal Welfare, the 2005 publication "Global Issues, Trends and Challenges" and the decision to hold the Second Global Conference on Animal Welfare in Cairo in October 2008 are all important elements of the strategic commitment to communication and stakeholder engagement.

Possible involvement of the OIE in laboratory animal welfare was first proposed in 2002, raised again during the first OIE Global Conference in 2004 and identified as a strategic priority by the AWWG and the OIE International Committee in 2005.

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Meetings in Salt Lake City in 2006 and Lake Como in 2007 and the formal agreement with the International Council for Laboratory Animal Science (ICLAS) were the most important precursors to the establishment of this *ad hoc* Group. The OIE has particular interest in the use of laboratory animals in animal health research, disease diagnosis, regulatory testing and transport.

It was agreed that there is a significant need to raise OIE delegate awareness of the OIE's work in setting standards for Laboratory Animal Welfare. This issue could be highlighted at the General Session in May 2008, when the Agreement between the OIE and ICLAS will be formally signed and Dr. Demers will make a brief presentation to the General Session. The second OIE Global Conference on Animal Welfare, to be held 20-22 October 2008, will address laboratory animal standards as an ongoing issue. Note: standards would not be in place as the earliest opportunity for adoption of new text in the Terrestrial Code would be May 2009. An invitation to the OIE to attend the ILAR Conference in September 2008 (Animal Research in a Global Environment: Meeting the Challenges') will provide a good opportunity for the OIE to inform the scientific community of its involvement in this important area of work.

The terms of reference of this *ad hoc* Group (see Appendix IV) were based on the discussion paper prepared by Dr Bayvel (see Appendix V).

Agenda Item 3

The *ad hoc* Group discussed the working documents and identified some additional inputs, as follows. Dr Demers provided an update on his recent participation on the 74th Session Executive Committee of the Council for International Organisations of Medical Sciences (CIOMS) held in Geneva on December 3 and 4, 2007. ICLAS is an associate member of CIOMS. Dr Demers indicated that ICLAS will participate in a review of the International Guiding Principles for Biomedical Research Involving Animals (the CIOMS Guiding Principles) (1985) through a joint CIOMS/ICLAS Working Group. This important document has been used over the years as reference document by several scientific organizations dealing with the production of guidelines worldwide. Since 2004, ICLAS has used the Preamble of this document to implement the work of the ICLAS Working Group on Harmonization of Guidelines for the use of animals in research. It was suggested that this document would be discussed for revision during the Fourth meeting of the ICLAS Working Group on Harmonization of Guidelines, to be held in November 2008 before the AALAS meeting in Indianapolis, USA. The terms of reference for this activity will be developed during the next 12 months. The process of reviewing CIOMS guidelines normally takes 2-3 years.

Dr Bayne noted that over the last two decades the CIOMS principles have had a significant global influence on animal welfare. Moreover, while the CIOMS principles do not specifically address research animal welfare, the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (IRAC 1985) extrapolate the key concepts of the CIOMS principles to the animal research milieu. Dr Bayne also brought to the Committee's attention the AVMA's eight animal welfare guiding principles. However, like the OIE Guiding Principles on animal welfare, these are overarching in scope to encompass the entire veterinary profession, and do not speak specifically to research animal welfare. Nonetheless, the philosophical approach articulated in the 3Rs is embedded in the guiding principles, thereby increasing their relevance to research animal welfare. It is important to note that the Guide for the Care and Use of Laboratory Animals (NRC 1996 et seq.) has been translated into several languages and is therefore available to support implementation worldwide.

Dr Kurosawa made some introductory comments in relation to ISO Standard 10993, Biological Evaluation of Medical Devices: Part 2 Animal Welfare requirements. Members of the *ad hoc* Group noted that the ISO document is quite detailed, in comparison with the 'guiding principles' approach taken in the CIOMS and AVMA documents.

Dr Joubert and Dr MacArthur Clark made some introductory comments on the revision of EC Directive 86/609/EEC. Dr MacArthur Clark indicated that the revision of Appendix A of the Council of Europe Convention (ETS 123) had been completed. This was adopted by the European Commission in June 2007. She also noted that the EU Directive (86/609/EEC) is being revised and an extensive consultation has taken place, involving both citizens and experts. A draft directive is expected to be issued in early 2008. Finally Dr MacArthur Clark commented that EU Member states will need to revise their domestic legislation to reflect the new EC Directive, once approved, together with the revised standards for housing and care.

Dr Bayvel reported on a recent meeting with Dr. Dehaumont, Director of AFSSA Fougères (an OIE Collaborating Centre on Veterinary Medicinal Products). Dr. Bayvel commented on the state of play with the programme known as Veterinary International Cooperation on Harmonisation (VICH) - a trilateral (EU-Japan-USA) programme aimed at harmonizing technical requirements for veterinary product registration, which was initially developed under the auspices of the OIE some 10 years ago. The OIE will take steps to raise the profile of the VICH initiative amongst Member Countries and Territories.

Dr Bayvel also reported on a recent meeting with Dr Le Neindre, of the French National Institute for Agricultural Research (INRA) and Member of the Scientific Committee of the European Food Safety Agency (EFSA). Dr Le Neindre had provided an update on some interesting and relevant work that is being undertaken within Europe on the use of laboratory animals and on cloning animals. It was agreed that the OIE Central Bureau continue to liaise closely with both INRA and EFSA

Agenda Item 4

The *ad hoc* Group addressed the issues identified in the Terms of Reference, and, as an initial priority, developed a draft text: '**OIE Guidelines on Research Animal Welfare**' for consideration by the Code Commission at its March 2008 meeting.

The draft text, including proposed definitions, is at Appendix VI.

The *ad hoc* Group also identified the following three priority areas for future OIE attention:

- **Veterinary Training in Laboratory Animal Medicine**
- **Laboratory Animal Transport**
- **Regulatory Testing and the adoption of alternatives**

Strategies to follow in regard to these priority areas should be developed by the *ad hoc* Group for consideration by the Code Commission. The *ad hoc* Group will also address the other issues identified in its Terms of Reference as part of its future work programme.

Agenda Item 5

The *ad hoc* Group discussed and agreed on further work needed to complete the meeting report (see Appendix VII).

Agenda Item 6

The *ad hoc* Group developed a proposed future work programme (see Appendix VIII).

Next Meeting

It is proposed that a second meeting take place from 3 - 5 December 2008.

Annex XXXX (contd)

Meeting with the Director General

Following return from mission travel, Dr Vallat participated in the *ad hoc* Group meeting on the morning of Friday 7 December. After thanking the *ad hoc* Group members for their cooperation with the OIE in this important and new area of work, Dr Vallat commented on the importance of the OIE's standard setting work in the context of the World Trade Organisation (WTO). While animal welfare is not covered by the WTO Agreement on the Application of Sanitary and Phytosanitary Standards, OIE Members are nonetheless highly supportive of the OIE's work in animal welfare and this will continue to be an area of strategic importance for the OIE. Dr Vallat also noted the importance of having balanced geographic representation in all Commissions, Working Groups and *ad hoc* Groups, to ensure that the needs of developing countries are taken fully into account in developing standards and other recommendations.

Dr Vallat noted that the OIE places high priority on supporting OIE Members in the implementation of the OIE animal welfare standards.

.../Appendices

Annex XXXX (contd)

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON LABORATORY ANIMAL WELFARE

Paris, 5–7 December 2007

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Annex XXXX (contd)

Annex I (contd)

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MEETING OF THE OIE *AD HOC* GROUP ON LABORATORY ANIMAL WELFARE

Paris, 5–7 December 2007

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Adopted agenda

1. Welcome and introduction – Dr Jean Luc Angot
2. Confirmation of Terms of Reference and comments from Chair of AHG
3. Discussion of working documents and other relevant documents provided by the *ad hoc* Group Members
4. Development of draft text for consideration by the Terrestrial Animal Health Standards Commission
5. Review and finalise report of meeting
6. Programme for further work after this meeting

Annex XXXX (contd)

Appendix III

Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Original: English
September 2007

EXTRACT FROM THE REPORT OF THE FOURTH MEETING OF THE OIE WORKING GROUP ON ANIMAL WELFARE

6.6. Laboratory Animal Welfare

Drs Kahn and Bayvel provided an update on the interaction with ICLAS and other international laboratory animal science standards organisations since the last WG meeting

Dr Bayvel summarised the sequence of events and dialogue with ICLAS and the Central Bureau. The WG expressed its satisfaction with progress on this issue and supported the membership of the new *ad hoc* Group as being sufficiently broad and representative.

It was confirmed that an *ad hoc* Group will meet from 5 to 7 of December.

It was agreed that the *ad hoc* Group report would be circulated to the WG members for comments during January/February 2008

The WG agreed to forward the discussion paper to the TAHSC for information and to adopt the final points (under Recommendations) of this paper as the TOR for the *ad hoc* Group (Appendix K).

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Annex XXXX (contd)

Appendix IV

TERMS OF REFERENCE

OIE *AD-HOC* GROUP ON LABORATORY ANIMAL WELFARE

1. To review and provide specific advice on recommendations in Issues and Options paper
2. To advise on Guiding Principles for the OIE in the development of standards on laboratory animal welfare and to make recommendations on future priorities and strategies
3. To advise strategies for supporting OIE Members
4. To make recommendations on how the OIE can strengthen linkages with key international stakeholders in the field of laboratory animal science

Annex XXXX (contd)

Appendix V

DISCUSSION PAPER

ISSUES AND OPTIONS REGARDING A FUTURE INTERNATIONAL ROLE FOR THE OIE IN LABORATORY ANIMAL WELFARE

Purpose:

The purpose of this discussion paper is to assist the OIE in defining, and scoping, the unique international role it can play, in the future, in connection with laboratory animal welfare.

It is envisaged that the strategy underlying the OIE's involvement in laboratory animal welfare will include close liaison with the already established specialist international organisations. In this regard, a parallel already exists in relation to the working relationships between the OIE and IATA and AATA.

The unique benefit of OIE involvement would be the scientific and policy credibility provided by an internationally recognised inter-governmental body dedicated to animal health and welfare issues and representing172 member countries.

OIE Update:

The original version of this discussion paper was discussed at the fourth meeting of the OIE Permanent Working Group on Animal Welfare held in Teramo, Italy, in September, 2005.

It was agreed, at this meeting, to enter into dialogue with appropriate stakeholders to discuss what unique international role could be played by the OIE and what support there would be for the OIE assuming such a role.

It was initially proposed to hold such dialogue, in late 2005, but this did not prove possible. Arrangements were, however, made with the International Council of Laboratory Animal Science (ICLAS) to hold a half day OIE/ICLAS meeting in association with the 2006 meetings of the American Association of Laboratory Animal Science (AALAS) and ICLAS, in October 2006, in Salt Lake City. During 2006, a formal offer of support was also made to the OIE by the nascent International Association of Colleges of Laboratory Animal Medicine (IACLAM) by its inaugural President Dr Judy MacArthur Clark. IACLAM was subsequently invited to participate in the OIE/ ICLAS Meeting.

All participants at the Salt Lake City confirmed strong support for the OIE assuming an international laboratory animal welfare role.

Valuable additional discussions, with key international organisations involved in laboratory animal welfare, were also held in Lake Como in June 2007 and key matters arising from these discussions are included. These deliberations also provided important suggestions regarding ad hoc Group membership. A formal OIE/ ICLAS MoU was agreed at the May 2007 OIE General Session and it is anticipated that this will be formally signed in May 2008.

This version of the original paper has been prepared for discussion at the September 2007 meeting of the OIE Permanent Animal Welfare Working Group. The final agreed version of the paper will be considered at the December 2007 meeting of the Laboratory Animal ad hoc Group.

Annex XXXX (contd)

Appendix V (contd)

Introduction:

The use of animals in research, testing and teaching was discussed at the February, 2004 OIE Global Conference on Animal Welfare as a possible future element of the OIE's strategic initiative on animal welfare. This led to an offer of international stakeholder support from a consortium co-ordinated by Dr Marilyn Brown and an invitation to speak at both the AALAS annual conference and the ICLAS International Committee meeting in October 2004. Laboratory Animal Welfare, was one of four priority strategic items identified at the December, 2004 meeting of the Permanent Animal Welfare Working Group. At that time, the Director-General emphasized the importance of the OIE's international network of reference laboratories and diagnostic centres and the role that laboratory animals play both in these centres and in the regulatory testing of veterinary medicinal and biological products conducted by OIE member countries.

Support for OIE involvement in laboratory animal welfare was received at the May, 2005 OIE General Session and a written offer of support was subsequently received from the CVO of Finland. The opportunity was also taken to briefly discuss potential OIE involvement in this area, with staff from the Teramo OIE Collaborating Centre for Animal Welfare at meetings in London and Paris in March and May 2005 respectively.

Relevant review papers by Drs Clement Gauthier and Vera Baumanns were published in the August 2005, OIE Scientific and Technical Review Series issue "Animal Welfare: Global Issues Trends and Challenges". A number of key current international issues and trends were also addressed in the concluding paper of this publication. At the 2006 meeting of the OIE International Committee, delegates were updated on progress to date with this new area of strategic involvement.

This discussion paper is designed to provide some selected background information, identify some key issues and potential roles and make some recommendations for initial OIE involvement in this specialised and often controversial area of animal use.

Background:

The use of animals for scientific purposes is the subject of an extensive international literature, with a number of well-established international organisations playing key roles in promoting humane science and good laboratory animal practice, in encouraging ethical debate, in countering the misinformation promulgated by "antivivisection" groups and in fostering the ethical principles of the Three Rs of Russell and Burch.

Key organisations include:

- International Council for Laboratory Animal Science (ICLAS)
- American Association for Laboratory Animal Science (AALAS)
- Institute for Laboratory Animal Research (ILAR)
- Canadian Council for Animal Care (CCAC)
- Universities Federation for Animal Welfare (UFAW)
- Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART)
- American College of Laboratory Animal Medicine (ACLAM)
- Japanese College of Laboratory Animal Medicine (JCLAM)
- European College of Laboratory Animal Medicine (ECLAM)
- Korean College of Laboratory Animal Medicine (KCLAM)

- International Association of Colleges of Laboratory Animal Medicine (IACLAM)
- European Centre for the Validation of Alternative Methods (ECVAM)
- US Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM)
- Fund for the Replacement of Animals in Medical Experimentation (FRAME)
- Interniche
- Council of Europe ETS 123 Review
- European Food Safety Authority (EFSA) Working Group on Experimental Animal Welfare
- American Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC International)
- Various Governmental Three Rs Organisations
- The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)
- The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- International Organisation for Standardization (ISO)
- Federación de Sociedades Sudamericanas de la Ciencia de Animales de Laboratorio (FESSACAL)
- The Organisation for Economic Co-operation and Development (OECD)
- Japanese Center for the Validation of Alternative Methods (JacVAM)
- Federation of European Laboratory Animal Science Associations (FELASA)
- Asian Federation of Laboratory Animal Science Associations (AFLAS)
- Mexican Association for Laboratory Animal Science (AMCAL)

The Three Rs of Russell and Burch have provided an important ethical underpinning for the use of animals in science and groups are established in Baltimore, Davis, Utrecht, Palmerston North and London to specifically promote the Three Rs and encourage relevant research.

The six World Congresses on Alternatives and Animal Use in the Life Sciences, held from 1993 to 2007, have made a major contribution to international dialogue on this subject. These congresses are excellent examples of a forum where a range of view-points can be heard, within a framework of problem solving and trust. Regular updates are provided at these conferences on the reduction, refinement and replacement of animal use in regulatory testing of veterinary biological products, in particular.

Annex XXXX (contd)

Appendix V (contd)

The issue of international harmonisation of the use of animals in regulatory testing is being addressed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicine Products (VICH) programme. The VICH is an international forum to provide guidance on technical requirements for the registration of new veterinary medicinal products in order to protect public health and animal health and welfare, as well as the environment. VICH is a programme of collaboration primarily between the regulatory authorities and the animal health industry of the EU, Japan and the USA. Australia, New Zealand and Canada participate as active observer members, while the OIE participates as an associate member in supporting and disseminating outcomes worldwide.

VICH was officially launched in 1996, under the auspices of the OIE, and the factors which influenced its establishment specifically included:

– The drive to reduce the number of animals used in regulatory testing by eliminating the need for duplication of tests in each VICH region

– The international drive to harmonize regulatory standards and minimize their impact on trade

The objectives of VICH also specifically refer to establishing and monitoring harmonized regulatory requirements for veterinary medicinal products in the VICH regions, which meet high quality safety and efficacy standards and minimize the use of test animals and costs of product development.

Replacement of animal use in veterinary undergraduate teaching is another area where major advances have been made in recent years. Considerable expertise has been developed in, for example, the veterinary schools in Norway and New Zealand and there would be scope for the OIE to facilitate uptake and adoption of such teaching techniques.

ICLAS/OIE Salt Lake City Meeting, October 2006:

This well-attended and successful, by invitation only, meeting had the objectives detailed in Appendix 1. Appendices 2 and 3 provide agenda and participant details.

Key issues identified in the formal presentations, and arising from subsequent discussion, included the following:

- The important role being played by the ICLAS Working Group on the Harmonisation of Guidelines and the commitment to an international harmonisation, rather than a standard setting approach.

- ICLAS resourcing issues and the need to consider a new international location for the secretariat, after 10 years of being hosted by the CCAC in Canada.

- An indication that the European Commission might consider a case for financial support for a possible EU member country location.

- The OIE's commitment to ensuring that animal welfare standards and guidelines have broad applicability internationally.

- The potential for the OIE to raise awareness internationally at both a government and stakeholder level.

- The strategic significance of the establishment of IACLAM and its particular interest in laboratory animal transport (including primates) and *in-vitro* and *in-silico* testing methods for both animal and human pharmaceuticals.

- The important international role played by AAALAC International, with its commitment to performance standards and practical harmonisation.

- The important international role played by ILAR including the ILAR Journal, ILAR Care and Use Guidelines and other international reference documents.

- The role of the OECD model in facilitating the international regulatory acceptance of non-animal tests.

- The value of the ISO model in facilitating the international regulatory acceptance of human medical devices.

- The "European Partnership on Alternative Approaches to Animal Testing" (EPAA) as an example of an action programme including the EC and all stakeholders (Refer Appendix 4).

- The need for greater research support (Refer Framework 7 programme in Europe and research coordination).

Strong support was given to the OIE's proposed involvement in the international laboratory animal welfare area. In addition to the areas originally identified in 2005, the following were suggested as particular priorities:

- Revision, promulgation and, if necessary, updating of 1985 Committee of International Organisations of Medical Science (CIOMS) "International Guiding Principles for Biomedical Research involving Animals".

- Provision of expert international advice in relation to transport of laboratory animals, including primates, to ensure that the role played by such animal use in animal disease diagnosis and animal disease research is fully recognised and that the assessment of zoonoses transmission is both science- and risk-based

- Ongoing provision of secretariat support for ICLAS, as the established international platform for the harmonisation of laboratory animal welfare standards

- Value of OIE participation in the 2007 meeting of the ICLAS Working Group on Harmonisation

To complement the proposal that the OIE formalises and strengthens its ties with ICLAS, it was suggested that a similar strong relationship be developed with IACLAM. Appendices 5 and 6 outline the established international role of ICLAS and the expertise underpinning the priorities of IACLAM.

Recommendations:

In recognition of the complexity and specialised nature of this topic, it is recommended that the OIE adopt a very focused strategy and establish an ad hoc Group of experts to make recommendations regarding:

1) The need to establish Guiding Principles for Laboratory Welfare and the relevance of the 1985 CIOMS Principles.

2) The development of a strategy which would prioritise and address the following areas of potential involvement

   – The availability of guidelines for the use of animals in regulatory testing of veterinary medicinal, biologica and chemical products.

   – Liaison with VICH and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), to facilitate the regulatory acceptance and adoption of internationally validated non-animal test methods.

   – Potential OIE role in provision of expert international advice on the transport of laboratory animals, including primates

   – Issues relating to the use of animals in research and diagnostic testing.

Annex XXXX (contd)

Appendix V (contd)

- Options for OIE involvement in the use of animals in research and diagnostic testing.
- The availability of guidelines for the use of animals in education and teaching.
- Identification of key international stakeholders and availability of relevant resource material.

The valuable direct input to this paper from Drs Littin, Fraser and Kahn, plus the indirect input from ICLAS and IACLAM, is gratefully acknowledged.

Annex XXXX (contd)

Appendix VI

ANNEX

OIE GUIDELINES ON RESEARCH ANIMAL WELFARE

Preamble

The purpose of this Annex is to provide a conceptual framework for OIE Members to consider when formulating regulatory requirements for the use of live animals in research, testing and teaching.

The OIE recognises the vital role played by the use of live animals in research, testing and teaching. As stated in the OIE Guiding Principles, such use makes a major contribution to the wellbeing of people (and animals). The OIE also recognises the status of animals as sentient beings and the OIE Guiding Principles for animal welfare emphasise the importance of the Three Rs of Russell and Burch.

The system used in practice will vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in these Guidelines in formulating a regulatory framework that is appropriate to their conditions. This framework may be delivered through a combination of national, sub-national and local jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the central role played by veterinarians not only for their training and specialist skills but also as a member of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of animals has an ethical responsibility for the animals' welfare. The approach also ensures that animal use in science leads to high quality scientific outcomes and optimum welfare for the animals used.

In keeping with the overall approach to animal welfare, as detailed in the Guiding Principles, the OIE emphasises the importance of standards based on outcomes from the animal's perspective rather than inputs from a 'systems-design' perspective. At the institutional level the Animal Care and Use Committee plays a critical role in determining the acceptability and protocols for animal use, taking account of the animal welfare implications, the scientific merit and the societal benefit, in a risk-based assessment of each project using live animals.

Definitions (to be developed)

Animal Care and Use Committee (ACUC)

Project Proposal

Operant conditioning

Biocontainment

Bioexclusion

Humane endpoint

Genetically altered animals (GA animals)

Annex XXXX (contd)

Appendix VI (contd)

Scope

These guidelines apply to the use of animals as defined in the Terrestrial Animal Health Code (the *Terrestrial Code*) (excluding bees) in procedures in research, testing and teaching. Animals killed for the primary purpose of harvesting their cells, tissues and organs for use in scientific procedures are also covered. These recommendations are directed to:

All terrestrial vertebrate species, including foetal/embryonic developmental stages from the last third of the developmental period (refer AHAW Report).

In developing an appropriate regulatory framework, member countries should consider both the species and the developmental stage of the animal.

Note: the *ad hoc* Group also recommended that these Guidelines also address aquatic animals, including fish, some amphibians, and some invertebrate species (eg cyclostomes, Cephalopoda and decapod crustaceans) (refer AHAW Report). Given that the OIE's standard setting work in relation to these animals falls under the auspices of the Aquatic Animal Health Standards Commission, the OIE will forward the report of *ad hoc* Group to the this Commission for consideration.

Preamble

The *Terrestrial Code* states that the internationally recognised 'Three Rs' (reduction in numbers of animals, refinement of experimental methods and replacement of animals with non-animal techniques) provide valuable guidance for the use of animals in science.

Most scientists and governments agree that animal testing should cause as little pain and/or distress to animals as possible, and those animal tests should only be performed where necessary. The "Three Rs" of Russell and Burch (1959) (http://altweb.jhsph.edu/publications/humane_exp/het-toc.htm) are guiding principles for the use of animals in research, testing and training. They comprise:

- Reduction refers to methods that enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals.

- Replacement refers to the use of non-animal methods over animal methods, or a lower order species, whenever it is possible to achieve the same scientific aim.

- Refinement refers to methods that prevent, alleviate or minimise potential pain and/or distress and enhance animal welfare for the animals still used.

It is the responsibility of all researchers using animals to ensure that they give due regard to these principles in designing and implementing their research protocols.

Animal Care and Use Programme

Each facility using live animals for research, testing and teaching should have an Animal Care and Use Committee (ACUC) that is responsible, at the institutional level, for ensuring compliance with government requirements for the use of live animals and, in particular, their welfare.

The role of Competent Authorities is to implement a system (governmental or other) of verification of compliance by institutions. This often involves a system of approval (such as licensing of institutions, scientists, and projects) and compliance is assessed by a variety of methods

Critical elements of the Animal Care and Use Programme (ACUP) should be the subject of legislation to empower the government to take appropriate action to ensure compliance with requirements. In some countries, transparency is an important element in the ACUP and is desirable to support public confidence in the regulatory framework. Likewise, a requirement for keeping records on animal use as appropriate to the institution should be included. It may be appropriate to maintain such records on a regional or national basis and to provide some form of public access to such records in order to provide public transparency and confidence.

I. Animal Care and Use Committee (ACUC)

a) Roles and Responsibilities (To be developed)

i) Project Proposal Review

– Review – All projects should undergo an evaluation comprising of:

– assessment of the scientific aims;

– consideration of experimental design including statistics where appropriate;

– consideration of the husbandry and care of the species proposed to be used;

– incorporation of the Three Rs – replacement, reduction and refinement;

– assignment of a severity class,

– an assessment of any health and safety risks;

– an assessment of the harm-benefit analysis, and

– an assessment of methods of restraint and alternatives to restraint such as animal training and *operant conditioning.*

– The review might also include a non-technical summary of the project proposal

ii) Facility inspection

– The ACUC should perform regular inspections of the facilities, some of which should be unannounced. Principles of risk-management should be followed when determining the frequency and nature of inspections.

– The inspection team should include more than one member of the ACUC.

iii) ACUP Review

– The ACUC should be responsible for review of the overall ACUP including :

– Training and competency of all staff;

– The programme of veterinary care;

– The physical facility and environmental conditions;

– Husbandry and operational conditions;

– Sourcing of animals;

Annex XXXX (contd)

Appendix VI (contd)

- Staff Occupational Health and Safety programme; and
- Collection of accurate statistics on the use of animals within the facility to meet government requirements.

– Reporting structure. It is Important that the ACUC should report to a senior individual within the institution who has the authority to implement the Committee's recommendations.

b) Committee Composition

The ACUC should include:

one or more scientists, whose role is to ensure that protocols are designed and implemented in accordance with sound science, that the research is appropriate and valuable, and to ensure compliance with regulatory requirements relevant to research conducted at the establishment.

one or more veterinarians, preferably with competence to work with research animals, whose specific role is to provide advice on the care, use and welfare of the animals.

In addition, it is important to include a member of the animal care staff in the ACUC as these professionals are centrally involved in ensuring the welfare of animals used at the establishment.

Other participants in the ACUC may include statisticians, information scientists and ethicists as appropriate to the studies conducted at the establishment.

It may be appropriate to include representatives of the community (general public) in which the facility is located. This can help to support public confidence that the establishment management takes its responsibilities seriously and that the establishment consistently complies with regulatory requirements.

II. Assurance of Training and Competency

An essential component of the animal care and use program is the assurance that the personnel working with the animals are appropriately trained and qualified to work with the species used and to support the research mission. A system (e.g., institutional, regional, national, etc.) to assure competency should be in place. Continuing professional education opportunities should be made available to relevant staff.

a) Scientists. Due to the specialised nature of animal research, focused training should be offered to supplement educational and experiential backgrounds of researchers (including visiting scientists) before initiating the study. The laboratory animal veterinarian often is a resource for this focused training. Competency in performance of procedures related to their research (e.g., surgery, anaesthesia, dosing, etc.) should be verified.

b) Veterinarians. It is important that veterinarians working in an animal research environment have veterinary medical knowledge and experience in the species used and they should have a working knowledge of research methodology. Relevant approvals issued by the Veterinary Statutory Body and appropriate national schemes (where theses exist) should be adopted as the reference for veterinary training (also see Annex 2).

c) Animal Care Staff. Animal care staff should be offered training that is consistent with the scope of their work responsibilities and their competency in the performance of these tasks should be verified.

d) Students. Wherever possible, students should learn about animal research using non-animal methods (videos, computer models, etc). Wherever it is necessary for students to participate in classroom or research activities involving animals, they should receive appropriate oversight in the use of animals until such time that they have demonstrated competency in the related procedure(s).

III. Provisions of Veterinary Care

Adequate veterinary care includes responsibility for the promotion and monitoring of an animal's welfare before, during and after experimentation or testing. Animal welfare includes both physical and psychological aspects of an animal's condition evaluated in terms of environmental comfort, freedom from pain and distress and appropriate social interactions, both with conspecifics and with man. The veterinarian must have the authority and responsibility for making determinations concerning animal welfare and assuring that animal welfare is adequately monitored and promoted.

a) Clinical Responsibilities. Preventive medicine programmes such as vaccinations, ecto- and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular species and source. Disease surveillance is a major responsibility of the veterinarian and should include routine monitoring of colony animals for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical disease. The veterinarian must have authority to use appropriate treatment or control measures, including euthanasia if indicated, following diagnosis of an animal disease or injury. If possible, the veterinarian should discuss the situation with the principal investigator to determine a course of action consistent with experimental goals. The veterinarian has the responsibility to ensure that controlled drugs are managed in accordance with applicable regulations.

b) Veterinary Medical Records. Medical records are considered to be a key element of a programme of adequate veterinary care for animals used in research, teaching, and testing. Application of performance standards within the medical record program allows the veterinarian to effectively employ professional judgment, ensuring that the animal receives the highest level of care available.

c) Advice on zoonotic risks and notifiable diseases. The use of some species of research animals poses a risk of the transmission of zoonotic disease (e.g., nonhuman primates). The veterinarian should be consulted to identify sources of animals that minimize these risks and to advise on measures that may be taken in the animal facility to minimize the risk of transmission (e.g., personal protective equipment, air pressure differentials in animal holding rooms, etc.). Animals brought into the institution may carry diseases that require notification of government officials. It is important that the veterinarian be aware of, and comply, with these requirements.

d) Advice on surgery and postoperative care. A programme of adequate veterinary care includes the review and approval of all preoperative, surgical and postoperative procedures by a qualified veterinarian. A veterinarian's inherent responsibility includes monitoring and providing recommendations concerning preoperative procedures, surgical techniques, the qualifications of institutional staff to perform surgery and the provision of postoperative care.

e) Advice on analgesia and anaesthesia. Adequate veterinary care includes providing guidance to animal users and monitoring animal use to assure that appropriate methods of handling and restraint are being used and to ensure proper use of anaesthetics, analgesics, tranquilizers, and methods of euthanasia. Written guidelines regarding the selection and use of anaesthetics, analgesics and tranquilizing drugs and euthanasia practices for all species used must be provided and periodically reviewed by the veterinarian.

Annex XXXX (contd)

Appendix VI (contd)

f) Advice on humane endpoints and euthanasia. Humane endpoints are established for both experimental and humane reasons. An experimental endpoint is chosen to mark the planned end of an experimental manipulation and associated data gathering. In experiments with unrelieved or unanticipated pain/or distress, humane endpoints are criteria that indicate or predict pain, distress, or death and are used as signals to end a study early to avoid or terminate pain and/or distress. Ideal endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardizing the study's objectives. However, in most cases, humane endpoints are developed and used to reduce the severity and duration of pain and/or distress.

The veterinarian has a key role in ensuring that humane endpoints, as approved by the ACUC, are followed during the course of the study. It is essential that the veterinarian have the responsibility and authority to ensure euthanasia is administered as required to relieve pain and distress in research animals, provided such intervention is not specifically precluded in protocols reviewed and approved by the ACUC.

IV. Physical Facility and Environmental Conditions

A well-planned, well-designed, well-constructed, and properly maintained facility is an important element of good animal care and use, and it facilitates efficient, economical, and safe operation. The design and size of an animal facility depend on the scope of institutional research activities, the animals to be housed, the physical relationship to the rest of the institution, and the geographic location. An animal facility should be designed and constructed in accordance with all applicable building standards. Animals should be housed in facilities dedicated to or assigned for that purpose and should not be housed in laboratories merely for convenience. Security measures (e.g., locks, fences, cameras, etc.) should be in place to protect the animals. For many species (e.g., rodents, , environmental conditions should be controllable to minimize physiological changes in the animals due to the stress of accommodating to changing temperature, humidity, light, noise, etc.

V. Husbandry

High standards of care and accommodation enhance the welfare of the animals used and promote the scientific validity of animal research. Animal care and accommodation shall demonstrably, as a minimum, conform to relevant, published national or international animal care, accommodation and husbandry guidelines.

a) Acclimatisation. Regardless of the duration of quarantine, newly received animals should be given a period for physiological, psychological, and biochemical stabilization before their use. The length of time for stabilization will depend on the type and duration of animal transportation, the species involved, country of origin, and the intended use of the animals.

b) Enrichment. Animals should be housed with a goal of maximizing species-specific behaviors and minimizing stress-induced behaviors. One way to achieve this is to enrich the structural and social environment of the research animals, and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the animals or people or interfere with the research goals.

c) Normal Behavior. The housing environment and husbandry practices should take into consideration the normal behavior of the species to minimize stress and facilitate the production of sound research data.

VI. Source of animals

Animals to be used for research, testing and teaching should be of high quality to ensure reproducibility of research and testing accordingly.

a) Legal and humane procurement. The acquisition of animals should be made legally. It is preferable that animals are purchased from recognized institutions producing high quality research animals.

It is desirable to use purpose bred animals where these are available. The use of animals that are not bred for the intended use should be avoided if possible.

The use of non purpose bred animals, including farm animals, non traditional breeds and species and animals captured in the wild, is sometimes necessary to achieve study goals.

b) Animal health status. Animals should have appropriate health profiles for their intended use. Health status of animals should be known before initiating research.

c) Genetically altered animals. If genetically altered animals have to be used, relevant legislation should be observed. Records of biocontain ment requirements, genetic information, and individual identification should be kept and communicated between the provider and recipient.

d) Animals captured in the wild. If wild animals need to be used, the capture technique should be humane with due regard to human and animal health and safety.

e) Reuse of animals. If animals have to be reused, the approval of the ACUC should be obtained. All animals to be reused should have a good health status. JM to provide further advice

f) Transport, importation and exportation. Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and microbiological status, with care to ensure appropriate containment (see OIE Appendix on transport of animals)

g) Biosecurity risks. To reduce biosecurity risks related to research animals, the microbiological status of research animals should be confirmed and appropriate biocontainment and bioexclusion should be provided. Biosecurity risks to animals arising from exposure to humans should also be addressed.

VII. Occupational Health and Safety (To be developed -scratch, biting kicking, physical, chemical and radiation risks Study related risk)

Institutional measures for occupational health and safety should be extended to the animal care and use programme. Appropriate measures should be taken to protect animal users, animal care staff and students and others who may be exposed to animals or animal by products. An educational program for occupational health and safety should be implemented.

a) Infectious diseases including zoonotic diseases. To protect the staff in research settings, infectious diseases including zoonotic diseases should be identified. Appropriate health protection measures should be effected.

b) Allergies. Risks can be minimised by the occupational health and safety programme, including facility ventilation, biocontainment, appropriate equipment and health protection measures (e.g. mask, eye protection, gown, gloves).

Annex XXXX (contd)

Appendix VI (contd)

VIII. Importance of post approval monitoring and validation

Following the approval of a protocol, a post approval monitoring system should be implemented to ensure the consistency of procedures and the validation of results.

List of references (To be developed)

Annex XXXX (contd)

Appendix VII

Plan to complete the first report of the *ad hoc* Group on Laboratory Animal Welfare

December 2007 -February 2008

Topic	Deadline	Who	Specific Actions
1. Draft report	10/12/07	Central Bureau	To revise draft report
2. Draft report	14/12/07	*ad hoc* Group Members	Members to return the draft report with comments
3. Final report	05/01/08	Central Bureau	OIE to send final report to *ad hoc* Group Members
4. Final report	14/01/08	*ad hoc* Group Members	To finalise strategic priorities (Annexe)
5. Final report	16/01/08	Central Bureau	To circulate final report to the AWWG for comment
6. Final report	07/02/08	Central Bureau	To include final report on the Code Commission agenda

Annex XXXX (contd)

Appendix VIII

***Ad hoc* Group on Laboratory Animals Welfare - Work Programme**

General issue	Priorities of *Ad hoc* Group	Implementation /Responsibility	Status
Ad hoc Group report	To finalise the ad hoc Group report	*ad hoc* Group Members	
Ad hoc Group report	To finalise the proposed strategic priorities	*ad hoc* Group Members	
Ad hoc Group report	To complete the work on items identified in the Terms of Reference including the recommendations in the Issues and Options Discussion Paper	*ad hoc* Group Members and Central Bureau	

Annex XLI

FUTURE WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Topic		
Action	**How to be managed**	**Status (March 2008)**
1. Restructuring of the *Terrestrial Code* 2. Harmonisation of *Terrestrial* and *Aquatic Codes*		
1. Divide the *Terrestrial Code* into 2 volumes 2. Work with AAHSC towards harmonisation, as appropriate, of the Codes 3. Reorganization of semen & embryo appendices	TAHSC, ITD & experts	1. Proposal endorsed by TAHSC 2. Ongoing 3. To discuss in September 2008
Anthrax		
Develop APP on the inactivation of *B. anthracis*	TAHSC	Discuss in Sep 07
BSE – safety of gelatine and tallow		
Update CH	TAHSC	Modified text for adoption
BSE		
Consolidate CH, APP & questionnaire	New AHG under SCAD	Ongoing
Scrapie		
Update CH	TAHSC & experts	Modified text proposed for MC
Evaluation of VS and OIE PVS		
1. Ongoing review of PVS [2. Address aquatic animal health services]	1. AHG 2. AHG & ITD	1. AHG in September 2008 2. Ongoing
Containment zone		
Develop text for CH 1.3.5.	TAHSC	New text for adoption
Compartmentalisation general guidelines		
Develop APP	SCAD, AHG	New text for adoption
Compartmentalisation for vector born diseases		
To draft on a disease by disease basis	SCAD to provide recommendations on SURV and technical requirements	Modified text on establishment (BT SURV) for adoption. AHG in 2008 under SCAD
Surveillance for vector borne diseases		
Develop guidelines (APP)	SCAD	AHG in 2008 under SCAD
Harmonisation of international health certificates		
Review of model VCs under way	APFSWG; AHG in Jan 2008	New text for adoption.
Other *Terrestrial Code* texts in need of revision		
Update CH on EI	SCAD	Modified text for adoption.
Update CH and APP on AHS	TAHSC	Modified text for adoption.
Update CH on Brucellosis	SCAD; APFSWG	AHG in 2008 under SCAD
Update FMDV inactivation APP	SCAD / experts: further work to be done on inactivation in meat	Modified text on casings for adoption
Update CH on ND & develop APP on SURV & inactivation	SCAD / experts Virus inactivation pending expert advice	Modified CH & SURV APP for adoption
Update CH on CSF (disease freedom & wildlife)	SCAD	Modified text for adoption
Update CH on ASF	SCAD	Modified text for adoption

Annex XLI (contd)

Develop new CH on WNF	TAHSC, BSC (diagnostic testing)	Discuss in September 2007
Reformat Rinderpest & CBPP CH and SURV APP	SCAD	RP CH for adoption, RP SURV & CBPP proposed for MC
Develop CH on SHB	SCAD, experts	New CH for adoption
CH on Leptospirosis	TAHSC	Deletion of CH for adoption
CH on Paratuberculosis	BSC (diagnostic test) & SCAD	No new work until diagnostic issue resolved
Introduction to AMR CH	BSC	New work
Develop CH on Animal Health in the production of Animals using SCNT technique	BSC	New text for adoption
Animal Production Food Safety		
Publish a joint OIE/FAO Guide to Good Farming Practices	TAHSC & APFSWG	Ongoing
Salmonellosis 1. Consolidate CH on salmonella control. 2. Update hygiene and disease security procedures APP	APFSWG & AHG	Ongoing Revised texts proposed for MC
Cysticercosis	APFSWG	ongoing
Campylobacterosis	APFSWG	ongoing
APP on Animal Identification & Traceability	APFSWG & AHG	New text for adoption
APP on Animal Feeding	APFSWG & AHG	ongoing
Animal welfare		
New texts: 1. Dog populations 2. Lab animals 3. Livestock production systems	PAWWG & AHGs	1. Ongoing 2. Ongoing 3. AHG to be convened in April 2008.
Alternative approaches to providing OIE advice		
Develop alternative mechanism for providing guidance to Members on managing certain animal health and welfare issues outside the Code framework	TAHSC, PAWWG, APFS WG & ITD	Ongoing
Commodity-based measures for trade		
1. Prepare guidance doc on use of the *Terrestrial Code* to facilitate trade 2. Examine scientific evidence that beef (deboned matured pH tested) may safely traded regardless of disease status of exporting country/zone 3 OIE/DEFRA project	1. Expert/TAHSC 2. TAHSC/SCAD 3 ITD/S&T Dept	1 AHG in July 2008
Role of wildlife as disease reservoirs		
APP on disease SURV in wildlife	WG on Wildlife, SCAD	Ongoing
Compartmentalisation in other chapters		
Aujeszky's disease and FMD	TAHSC	Started working
Concept of Community animal health worker		
To prepare guidance on the topic	TAHSC & AHG	Started working
Role of the Veterinary Services in Food Safety		
For further consideration	APFSWG	New text for adoption

Note: MC; Member comments, APP: appendix, CH: chapter, SURV: surveillance, ITC: International Trade Department, S&T Dept: Scientific & Technical Department, IC: International Committee