

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

**Paris, 7–18 September 2009**

---

**List of participants**

**MEMBERS OF THE CODE COMMISSION**

---

**Dr A. Thiermann**

*(President)*

US Mission to the OIECD  
19, rue de Franqueville  
75016 Paris  
FRANCE  
Tel.: 33-(0)1 44 15 18 69  
E-mail: [a.thiermann@oie.int](mailto:a.thiermann@oie.int)

**Dr E. Bonbon**

*(Vice-President)*

Commission européenne  
DG SANCO-D1  
Rue Froissart 101  
1040 Bruxelles  
Belgique  
Tel: 32-2-2985845  
Fax: 32-2-2953144  
E-mail:  
[etienne.bonbon@ec.europa.eu](mailto:etienne.bonbon@ec.europa.eu)

**Dr J. Caetano**

*(Secretary General)*

Director of Animal Programme  
Secretaria de Defesa Agropecuaria  
Ministerio da Agricultura, Pecuaria e  
Abastecimento  
Espl. dos Ministerios  
Bloco D Anexo B4 -ANDAR  
70.043-900 Brasilia DF  
BRAZIL  
Tel.: (55-61) 321.823.14/321.823.15  
E-mail [jcaetano@agricultura.gov.br](mailto:jcaetano@agricultura.gov.br)

**Dr S.K. Hargreaves**

Principal Director of Livestock  
and Veterinary Services  
Ministry of Agriculture  
PO Box CY66  
Causeway Harare  
ZIMBABWE  
Tel.: (263-4) 791.355/722.358  
Fax: (263-4) 791.516  
E-mail: [skhargreaves@zol.co.zw](mailto:skhargreaves@zol.co.zw)

**Prof. A.M. Hassan**

Veterinary Expert  
Federal Ministry of Animal Resources  
and Fisheries  
Khartoum  
SUDAN  
Tel.: (249) 912.163.979  
Fax: (249) 834.75 996  
E-mail: [ahmedhassan32@hotmail.com](mailto:ahmedhassan32@hotmail.com)  
[hescobusiness@yahoo.com](mailto:hescobusiness@yahoo.com)

**Prof. S.C. MacDiarmid**

Principal International Adviser  
Risk Analysis, International Coordination  
Adjunct Professor in Veterinary Biosecur  
(Massey University)  
Biosecurity New Zealand  
P.O. Box 2526  
Wellington  
NEW ZEALAND  
Tel.: (64-4) 894.0420  
Fax: (64-4) 894.0731  
E-mail:  
[Stuart.MacDiarmid@maf.govt.nz](mailto:Stuart.MacDiarmid@maf.govt.nz)

**OTHER PARTICIPANTS**

**Prof. Michel Thibier**

Professeur Michel THIBIER  
Conseil Général de de l'Agriculture de l'Alimentation et des Espaces  
Ruraux  
Ministère de l'Alimentation, de l'Agriculture et de la Pêche  
251 rue de Vaugirard  
75732 Paris Cedex 15  
FRANCE  
Tel: +33 (0)1 49 55 84 33  
Fax :+33 (0)1 49 55 81 69  
[michel.thibier@agriculture.gouv.fr](mailto:michel.thibier@agriculture.gouv.fr)

Annex I (contd)**OIE HEADQUARTERS**

---

**Dr B. Vallat**  
Director General  
12, rue de Prony  
75017 Paris  
FRANCE  
Tel.: 33 (0)1 44 15 18 88  
Fax: 33 (0)1 42 67 09 87  
E-mail: [ois@ois.int](mailto:ois@ois.int)

**Dr Sarah Kahn**  
Head  
International Trade Department  
OIE  
Tel.: 33 (0)1 44.15.18.80  
E-mail: [s.kahn@ois.int](mailto:s.kahn@ois.int)

**Dr Y. Atagi**  
Deputy Head  
International Trade Department  
OIE  
Tel.: 33 (0)1 44.15.18.92  
E-mail: [y.atagi@ois.int](mailto:y.atagi@ois.int)

**Dr W. Pelgrim**  
Chargé de mission  
OIE  
Tel.: 33 (0)1 44 15 18 68  
E-mail: [w.pelgrim@ois.int](mailto:w.pelgrim@ois.int)

**Dr L. Stuardo**  
Chargé de mission  
International Trade Department  
OIE  
Tel.: 33 (0)1 44 15 18 72  
E-mail: [l.stuardo@ois.int](mailto:l.stuardo@ois.int)

**Dr Gillian Mylrea**  
Chargée de mission  
International Trade Department  
OIE  
Tel.: 33 (0)1 44.15.18.67  
E-mail: [g.mylrea@ois.int](mailto:g.mylrea@ois.int)

---

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

**Paris, 7–18 September 2009**

---

**Adopted agenda**

1. Welcome - Director General

**A. MEETING WITH THE DIRECTOR GENERAL**

**B. JOINT MEETING OF THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION**

1. Interface of wildlife and livestock how to incorporate the relevant wildlife aspects into disease-specific chapters
2. Joint discussion on specific chapters
  - a) Animal health surveillance
  - b) Foot and mouth disease
  - c) Swine vesicular disease
  - d) Avian influenza and Newcastle disease
  - e) Classical swine fever
  - f) Other issues

**C. EXAMINATION OF MEMBER COMMENTS AND WORK OF RELEVANT EXPERT GROUPS**

1. Update on reports of other commissions and other relevant activities of the OIE - President of the Commission
2. Code revision
  - Item 1 Glossary
  - Item 2 Animal health surveillance (Chapter 1.4.)
  - Item 3 Surveillance of arthropod vectors of animal disease (Chapter 1.5.)

Annex II (contd)

- Item 4 Status for OIE listed diseases (Chapter 1.6.)
- Item 5 Import risk analysis (Chapter 2.1. and report of the *ad hoc* Group)
- Item 6 Evaluation of veterinary services (Chapters 3.1. and 3.2.)
  - a) Draft revisions to Chapter 3.1. and 3.2.
  - b) Guidelines on veterinary legislation
  - c) PVS Feed back session in December 2009
- Item 7 Design and implementation of identification systems to achieve animal traceability (Chapter 4.2.)
- Item 8 Zoning and compartmentalisation
  - a) Zoning and compartmentalisation (Chapter 4.3.)
  - b) Application of compartmentalisation (Chapter 4.4.)
- Item 9 Semen and embryo chapters (Chapters 4.5.- 8., 10.)
- Item 10 General obligations related to certification (Chapter 5.1.)
- Item 11 Control of hazards of animal health and public health importance in animal feed (Chapter 6.3.)
- Item 12 Control of hazards of animal health and public health importance in heat treated pet food (new draft Chapter)
- Item 13 Salmonellosis
  - a) Report on the Codex Working Group meeting (Brazil 7-12 September 2009)
  - b) Biosecurity procedures in poultry production (revised Chapter 6.4.)
  - c) Prevention, detection and control of Salmonella in poultry (Chapter 6.5.) and Salmonella enteritidis and Salmonella typhimurium in poultry (Chapter 6.6.).
- Item 14 Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.7.)

## Item 15 Animal welfare

- a) Use of animals in research and education (new draft chapter) and report of the third meeting of the OIE *ad hoc* Group on Laboratory Animal Welfare (including OIE discussion paper on air transport of laboratory animals).
- b) Animal welfare definition (Chapter 7.1.)
- c) Stray dog population control (Chapter 7.7.)
- d) Report of the eighth meeting of the OIE Animal Welfare Working Group
- e) Report of the OIE Electronic Consultation Group on Poultry Welfare
- f) Report of the first meeting of the OIE *ad hoc* Group on Animal Welfare and Broiler Chicken Production Systems
- g) Report of the first meeting of the OIE *ad hoc* Group on Animal Welfare and Beef Cattle Production Systems.

## Item 16 Other horizontal chapters

- a) Animal health measures applicable before and at departure (Chapter 5.4.)
- b) Border posts and quarantine stations in the importing country (Chapter 5.6.)

## Item 17 Anthrax (Chapter 8.1.)

## Item 18 Bluetongue (Chapter 8.3.)

## Item 19 Foot and mouth disease (Chapter 8.5.)

## Item 20 Paratuberculosis (Chapter 8.9.)

## Item 21 Rabies (Chapter 8.10.)

## Item 22 West Nile fever (Chapter 8.16.)

## Item 23 Diseases of bees (Chapters 9.1. –6.)

## Item 24 Avian influenza (Chapter 10.4.)

## Item 25 Newcastle disease (Chapter 10.13.)

## Item 26 Bovine brucellosis (Chapter 11.3.)

Annex II (contd)

- Item 27 Bovine spongiform encephalopathy (Chapter 11.6.)
- Item 28 Bovine tuberculosis (Chapter 11.7.) and Bovine tuberculosis of farmed cervidae (Chapter 11.8.)
- Item 29 Contagious bovine pleuropneumonia (Chapter 11.9.)
- Item 30 Enzootic bovine leukosis (Chapter 11.11.)
- Item 31 Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis (Chapter 11.13.)
- Item 32 Equine diseases
  - a) African horse sickness (Chapter 12.1. inactivated vaccine from GS77)
  - b) Equine influenza (Chapter 12.7.)
  - c) Equine viral arteritis (Chapter 12.10.)
- Item 33 Scrapie (Chapter 14.9., semen/embryo issue with IETS, historical freedom)
- Item 34 Classical swine fever (Chapter 15.3.)
- Item 35 Swine vesicular disease (Chapter 15.5.)
- Item 36 Teschovirus encephalomyelitis (Chapter 15.6.)

**C. Other issues**

- Item 37 Private standards for sanitary measures and animal welfare – update.
- Item 38 Trade in Animal Products (“commodities”) – status report.
- Item 39 Wildlife disease reporting: update on developments with WAHIS
- Item 40 Future work programme of the Code Commission
- Item 41 Other issues

## GLOSSARY

For the purposes of the *Terrestrial Code*:

### **Central Bureau Headquarters**

means the Permanent Secretariat of the World Organisation for Animal Health ~~which headquarters are located at:~~

12, rue de Prony, 75017 Paris, FRANCE

Telephone: 33-(0)1 44 15 18 88

Fax: 33-(0)1 42 67 09 87

Electronic mail: oie@oie.int

WWW: <http://www.oie.int>

### ***Early detection system***

means a system for the timely detection and identification of an incursion or emergence of *diseases/infections* in a country, *zone* or *compartment*. An early detection system should be under the control of the *Veterinary Services* and should include the following characteristics:

- a. representative coverage of target animal *populations* by field services;
- b. ability to undertake effective *disease* investigation and reporting;
- c. access to laboratories capable of diagnosing and differentiating relevant *diseases*;
- d. a training programme for *veterinarians*, *veterinary para-professionals*, livestock owners/keepers and others involved in handling *animals* for detecting and reporting unusual animal health incidents;
- e. the legal obligation of private *veterinarians* to report to the *Veterinary Authority*;
- f. a national chain command.

### ***Quarantine station***

means a ~~premises~~ an establishment under the control of the *Veterinary Authority* where *animals* are maintained in isolation with no direct or indirect contact with other *animals*, to ~~prevent~~ ensure that there is no the transmission of specified pathogen(s) outside the establishment while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing and treatment. The presence of disease or infection in animals in the quarantine station does not affect the animal health status of the country or zone.

### ***Uncertainty***

means the lack of precise knowledge of the input values ~~which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the scenario being assessed.~~

### ***Variability***

means a real-world complexity in which the value of an input is not the same for each case due to natural diversity in a given population.

-----  
— text deleted



## PROPOSED CHAPTER ON COMMUNICATION

### General considerations

#### *Introduction*

There is a need to institutionalize communication as a discipline within Veterinary Services in order for them to achieve effective internal and external communication. Communication underpins everything that Veterinary Services do including prevention, surveillance, animal welfare, disease response, public health and food safety. The integration/combination of veterinary and communication expertise is essential for effective communication.

#### *Principles*

- Communication is a continuous process
- Veterinary Services should be mandated and have the authority to communicate
- Veterinary Services are responsible to plan, implement, monitor, evaluate and revise communication
- Importance of joint technical veterinary expertise and professional communication skills when intending to disseminate scientific information
- Suitable criteria for communication
  - Transparency
  - Consistency
  - Timeliness
  - Balance
  - Accuracy
  - Honesty
  - Targeted

### Definitions

#### ***Communication***

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

#### ***Crisis***

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

#### ***Crisis Communication***

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

#### ***Outbreak communication***

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

Annex III (contd)

## Required elements

- Proper organizational structure within VS
  - VS should be mandated and have the authority to communicate
  - Dedicated communication unit
  - Official contact points
  - Clearly defined chain of command (governance)
- Human resources
  - Qualified personnel
  - Training
  - Adequate number (back-up)
  - Job descriptions
- Financial and material resources
  - Budget
  - Equipment
    - Office equipment
    - Technical equipment
    - Access to the Internet
  - Suitable premise/accommodation
- Documentation for demonstration (evidence to demonstrate capabilities)
  - Policies on communication
  - Work plans
  - Communication products
- Quality assessment and evaluation
  - Monitoring system in place
- Consequences
 

For the society

  - Increased knowledge and awareness
  - Acceptance of policy decisions
  - Consequential change of perception, attitude and/or behaviour

For VS

  - Raising the profile/awareness/knowledge
  - Improve trust/credibility

---

-----  
 — text deleted

## CHAPTER 1.4.

**ANIMAL HEALTH SURVEILLANCE**

## Article 1.4.1.

**Introduction and objectives**

1. In general, *surveillance* is aimed at demonstrating the absence of *disease* or *infection*, determining the occurrence or distribution of *disease* or *infection*, while also detecting as early as possible exotic or *emerging diseases*. The type of *surveillance* applied depends on the desired outputs needed to support decision-making. The following recommendations may be applied to all *diseases*, their agents and all susceptible species (including wildlife) as listed in the *Terrestrial Code*, and are designed to assist with the development of *surveillance* methodologies. Except where a specific *surveillance* method for a certain *disease* or *infection* is already described in the *Terrestrial Code*, the recommendations in this chapter may be used to further refine the general approaches described for a specific *disease* or *infection*. Where detailed *disease/infection*-specific information is not available, suitable approaches should be based on the recommendations in this chapter.
2. Animal health *surveillance* is an essential tool to detect *disease* or *infection*, to monitor disease trends, to facilitate the control of *disease* or *infection*, to support claims for freedom from *disease* or *infection*, to provide data for use in *risk analysis*, for animal and/or public health purposes, and to substantiate the rationale for sanitary measures. Both domestic and wild *animals* are susceptible to certain *disease/infection*. However, ~~in the presence of appropriate biosecurity measures, *disease/infection* in wild *animals* does not imply mean~~ that the same *disease/infection* is necessarily present in domestic *animals* in the same country or *zone*. *Surveillance* data underpin the quality of disease status reports and should satisfy information requirements of *risk analysis* for *international trade* and for national decision-making. Wildlife may be included because they can serve as reservoirs and as indicators of human and domestic animal and wildlife *disease*. Wildlife *disease/infection surveillance* presents specific challenges that may differ significantly from *surveillance* in livestock.
3. Prerequisites to enable an OIE Member to provide information for the evaluation of its animal health status are:
  - a. that the Member complies with the provisions of Chapter 3.1. of the *Terrestrial Code*;
  - b. that, where possible, *surveillance* data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);
  - c. that transparency in the planning and execution of *surveillance* activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1. of the *Terrestrial Code*.
4. The objectives of this chapter are to:
  - a. provide guidance to the type of outputs that a *surveillance* system should generate;
  - b. provide recommendations to assess the quality of *disease/infection surveillance* systems.

Annex IV (contd)

## Article 1.4.2.

**Definitions**

The following definitions apply for the purposes of this chapter:

**Bias:** means a tendency of an estimate to deviate in one direction from a true value.

**Case definition:** means a set of criteria used to classify an *animal* as a *case*.

**Confidence:** in the context of demonstrating freedom from *infection*, confidence is the probability that the type of *surveillance* applied would detect the presence of *infection* if the population were infected. The confidence depends on, among other parameters, the assumed level of *infection* in an infected population. The term refers to confidence in the ability of the *surveillance* applied to detect *disease/infection*, and is equivalent to the sensitivity of the *surveillance* system.

**Probability sampling:** means a sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

**Sample:** means the group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide *surveillance* information.

**Sampling units:** means the unit that is sampled, either in a random survey or in non-random *surveillance*. This may be an individual *animal* or a group of *animals* (e.g. an *epidemiological unit*). Together, they comprise the sampling frame.

**Sensitivity:** means the proportion of truly positive units that are correctly identified as positive by a test.

**Specificity:** means the proportion of truly negative units that are correctly identified as negative by a test.

**Study population:** means the population from which *surveillance* data are derived. This may be the same as the target population or a subset of it.

**Surveillance system:** means a method of *surveillance* that may involve one or more component activities that generates information on the health, disease or zoonosis status of animal populations.

**Survey:** means an investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

**Target population:** means the population about which conclusions are to be inferred.

**Test:** means a procedure used to classify a unit as either positive, negative or suspect with respect to a *disease* or an *infection*.

**Test system:** means a combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

## Article 1.4.3.

**Principles of surveillance**1. Types of surveillance

- a. *Surveillance* may be based on many different data sources and can be classified in a number of ways, including:
- i. the means by which data are collected (active versus passive *surveillance*);
  - ii. the disease focus (pathogen-specific versus general *surveillance*); and
  - iii. the way in which units for observation are selected (structured surveys versus non-random data sources).
- b. In this chapter, *surveillance* activities are classified as being based on:

## EITHER

- i. structured population-based surveys, such as:
  - systematic sampling at *slaughter*;
  - random surveys;
  - surveys for *infection* in clinically normal *animals*, including wildlife;

## OR

- ii. structured non-random *surveillance* activities, such as:
  - *disease* reporting or notifications;
  - control programmes/health schemes;
  - targeted testing/screening;
  - ante-mortem and post-mortem inspections;
  - laboratory investigation records;
  - biological specimen banks;
  - sentinel units;
  - field observations;
  - farm production records;
  - wildlife disease data.

Annex IV (contd)

- c. In addition, *surveillance* data should be supported by related information, such as:
- i. data on the epidemiology of the *disease/infection*, including environmental, host population distribution, and climatic information;
  - ii. data on animal movements, including transhumance, as well as natural wildlife migrations;
  - iii. trading patterns for *animals* and animal products;
  - iv. national animal health regulations, including information on compliance with them and their effectiveness;
  - v. history of imports of potentially infected material; and
  - vi. biosecurity measures in place;
  - vii. the ~~risk~~ likelihood and consequence of *disease/infection* introduction.
- d. The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

In assessing the quality of a *surveillance* system, the following critical elements need to be addressed over and above quality of *Veterinary Services* (Chapter 3.1.).

## a. Populations

Ideally, *surveillance* should be carried out in such a way as to take into account all animal species susceptible to the *infection* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the population or part of them. When *surveillance* is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease chapters of the *Terrestrial Code*.

## b. Time frame (or temporal values of surveillance data)

*Surveillance* should be carried out at a frequency that reflects the biology of the *infection* and the *risks* of its introduction.

## c. Epidemiological unit

The relevant *epidemiological unit(s)* for the *surveillance* system should be defined to ensure that it is ~~representative of the population~~ appropriate to meet the objectives of *surveillance*. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, *vectors*, immune status, genetic resistance and age, sex, and other host criteria.

## d. Clustering

*Infection* in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected *animals* within a *herd*, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of *surveillance* activities and the statistical analysis of *surveillance* data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

## e. Case definition

A ~~clear case definition~~ should be defined ~~developed~~ for each *disease* /*infection* under *surveillance*, using clear criteria and, where they exist, the standards in the *Terrestrial Code*. For wildlife *disease/infection surveillance*, it is essential to correctly identify and report host animal taxonomy (including genus and species).

## f. Analytical methodologies

*Surveillance* data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant host species, pathogens, varying production and *surveillance* systems, and types and amounts of data and information available.

The methodology used should be based on the best information available. It should also be in accordance with this chapter, fully documented and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

## g. Testing

*Surveillance* involves the detection of *disease* or *infection* by the use of appropriate case definitions based on the results of one or more tests for evidence of *infection* or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an impact on the conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

The values of sensitivity and specificity for the tests used should be specified for each species in which they may be used, and the method used to determine or estimate these values should be documented. Alternatively, where values for sensitivity and/or specificity for a particular test are specified in the *Terrestrial Manual*, these values may be used as a guide.

Annex IV (contd)

Samples from a number of *animals* or units may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

## h. Quality assurance

*Surveillance* systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

## i. Validation

Results from animal health *surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

## j. Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as government ministries, non-governmental organisations, and others, particularly for data involving wildlife;
- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- maintenance of disaggregated data rather than the compilation of summary data;
- minimisation of transcription errors during data processing and communication.

## Article 1.4.4.

**Structured population-based surveys**

In addition to the principles for *surveillance* discussed above, the following recommendations should be used when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of the two following ways:

Annex IV (contd)

- a. non-probability based sampling methods, such as:
  - i. convenience;
  - ii. expert choice;
  - iii. quota;
- b. probability based sampling methods, such as:
  - i. simple random selection;
  - ii. cluster sampling;
  - iii. stratified sampling;
  - iv. systematic sampling.

Periodic or repeated surveys conducted in order to document *disease* freedom should be done using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

## 2. Survey design

The population of *epidemiological units* should first be clearly defined; hereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size ~~and~~, structure and degree of understanding of the population being studied, the epidemiology of the *infection* and the resources available.

Data on wild animal population size often do not exist and should be determined before a survey can be designed. The expertise of wildlife biologists may be sought in the gathering and interpretation of such population data. Historical population data should be updated since these may not reflect current populations.

## 3. Sampling

The objective of sampling from a population is to select a subset of units that is representative of the population of interest with respect to the objective of the study. Sampling should provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems.

Specimens from wildlife for *surveillance* may be available from sources such as hunters and trappers, road-kills, wild animal *meat* markets, sanitary inspection of hunted *animals*, morbidity-mortality observations by the general public, wildlife rehabilitation centres, wildlife biologists and wildlife agency field personnel, farmers, and other landholders, naturalists and conservationists. Wildlife data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

Annex IV (contd)4. Sampling methods

When selecting *epidemiological units* from within a population, probability sampling (e.g. simple random selection) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 1.4.5.

**Structured non-random surveillance**

*Surveillance* systems routinely use structured non-random data, either alone or in combination with surveys.

1. Common non-random surveillance sources

A wide variety of non-random *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide. Some *surveillance* systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes).

## a. Disease reporting or notification systems

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for *risk analysis*, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimized (to hours in the case of introduction of a foreign animal disease).

Whenever the responsibility for disease notification falls outside the scope of the *Veterinary Authority*, for example in some countries for *diseases* in wildlife, effective communication and data sharing should be established with the relevant authorities to ensure comprehensive and timely disease reporting.

## b. Control programmes / health schemes

Animal *disease* control programmes or health schemes, while focusing on the control or eradication of specific *diseases*, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured *surveillance*.

## c. Targeted testing / screening

This may involve testing targeted to selected sections of the population (subpopulations), in which *disease* is more likely to be introduced or found. Examples include testing culled and dead *animals*, swill fed *animals*, those exhibiting clinical signs, *animals* located in a defined geographic area and specific age or commodity group.

## d. Ante-mortem and post-mortem inspections

Inspections of *animals* at *slaughterhouses* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse* inspection for detecting the presence of specified *diseases* under the inspection system in place should be pre-determined. The accuracy of the inspection system will be influenced by:

- i. the training, experience and number of the inspection staff;
- ii. the involvement of the *Competent Authorities* in the supervision of ante-mortem and post-mortem inspections;
- iii. the quality of construction of the *slaughterhouse*, speed of the slaughter chain, lighting quality, etc.; and
- iv. staff morale and motivation for efficient performance.

*Slaughterhouse* inspections are likely to provide good coverage for particular age groups and geographical areas only. *Slaughterhouse surveillance* data are subject to biases in relation to target populations (e.g. only *animals* of a particular class and age are likely to be slaughtered for human consumption in significant numbers). Such biases need to be recognised when analysing *surveillance* data.

For traceback and analysis of spatial and *herd*-level coverage, there should be, if possible, an effective identification system that relates *animals* in the *slaughterhouse* to their locality of origin.

## e. Laboratory investigation records

Analysis of laboratory investigation records may provide useful *surveillance* information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with *abattoir* inspections, there needs to be a mechanism to relate specimens to the farm of origin.

## f. Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

## Annex IV (contd)

### g. Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of *animals* of known health/immune status in a specified geographical location to detect the occurrence of *disease/infection* (usually serologically). They are particularly useful for *surveillance of for diseases/infections* with a strong spatial component, such as *vector-borne diseases/infections*. Sentinel units provide the opportunity to target *surveillance* depending on the likelihood of *infection* (related to *vector* habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease/infection*.

### h. Field observations

Clinical observations of *animals* in the field are an important source of *surveillance* data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

### i. Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease/infection* at the *herd* or *flock* level. In general, the sensitivity of this approach may be quite high (depending on the *disease*), but the specificity is often quite low.

### j. Wildlife data

Specimens from wild *animals* for *disease/infection surveillance* may be available from sources such as hunters and trappers, road-kills, wild animal *meat* markets, sanitary inspection of hunted *animals*, morbidity and mortality observations by the general public, wildlife rehabilitation centres, wildlife biologists and wildlife agency field personnel, farmers and other landholders, naturalists and conservationists. Wildlife data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

## 2. Critical elements for structured non-random surveillance

There are a number of critical factors which should be taken into account when using structured non-random *surveillance* data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. *Surveillance* data from non-random sources can, however, be a cost-efficient method of early detection, and may increase the level of confidence or detect a lower level of prevalence compared to random sampling surveys.

## 3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random *surveillance* data. Where no data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

#### 4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

*Surveillance* information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in ~~just one year~~ a shorter period of time.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

Article 1.4.6.

### Surveillance to demonstrate freedom from disease/infection

#### 1. Requirements to declare a country, zone or compartment free from disease/infection without pathogen specific surveillance

This Article provides general principles for declaring a country, *zone* or *compartment* free from *disease/infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this Article are based on the principles described in Article 1.4.3. of this chapter and the following premises:

- in the absence of *disease* and vaccination, the animal population would become susceptible over a period of time;
- the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible *animals*;
- competent and effective *Veterinary Services* will be able to investigate, diagnose and report disease, if present;
- *disease/infection* can affect both wild and domestic *animals*;
- the absence of *disease/infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member.

##### a. Historically free

Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be recognised free from *infection* without formally applying a pathogen-specific *surveillance* programme when:

Annex IV (contd)

- i. there has never been occurrence of *disease*, or
  - ii. eradication has been achieved or the *disease/infection* has ceased to occur for at least 25 years, provided that for at least the past 10 years:
  - iii. it has been a *notifiable disease*;
  - iv. an early detection system has been in place for all relevant species;
  - v. measures to prevent *disease/infection* introduction have been in place; no vaccination against the *disease* has been carried out unless otherwise provided in the *Terrestrial Code*;
  - vi. *infection* is not known to be established in wildlife within the country or *zone* intended to be declared free. A country or *zone* cannot apply for historical freedom if there is any evidence of *infection* in wildlife.
- b. Last occurrence within the previous 25 years

Countries, *zones* or *compartments* that have achieved eradication (or in which the *disease/infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific *surveillance* requirements in the *Terrestrial Code* if they exist. In the absence of specific requirements for *surveillance* in the *Terrestrial Code*, countries should follow the general recommendations on *surveillance* to demonstrate animal health status outlined in this chapter provided that for at least the past 10 years:

- i. it has been a *notifiable disease*;
  - ii. an early detection system has been in place;
  - iii. measures to prevent *disease/infection* introduction have been in place;
  - iv. no vaccination against the *disease* has been carried out unless otherwise provided in the *Terrestrial Code*;
  - v. *infection* is not known to be established in wildlife within the country or *zone* intended to be declared free. A country or *zone* cannot apply for freedom if there is any evidence of *infection* in wildlife.
2. Recommendations for the discontinuation of pathogen-specific screening after recognition of freedom from infection

A country, *zone* or *compartment* that has been recognised as free from *infection* following the provisions of the *Terrestrial Code* may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

- a. it is a *notifiable disease*;
- b. an early detection system is in place;
- c. measures to prevent *disease/infection* introduction are in place;

- d. vaccination against the *disease* is not applied;
- e. *infection* is known not to be established in wildlife. It can be difficult to collect sufficient epidemiological data to prove absence of *disease/infection* in wild animal populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

### 3. Self declaration of disease/infection

Members may make a self declaration that a country, *zone* or *compartment* is free from a *listed disease*, based on the implementation of the provisions of the *Terrestrial Code* and the *Terrestrial Manual* - see relevant provisions in Chapter 1.5. The *Veterinary Authority* may wish to transmit this information to the OIE ~~Central Bureau~~ Headquarters, which may publish the information.

### 4. International recognition of disease/infection free status

For *diseases* for which procedures exist whereby the OIE can officially recognise the existence of a *disease/infection* free country or zone ~~or compartment~~, a Member wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country or zone ~~or compartment~~ concerned. Such documentation should be presented according to the recommendations prescribed by the OIE for the appropriate animal *diseases*.

### 5. Demonstration of freedom from infection

A *surveillance* system to demonstrate freedom from *infection* should meet the following requirements in addition to the general requirements for *surveillance* outlined in Article 1.4.3. of this chapter.

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*. Demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Members) that *infection* with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from *infection* (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *infection*, if present, is present in less than a specified proportion of the population.

However, finding evidence of *infection* at any level in the target population automatically invalidates any freedom from *infection* claim unless otherwise stated in the relevant *disease* chapter. The implications of *disease/infection* in wildlife for the status of domestic *animals* in the same country or *zone* should be assessed in each situation, as indicated in the relevant chapter on each *disease* in the *Terrestrial Code*.

Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

Article 1.4.7.

### **Surveillance for distribution and occurrence of infection**

*Surveillance* to determine distribution and occurrence of *infection* or of other relevant health related events is widely used to assess progress in the control or eradication of selected *diseases* and pathogens and as an aid to decision making. It has, however, relevance for the international movement of *animals* and products when movement occurs among infected countries.

Annex IV (contd)

In contrast to *surveillance* to demonstrate freedom from *infection*, *surveillance* used to assess progress in control or eradication of selected *diseases* and pathogens is usually designed to collect data about a number of variables of animal health relevance, for example:

1. prevalence or incidence of *infection*;
2. morbidity and mortality rates;
3. frequency of *disease/infection risk* factors and their quantification;
4. frequency distribution of *herd* sizes or the sizes of other *epidemiological units*;
5. frequency distribution of antibody titres;
6. proportion of immunised *animals* after a vaccination campaign;
7. frequency distribution of the number of days elapsing between suspicion of *infection* and *laboratory* confirmation of the diagnosis and/or to the adoption of control measures;
8. farm production records;
9. role of wildlife in maintenance or transmission of the *infection*.

---

-----  
— text deleted

CHAPTER 1.5.

**SURVEILLANCE  
OF ARTHROPOD VECTORS OF ANIMAL DISEASES**

Article 1.5.1.

**Introduction**

*Vector-borne diseases* are of increasing importance economically and to human and animal health.

Environmental (including climate change), sociological and economical changes may affect the distribution and impact of these *diseases*.

Improved understanding of the distribution and population dynamics of the *vectors* is a key element for assessing and managing the *risks* associated with *vector-borne* animal and zoonotic *diseases*.

The *Terrestrial Code* contains recommendations for the *surveillance* of several *vector-borne diseases* and general recommendations for animal health surveillance.

The need has arisen to complement these general recommendations on *surveillance* with additional advice on the *surveillance* of *vectors* themselves. This chapter only addresses *surveillance* for arthropod *vectors*.

For the purpose of trade, it must be noted that there is no conclusive relationship between the presence of a *vector(s)* and the disease status of a country/*zone*, and also that the apparent absence of a *vector(s)* does not by itself confirm *vector-free* status.

A decision tree for *vector surveillance* is presented in Figure 1.

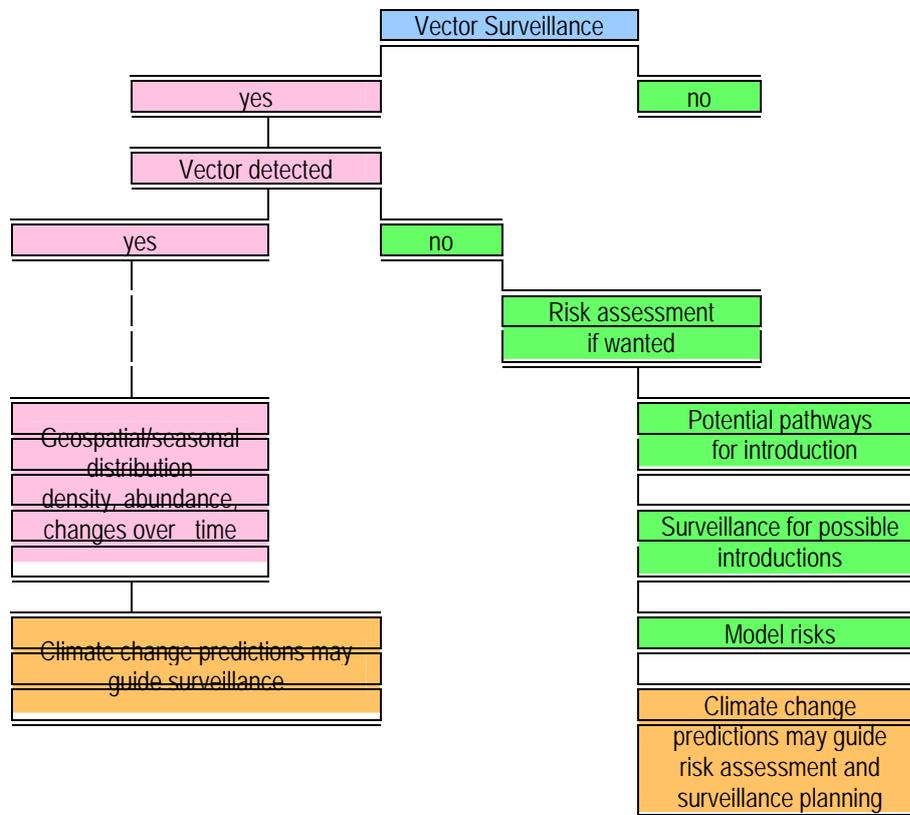
Article 1.5.2.

**Objectives**

The objective of these recommendations is to provide methods for:

1. gathering up-to-date information on the spatial and temporal distribution and abundance of *vectors* of the arthropod-borne *OIE-listed diseases* and *emerging diseases*;
2. monitoring changes in the spatial and temporal distribution and abundance of these *vectors*;
3. collecting relevant data to inform *risk assessment* (including *vector competency*) and *risk management* of these *vector-borne diseases*;
4. detecting the presence of specific *vectors* or confirming their absence;
5. understanding pathways of entry for *vectors* and *vector-borne* pathogenic agents.

Figure 1 Decision Tree for Vector Surveillance



Article 1.5.3.

## Sampling methodology

### 1. Sampling plan

- a. The objective of the *surveillance* programme should be determined and stated before planning begins.
- b. All available historical data on the *vector* or the *disease* for the country or *zone* should be collated and assessed.
- c. The sampling plan should consider the following:
  - i. the biology and ecology of the *vector(s)*,
  - ii. the presence, distribution and abundance of the *vectors'* host animal population(s),
  - iii. the environmental, climatic, ecological and topographic conditions of relevance to *vector* ecology,
  - iv. the need for a *risk assessment* to indicate the areas at highest *risk* of introduction of a *vector* that is unlikely to be present.

- d. Sampling should be aimed at:
- i. establishing *vector* presence or confirming *vector* absence in the country or *zone*,
  - ii. describing the distribution of the *vector(s)* within the country or *zone*,
  - iii. providing additional information on *vector* density and spatial/temporal variability (both over the short- and the long-term),
  - iv. early detection of *vectors* or *vector*-borne pathogenic agents in areas with *risks* of entry and establishment.
- e. The sampling plan should be designed to provide appropriate estimates of the indicators listed above. Consideration should be given to the following:

The recommended general approach to sampling is via a three-stage hierarchy:

- i. Stratification based on ecological criteria (where possible), and *risk assessment* for *vector* introduction,
- ii. subdivision of strata into spatial sampling units, and
- iii. establishment of actual sampling sites within selected spatial sampling units.

If adequate entomological, epidemiological and historical data and/or expert opinion exists, the sampling plan may be refined or targeted by defining strata which are as ~~homogenous~~ homogeneous as possible with respect to the following known or suspected *risk*-factors, as appropriate for the country or *zone*:

- i. domestic or wild populations of host animals preferred by the *vector*,
- ii. *vector* habitat suitability,
- iii. climatic patterns (including seasonal),
- iv. areas endemically and/or epidemically affected by the disease(s) of concern,
- v. areas of known *vector* occurrences,
- vi. fringe *zone(s)* around areas of known *vector* occurrences or other high *risks* areas for *vector* introduction, such as ports,
- vii. areas in which the *disease(s)* or *vector(s)* of concern have not been reported currently or historically,
- viii. each stratum (or the whole country or *zone*, if not stratified) should be divided into spatial sampling units according to standard methodologies such as a grid system,
- ix. the number and size of the spatial sampling units should be defined to provide appropriate estimates of the indicators listed above,

Annex V (contd)

- x. the number and location of actual sampling sites within each spatial sampling unit also should be defined to provide appropriate estimates of the indicators listed above,
- xi. different levels of sampling intensity (spatial sampling unit size, number of units sampled, number of sites sampled within units, and sampling frequency) may be applied to different strata into which the country or *zone* has been divided. For example, more intensive sampling might be carried out in strata where *vector* presence seems most likely, based on biological or statistical criteria.

2. Sampling methods

Many sampling methods have been developed for the capture of *vector* arthropods, and these differ according to the *disease/vector* system under consideration.

- a. The collection methods used should be adapted as required to ensure reasonable confidence of collecting the *vector(s)* of concern.
- b. Collection methods should obtain the various developmental stages (such as eggs, larvae, nymphs, adults) and adult age categories, as appropriate to the species in question, required to estimate population survival rates and population dynamics in relation to *disease* transmission.
- c. Different collection methods may be required to obtain samples from a single *vector* species, depending on the life stage or place of capture (such as from the environment or from the host animals). The collection method must be appropriate to the species and life stage of interest.

The collection methods should preserve the *vector(s)* in a manner suitable for their morphological identification or identification with molecular techniques. Where the purpose of sampling is to detect or isolate a pathogenic agent(s), specific protocols should be followed to ensure the samples are suitable for these assays.

3. Data management, analysis and interpretation

Data management and analytical methodologies should be done in accordance with Chapter 1.4.

---

-----

— text deleted

## CHAPTER 1.6.

**STATUS FOR OIE LISTED DISEASES:  
PROCEDURES FOR SELF DECLARATION AND  
FOR OFFICIAL RECOGNITION BY THE OIE**

## Article 1.6.1.

**General principles**

Members may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not ~~recognise~~ publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), rinderpest and contagious bovine pleuropneumonia (CBPP).

Members may request official recognition by the OIE as to:

1. the risk status of a country or *zone* with regard to BSE;
2. the freedom of a country or *zone* from FMD, with or without vaccination;
3. the freedom of a country from rinderpest;
4. the freedom of a country or *zone* from CBPP.

The OIE does not grant official recognition for other *diseases*.

In these cases, Members should present documentation setting out the compliance of the *Veterinary Services* of the applicant country or *zone* with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant *disease* chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status, the Member should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.2. (for BSE), 1.6.3. (for FMD), 1.6.4. (for rinderpest) or 1.6.5. (for CBPP).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXII (administrative procedures) and Resolution N° XXIII (financial obligations) adopted during the 76th General Session in May 2008.

## Article 1.6.2.

**Questionnaire on bovine spongiform encephalopathy****GENERAL INTRODUCTION**

Acceptance of this submission is based on the compliance of the *Veterinary Service* of the applicant country, *zone* or *compartment* with the provisions of Chapter 3.1. of the *Terrestrial Code* and the compliance of BSE diagnostic laboratories with the provisions of Chapter 1.1.3. of the *Terrestrial Manual*. Documentary evidence should be provided to support this based on Chapter 3.2. of the *Terrestrial Code*.

Annex VI (contd)

Article 11.6.2. of the *Terrestrial Code* Chapter on BSE prescribes the criteria to determine the BSE risk status of a the cattle population of a country, *zone* or *compartment*. This document is the means whereby a claim for negligible risk (Article 11.6.3.) or controlled risk (Article 11.6.4.) can be made to the OIE.

The document comprises the following:

- Section 1 – Risk assessment (see point 1 of Article 11.6.2.)
- Section 2 – Other requirements of points 2 to 4 of Article 11.6.2.
  - Ongoing awareness programme
  - Compulsory notification and investigation
  - Diagnostic capability
- Section 3 – Surveillance (Article 11.6.2. and Articles 11.6.20. to 11.6.22.)
- Section 4 – BSE history of the country, *zone* or *compartment* (Articles 11.6.3. and 11.6.4.).

N.B. Where, during the completion of this questionnaire, the submitting *Veterinary Service* provides documentation regarding the legislation under which it is mandated, it should provide the content of any legal act described (in one of the three official languages of OIE), as well as the dates of official publication and implementation. Submitting countries are encouraged to follow the format and numbering used in this document.

### **SECTION 1: RISK ASSESSMENT (see point 1 of Article 11.6.2.)**

#### **Introduction**

The first step in determining the BSE risk status of the cattle population of a country, *zone* or *compartment* is to conduct a *risk assessment* (reviewed annually), based on Sections 2. and 3. and Chapter 4.3. of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

#### **Documentation guidelines**

This section provides guidance on the data gathering and presentation of information required to support the risk release and exposure assessments in respect of:

##### *Release assessment:*

1. The potential for the release of the BSE agent through importation of *meat-and-bone meal* or *greaves*.
2. The potential for the release of the BSE agent through the importation of potentially infected live cattle.
3. The potential for the release of the BSE agent through the importation of potentially infected products of bovine origin.

*Exposure assessment:*

4. The origin of bovine carcasses, by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of cattle feed production.
5. The potential for the exposure of cattle to the BSE agent through consumption of *meat-and-bone meal* or *greaves* of bovine origin.

In each of the five areas of release and exposure assessment that follow, the contributor is guided in terms of the question, the rationale and the evidence required to support the country, *zone* or *compartment* status claim.

**Release assessment****1. The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves**

*Question to be answered:* Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either, been imported within the past 8 years? If so, where from and in what quantities?

*Rationale:* Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

This point is irrelevant if the exposure assessment outlined below in Article 11.6.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to cattle.

*Evidence required:*

- a) Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
  - b) Documentation on annual volume, by country of origin, of *meat-and-bone meal*, *greaves* or feedstuffs containing them imported during the past 8 years.
  - c) Documentation describing the species composition of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
  - d) Documentation, from the *Veterinary Service* of the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- 2. The potential for the release of the BSE agent through the importation of potentially infected live cattle**

*Question to be answered:* Have live cattle been imported within the past 7 years?

Annex VI (contd)

*Rationale:* The release risks are dependent on:

- country, *zone* or *compartment* of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the imported cattle in the country, *zone* or *compartment* of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported cattle represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- dairy versus meat breeds, where there are differences in exposure in the country, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

*Evidence required:*

- a) Documentation including tables on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of the cattle, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.
- b) Documentation including tables describing origin and volume of imports.
- c) Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country, *zone* or *compartment* of origin.

### 3. The potential for the release of the BSE agent through the importation of potentially infected products of bovine origin

*Question to be answered:* What products of bovine origin have been imported within the past 7 years?

*Rationale:* The release risks are dependent on:

- the origin of the cattle products and whether these products contain tissues known to contain BSE infectivity (Article 11.6.13.);
- country, *zone* or *compartment* of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and *management* of the cattle in the country, *zone* or *compartment* of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported cattle represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;

Annex VI (contd)

- dairy versus meat breeds, where there are differences in exposure in the country, *zone* or *compartment* of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

*Evidence required:*

- a) Documentation on the country, *zone* or *compartment* of origin of imports. This should identify the country, *zone* or *compartment* of origin of cattle from which the products were derived, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.
- b) Documentation describing origin and volume of imports.
- c) Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country, *zone* or *compartment* of origin.

**Exposure assessment****4. The origin of bovine carcasses, by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of cattle feed production**

*Question to be answered:* How have bovine carcasses, by-products and *slaughterhouse* waste been processed over the past 8 years?

*Rationale:* The overall risk of BSE in the cattle population of a country, *zone* or *compartment* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country, *zone* or *compartment* is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity. Where *meat-and-bone meal* is utilized in the production of any cattle feed, the risk of cross-contamination exists.

*Evidence required:*

- a) Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- b) Documentation including tables describing the fate of imported cattle, including their age at *slaughter* or *death*.
- c) Documentation describing the definition and disposal of specified risk material, if any.
- d) Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- e) Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.

Annex VI (contd)

- f) Documentation describing the end use of imported cattle products and the disposal of waste.
- g) Documentation describing monitoring and enforcement of the above.

**5. The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine origin**

*Question to be answered:* Has *meat-and-bone meal* or *greaves* of bovine origin been fed to cattle within the past 8 years (Articles 11.6.3. and 11.6.4. in the *Terrestrial Code*)?

*Rationale:* If cattle have not been fed products of bovine origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of bovine origin within the past 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

In the case of countries applying for negligible risk status, it will be required to demonstrate that the ruminant feed ban has been effective for at least 8 years following the birth of the youngest *case*.

*Evidence required:*

- a) Documentation describing the use of imported *meat-and-bone meal* and *greaves*, including the feeding of any animal species.
- b) Documentation describing the use made of *meat-and-bone meal* and *greaves* produced from domestic cattle, including the feeding of any animal species.
- c) Documentation on the measures taken to control cross-contamination of cattle feedstuffs with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding.
- d) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing ruminant material or mixed species containing ruminant material, related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Number of plants processing ruminant material	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
		(A)	(B)			(C)	
Year 1	Renderer						
	Feed mill						
Year 2, etc.	Renderer						
	Feed mill						

## Annex VI (contd)

- e) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing non-ruminant material, related to the prohibition of the feeding of *meat-and-bone meal* and *greaves* to ruminants.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Number of plants processing ruminant material	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
		(A)	(B)			(C)	
Year 1	Renderer						
	Feed mill						
Year 2, etc.	Renderer						
	Feed mill						

- f) Documentation, in the form of the following table, on each plant above processing ruminant material or mixed species containing ruminant material with infractions, specifying the type of infraction and the method of resolution.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow-up results
	Renderer	ID 1			
		ID 2			
Year 1		ID 3, etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	Renderer				
	Feed mill				

Annex VI (contd)

- g) Documentation, in the form of the following table, on each plant above processing non-ruminant material with infractions, specifying the type of infraction and the method of resolution.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant or (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow-up results
Year 1	Renderer	ID 1			
		ID 2			
		ID 3, etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	Renderer				
	Feed mill				

- h) Documentation explaining why, in light of the findings displayed in the preceding four tables, it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of *meat-and-bone meal* or *greaves* of bovine origin.
- i) Documentation of husbandry practices (multiple species farms) which could lend themselves to cross-contamination of cattle feed with meat-and-bone meal and greaves destined to other species.

**SECTION 2: OTHER REQUIREMENTS (see points 2 to 4 of Article 11.6.2.)****1. Awareness programme (see point 2 of Article 11.6.2.)**

*Questions to be answered:*

- Is there an awareness programme?
- What is the target audience?
- What is the curriculum and how long has it been in place?
- Is there a contingency and/or preparedness plan that deals with BSE?

*Rationale:*

An awareness programme is essential to ensure detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses.

Annex VI (contd)*Evidence required:*

- a) Documentation indicating when the awareness programme was instituted and its continuous application and geographical coverage.
- b) Documentation on the number and occupation of persons who have participated in the awareness programme (veterinarians, producers, workers at auctions, *slaughterhouses*, etc.).
- c) Documentation of materials used in the awareness programme (the manual, supportive documents, or other teaching materials).
- d) Documentation on the contingency plan.

**2. Compulsory notification and investigation (see point 3 of Article 11.6.2.)***Questions to be answered:*

- What guidance is given to veterinarians, producers, workers at auctions, *slaughterhouses*, etc.) in terms of the criteria that would initiate the investigation of an animal as a BSE suspect? Have these criteria evolved?
- What were the date and content of the legal act making notification of BSE suspects compulsory?
- What are the measures in place to stimulate notification, such as compensation payments or penalties for not notifying a suspect?

*Rationale:*

The socio-economic implications associated with BSE require that there be incentives and/or obligations to notify and investigate suspect *cases*.

*Evidence required:*

- a) Documentation on the date of official publication and implementation of compulsory notification. Including a brief description of incentives and penalties.
- b) Documentation on the manual of procedures for investigation of suspect *animals* and follow-up of positive findings.

**3. Examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system (see point 4 of Article 11.6.2.)***Questions to be answered:*

- Are the diagnostic procedures and methods those described in Chapter 2.4.6. of the *Terrestrial Manual*?
- Have these diagnostic procedures and methods been applied through the entire *surveillance* period?

Annex VI (contd)*Rationale:*

The OIE only recognizes for the purpose of this submission samples that have been tested in accordance with the Terrestrial Manual.

*Evidence required:*

- a) Documentation as to the approved laboratories where samples of cattle tissues from the country, *zone* or *compartment* are examined for BSE. (If this is located outside the country, information should be provided on the cooperation agreement).
- b) Documentation of the diagnostic procedures and methods used.
- c) Documentation that the diagnostic procedures and methods have been applied through the entire *surveillance* period.

**SECTION 3: BSE SURVEILLANCE AND MONITORING SYSTEM (see point 4 of Article 11.6.2.)**

*Questions to be answered:*

- o Does the BSE *surveillance* programme comply with the guidelines in Articles 11.6.20. to 11.6.22. of the *Terrestrial Code*?
- o What were the results of the investigations?

*Rationale:*

Point 4 of Article 11.6.2. and Articles 11.6.20. to 11.6.22. prescribe the number of cattle, by subpopulation, that need to be tested in order to ensure the detection of BSE at or above a minimal threshold prevalence.

*Evidence required:*

1. Documentation that the samples collected are representative of the distribution of cattle population in the country, *zone* or *compartment*.
2. Documentation of the methods applied to assess the ages of *animals* sampled and the proportions for each method (individual identification, dentition, other methods to be specified).
3. Documentation of the means and procedures whereby samples were assigned to the cattle subpopulations described in Article 11.6.21., including the specific provisions applied to ensure that *animals* described as clinical met the conditions of point 1 of Article 11.6.21.
4. Documentation of the number of *animals* meeting the conditions in point 1 of Article 11.6.21. as compared to the numbers of clinical samples submitted in previous years in accordance to the former provisions in the *Terrestrial Code*, and explanation of possible differences.
5. Documentation, based on the following table, of all clinically suspect *cases* notified complying with the definition in point 1 of Article 11.6.21.

Laboratory identification number	Age	Clinical signs	Point of detection (farm, market channels, slaughterhouse)

6. Documentation according to the following table, that the number of target points applicable to the country, *zone* or *compartment* and its BSE *surveillance* requirements (Type A or type B *surveillance* as a result of the *risk assessment* of section 1) are met as described in Articles 11.6.21. and 11.6.22.

SUMMARY TABLE FOR BSE SURVEILLANCE								
Year: (complete a separate table for each year of surveillance)								
	Surveillance subpopulations							
	Routine slaughter		Fallen stock		Casualty slaughter		Clinical suspect	
	Samples	Points	Samples	Points	Samples	Points	Samples	Points
>1 and <2 years								
≥2 and <4 years								
≥4 and <7 years								
≥7 and <9 years								
≥9 years								
<b>Subtotals</b>								
<b>Total points</b>								

7. Indicate the number of adult cattle (over 24 months of age) in the country, *zone* or *compartment*.

**SECTION 4: BSE HISTORY OF THE COUNTRY, ZONE OR COMPARTMENT (see Articles 11.6.3. and 11.6.4.)**

*Questions to be answered:*

- Has BSE occurred in the country, *zone* or *compartment*?
- How has it been dealt with?

Annex VI (contd)*Rationale:*

The categorization of a country, *zone* or *compartment* in either negligible or controlled risk is dependent upon, the outcome of the *risk assessment* described in section 1, compliance with the provisions described in section 2, the results of *surveillance* described in section 3, and the history of BSE in the country, *zone* or *compartment*. This section provides the opportunity to describe the BSE history in the country, *zone* or *compartment*.

*Evidence required:*

1. Documentation of whether a *case* of BSE has ever been diagnosed in the country, *zone* or *compartment*.

In the case of positive BSE findings:

2. Documentation on the origin of each BSE *case* in respect to the country, *zone* or *compartment*. Indicate the birth date and place of birth.
3. Indicate the most recent year of birth in relation to all BSE *cases*.
4. Documentation that:
  - o the *case(s)* and all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the *disease*, and
  - o all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
  - o if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,
  - o if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 1.6.3.

**Questionnaire on foot and mouth disease**

<b>FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED</b>
--

Report of a Member which applies for recognition of status, under Chapter 8.5. of the <i>Terrestrial Animal Health Code</i> (2009), as a FMD free country not practising vaccination
---

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

Annex VI (contd)1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the Terrestrial Code and 1.1.3. of the Terrestrial Manual and describe how the Veterinary Services supervise and control all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication.
- c) Vaccines and vaccination. Was FMD vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated?
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

Annex VI (contd)

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
  - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - ii) Give details of participation in inter-laboratory validation tests (ring tests).
  - iii) Is live virus handled?
  - iv) Biosecurity measures applied.
  - v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd density*, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

## b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past two years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
- *animals*,
  - genetic material (semen and embryos),
  - animal products,
  - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

Annex VI (contd)

- c) In the event of an FMD *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
  - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
  - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
  - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
  - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

- a) In addition to the documentary evidence that the provisions of Article 8.5.2. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:
- i) there has been no *outbreak* of FMD during the past 12 months;
  - ii) no evidence of FMDV *infection* has been found during the past 12 months;
  - iii) no vaccination against FMD has been carried out during the past 12 months,
- b) and should confirm that since the cessation of vaccination no *animals* vaccinated against FMD have been imported.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

<b>FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED</b>
--

Report of a Member which applies for recognition of status, under Chapter 8.5. of the <i>Terrestrial Animal Health Code</i> (2009), as a FMD free country practising vaccination
--

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.

Annex VI (contd)

- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country, provide date of first detection, origin of *infection*, date of eradication (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication.
- c) Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability, including vaccination data. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to and the follow-up procedures and the timeframe for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:

Annex VI (contd)

- i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
- ii) Give details of participation in inter-laboratory validation tests (ring tests).
- iii) Is live virus handled?
- iv) Biosecurity measures applied.
- v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.44.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

## b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past two years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
  - *animals*,
  - genetic material (semen and embryos),
  - animal products,
  - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of an FMD *outbreak*:
  - i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
  - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;

Annex VI (contd)

- iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial slaughter/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
- iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
- v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that:

- a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.40. to 8.5.46. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- b) routine vaccination is carried out for the purpose of the prevention of FMD;
- c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

**FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED**

Report of a Member which applies for recognition of status, under Chapter 8.5. of the *Terrestrial Animal Health Code* (2009), as a FMD free zone not practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

## 2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

## 3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out), provide timeframe for eradication.
- c) Vaccines and vaccination. If vaccination is used in the rest of the country, what type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.5.9. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

## 4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed, the follow-up procedures and the time frame for obtaining results.

Annex VI (contd)

- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
- a) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - b) Give details of participation in inter-laboratory validation tests (ring tests).
  - c) Is live virus handled?
  - d) Biosecurity measures applied.
  - e) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past 2 years, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* without vaccination is situated in an FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 2 years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
- *animals*,
  - genetic material (semen and embryos),
  - animal products,
  - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

Annex VI (contd)7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of an FMD *outbreak*:
  - i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
  - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
  - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
  - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
  - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.5.4. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) there has been no *outbreak* of FMD during the past 12 months;
- b) no evidence of FMDV *infection* has been found during the past 12 months;
- c) no vaccination against FMD has been carried out during the past 12 months;
- d) no vaccinated animal has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.9.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

## FMD FREE ZONE WHERE VACCINATION IS PRACTISED

Report of a Member which applies for recognition of status, under Chapter 8.5.  
of the *Terrestrial Animal Health Code* (2009), as a FMD free zone practising vaccination

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

### 1. Introduction

- a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

### 2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to FMD.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all FMD related activities in the country and in the *zone*. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

### 3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out), provide timeframe for eradication.
- c) Vaccines and vaccination. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the vaccination programme in the country and in the *zone*, including records kept, and provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc.).
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

Annex VI (contd)

- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability, including vaccination data. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.5.9. are applied? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points.
- i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - ii) Give details of participation in inter-laboratory validation tests (ring tests).
  - iii) Is live virus handled?
  - iv) Biosecurity measures applied.
  - v) Details of the type of tests undertaken.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with the provisions of Articles 8.5.40. to 8.5.46. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for FMDV, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Surveillance. Are serological and virological surveys conducted, in particular applying the provisions of Article 8.5.44.? If so, provide detailed information on the survey design (confidence level, sample size, stratification). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? Provide a summary table indicating, for the past 2 years, the number of samples tested for FMD and FMDV, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

Annex VI (contd)

- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country and in the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* with vaccination is situated in an FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying the country or *zone* of origin, the species and the volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 2 years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

Annex VI (contd)

- *animals*,
  - genetic material (semen and embryos),
  - animal products,
  - veterinary medicinal products (i.e. biologics).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of an FMD *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
  - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with FMD;
  - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken. Include details on antigen and vaccine banks;
  - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
  - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the Terrestrial Code

In addition to the documentary evidence that the provisions of Article 8.5.5. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) that there has been no *outbreak* of FMD for the past 2 years,
- b) no evidence of FMDV circulation for the past 12 months,
- c) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.40. to 8.5.46. is in operation.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.5.8. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

## Article 1.6.4.

## Questionnaire on rinderpest

**RINDERPEST FREE COUNTRY**

Report of a Member which applies for recognition of status, under Chapter 8.12. of the *Terrestrial Animal Health Code* (2009), as a rinderpest infection free country

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to rinderpest dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to rinderpest.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all rinderpest related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in rinderpest *surveillance* and control (include a description of training and awareness programmes on rinderpest).
- d) Role of private veterinary profession in rinderpest *surveillance* and control.

3. Rinderpest eradication

- a) History. Provide a description of the rinderpest history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*), lineage(s) present.
- b) Strategy. Describe how rinderpest was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication.
- c) Vaccines and vaccination. Was rinderpest vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated? Has heterologous vaccine been used in cattle, buffalo or yak?

Annex VI (contd)

- d) Legislation, organisation and implementation of the rinderpest eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and related paths of movement.

4. Rinderpest diagnosis

Provide evidence that a system is in place for the rapid confirmation of a suspected *outbreak* i.e. that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.15. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is rinderpest laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow up procedures and the time frame for obtaining results.
- b) Provide an overview of the rinderpest approved laboratories, in particular to address the following points:
  - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - ii) Give details of participation in inter-laboratory validation tests (ring tests).
  - iii) Is live virus handled?
  - iv) Biosecurity measures applied.
  - v) Details of the type of tests undertaken.

5. Rinderpest surveillance

Provide documentary evidence that *surveillance* for rinderpest in the country complies with the provisions of Articles 8.12.20. to 8.12.27. of the *Terrestrial Code* and Chapter 2.1.15. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of rinderpest? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of Articles 8.12.20. to 8.12.27. of the *Terrestrial Code*.

Annex VI (contd)

- b) Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with Articles 8.12.20. to 8.12.27. of the *Terrestrial Code*<sup>1</sup>. Are wildlife susceptible species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past 2 years, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc., of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- e) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions.

6. Rinderpest prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

## b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals* or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* and their products for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

Annex VI (contd)

- *animals*,
  - genetic material (semen and embryos),
  - animal products,
  - veterinary medicinal products (i.e. biologics).
- iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of rinderpest.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of a rinderpest *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
  - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with rinderpest;
  - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken;
  - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
  - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

The Delegate of the country must submit documentary evidence that the provisions of Article 8.12.2. or point 1 of Article 1.4.6. (historical freedom) of the *Terrestrial Code* have been properly implemented and supervised.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 8.12.3. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.6.5.

**Questionnaire on contagious bovine pleuropneumonia****CBPP FREE COUNTRY**

Report of a Member which applies for recognition of status, under Chapter 11.9. of the *Terrestrial Animal Health Code* (2009), as a CBPP free country

Annex VI (contd)

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to CBPP.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all CBPP related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in CBPP *surveillance* and control (include a description of training and awareness programmes on CBPP).
- d) Role of private veterinary profession in CBPP *surveillance* and control.

3. CBPP eradication

- a) History. Provide a description of the CBPP history in the country, date of first detection, origin of *infection*, date of eradication (date of last *case*).
- b) Strategy. Describe how CBPP was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), and provide timeframe for eradication.
- c) Vaccines and vaccination. Was CBPP vaccine ever used? If so, when was the last vaccination carried out?
- d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

Annex VI (contd)

- a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the CBPP approved laboratories, in particular to address the following points:
  - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - ii) Give details of participation in inter-laboratory validation tests (ring tests).
  - iii) Biosecurity measures applied.
  - iv) Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.9.12. to 11.9.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Slaughterhouses, *slaughter* slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- c) Provide details on training programmes for personnel involved in clinical and *slaughter* facilities *surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.
- d) For countries where a significant proportion of *animals* are not slaughtered in controlled *abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programmes, laboratory follow-up).
- e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds* of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- f) Slaughterhouses and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the *animals* transported and handled during these transactions?

Annex VI (contd)

- g) Provide a description of the means employed during the 2 years preceding this application to rule out the presence of any *MmmSC* strain in the susceptible population. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

- b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:
- *animals*,
  - veterinary medicinal products (i.e. biologics).
- iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of CBPP.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?
- c) In the event of a CBPP *outbreak*:

Annex VI (contd)

- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
- ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;
- iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken;
- iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
- v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 11.9.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:

- a) no clinical CBPP has been detected for at least 2 years;
- b) no CBPP vaccines have been used for at least 2 years in any susceptible species;
- c) the country operates both clinical *surveillance* and *disease* reporting systems for CBPP adequate to detect clinical *disease* if it were present;
- d) all clinical and pathological evidence suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;
- e) there are effective measures in force to prevent the re-introduction of the *disease*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 11.9.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

**CBPP FREE ZONE**

 Report of a Member which applies for recognition of status, under Chapter 11.9. of the *Terrestrial Animal Health Code* (2009), as a CBPP free zone

Please address concisely the following topics. National regulations laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to CBPP dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above. The boundaries of the *zone* must be clearly defined. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislation in relation to CBPP.
- b) Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how the *Veterinary Services* supervise and control all CBPP related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in CBPP *surveillance* and control (include a description of training and awareness programmes on CBPP).
- d) Role of private veterinary profession in CBPP *surveillance* and control.

3. CBPP eradication

- a) History. Provide a description of the CBPP history in the *zone*, date of first detection, origin of *infection*, date of eradication (date of last *case*).
- b) Strategy. Describe how CBPP was controlled and eradicated in the *zone* (e.g. stamping-out, modified stamping-out, zoning) and provide timeframe for eradication.
- c) Vaccines and vaccination. Was CBPP vaccine ever used? In the entire country? If vaccination was used, when was the last vaccination carried out? Where in the country?
- d) Legislation, organisation and implementation of the CBPP eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Animal identification and movement control. Are susceptible *animals* identified (individually or at a group level)? Provide a description of the methods of animal identification, *herd* registration and traceability. How are animal movements controlled in the *zone*? Provide evidence on the effectiveness of animal identification and movement controls. Please provide information on pastoralism, transhumance and the related paths of movement.

4. CBPP diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

Annex VI (contd)

- a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the CBPP approved laboratories, in particular to address the following points:
  - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - ii) Give details of participation in inter-laboratory validation tests (ring tests).
  - iii) Biosecurity measures applied.
  - iv) Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.

5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with the provisions of Articles 11.9.12. to 11.9.17. of the *Terrestrial Code* and Chapter 2.4.9. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical surveillance. What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- b) Slaughterhouses, *slaughter* slabs, abattoirs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for CBPP agent, species, type of sample, testing method(s) and results (including differential diagnosis).
- c) Provide details on training programmes for personnel involved in clinical and *slaughter* facilities *surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.
- d) For countries where a significant proportion of *animals* in the *zone* are not slaughtered in controlled *abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g. active clinical *surveillance* programme, laboratory follow-up).
- e) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds* of each susceptible species are in the *zone*? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- f) Slaughterhouses and *markets*. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country and the *zone*? How are the *animals* transported and handled during these transactions?

Annex VI (contd)

- g) Provide a description of the means employed during the 2 years preceding this application to rule out the presence of any *MmmSC* strain in the susceptible population of the *zone*. Provide criteria for selection of populations for targeted *surveillance* and numbers of *animals* examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

6. CBPP prevention

- a) Coordination with neighbouring countries and *zones*. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or *animals*)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. If the CBPP free *zone* is situated in a CBPP infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Import control procedures

From what countries or *zones* does the country authorize the import of susceptible *animals*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals*, and subsequent internal movement? What import conditions and test procedures are required? Are imported *animals* of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible *animals* for the past 2 years, specifying country or *zone* of origin, species and volume.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the *zone* and/or their final destination, concerning the import and follow-up of the following:
- *animals*,
  - veterinary medicinal products (i.e. biologics).
- iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and contingency planning

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of CBPP.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases*?

Annex VI (contd)

- c) In the event of a CBPP *outbreak*:
- i) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
  - ii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;
  - iii) indicate the control and/or eradication procedures (e.g. vaccination, stamping-out, partial *slaughter*/vaccination, etc.) that would be taken;
  - iv) describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including any restrictions on restocking;
  - v) give details of any compensation payments made available to farmers, etc. when *animals* are slaughtered for *disease* control/eradication purposes.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 11.9.3. are properly implemented and supervised, the Delegate of the country must submit a declaration indicating that in the *zone*:

- a) no clinical CBPP has been detected for at least 2 years;
- b) no CBPP vaccines have been used for at least 2 years in any susceptible species;
- c) the country operates both clinical *surveillance* and *disease* reporting systems for CBPP adequate to detect clinical *disease* if it were present in the *zone*;
- d) all clinical and pathological suggestive of CBPP is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of CBPP;
- e) there are effective measures in force to prevent the re-introduction of the *disease*.

9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 11.9.4. of the *Terrestrial Code* and provide detailed information as specified in sections 3.a), 3.b), 3.c), 5.b), 5.c) and 5.d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

-----  
 — text deleted

- 
1. Accounts of the ages for eruption of the incisor teeth vary markedly and are clearly dependent on species, breed, nutritional status and nature of the feed. Therefore, for the purposes of serosurveillance, it should be noted that a) cattle having only one pair of erupted permanent central incisor teeth are aged between 21 and 36 months (Asian buffalos 24-48 months) and b) cattle having only two pairs of erupted permanent central incisor teeth are aged between 30 and 48 months (Asian buffalos 48-60 months).

## CHAPTER 2.1.

## IMPORT RISK ANALYSIS

## Article 2.1.1.

**Introduction**

The importation of *animals* and animal products involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

*Transparency* is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This Chapter alludes to the role of the OIE with respect to the Agreement on the Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement) of the World Trade Organization (WTO), provides definitions and describes the OIE informal procedure for dispute mediation.

Chapter 2.2. provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* described in that Chapter are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. The four components of risk analysis



The *risk assessment* is the component of the analysis which estimates the *risks* associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many *diseases*, particularly for those *diseases* listed in this *Terrestrial Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import *risk analysis* usually needs to take into consideration the results of an evaluation of *Veterinary Services*, zoning, compartmentalisation and *surveillance* systems in place for monitoring of animal health in the *exporting country*. These are described in separate Chapters in the *Terrestrial Code*.

Annex VII (contd)

## Article 2.1.2.

**Hazard identification**

The *hazard identification* involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a *commodity*.

The potential *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each potential *hazard* is already present in the *importing country*, and whether it is a *notifiable disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

*Hazard identification* is a categorisation step, identifying biological agents dichotomously as potential *hazards* or not. The *risk assessment* may be concluded if *hazard identification* fails to identify potential *hazards* associated with the importation.

The evaluation of the *Veterinary Services*, *surveillance* and control programmes and zoning and compartmentalisation systems are important inputs for assessing the likelihood of *hazards* being present in the animal population of the *exporting country*.

An *importing country* may decide to permit the importation solely based on the appropriate sanitary standards recommended in the *Terrestrial Code*, thus eliminating the need for a *risk assessment*.

## Article 2.1.3.

**Principles of risk assessment**

1. *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* must be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.
2. Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid. ~~Although quantitative assessment is recognised as being able to provide deeper insights into a particular problem, qualitative methods may be more relevant when available data are limited.~~
3. The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
4. Consistency in *risk assessment* methods should be encouraged and *transparency* is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
5. *Risk assessments* should document the *uncertainties*, the assumptions made, and the effect of these on the final risk estimate.
6. *Risk* increases with increasing volume of *commodity* imported.
7. The *risk assessment* should be amenable to updating when additional information becomes available.

## Article 2.1.4.

**Risk assessment steps**1. Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The release assessment describes the probability of the 'release' of each of the potential *hazards* (the pathogenic agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the release assessment are:

- a) Biological factors
  - species, age and breed of *animals*
  - agent predilection sites
  - vaccination, testing, treatment and quarantine.
- b) Country factors
  - incidence/prevalence
  - evaluation of *Veterinary Services, surveillance* and control programmes and zoning and compartmentalisation systems of the *exporting country*.
- c) Commodity factors
  - quantity of *commodity* to be imported
  - ease of contamination
  - effect of processing
  - effect of storage and transport.

If the release assessment demonstrates no significant *risk*, the *risk assessment* does not need to continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of *animals* and humans in the *importing country* to the *hazards* (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure (e.g. ingestion, inhalation, or insect bite), and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

Annex VII (contd)

- a) Biological factors
  - properties of the agent.
- b) Country factors
  - presence of potential vectors
  - human and animal demographics
  - customs and cultural practices
  - geographical and environmental characteristics.
- c) Commodity factors
  - quantity of *commodity* to be imported
  - intended use of the imported *animals* or products
  - disposal practices.

If the exposure assessment demonstrates no significant *risk*, the *risk assessment* may conclude at this step.

3. Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

- a) Direct consequences
  - animal *infection, disease* and production losses
  - public health consequences.
- b) Indirect consequences
  - *surveillance* and control costs
  - compensation costs
  - potential trade losses
  - adverse consequences to the environment.

4. Risk estimation

*Risk* estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus risk estimation takes into account the whole of the *risk* pathway from *hazard* identified to unwanted outcome.

Annex VII (contd)

For a quantitative assessment, the final outputs may include:

- estimated numbers of *herds, flocks, animals* or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the *uncertainties* in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the *risk* estimation output;
- analysis of the dependence and correlation between model inputs.

## Article 2.1.5.

**Principles of risk management**

1. *Risk management* is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimized. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimize the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.
2. The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions in the standards.

## Article 2.1.6.

**Risk management components**

1. Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member's appropriate level of protection.
2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation in order to bring it into line with the Member's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.
3. Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.
4. Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Annex VII (contd)

## Article 2.1.7.

**Principles of risk communication**

1. *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.
2. A *risk communication* strategy should be put in place at the start of each *risk analysis*.
3. The *communication of the risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.
4. The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.
5. The assumptions and *uncertainty* in the model, model inputs and the risk estimates of the *risk assessment* should be communicated.
6. Peer review is a component of *risk communication* in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

---

-----  
— text deleted

## CHAPTER 3.1.

**VETERINARY SERVICES**

## Article 3.1.1.

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

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

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

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

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

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

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

## Article 3.1.2.

**Fundamental principles of quality**

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

1. Professional judgement

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

2. Independence

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

3. Impartiality

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

Annex VIII (contd)4. Integrity

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

5. Objectivity

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

6. Veterinary legislation

Veterinary legislation is a fundamental element of quality as it supports good governance and provides the legal framework for all key activities of the *Veterinary Services*.

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

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

6. General organisation

The *Veterinary Services* must be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of animal health measures, and of international veterinary certification activities. ~~Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, they should define and document the responsibilities and structure of the organisations in charge of the animal identification system, control of animal movements, animal disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.~~

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

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

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

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

78. Quality policy

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

89. Procedures and standards

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

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

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

910. Information, complaints and appeals

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

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

4011. Documentation

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

Annex VIII (contd)412. Self-evaluation

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

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

4213. Communication

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

4314. Human and financial resources

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

## Article 3.1.3.

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

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

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

## Article 3.1.4.

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

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

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

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

Annex VIII (contd)

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

## Article 3.1.5.

**Evaluation facilitated by OIE experts under the auspices of the OIE**

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

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

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

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

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

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

---

-----  
— text deleted



## CHAPTER 3.2.

EVALUATION OF  
VETERINARY SERVICES

## Article 3.2.1.

**General considerations**

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

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

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

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

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

Annex VIII (contd)

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

## Article 3.2.2.

**Scope**

1. In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:
  - organisation, structure and authority of the *Veterinary Services*;
  - human resources;
  - material (including financial) resources;
  - veterinary legislation and functional capabilities ~~and legislative support~~;
  - animal health and veterinary public health controls;
  - formal quality systems including quality policy;
  - performance assessment and audit programmes;
  - participation in OIE activities and compliance with OIE Members' obligations.
2. To complement the evaluation of *Veterinary Services*, the legislative framework, organisational structure and functioning of the *veterinary statutory body* should also be considered.
3. Article 3.2.14. outlines appropriate information requirements for:
  - self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;

Annex VIII (contd)

- o evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
- o verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
- o evaluation by third parties such as OIE PVS experts or regional organisations.

## Article 3.2.3.

**Evaluation criteria for the organisational structure of the Veterinary Services**

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

Annex VIII (contd)

## Article 3.2.4.

**Evaluation criteria for quality systems**

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

## Article 3.2.5.

**Evaluation criteria for human resources**

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

## Article 3.2.6.

**Evaluation criteria for material resources**1. Financial

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

2. Administrative

## a. Accommodation

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

## b. Communications

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

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

## c. Transport systems

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

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

Annex VIII (contd)3. Technical

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

## a. Cold chain for laboratory samples and veterinary medicines

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

## b. Diagnostic laboratories

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

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

## c. Research

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

## Article 3.2.7.

Legislation and functional capabilities and legislative support1. Animal health and veterinary public health

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

## 2. Export/import inspection

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

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

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

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

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

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

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

Annex VIII (contd)

## Article 3.2.8.

**Animal health controls**1. Animal health status

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

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

2. Animal health control

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

3. National animal disease reporting systems

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

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

## Article 3.2.9.

**Veterinary public health controls**1. Food hygiene

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

2. Zoonoses

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

3. Chemical residue testing programmes

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

4. Veterinary medicines

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

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

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

Annex VIII (contd)5. Integration between animal health controls and veterinary public health

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

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

Article 3.2.10.

**Performance assessment and audit programmes**1. Strategic plans

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

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

2. Performance assessment

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

3. Compliance

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

It is desirable that the *Veterinary Services* contain (or have a formal linkage with) an independent internal unit/section/commission the function of which is to critically scrutinise their operations. The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

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

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

#### 4. Veterinary Services administration

##### a. Annual reports

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

##### b. Reports of government review bodies

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

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

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

##### d. In-service training and development programme for staff

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

##### e. Publications

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

##### f. Formal linkages with sources of independent scientific expertise

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

##### g. Trade performance history

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

Annex VIII (contd)

## Article 3.2.11.

**Participation in OIE activities**

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

## Article 3.2.12.

**Evaluation of veterinary statutory body**1. Scope

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

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

2. Evaluation of objectives and functions

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

- a. to regulate *veterinarians* and *veterinary para-professionals* through licensing and/or registration of such persons;
- b. to determine the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;
- c. to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

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

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

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

4. Evaluation of membership representation

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

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

5. Evaluation of accountability and transparency of decision-making

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

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

6. Evaluation of financial sources and financial management

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

Annex VIII (contd)7. Evaluation of training programmes and programmes for continuing professional development, for veterinarians and veterinary para-professionals

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

## Article 3.2.13.

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

## Article 3.2.14.

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

1. Organisation and structure of Veterinary Services

## a. National Veterinary Authority

Organisational chart including numbers, positions and numbers of vacancies.

## b. Sub-national components of the Veterinary Authority

Organisational charts including numbers, positions and number of vacancies.

## c. Other providers of veterinary services

Description of any linkage with other providers of veterinary services.

## 2. National information on human resources

### a. Veterinarians

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

ii. Numbers of:

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

iii. Animal health:

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

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

iv. Veterinary public health:

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

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

v. Numbers of veterinarians relative to certain national indices:

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

Annex VIII (contd)

- vi. Veterinary education:
  - number of veterinary schools;
  - length of veterinary course (years);
  - international recognition of veterinary degree.
- vii. Veterinary professional associations.
- b. Graduate personnel (non-veterinary)
 

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

Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).
- e. Descriptive summary of the functions of the various categories of staff mentioned above
- f. Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations
- g. Additional information and/or comments.

Annex VIII (contd)3. Financial management information

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

4. Administration details

## a. Accommodation

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

## b. Communications

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

## c. Transport

- i. Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.
- ii. Details of annual funds available for maintenance and replacement of motor vehicles.

Annex VIII (contd)5. Laboratory services

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

6. Veterinary legislation and functional capabilities and legislative support

a. Animal health and veterinary public health

- i. Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:
  - animal and veterinary public health controls at national frontiers;
  - control of endemic animal diseases, including *zoonoses*;
  - emergency powers for control of exotic disease outbreaks, including *zoonoses*;
  - inspection and registration of facilities;
  - veterinary public health controls of the production, processing, storage and marketing of *meat* for domestic consumption;
  - veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods of animal origin for domestic consumption;
  - registration and use of veterinary pharmaceutical products including vaccines.
- ii. Assessment of ability of *Veterinary Services* to enforce legislation.

b. Export/import inspection

- i. Assessment of the adequacy and implementation of relevant national legislation concerning:
  - veterinary public health controls of the production, processing, storage and transportation of *meat* for export;
  - veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other foods of animal origin for export;
  - animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
  - animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;
  - animal health controls of importation of veterinary biological products including vaccines;
  - administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
  - documentation and compliance.
- ii. Assessment of ability of *Veterinary Services* to enforce legislation.

Annex VIII (contd)7. Animal health and veterinary public health controls

## a. Animal health

- i. Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.
- ii. Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.
- iii. Description and relevant data of current official control programmes including:
  - epidemiological surveillance or monitoring programmes;
  - officially approved industry administered control or eradication programmes for specific *diseases*.
- iv. Description and relevant details of animal disease emergency preparedness and response plans.
- v. Recent history of animal disease status:
  - animal *diseases* eradicated nationally or from defined sub-national zones in the last ten years;
  - animal *diseases* of which the prevalence has been controlled to a low level in the last ten years;
  - animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;
  - *emerging diseases* in the last ten years;
  - animal *diseases* of which the prevalence has increased in the last ten years.

## b. Veterinary public health

- i. Food hygiene
  - Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).
  - Estimate of total annual slaughterings which occur but are not recorded under official statistics.
  - Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.
  - Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.

Annex VIII (contd)

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

Annex VIII (contd)

## iv. Veterinary medicines

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

8. Quality systems

## a. Accreditation

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

## b. Quality manuals

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

## c. Audit

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

9. Performance assessment and audit programmes

## a. Strategic plans and review

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

## b. Compliance

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

## c. Annual reports of the Veterinary Authority

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

## d. Other reports

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

Annex VIII (contd)

## e. Training

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

## f. Publications

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

## g. Sources of independent scientific expertise

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

10. Membership of the OIE

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

11. Other assessment criteria


---

-----

— text deleted



## CHAPTER 4.2.

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

## Article 4.2.1.

**Introduction and objectives**

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

## Article 4.2.2.

**Glossary**

For the purpose of this chapter:

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

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

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

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

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

## Article 4.2.3.

**Key elements of the animal identification system**1. Desired outcomes

Desired outcomes should be defined through consultation between the *Veterinary 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:

Annex IX (contd)

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

2. Scope

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

3. Performance criteria

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

4. Preliminary studies

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

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

Annex IX (contd)

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

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

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

## 5. Design of the programme

### a. General provisions

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

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

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

### b. Means of animal identification

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

Annex IX (contd)

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

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

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

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

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

c. Registration

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

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

i. Establishments/owners or responsible keepers

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

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

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

Annex IX (contd)

## ii. Animals

*Animal identification* and species should be registered for each establishment/owner. Other relevant information about the *animals* at each establishment/owner may also be recorded e.g. date of birth, production category, sex, breed, *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. When establishments are not registered as part of the *animal identification system*, ownership and location changes constitute a movement record.

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

~~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 at 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 owner or keeper regardless of change of establishment,
- observation of an *animal* on an establishment (testing, health investigation, health certification, etc.),
- animal imported: a record of the *animal identification* from the *exporting country* should be kept and linked with the *animal identification* assigned in the *importing country*,
- animal exported: a record of the *animal identification* from the *exporting country* should be provided to the *Veterinary Authority* in the *importing country*,
- animal identifier lost or replaced,
- animal missing (lost, stolen, etc.),
- animal identifier retired (at *slaughter*, following loss of the identifier or *death* of the *animal* on a farm, at diagnostic *laboratories*, etc.).

Annex IX (contd)

## 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 Authority* by the person responsible for the *animals*.

## f. Information system

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

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

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

## g. Laboratories

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

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

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

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

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

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

Annex IX (contd)

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.

6. Legal framework

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

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

This legal framework should address:

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

Annex IX (contd)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 Authority* in order to determine compliance with the legal framework and operational requirements.

## c. Auditing

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

## d. Review

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

---

-----  
— text deleted

## CHAPTER 4.3.

## ZONING AND COMPARTMENTALISATION

## Article 4.3.1.

**Introduction**

For the purposes of the *Terrestrial Code*, ‘zoning’ and ‘regionalisation’ have the same meaning.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, given the difficulty of establishing and maintaining a *disease* free status for an entire territory, especially for *diseases* the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member in establishing and maintaining a *subpopulation* with a distinct health status within its territory. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a Member under the provisions of this Chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*. While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management including *biosecurity plans* play important roles in the application of both concepts.

A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of limited *outbreaks* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

This Chapter is to assist OIE Members wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* Chapter(s). This Chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *disease outbreaks*.

Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.

As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within a Member's territory. Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or wild animals through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following a *disease outbreak*, the use of compartmentalisation may allow a Member to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the continuation of trade.

Annex X (contd)

Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain free status following a *disease outbreak* in a *zone* or *compartment*, Members should follow the recommendations in the relevant *disease* Chapter in the *Terrestrial Code*.

## Article 4.3.2.

**General considerations**

The *Veterinary Services* of an *exporting country* which is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant Chapters in the *Terrestrial Code*, including those on *surveillance*, and the *identification* and *traceability* of live *animals*. The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, in particular, the presence and importance of susceptible wildlife species, environmental factors and applicable appropriate biosecurity measures.

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, must be clearly documented in accordance with the Chapter on the evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*.

In the context of maintaining the health status of a *population*, references to ‘import’, ‘importation’ and ‘imported animals/products’ found in the *Terrestrial Code* apply both to importation into a country and to the movement of *animals* and their products into *zones* and *compartments*. Such movements should be the subject of appropriate measures to preserve the *animal health status* of the *zone/compartment*.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry, in the case of a *compartment*) including *disease surveillance* and diagnosis.

Biosecurity and *surveillance* are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.

Industry's responsibilities include the application of biosecurity measures, documenting and recording movements of *animals* and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, biosecurity measures, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting and *laboratory* diagnostic examinations.

#### Article 4.3.3.

### Principles for defining a zone or compartment, including protection and containment zones

In conjunction with the above considerations, the following principles should apply when Members define a *zone* or a *compartment*.

1. The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial and/or legal boundaries, and made public through official channels.
2. A *protection zone* may be established to preserve the health status of *animals* in a free country or *zone*, from adjacent countries or *zones* of different animal health status. Measures should be implemented based on the epidemiology of the *disease* under consideration to prevent introduction of the pathogenic agent. These measures should include intensified movement control and *surveillance* and may also include vaccination, special identification, raised awareness or other measures.

The application of these measures can be in the entire free *zone* or in a defined area within and/or outside the free *zone*.

23. In the event of limited *outbreaks* in a country or *zone* previously free of a *disease*, a *containment zone* may be established for the purposes of trade. Establishment of a *containment zone* should be based on a rapid response including:
  - a. appropriate standstill of movement of *animals* and *commodities* upon notification of suspicion of the specified *disease* and the demonstration that the *outbreaks* are contained within this zone through epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*. The primary *outbreak* and likely source of the *outbreak* should be identified and all *cases* shown to be epidemiologically linked.
  - b. A *stamping-out policy* or another effective control strategy aimed at eradicating the *disease* should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*.
  - c. Measures consistent with the disease specific chapter should be in place to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing *surveillance* in the *containment zone*.
  - d. For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.

Annex X (contd)

- e. The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated, once the *containment zone* is clearly established, irrespective of the provisions of the disease specific chapter.
  - f. The *containment zone* should be managed in such a way that it can be demonstrated that *commodities for international trade* can be shown to have originated outside the *containment zone*.
  - g. The recovery of the free status of the *containment zone* should follow the provisions of the disease specific chapter.
34. The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.
45. *Animals* and *herds* belonging to such *subpopulations* need to be recognisable as such through a clear epidemiological separation from other animals and all things presenting a *disease risk*. For a *zone* or *compartment*, the *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its health status through a *biosecurity plan*. The measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and will depend on the epidemiology of the *disease*, environmental factors, the health status of *animals* in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *animals*, and commercial management and husbandry practices), and *surveillance*.
56. Relevant *animals* within the *zone* or *compartment* should be identified in such a way that their history can be audited. Depending on the system of production, identification may be done at the *herd, flock* lot or individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented, controlled and supervised. The existence of a valid *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.
67. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted, the live *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on animal movement controls, the plan should include *herd* or *flock* production records, feed sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk* mitigation. The information required may vary according to the species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.

---

-----  
 — text deleted

## CHAPTER 4.4.

## APPLICATION OF COMPARTMENTALISATION

## Article 4.4.1.

**Introduction and objectives**

The recommendations in this Chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.3. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease free-status throughout the country should be the final goal for OIE Members. However, establishing and maintaining a *disease-free* status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based of management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease-free herds/flocks*.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease-specific* separation between *subpopulations*.

In *disease-free* countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* must be under the responsibility of the *Veterinary Authority* in the country. For the purposes of this Chapter, compliance by the Members with Chapters 1.1. and 3.1. is an essential prerequisite.

## Article 4.4.2.

**Principles for defining a compartment**

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* must be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the *animals* in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and *surveillance*.

Annex X (contd)

## Article 4.4.3.

**Separation of a compartment from potential sources of infection**

The management of a *compartment* must provide to the *Veterinary Authority* documented evidence on the following:

1. Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and *surveillance* measures:

- a. disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;
- b. location, disease status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
  - i. *flocks* or *herds* with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;
  - ii. *slaughterhouses*, rendering plants or feed mills;
  - iii. *markets*, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

2. Infrastructural factors

Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

- a. fencing or other effective means of physical separation;
- b. facilities for people entry including access control, changing area and showers;
- c. *vehicle* access including washing and *disinfection* procedures;
- d. *unloading* and *loading* facilities;
- e. isolation facilities for introduced *animals*;
- f. facilities for the introduction of material and equipment;
- g. infrastructure to store feed and veterinary products;
- h. disposal of carcasses, manure and waste;
- i. water supply;
- j. measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;

- k. air supply;
- l. feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 4 and 6 of the *Terrestrial Code*.

### 3. Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

- a. potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- b. the critical control points for each pathway;
- c. measures to mitigate exposure for each critical control point;
- d. standard operating procedures including:
  - i. implementation, maintenance, monitoring of the measures,
  - ii. application of corrective actions,
  - iii. verification of the process,
  - iv. record keeping;
- e. contingency plan in the event of a change in the level of exposure;
- f. reporting procedures to the *Veterinary Authority*;
- g. the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;
- h. the *surveillance* programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the *compartment*.

## Annex X (contd)

### 4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid *traceability* system. All *animals* within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary Authority* should provide sufficient assurance of *traceability*.

All animal movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Article 4.4.4.

### **Documentation**

Documentation must provide clear evidence that the biosecurity, *surveillance*, *traceability* and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include *herd* or *flock* production records, feed sources, *laboratory* tests, birth and *death* records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* Chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* a baseline animal health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration must be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information must be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Authority*.

Article 4.4.5.

### **Surveillance for the agent or disease**

The *surveillance* system should comply with Chapter 1.4. on Surveillance and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased *risk* of exposure to the agent for which the *compartment* has been defined, the detection level of the internal and external *surveillance* should be reviewed and, where necessary, raised. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

### 1. Internal surveillance

*Surveillance* should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

### 2. External surveillance

The biosecurity measures applied in a *compartment* must be appropriate to the level of exposure of the *compartment*. External *surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted *surveillance* based on an assessment of *risk* factors may be the most efficient *surveillance* approach. Targeted *surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.4.6.

## **Diagnostic capabilities and procedures**

Officially-designated *laboratory* facilities complying with the OIE standards for quality assurance, as defined in Chapter 1.1.3. of the *Terrestrial Manual*, should be available for sample testing. All *laboratory* tests and procedures should comply with the recommendations of the *laboratory* for the specific *disease*. Each *laboratory* that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.4.7.

## **Emergency response and notification**

Early detection, diagnosis and notification of *disease* are critical to minimize the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, ~~export certification~~ the free status of the compartment should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.

In case of an occurrence of any infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in Article 4.4.4., the management of the *compartment* should notify the *Veterinary Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures. If a significant breach in biosecurity, even in the absence of *outbreak*, is detected, export certification as a free *compartment* should be suspended. Disease free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original biosecurity level and the *Veterinary Authority* re-approves the status of the *compartment*.

Annex X (contd)

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and ~~consider~~ consider any additional biosecurity measures needed to ensure that the integrity of the *compartment* is maintained.

## Article 4.4.8.

**Supervision and control of a compartment**

The authority, organisation, and infrastructure of the *Veterinary Services*, including *laboratories*, must be clearly documented in accordance with the Chapter on the Evaluation of *Veterinary Services* of the *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this Chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

---

-----  
— text deleted

CHAPTER 4.56.COLLECTION AND PROCESSING OF  
BOVINE, SMALL RUMINANT AND PORCINE SEMENArticle 4.56.1.**General considerations**

The purposes of official sanitary control of semen production are to:

1. maintain the health of *animals* on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible *risk* of infecting other *animals* or humans with pathogens transmissible by semen;
2. ensure that semen is hygienically collected, processed and stored.

*Artificial insemination centres* should comply with recommendations in Chapter 4.65.

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

Article 4.56.2.**Conditions applicable to testing of bulls and teaser animals**

Bulls and teaser animals should enter an *artificial insemination centre* only if they fulfil the following requirements.

1. ~~Pre-quarantine~~ Prior to entering pre-entry isolation facility

The *animals* should comply with the following requirements prior to entry into isolation at the ~~quarantine station~~ pre-entry isolation facility where the country of origin is not free.

- a. Bovine brucellosis ~~=The *animals* should comply with~~ point 3 or 4 of Article 11.3.5.
- b. Bovine tuberculosis ~~=The *animals* should comply with~~ point 3 or 4 of Article 11.7.5.
- c. Bovine viral diarrhoea-mucosal disease (BVD-MD)

The *animals* should be subjected to ~~the following tests~~:

- i. a virus isolation test or a test for virus antigen, with negative results; and
- ii. a serological test to determine the serological status of every *animal*.
- d. Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis

If the *artificial insemination centre* is to be considered as infectious bovine rhinotracheitis-infectious pustular vulvovaginitis free (IBR/IPV), the *animals* should either:

- i. come from an IBR/IPV free *herd* as defined in Article 11.13.3.; or

Annex XI (contd)

- ii. be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.
- e. Bluetongue

The *animals* should comply with Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country of origin of the *animals*.

2. Testing in the ~~quarantine station~~ pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, bulls and teaser animals should be kept in a ~~quarantine station~~ pre-entry isolation facility for at least 28 days. The *animals* should be ~~subjected to diagnostic tests~~ tested as described below a minimum of 21 days after entering the ~~quarantine station~~ pre-entry isolation facility, except for *Campylobacter fetus* subsp. *venerealis* and *Tritrichomonas foetus*, for which testing may commence after 7 days in ~~quarantine~~ pre-entry isolation. All the results should be negative except in the case of BVD-MD antibody serological testing (see point 2b)i) below).

a. Bovine brucellosis

The *animals* should be subjected to a serological test with negative results.

b. BVD-MD

- i. All *animals* should be tested for viraemia as described in point 1c) above.

Only when all the *animals* in ~~quarantine~~ pre-entry isolation test negative for viraemia, may the *animals* enter the semen collection facilities upon completion of the 28-day ~~quarantine~~ pre-entry isolation period.

- ii. After 21 days in ~~quarantine~~ pre-entry isolation, all *animals* should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.
- iii. Only if no sero-conversion occurs in the *animals* which tested seronegative before entry into the ~~quarantine station~~ pre-entry isolation facility, may any *animal* (seronegative or seropositive) be allowed entry into the semen collection facilities.
- iv. If sero-conversion occurs, all the *animals* that remain seronegative should be kept in ~~quarantine~~ pre-entry isolation ~~over a prolonged time~~ until there is no more seroconversion in the group for a period of 3 weeks. Serologically positive *animals* may be allowed entry into the semen collection facilities.

c. *Campylobacter fetus* subsp. *venerealis*

- i. *Animals* less than 6 months old or kept since that age only in a single sex group prior to ~~quarantine~~ pre-entry isolation should be tested once on a preputial specimen, with a negative result.
- ii. *Animals* aged 6 months or older that could have had contact with females prior to ~~quarantine~~ pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

## Annex XI (contd)

d. *Trichostrongylus axei*

- i. *Animals* less than 6 months old or kept since that age only in a single sex group prior to ~~quarantine~~ pre-entry isolation, should be tested once on a preputial specimen, with a negative result.
- ii. *Animals* aged 6 months or older that could have had contact with females prior to ~~quarantine~~ pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

## e. IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any *animal* tests positive, the *animal* should be removed immediately from the ~~quarantine station~~ pre-entry isolation facility and the other *animals* of the same group should remain in quarantine pre-entry isolation and be retested, with negative results, not less than 21 days after removal of the positive *animal*.

## f. Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.69., 8.3.710. or 8.3.811., depending on the bluetongue status of the country or zone where the semen collection centre is located ~~of origin of the animals~~.

3. ~~Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull~~

~~Prior to the initial dispatch of semen from BVD-MD serologically positive bulls, a semen sample from each *animal* should be subjected to a virus isolation or virus antigen test for BVD-MD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.~~

4. ~~Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free~~

~~Each aliquot of frozen semen should be tested as per Article 11.13.7.~~

53. Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country or zone where the semen collection centre is located ~~of origin~~ is not free:

- a. Bovine brucellosis
- b. Bovine tuberculosis
- c. BVD-MD

*Animals* negative to previous serological tests should be retested to confirm absence of antibodies.

Should an *animal* become serologically positive, every ejaculate of that *animal* collected since the last negative test should be either discarded or tested for virus with negative results.

Annex XI (contd)d. *Campylobacter fetus* subsp. *venerealis*

- i. A preputial specimen should be cultured.
- ii. Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

## e. Bluetongue

The *animals* should comply with the provisions referred to in Articles ~~8.3.6., 8.3.7. or 8.3.8~~11., ~~depending on the bluetongue status of the country of origin of the *animals*.~~

f. *Tritrichomonas foetus*

- i. A preputial specimen should be cultured.
- ii. Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay off of more than 6 months should be tested not more than 30 days prior to resuming production.

## g. IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should comply with the provisions in point 2)c) of Article 11.13.3.

4. Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD-MD serologically positive bulls, a semen sample from each *animal* should be subjected to a virus isolation or virus antigen test for BVD-MD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

5. Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 11.13.7.

Article 4.~~5~~6.3.

**Conditions applicable to testing of rams/bucks and teaser animals**

Rams/bucks and teaser animals should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Pre quarantine Prior to entering pre-entry isolation facility

The *animals* should comply with the following requirements prior to entry into isolation at the ~~quarantine station~~ pre-entry isolation facility.

- a. Caprine and ovine brucellosis = ~~The *animals* should comply with~~ Article 14.1.6.
- b. Ovine epididymitis = ~~The *animals* should comply with~~ Article 14.7.3.

Annex XI (contd)

- c. Contagious agalactia  $\equiv$  ~~The *animals* should comply with points 1 and 2 of Article 14.3.1.~~
- d. Peste des petits ruminants  $\equiv$  ~~The *animals* should comply with points 1, 2, and 4 or 5 of Article 14.8.7.~~
- e. Contagious caprine pleuropneumonia  $\equiv$  ~~The *animals* should comply with Article 14.4.5. or Article 14.4.7., depending on the CCPP status of the country of origin of the *animals*.~~
- f. Paratuberculosis  $\equiv$  ~~The *animals* should be free from clinical signs for the past 2 years.~~

- g. ~~Scrapie~~

~~If the *animals* do not originate from a scrapie free country or zone as defined in Article 14.9.3., the *animals* should comply with Article 14.9.6.~~

- hg. Maedi-visna  $\equiv$  ~~The *animals* should comply with Article 14.6.2.~~

- ih. Caprine arthritis/encephalitis  $\equiv$  ~~In the case of goats, the *animals* should comply with Article 14.2.2.~~

- ji. Bluetongue

The *animals* should comply with Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country of origin of the *animals*.

- kj. Tuberculosis  $\equiv$  ~~In the case of goats, the *animals* should be subject to a single or comparative tuberculin test, with negative results.~~

- l. ~~Border disease~~

~~The *animals* should be subject to a viral agent isolation test with negative results.~~

2. Testing in the ~~quarantine station~~ pre-entry isolation facility station prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, rams/bucks and teasers should be kept in a ~~quarantine station~~ pre-entry isolation facility for at least 28 days. The *animals* should be ~~subjected to diagnostic tests~~ tested as described below a minimum of 21 days after entering the ~~quarantine station~~ pre-entry isolation facility, with negative results.

- a. Caprine and ovine brucellosis  $\equiv$  ~~The *animals* should be subject to testing as described in point 1c) of Article 14.1.8.~~
- b. Ovine epididymitis  $\equiv$  ~~The *animals* and semen should be subject to testing as described in points 1d) and 2 of Article 14.7.4.~~
- c. Maedi-visna and caprine arthritis/encephalitis  $\equiv$  ~~The *animals* and semen should be subjected to a serological test for antibodies on *animals* and semen.~~
- d. Bluetongue

The *animals* should comply with the provisions referred to in Articles 8.3.6~~9~~, 8.3.7~~10~~ or 8.3.8~~11~~, depending on the bluetongue status of the country or zone where the semen collection centre is located ~~of origin of the *animals*.~~

Annex XI (contd)3. Testing programme for rams/bucks and teasers resident in the semen collection facilities

All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the country or zone where the semen collection centre is located ~~of origin~~ is not free:

- a. caprine and ovine brucellosis;
- b. ovine epididymitis;
- c. Maedi-visna and caprine arthritis/encephalitis;
- d. tuberculosis (for goats only);
- e. bluetongue

The animals should comply with the provisions referred to in Article 8.3.11.

Article 4.56.4.

**Conditions applicable to testing of boars**

Boars should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Pre quarantine Prior to entering pre-entry isolation facility

The *animals* should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the ~~quarantine station~~ pre-entry isolation facility.

- a. Porcine brucellosis ~~≡ The animals should comply with Article 15.4.3.~~
- b. Foot and mouth disease ~~≡ The animals should comply with Articles 8.5.10., 8.5.11. or 8.5.12.~~
- c. Aujeszky's disease ~~≡ The animals should comply with Article 8.2.8. or Article 8.2.9.~~
- d. ~~Teschovirus encephalomyelitis~~

~~The animals should comply with Article 15.6.4. or Article 15.6.6.~~

- e. Transmissible gastroenteritis ~~≡ The animals should comply with Article 15.7.2.~~
- f. Swine vesicular disease ~~≡ The animals should comply with Article 15.5.5. or Article 15.5.7.~~
- g. African swine fever ~~≡ The animals should comply with Article 15.1.5. or Article 15.1.6.~~
- h. Classical swine fever ~~≡ The animals should comply with Articles 15.3.5. or 15.3.6.~~
- i. Porcine reproductive and respiratory syndrome ~~≡ The animals should be subject to the test complying with the standards in the Terrestrial Manual.~~

2. Testing in the ~~quarantine station~~ pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the *artificial insemination centre*, boars should be kept in a ~~quarantine station~~ pre-entry isolation facility for at least 28 days. The *animals* should be subjected to diagnostic tests as described below a minimum of 21 days after entering the ~~quarantine station~~ pre-entry isolation facility, with negative results.

- a. Porcine brucellosis = ~~The animals should comply with~~ Article 15.4.5.
- b. Foot and mouth disease = ~~The animals should comply with~~ Articles 8.5.13., 8.5.14., 8.5.15. or 8.5.16.
- c. Aujeszky's disease = ~~The animals should comply with~~ Articles 8.2.12., 8.2.13. or 8.2.14.
- d. ~~Teschovirus encephalomyelitis~~  
~~The animals should comply with Article 15.6.8. or Article 15.6.9.~~
- e. Transmissible gastroenteritis = ~~The animals should comply with~~ Article 15.7.4.
- f. Swine vesicular disease = ~~The animals should comply with~~ Article 15.5.9. or Article 15.5.10.
- g. African swine fever = ~~The animals should comply with~~ Article 15.1.8. or Article 15.1.9.
- h. Classical swine fever = ~~The animals should comply with~~ Articles 15.3.8. or 15.3.9.
- i. Porcine reproductive and respiratory syndrome = ~~The animals should be subject to the test complying with~~ the test complying with the standards in the *Terrestrial Manual*.

3. Testing programme for boars resident in the semen collection facilities

All boars resident in the semen collection facilities should be tested at least annually for the following *diseases*, with negative results, where the *compartment/zone* or country is not free:

- a. Porcine brucellosis = ~~The animals should comply with~~ Article 15.4.5.
- b. Foot and mouth disease = ~~The animals should comply with~~ Articles 8.5.13., 8.5.14., 8.5.15. or 8.5.16.
- c. Aujeszky's disease = ~~The animals should comply with~~ Articles 8.2.12., 8.2.13. or 8.2.14. regarding testing every four months.
- d. ~~Teschovirus encephalomyelitis~~  
~~The animals should comply with Article 15.6.8. or Article 15.6.9.~~
- e. Transmissible gastroenteritis = ~~The animals should comply with~~ Article 15.7.4.
- f. Swine vesicular disease = ~~The animals should comply with~~ Article 15.5.9. or Article 15.5.10.
- g. African swine fever = ~~The animals should comply with~~ Article 15.1.8. or Article 15.1.9. Routine test to be applied at least every six months.

Annex XI (contd)

hg. Classical swine fever = ~~The animals should comply with~~ Articles 15.3.8. or 15.3.9.

ih. Porcine reproductive and respiratory syndrome = ~~The animals should be subject to~~ the test complying with the standards in the *Terrestrial Manual*.

Article 4.56.5.

**General considerations for hygienic collection and handling of semen**

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 4.56.6.

**Conditions applicable to the collection of semen**

1. The floor of the mounting area should be easy to clean and to disinfect. A dusty floor should be avoided.
2. The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animal should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.
3. The hand of the person collecting the semen should not come into contact with the *animal's* penis. Disposable gloves should be worn by the collector and changed for each collection.
4. The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.
5. The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.
6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.
7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the *animal* has inserted its penis without ejaculating.
8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.
9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

## Article 4.56.7.

**Conditions applicable to the handling of semen and preparation of semen samples in the laboratory**1. Diluents

- a. All receptacles used should have been sterilised.
- b. Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
- c. If the constituents of a diluent are supplied in commercially available powder form, the water used must have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
- d. Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product must be free of pathogens or sterilised; milk heat-treated at 92°C for 3-5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives must also be sterilized before use.
- e. Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.
- f. A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75µg), divekacin (25µg).

The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

2. Procedure for dilution and packing

- a. The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
- b. After dilution and during refrigeration, the semen should also be kept in a stoppered container.
- c. During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.
- d. If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage of semen

Semen for export should be stored separately from other genetic material not meeting these ~~recommendations~~ requirements of this chapter ~~in~~ with fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Annex XI (contd)

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR)<sup>1</sup>.

Prior to export, semen straws or pellets should clearly and permanently be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an *Official Veterinarian*. The contents of the container or flask should be verified by the *Official Veterinarian* prior to sealing with an official numbered seal before export and accompanied by an *international veterinary certificate* listing the contents and the number of the official seal.

4. Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between *animals* according to the ~~manufacturer's~~ recommendations of the licenser of the system.

Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from *animals* of same or better health status.

---

-----  
— text deleted

- 
1. The ICAR international standards on straws are contained in *Recording Guidelines* - Appendices to the international agreement of recording practices.

The text of this document is available at the following web site: [www.icar.org](http://www.icar.org)

## CHAPTER 4.65.

## GENERAL HYGIENE IN SEMEN COLLECTION AND PROCESSING CENTRES

## Article 4.65.1.

**General considerations**

Observation of the recommendations described in the articles below will very significantly reduce the likelihood of the semen being contaminated with common micro-organisms some of bacteria which are potentially pathogenic.

## Article 4.65.2.

**Conditions applicable to artificial insemination centres**

1. The *artificial insemination centre* is comprised of:
  - a. animal accommodation areas (including one isolation facility for sick *animals*) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;
  - b. a semen laboratory and semen storage areas;
  - c. administration offices;
  - d. A quarantine station pre-entry isolation facility which may also be attached to either situated on the same premises as a), b) and c) above but isolated from the aforementioned, or be established at a different site to the centre, provided that it is on a different location from that of those two first parts.
2. The centre should be officially approved by the *Veterinary Authority*.
3. The centre should be under the supervision and control of the *Veterinary Services* which will be responsible for regular audits, at an interval of no more than 6 months, of protocols, procedures and ~~prescribed~~ records on the health and *welfare* of the *animals* in the centre and on the hygienic production, storage and dispatch of semen.
4. The centre should be under the direct supervision and control of an *Official Veterinarian*.
5. Only ~~swine~~ *animals* associated with semen production should be permitted to enter the centre. Other species of livestock may exceptionally be resident on the centre, provided that they are kept physically apart from ~~the swine~~ these *animals*.
6. Swine Donors and teasers on the centre should be adequately isolated from farm livestock on adjacent land or buildings for instance by natural or artificial means.
7. The entry of visitors should be strictly controlled. Personnel at a centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Protective clothing and footwear for use only on the centre should be provided.
8. Individual semen containers and storage rooms should be capable of being disinfected.

Annex XI (contd)

## Article 4.65.3.

**Conditions applicable to semen collection facilities**

1. The semen collection facilities should include separate and distinct areas for accommodating resident *animals*, for semen collection, for feed storage, for manure storage, and for the isolation of *animals* suspected of being infected.
2. Only *animals* associated with semen production should be permitted to enter the semen collection facilities. Other species of *animals* may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All *animals* resident at the semen collection facilities must meet the minimum health requirements for donors.
3. The donors and teasers should be adequately isolated to prevent the transmission of *diseases* from farm livestock and other *animals*. Measures should be in place to prevent the entry of wild *animals* susceptible to ruminant and swine *diseases* transmissible via semen.
4. Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.
5. Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises must be examined and treated if necessary to ensure that they cannot introduce *disease*.
6. *Vehicles* used for transport of *animals* to and from the semen collection facilities should not be allowed to enter the facilities.
7. The semen collection area should be cleaned daily after collection. The *animals'* accommodation and semen collection areas should be cleaned and disinfected at least once a year.
8. Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

## Article 4.65.4.

**Conditions applicable to semen laboratories**

1. The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.
2. The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.
3. Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.

Annex XI (contd)

4. The laboratory should be constructed with materials that permit effective cleaning and *disinfection*.
5. The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.
6. The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.
7. The storage rooms and individual semen containers should be easy to clean and disinfect.
8. Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

## Article 4.65.5.

**Conditions applicable to the management of bulls, rams, bucks and boars**

The objective is to keep the *animals* in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1. Whether on pasture or housed, the *animal* should be kept under hygienic conditions. If housed, the litter must be kept clean and renewed as often as necessary.
2. The coat of the *animal* should be kept clean.
3. For bulls, the length of the tuft of hairs at the preputial orifice, which is invariably soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.
4. The *animal* should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.
5. In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.
6. When the *animal* is brought into the collection area, the technician must make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves, for such materials are always heavily contaminated.

---

-----

— text deleted



## CHAPTER 4.7.

**COLLECTION AND PROCESSING OF  
IN VIVO DERIVED EMBRYOS FROM  
LIVESTOCK AND HORSES**

## Article 4.7.1.

**Aims of control**

The purpose of official sanitary control of *in vivo* derived embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided.

## Article 4.7.2.

**Conditions applicable to the embryo collection team**

The embryo collection team is a group of competent technicians, including at least one *veterinarian*, to perform the collection, processing and storage of embryos. The following conditions should apply:

1. The team should be approved by the *Competent Authority*.
2. The team should be supervised by a team *veterinarian*.
3. The team *veterinarian* is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and *disinfection* and hygienic procedures.
4. The team *veterinarian* should be specifically approved for this purpose.
5. Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practiced to preclude the introduction of *infection*.
6. The collection team should have adequate facilities and equipment for:
  - a. collecting embryos;
  - b. processing and treatment of embryos at a permanent site or mobile laboratory;
  - c. storing embryos.

These facilities need not necessarily be at the same location.

7. The embryo collection team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority* for a period of at least 2 years after the embryos have been exported.
8. The embryo collection team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

Annex XI (contd)

## Article 4.7.3.

**Conditions applicable to processing laboratories**

A processing laboratory used by the embryo collection team may be mobile or permanent. It is a facility in which embryos are recovered from collection media, examined and subjected to any required treatments such as washing and being examined and prepared for freezing and storage.

A permanent laboratory may be part of a specifically designed collection and processing unit, or a suitably adapted part of an existing building. It may be on the premises where the donor animals are kept. In either case, the laboratory should be physically separated from animals. Both mobile and permanent laboratories should have a clear separation between dirty areas (animal handling) and the clean processing area.

Additionally:

1. The processing laboratory should be under the direct supervision of the team *veterinarian* and be regularly inspected by an *Official Veterinarian*.
2. While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of a lesser health status should be processed.
3. The processing laboratory should be protected against rodents and insects.
4. The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently, and always before and after each occasion on which embryos for export are processed.

## Article 4.7.4.

**Conditions applicable to the introduction of donor animals**1. Donor animals

- a. The *Veterinary Authority* should have knowledge of, and authority over, the *herd/flock* from which the donor animals have been sourced.
- b. The donor animals should not be situated in a *herd/flock* subject to veterinary restrictions for OIE *listed disease* or pathogens for relevant species (see Chapter 1.2. of the *Terrestrial Code*), other than those that are in IETS Category 1 for the species of embryos being collected (see Article 4.7.14., and footnote<sup>1</sup>).
- c. At the time of collection, the donor animals should be clinically inspected by the team *veterinarian*, or by a *veterinarian* responsible to the team *veterinarian* and certified to be free of clinical signs of *diseases*.

2. Semen donors

- a. Semen used to inseminate donor animals artificially should have been produced and processed in accordance with the provisions of Chapter 4.56.

Annex XI (contd)

- b. When the donor of the semen used to inseminate donor females for embryo production is dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests may be required of the inseminated donor female after embryo collection to verify that these infectious *diseases* were not transmitted. An alternative may be to test ~~subject~~ an aliquot of semen from the same collection date ~~to testing~~.
- c. Where natural service or fresh semen is used, donor sires should meet the health conditions set out in Chapter 4.56, as appropriate to the species.

## Article 4.7.5.

**Risk management**

With regard to *disease* transmission, transfer of *in vivo* derived embryos is a very low risk method for moving animal genetic material. Irrespective of animal species, there are three phases in the embryo transfer process that determine the final level of risk:

1. The first phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation<sup>1</sup> (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:
  - a. the disease situation in the *exporting country* and/or *zone*;
  - b. the health status of the *herds/flocks* and the donors from which the embryos are collected;
  - c. the pathogenic characteristics of the specified disease agents that are of concern to the *Veterinary Authority* of the *importing country*.
2. The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual<sup>2</sup>. These include the following:
  - a. The embryos must be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette must be used for transferring the embryos through each wash.
  - b. Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.
  - c. Sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, and Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual<sup>2</sup>.
  - d. The zona pellucida of each embryo, after washing, must be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.

*[NOTE: All shipments of embryos must be accompanied by a statement signed by the team veterinarian certifying that these embryo processing procedures have been completed.]*

3. The third phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation (Article 4.7.14.) and which are of concern to the *Veterinary Authority* of the *importing country*, encompasses the risk reductions resulting from:

Annex XI (contd)

- a. post-collection *surveillance* of the donors and donor *herd/flock* based on the recognized *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*;
- b. testing of embryo-collection (flushing) fluids and non-viable embryos, or other samples such as blood, in a laboratory for presence of specified disease agents.

## Article 4.7.6.

**Conditions applicable to the collection and storage of embryos**1. Media

Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos should be free of pathogenic micro-organisms. Media and solutions used in the collection and storage of embryos should be sterilized by approved methods according to the IETS Manual<sup>2</sup> and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to collection, processing, washing and storage media as recommended in the IETS Manual<sup>2</sup>.

2. Equipment

- a. All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilized prior to use as recommended in the IETS Manual<sup>2</sup>.
- b. Used equipment should not be transferred between countries for re-use by the embryo collection team.

## Article 4.7.7.

**Optional tests and treatments**

1. The testing of samples can be requested by an *importing country* to confirm the absence of pathogenic organisms that may be transmitted via *in vivo* derived embryos, or to help assess whether the degree of quality control of the collection team (with regard to adherence to procedures as described in the IETS Manual<sup>2</sup>) is at an acceptable level. Samples may include:

- a. Non-viable embryos/oocytes

Where the viable, zona pellucida intact embryos from a donor are intended for export, all non-fertilized oocytes and degenerated or zona pellucida compromised embryos collected from that donor should be washed according to the IETS Manual<sup>2</sup> and pooled for testing if requested by the *importing country*. Non-viable embryos/oocytes from the donor should be processed and stored together.

- b. Embryo collection (flushing) fluids

The collection fluid should be placed in a sterile, closed container and, if there is a large amount, it should be allowed to stand undisturbed for one hour. The supernatant fluid should then be removed and the bottom 10-20 ml, along with accumulated debris, decanted into a sterile bottle. If a filter is used in the collection of embryos/oocytes then any debris that is retained on the filter must be rinsed off into the retained fluid.

Annex XI (contd)

## c. Washing fluids

The last four washes of the embryos/oocytes should be pooled (IETS Manual<sup>2</sup>).

## d. Samples

The samples referred to above should be stored at 4°C and tested within 24 hours. If this is not possible, then samples should be stored frozen at -70°C or lower.

2. When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see paragraph 2c) in Article 4.7.5.), the procedure should be carried out according to the IETS Manual<sup>2</sup>. Enzyme treatment is necessary only when pathogens for which the IETS recommends this additional treatment (such as with trypsin) may be present. It should be noted that such treatment is not necessarily always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme.

## Article 4.7.8.

**Conditions applicable to the storage and transport of embryos**

1. The embryos for export should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the *Veterinary Authority* of the *exporting country* where there is no risk of contamination of the embryos.
2. Only embryos from the same individual donor should be stored together in the same ampoule, vial or straw.
3. The embryos should if possible, depending on the species, be frozen, stored with fresh liquid nitrogen in cleaned and sterilized tanks or containers under strict hygienic conditions at the approved storage place.
4. Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible), and they should be clearly identified by labels according to the standardised system recommended in the IETS Manual<sup>2</sup>.
5. Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.
6. Embryos must not be exported until the appropriate veterinary certificates are completed.

## Article 4.7.9.

**Procedure for micromanipulation**

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.7.5. and conducted in accordance with Chapter 4.9.

## Article 4.7.10.

**Specific conditions applicable to porcine embryos**

The *herd* of origin should be free of clinical signs of swine vesicular disease, brucellosis and pathogenic enterovirus encephalomyelitis.

Annex XI (contd)

The development of effective cryopreservation methods for the storage of zona pellucida-intact porcine embryos is still at a very early stage.

Article 4.7.11.

**Specific conditions/comments applicable to equine embryos**

The recommendations apply principally to embryos from *animals* continuously resident in national equine populations and therefore may be found unsuitable for those from equines routinely involved in events or competitions at the international level. For instance, in appropriate circumstances horses travelling with an *international veterinary certificate* (e.g. competition horses) may be exempt where mutually agreed upon on a bilateral basis between the respective *Veterinary Authorities*.

Article 4.7.12.

**Specific conditions/comments applicable to camelid embryos**

South American camelid embryos recovered from the uterine cavity by the conventional non-surgical flushing technique at 6.5 to 7 days post-ovulation are almost invariably at the hatched blastocyst stage, and thus the zona pellucida has already been shed. Since the embryos do not enter the uterus and cannot be recovered before 6.5 to 7 days, it would be unrealistic to stipulate for these species that only zona pellucida-intact embryos can be used in *international trade*. It must be noted that in 2008 the development of cryopreservation methods for storage of camelid embryos is still at a very early stage, and also that pathogen interaction studies with camelid embryos have not yet been carried out.

Article 4.7.13.

**Specific conditions/comments applicable to cervid embryos**

The recommendations apply principally to embryos derived from *animals* continuously resident in national domestic or ranched cervid populations and therefore may be found to be unsuitable for those from cervids in feral or other circumstances related to biodiversity or germplasm conservation efforts.

Article 4.7.14.

**Recommendations regarding the risk of disease transmission via *in vivo* derived embryos**

The IETS has categorised<sup>1</sup> the following *diseases* and pathogenic agents into four categories, which applies only to *in vivo* derived embryos.

## 1. Category 1

- a. Category 1 *diseases* or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual<sup>2</sup>.
- b. The following *diseases* or pathogenic agents are in category 1:
  - Aujeszky's disease (pseudorabies) (swine): trypsin treatment required
  - Bluetongue (cattle)
  - Bovine spongiform encephalopathy (cattle)

Annex XI (contd)

- *Brucella abortus* (cattle)
- Enzootic bovine leukosis
- Foot and mouth disease (cattle)
- Infectious bovine rhinotracheitis: trypsin treatment required.

## 2. Category 2

- a. Category 2 *diseases* are those for which substantial evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual<sup>2</sup>, but for which additional transfers are required to verify existing data. pathogenic agents are in category 2:
  - Bluetongue (sheep)
  - Caprine arthritis/encephalitis
  - Classical swine fever (hog cholera)
  - Scrapie (sheep).

## 3. Category 3

- a. Category 3 *diseases* or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual<sup>2</sup>, but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.
- b. The following *diseases* or pathogenic agents are in category 3:
  - Bovine immunodeficiency virus
  - Bovine spongiform encephalopathy (goats)
  - Bovine viral diarrhea virus (cattle)
  - *Campylobacter fetus* (sheep)
  - Foot and mouth disease (swine, sheep and goats)
  - *Haemophilus somnus* (cattle)
  - Maedi-visna (sheep)
  - *Mycobacterium paratuberculosis* (cattle)
  - *Neospora caninum* (cattle)
  - Ovine pulmonary adenomatosis

Annex XI (contd)

- Porcine reproductive and respiratory disease syndrome (PRRS)
- Rinderpest (cattle)
- Swine vesicular disease.

## 4. Category 4

- a. Category 4 *diseases* or pathogenic agents are those for which studies have been done, or are in progress, that indicate:
  - i. that no conclusions are yet possible with regard to the level of transmission risk; or
  - ii. the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual<sup>2</sup> between collection and transfer.
- b. The following *diseases* or pathogenic agents are in category 4:
  - African swine fever
  - Akabane (cattle)
  - Bovine anaplasmosis
  - Bluetongue (goats)
  - Border disease (sheep)
  - Bovine herpesvirus-4
  - *Chlamydia psittaci* (cattle, sheep)
  - Contagious equine metritis
  - Enterovirus (cattle, swine)
  - Equine rhinopneumonitis
  - *Escherichia coli* 09:K99 (cattle)
  - *Leptospira borgpetersenii* serovar *hardjobovis* (cattle)
  - *Leptospira* sp. (swine)
  - *Mycobacterium bovis* (cattle)
  - *Mycoplasma* spp. (swine)
  - Ovine epididymitis (*Brucella ovis*)
  - Parainfluenza-3 virus (cattle)
  - Parvovirus (swine)

Annex XI (contd)

- Porcine circovirus (type 2) (pigs)
  - Scrapie (goats)
  - *Trichomonas foetus* (cattle)
  - *Ureaplasma/Mycoplasma* spp. (cattle, goats)
  - Vesicular stomatitis (cattle, swine).
- 

-----  
— text deleted

---

1. Based on available research and field information, the Research Subcommittee of the Health and Safety Advisory Committee (HASAC) of the International Embryo Transfer Society (IETS) has categorised some diseases based on their relative risk of dissemination by properly processed and handled *in vivo* derived embryos. This Chapter that contains the complete list of IETS categorised diseases is shown in Article 4.7.14.
2. Manual of the International Embryo Transfer Society.



## CHAPTER 4.8.

**COLLECTION AND PROCESSING OF  
IN VITRO PRODUCED EMBRYOS / OOCYTES FROM  
LIVESTOCK AND HORSES**

## Article 4.8.1.

**Aims of control**

Production of embryos *in vitro* involves the collection of oocytes from the ovaries of donors, *in vitro* maturation and fertilization of the oocytes, then *in vitro* culture to the morula/blastocyst stage at which they are ready for transfer into recipients. The purpose of official sanitary control of *in vitro* produced embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with such embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided. The conditions outlined in this chapter are also applicable where the movement of *in vitro* maturing (IVM) oocytes is intended.

## Article 4.8.2.

**Conditions applicable to the embryo production team**

The embryo production team is a group of competent technicians, including at least one *veterinarian*, to perform the collection and processing of ovaries/oocytes and the production and storage of *in vitro* produced embryos. The following conditions should apply:

1. The team should be approved by the *Competent Authority*.
2. The team should be supervised by a team *veterinarian*.
3. The team *veterinarian* is responsible for all team operations which include the hygienic collection of ovaries and oocytes and all other procedures involved in the production of embryos intended for international movement.
4. The team *veterinarian* should be specifically approved for this purpose.
5. Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practised to preclude the introduction of *infection*.
6. The production team should have adequate facilities and equipment for:
  - a. collecting ovaries and/or oocytes;
  - b. processing of oocytes and production of embryos at a permanent ~~site~~ or mobile laboratory;
  - c. storing oocytes and/or embryos.

These facilities need not necessarily be at the same location.

Annex XI (contd)

67. The embryo production team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority* for a period of at least 2 years after the embryos have been exported.
78. The embryo production team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection and processing of oocytes and the production and storage of embryos.

## Article 4.8.3.

**Conditions applicable to the processing laboratories**

A processing laboratory used by the embryo production team may be mobile or permanent. It may be contiguous with the oocyte recovery area or at a separate location. It is a facility in which oocytes which have been recovered from ovaries are then matured and fertilised, and where the resulting embryos are further cultured *in vitro*.

Embryos may also be subjected to any required treatments such as washing and storage and quarantine in this laboratory.

Additionally:

1. The laboratory should be under the direct supervision of the team *veterinarian* and regularly inspected by an *Official Veterinarian*.
2. While embryos for export are being produced prior to their storage in ampoules, vials or straws, no oocyte/embryo of a lesser health status should be recovered or processed in the same laboratory.
3. The laboratory should be protected against rodents and insects.
4. The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently and always before and after each occasion when embryos for export are processed.

## Article 4.8.4.

**Conditions applicable to donor animals**

Oocytes for the *in vitro* production of embryos are obtained from donors basically in two different ways: individual collection or batch collection. The recommended conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of individual live *animals* on the farm where the *animal* resides, or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. When oocytes are recovered from individual live *animals*, the conditions for these donors should resemble those set out in Article 4.7.4.

In these cases the cleaning and sterilisation of equipment (e.g. ultrasound guided probes) is especially important and must be carried out between each donor in accordance with the recommendations in the Manual of the International Embryo Transfer Society (IETS)<sup>1</sup>.

Annex XI (contd)

Batch collection involves the removal of ovaries from batches of donors slaughtered at a slaughterhouse/*abattoir* (hereafter '*abattoir*'); these ovaries are then transported to the processing laboratory where the oocytes are recovered from the ovarian follicles by aspiration. Batch collection has the disadvantage that it is usually impractical to relate the ovaries which are transported to the laboratory to the donors which were slaughtered at the *abattoir*. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors and transported to the laboratory in a hygienic manner.

Additionally:

1. The *Veterinary Authority* should have knowledge of, ~~and authority over,~~ the *herd(s)/flock(s)* from which the donor animals have been sourced.
2. The donor animals should not originate from *herds / flocks* ~~which that~~ are subject to veterinary restrictions for *listed diseases of concern* (under study), and neither should the removal of any tissue or aspiration of oocytes take place in an *infected zone*, or one that is subject to veterinary restrictions for *listed diseases of concern* (under study)
3. In the case of oocyte recovery from live donors, post-collection surveillance of the donors and donor *herd(s) /flock(s)* should be conducted based on the recognized *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors.
4. In the case of oocyte recovery from batches of ovaries collected from an *abattoir*, the *abattoir* should be officially approved and under the supervision of a *veterinarian* whose responsibility is to ensure that ante-mortem and post-mortem inspections of potential donor animals are carried out, and to certify them to be free of clinical or pathological signs of *infectious diseases* (under study).
5. Donor animals slaughtered at an *abattoir* should not have been designated for compulsory *slaughter* for a *notifiable disease* and should not be slaughtered at the same time as donors from which ovaries and other tissues will be removed.
6. Batches of ovaries and other tissues collected from an *abattoir* should not be transported to the processing laboratory before confirmation has been obtained that ante- and post-mortem inspection of donors has been satisfactorily completed.
7. Equipment for the removal and transport of ovaries and other tissues should be cleaned and sterilised before use and exclusively used for these purposes.
8. Records of the identities and origins of all donors should be maintained for inspection by the *Veterinary Authority* for a period of at least 2 years after the embryos have been exported. While this may be difficult to achieve in the case of batch collection, it is to be expected that the identities of the *herds/flocks* from which the donors originated will be maintained.

Article 4.8.5.

### **Optional tests and treatments**

~~The main~~ A supplementary approach for ensuring that *in vitro* produced embryos do not transmit *disease* is by testing various materials to confirm the absence of pathogenic organisms ~~which that~~ are of concern to the *importing country*.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are of an acceptable standard.

Annex XI (contd)

Tests may be carried out on the following materials:

- a. non-viable oocytes/embryos from any stage of the *in vitro* production line from batches intended for export;
- b. samples of *in vitro* maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;
- c. samples of embryo culture medium taken immediately prior to embryo storage.

These samples should be stored at 4°C and tested within 24 hours. If this is not possible, then the samples should be stored frozen at -70°C or lower.

Additionally:

1. Semen used to fertilise oocytes *in vitro* should meet the health requirements and standards set out in Chapter 4.56, as appropriate to the species.

When the donor of the semen used to fertilise the oocytes is ~~no longer living~~ dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests on the spare embryos may be required to verify that these infectious *diseases* were not transmitted. An alternative may be to test an aliquot of semen from the same collection date.

2. Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free of living pathogens. Media should be sterilised prior to use by approved methods according to the IETS Manual<sup>1</sup> and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual<sup>1</sup>.
3. All equipment used to recover, handle, culture, wash, freeze and store oocytes/embryos should be new or cleaned and sterilised prior to use as recommended in the IETS Manual<sup>1</sup>.

Article 4.8.6.

### **Risk management**

With regard to disease transmission, transfer of *in vitro* produced embryos is a low risk method for moving animal genetic material although the risk is not quite as low as for *in vivo* derived embryos. It should be noted that categorisation of *diseases*/disease agents by the IETS, as described for *in vivo* derived embryos in Article 4.7.14., does not apply in the case of *in vitro* produced embryos. Irrespective of the animal species, there are three phases in the embryo production and transfer process that determine the final level of risk. These are as follows:

1. the first phase comprises the risk potential for ovary/oocyte/embryo contamination and depends on:
  - a. the disease situation in the *exporting country* and/or *zone*;
  - b. the health status of the *herds/flocks* and the donors from which the ovaries/oocytes/ embryos are collected;
  - c. the pathogenic characteristics of the specified disease agents (under study) that are of concern to the *Veterinary Authority* of the *importing country*;

Annex XI (contd)

2. the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the IETS Manual<sup>1</sup>. These include the following:
  - a. after the *in vitro* culture period is finished the embryos should be washed at least ten times with at least 100-fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash;
  - b. only embryos from the same donor (in the case of individual collection) or from the same batch (in the case of batch collection) should be washed together, and no more than ten embryos should be washed at any one time;
  - c. sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, or Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual<sup>1</sup>;
  - d. the zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material;
3. the third phase, which is applicable to *diseases* (under study) which are of concern to the *Veterinary Authority* of the *importing country*, encompasses the risk reductions resulting from:
  - a. post-collection surveillance of the donors and donor *herds/flocks* based on the recognised *incubation periods* of the *diseases* of concern to determine retrospectively the health status of the donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*. Post-collection surveillance of donors is not, of course, possible in the case of batch collection from an *abattoir*, although surveillance of the *herds/flocks* of origin may be possible;
  - b. testing of oocytes/embryos, co-culture cells, media and other samples (e.g. blood) (as referred to in Article 4.8.4.) in a laboratory for presence of disease agents.

## Article 4.8.7.

**Conditions applicable to the storage and transport of embryos**

1. Only embryos from the same individual donor or from the same batch collection should be stored together in the same ampoule, vial or straw.
2. The embryos should if possible, depending on the species, be frozen in fresh liquid nitrogen or other cryoprotectant and then stored in fresh cryoprotectant in cleaned and sterilised tanks or containers under strict hygienic conditions at a storage place.
3. Ampoules, vials or straws must be sealed at the time of freezing and should be labelled according to the IETS Manual<sup>1</sup>.
4. Liquid nitrogen containers should be sealed prior to shipment from the *exporting country*.
5. Embryos must not be exported until the appropriate veterinary certificates are completed.

Annex XI (contd)

Article 4.8.8.

**Procedure for micromanipulation**

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.8.6. and conducted in accordance with Chapter 4.9.

---

-----  
— text deleted

- 
1. Manual of the International Embryo Transfer Society.

## CHAPTER 4.10.

COLLECTION AND PROCESSING OF LABORATORY  
RODENT AND RABBIT EMBRYOS / OVA

## Article 4.10.1.

**Conditions applicable to the maintenance of laboratory animal colonies**

Maintenance of laboratory animal colonies of specific genotypes requires intensive breeding management within specialised premises. They may be kept in a gnotobiotic environment, in either a 'germfree' system or a 'barrier' room (usually with defined flora), in a conventional colony, or under undefined conditions. In both the germfree and barrier systems, the animals are raised in a controlled environment according to protocols that attempt to eliminate potential sources of microbiological contamination. The primary difference is that the barrier maintained animals have been inoculated with known (defined) microbes<sup>†</sup> using a cocktail of non-pathogenic flora, whereas germfree animals are kept free from both pathogenic and non-pathogenic microbes.

A second category is where laboratory animals are kept in closed, conventional colonies within which known pathogens may exist. Here, less rigid colony management protocols are used to control potential sources of contamination, but implementation of simple aseptic precautions (e.g. autoclaving of feed and bedding) should allow animals to be maintained in a microbiologically defined system. Finally, laboratory animals may live in environments with undefined microbiological conditions (e.g. non-restricted colonies, free ranging animals).

*Disease* testing and donor animal/embryo handling requirements can therefore be considered as being of three distinct types, depending on the type of colony being dealt with, i.e. defined floral, conventional and undefined. The health status of all colonies should be confirmed quarterly by bacteriological, virological, parasitological, serological and immunohistochemical tests on pre-designated sentinel animals or other representative animals of the colony (e.g. older breeding males which have sired multiple litters).

**Microbial status of laboratory animal colonies**

Colonies of the various species and genotypes of laboratory animals are usually kept within specialised premises and their microbial status depends largely on the system whereby the colony was formed and is maintained. In this Chapter the microbial status of colonies is considered to be of three main types: 'defined', 'conventional' and 'undefined'. Colonies of defined status are those where, at least initially, the animals are totally free of pathogenic and non-pathogenic micro-organisms (i.e. gnotobiotic), although sometimes a cocktail of known, non-pathogenic micro-organisms has been given subsequently. In either case defined colonies are kept in highly controlled environments in barrier maintained rooms, with strict protocols in place to exclude all potential sources of unwanted microbiological contamination. Colonies of conventional status are those where the animals are kept in closed colonies but where known ('specific') pathogens as well as non-pathogenic micro-organisms may exist. While management protocols for conventional colonies may be less rigid than those for defined colonies, they are designed to control potential sources of microbial contamination. Simple aseptic precautions (e.g. the autoclaving of food and bedding) are taken to ensure that the animals do not become infected with any unwanted microflora. Finally, laboratory animals may be kept in microbiologically undefined colonies which are unrestricted and may include free ranging animals. Details of these different types of colony can be found in the FELASA Report<sup>1</sup>.

Annex XI (contd)

The health status of defined and conventional colonies should be confirmed at least quarterly by bacteriological, virological, parasitological, serological and other tests on pre-designated sentinel animals or other representative members of the colony. Older breeding males which have sired multiple litters are often selected for this purpose.

The purpose of official sanitary control of laboratory rodent and rabbit embryos intended for movement internationally is to ensure that specific pathogenic micro-organisms, which could be associated with such embryos, are controlled and transmission of *infection* to recipient animals, progeny and colonies, is avoided. Requirements for the management of donors and processing of embryos vary depending on the microbial status of the colony, i.e. whether it is defined (including gnotobiotic), conventional, or undefined.

## Article 4.10.2.

**Conditions applicable to the embryo ~~production~~ collection team/~~laboratory~~**

The embryo collection team is a group of competent technicians including at least one experienced professional to perform the collection, processing and storage of embryos/oocytes.

The following conditions should apply:

1. The embryo ~~production~~ team ~~must~~ should be composed of competent technicians supervised by an experienced embryologist team professional holding a graduate academic degree (e.g. M.S., Ph.D., D.V.M.).
2. The team professional is responsible for all team operations which include verification of colony and donor health status, sanitary handling and surgery of donors, *disinfection* and hygienic procedures. The team professional should be responsible to the institute *veterinarian*.
3. The institute *veterinarian* should be certified or accredited in laboratory animal care and should be specifically *approved* for the purpose of embryo collection for export. It is the responsibility of the institute *veterinarian* to ensure that required health profiling procedures appropriate for the colony status are implemented. He/she is responsible for certifying that the embryo handling procedures and laboratory facilities conform to the requirements laid down in this Chapter.
24. Team personnel should be adequately trained in the techniques and principles of *disease* control and in the use of aseptic techniques in embryo handling. ~~Laboratory sanitary procedures must conform with requirements in the IETS Manual<sup>2</sup>~~The zoonotic potential of specific pathogens affecting the various laboratory animal species should be identified and understood so as to avoid contamination of colonies via human vectors, and vice versa.
35. The embryo ~~production~~ team ~~must~~ should use all necessary precautions to protect the animals, animal facilities, laboratory and equipment against microbiological contamination. In particular, the zoonotic potential of specific pathogens should be identified and understood by staff members ~~to avoid contamination of colonies via human vectors, or vice versa~~ High standards of hygiene should be practiced to preclude the introduction of *infection* to the donor animals, colonies, facilities, and equipment. Restrictions should be established to prevent free access of personnel into the embryo collection and handling laboratory facilities especially after ~~their exposure~~ such personnel have been exposed to other animal facilities.

6. The team should have adequate facilities and equipment for:

- a) collecting embryos;
- b) processing and treatment of embryos at a permanent site or mobile laboratory;
- c) storing embryos.

4. Proper records must ~~should~~ be maintained for inspection by the chief embryologist (i.e. supervisor):

~~Until standardised record sheets are developed for laboratory animals, it is the responsibility of each laboratory to maintain complete animal and embryo records (i.e. embryo collection, cryopreservation data). Information of the type shown in standard IETS record sheets<sup>2</sup> for livestock species should be incorporated, where applicable, and data such as embryo quality grading system, morphological stage at cryopreservation and genotypic identification of the donors should be clearly given in the records.~~

57. It is the responsibility of the ~~chief embryologist (i.e. laboratory supervisor)~~ *institute veterinarian* to ensure that the complete animal and embryos are properly stored in sterile, sealed containers (e.g. ampoules or straws) records, including records of collection, processing and storage of embryos are maintained. In addition, the containers must be correctly identified using a standard format which includes embryo species/genotype, cryopreservation date, number and stage of embryos, container number and indication of any specialised procedure (e.g. *in vitro* fertilisation, micromanipulation) or condition (e.g. germfree, microbiologically defined). Record sheets of the type shown in the IETS Manual<sup>2</sup> for livestock species should be used where applicable, and data such as genotypic identification of the donors, embryo quality grading, morphological stage and should be given. If appropriate the embryo collection team should keep a record of its activities which should be maintained for inspection by the *Veterinary Authority* for at least 2 years after the embryos have been exported.

8. The embryo collection team, if involved in the export of embryos, should be subject to regular inspection, preferably annually, by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

#### Article 4.10.2bis.

#### Conditions applicable to the processing laboratory

A processing laboratory used by the embryo collection team is a facility in which embryos are recovered from donors (or from their excised reproductive tracts), and from the collection media. Here also the embryos are examined and subjected to any required treatments such as washing, cryopreservation for storage and quarantine pending results of any diagnostic procedures. The processing laboratory may be part of a specifically designed collection and processing unit, or a suitably adapted part of an existing building. It may be on the premises where the donor animals are kept but in this case should be physically separated from animals.

Additionally:

1. The processing laboratory should be under the supervision of the *institute veterinarian* and be inspected by an *Official Veterinarian*.
2. While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of lesser health status should be processed.

Annex XI (contd)

3. The processing laboratory should be constructed with materials which permit its effective cleansing and disinfection. This should be done frequently, and always before and after each occasion on which embryos for export are processed.

Article 4.10.2tris.**Risk management**

With regard to disease transmission, transfer of *in vivo* derived embryos is a very low risk method for moving the genetic material of laboratory animals. Irrespective of animal species, there are three phases in the embryo transfer process that determine the final level of risk:

1. The first phase comprises the risk potential for embryo contamination and depends on:
  - a) the disease situation in the exporting country and/or zone;
  - b) the microbial status of the colony (i.e. defined, conventional or undefined) and the donors from which the embryos are collected;
  - c) the pathogenic characteristics of the specified disease agents that are of concern to the Veterinary Authority of the importing country.
  
2. The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual<sup>2</sup>. These include the following:
  - a) Depending on microbial status of the colony, the embryos should be washed up to ten times with at least 100-fold dilutions between each wash, with a fresh pipette being used for transferring the embryos through each wash.
  - b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.
  - c) Sometimes, for example when removal of certain viruses (e.g. herpesviruses) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual<sup>2</sup>.
  - d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and (apart from the mucin layer in the case of rabbit embryos) free of adherent material.
  
3. The third phase, which is applicable to diseases of concern to the Veterinary Authority of the importing country, encompasses risk mitigation resulting from:
  - a) post-collection surveillance of the microbial status of the donor colony based on the recognized incubation periods of the diseases of concern to determine retrospectively the health status of the colony whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the exporting country;
  - b) post-mortem testing of the donor(s) or other samples such as blood, embryo-collection (flushing) fluids and non-viable embryos, in a laboratory for presence of specified disease agents.

## Article 4.10.3.

**Conditions applicable to the embryo team/institute veterinarian**

1. ~~The veterinarian, certified in laboratory animal care or laboratory animal accredited, must ensure that the required colony health profiling procedures are implemented, and the results are reviewed and properly recorded before shipment of embryos. He/she is also responsible for confirming that proper animal management/sanitation conditions have been maintained~~ It is the responsibility of the institute veterinarian to ensure that required health testing procedures are implemented to demonstrate microbial status of the colony (i.e. defined, conventional or undefined). Colony microbial status should be reviewed by the institute veterinarian before shipment of the embryos.
2. The veterinarian is responsible for certifying that the embryo handling procedures and laboratory conditions were maintained in accordance with ~~the IETS Manual<sup>2</sup>~~ Articles 4.10.2. and 4.10.2bis.
3. ~~The veterinarian must supervise all quarantine practices to protect against unwanted contamination and spread of disease, and to ensure that valid results are generated~~ is responsible for the risk management procedures outlined in Article 4.10.2tris.
4. ~~The veterinarian must~~ should authorise all embryo shipments, ensuring that the correct embryo collection records and veterinary certification documents ~~and embryo collection records are~~ have been completed and are included in the shipments.

~~Article 4.10.4.~~**Test programmes for donor animals**

~~Sentinel animals in each donor colony should be subjected to routine monthly microbial screening. Testing for specific pathogens is species dependent and will undoubtedly also be influenced by geographic location. Recommendations regarding specific microbial agents to be tested for in mice, rats, cotton rats, hamsters, guinea pigs, gerbils and rabbits have been published elsewhere<sup>3</sup>.~~

## Article 4.10.5.

**Conditions applicable to ~~the embryo/animal handling~~ donors from animal colonies of different microbial status**

It should be noted that the conditions applicable to donor animals vary according to the microbial status of the colony from which they originate, i.e. defined, conventional or undefined.

Sentinel animals in each donor colony of defined and conventional status should be subjected to routine microbial screening, preferably monthly, but at least quarterly. Testing for specific pathogens depends on the animal species and may be influenced by geographical location. Recommendations regarding specific microbial agents to be tested for in different laboratory animal species have been published elsewhere.

1. Defined microbial ~~conditions~~ status
  - a) ~~Germfree and m~~ Microbiologically defined colonies (Article 4.10.1.), barrier maintained animals represent the cleanest sources of gametes, and the embryos recovered from these animals can be regarded as pathogen free.

Annex XI (contd)

- b) Since the ~~animals themselves~~ male and female donors are pathogen free ~~or possess defined flora (usually based on random, monthly testing of sentinel animals)~~, dissection of the female reproductive tract and embryo isolation collection procedures ~~can~~ should be performed under aseptic laboratory conditions, ~~and do not require the use of using~~ a biological safety cabinet if appropriate.
- c) ~~Strict aseptic procedures should nevertheless be followed and, while embryo washing is not essential to safeguard against any possible air-borne contamination in the laboratory, it is recommended that embryos undergo at least a 3-step washing procedure. In each wash, embryos should be gently agitated in the medium, and the wash volume must constitute at least a one hundred-fold dilution of the volume in which the embryos are transferred. Embryo washed as described in point 2 of Article 4.10.2tris is not necessary but it is recommended that embryos are washed 2 or 3 times. In each wash, embryos should be gently agitated in the medium.~~
- d) ~~Microbial testing of flush or washing media is not required.~~
- ed) ~~Cryopreserved embryos should be designated, in the appropriate records, The embryos should be recorded as coming from a germfree or microbiologically defined, barrier maintained colony, thus indicating that additional safeguards special risk management procedures (Article 4.10.2tris.) for pathogen removal are not necessary. Isolation and health status monitoring of The need to quarantine the embryo recipients should be considered but the need to quarantine them is a decision is a matter for the importing laboratory institute.~~

2. Conventional conditions

- a) ~~Animals maintained under these conditions generally represent closed colonies whose Colonies of conventional microbial status are usually closed and their health status is routinely profiled monitored (Article 4.10.1). They The animals may have been exposed to various pathogens, resulting in infection the isolation of infectious agents, with positive antibody titres or even active clinical disease. However, prior to embryo collection there should be familiarity with but the pathogen(s) of particular concern in each individual the colony should be well known.~~
- b) Reproductive tracts (uteri, oviducts and/or ovaries) should be removed at a separate site and then taken into the embryo processing laboratory. These procedures should be performed by separate different technicians or, at the ~~very~~ minimum, their protective clothing should be changed between locations. If ~~the animals are to~~ should be handled in the laboratory, the tracts should be dissected out within a biological safety cabinet. This will help protect against the possible shedding of pathogens into the laboratory itself.
- c) Once the reproductive tracts have been removed, embryo recovery should be performed under aseptic conditions. ~~Embryos must be inspected (>100x) for the presence of cracks in the zona pellucida and only zona intact embryos should be kept. They must then be washed using the standard 10-step procedure, described Depending on which, if any, pathogens are known to occur in the colony, embryos should be processed according to the risk management procedures, including washing, as described in Article 4.10.2tris, and in the IETS Manual?. This recommendation could be waived in the future if sufficient research evidence from embryo-pathogen interaction studies warranted it.~~

## Annex XI (contd)

- d) Embryos derived from animals that have positive antibody titres or other evidence of specific pathogens should only be transferred into a new colony via a *quarantine* system, using microbiologically defined recipient females. ~~As an additional safeguard, *Quarantine* may also be appropriate if there is any uncertainty about the donor or disease status of the embryos, quarantining of recipients should be applied~~ the microbial status of the donor colony or the donors. In ~~certain~~ situations where the embryos might could have been exposed to bacterial infection (e.g. *mycoplasma*), they should be cultured in a medium containing an appropriate antibiotic for 24 h ~~pre-freezing, or post-thawing and prior to transfer~~ before cryopreservation, or in the interval between thawing and transfer into recipients.
- e) ~~If the embryos were not handled in the recommended manner, this must be indicated on the shipment records, and mandatory quarantining of the recipient dam and offspring should be imposed by the recipient institution until their health status is confirmed. The recipient dam should then be tested post-weaning for pathogens, and introduction of the progeny into the colony should only take place if test results are satisfactory. If the recipient institution does decide to quarantine the recipient dam and offspring until their health status is confirmed, the recipients should be tested post-weaning for pathogens of concern, and introduction of offspring into the colony should only take place if the test results are satisfactory.~~
3. Undefined microbial conditions
- a) ~~These animals are derived from either the wild~~ Embryos from free ranging animals or from colonies of unknown health status ~~and embryos from them~~ require ~~maximum precautions~~ the full range of risk management procedures that are described in Article 4.10.2tris and in the IETS Manual<sup>2</sup>. The health status of breeder males and donor females should be determined The procedures resemble those used for embryos of livestock as recommended in Chapter 4.7. and Chapter 4.8. of this *Terrestrial Code*. Ideally, the breeder males and donor females should be separated from other animals and tested 15 days before and on the day of breeding (for males) or at embryo collection (for females). Alternatively, the animals could be incorporated into a conventional colony, where, over time, a health history can be documented to reduce the strict monitoring and embryo handling requirements.
- b) ~~A~~ Biological safety cabinet should be used for all animal, tissue and embryo handling donors and reproductive tissues, and for processing embryos.
- c) Post-mortem testing of the donor females for diseases or pathogens of concern to the importing country may be appropriate after the embryos/oocytes have been collected. Alternatively if embryos are collected surgically ~~a~~ An aliquot of flush fluid from each donor, or a pooled sample, should be tested for the presence of specific pathogens of concern to the importing country and laboratory.
- d) Embryos must be washed at least 10 times in accordance with the protocols in the IETS Manual<sup>2</sup> (i.e. the 10 step wash, possibly including trypsin treatment in the case of certain herpesviruses) and an aliquot of media from the last four (pooled) washes should be tested for pathogens trypsin treatment should be used if presence of certain pathogenic herpesviruses is of concern.
- e) Cryopreserved embryos must be stored in the exporting laboratory until such time as the necessary disease screening of colonies, tissues and or fluids is completed and the certification supporting documents for certification completed and signed by the institute veterinarian.

Annex XI (contd)

- f) ~~On arrival in the *importing country* the All embryos from these animals must should~~ be transferred into a colony via recipients in a quarantine system, as discussed above. Recipients should be tested at intervals appropriate to recognized *incubation periods* of the *diseases* of concern. In addition to testing the recipients ~~and~~ after transfer, all-the offspring should be tested at 12 weeks of age and/or individuals from successive generations should be tested before their introduction into breeding colonies outside the quarantine facility.

Article 4.10.5.bis.Conditions applicable to the storage and transport of embryos

1. Embryos for export should be frozen in fresh liquid nitrogen and then stored in fresh liquid nitrogen in cleaned and disinfected tanks or containers.
2. The embryos should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the *Veterinary Authority* of the *exporting country*. Only embryos from the same donor should be stored together in the same ampoule, vial or straw.
3. Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible) and they should be clearly identified according to or similar to the system recommended in the IETS Manual<sup>2</sup>. Identification should include details of the species/genotype of the donors, microbial status (e.g. defined, conventional or undefined), collection/cryopreservation date, number and developmental stage of the embryos, container number and details of any specialized procedure such as *in vitro* fertilization, micromanipulation.
4. Liquid nitrogen storage containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.
5. Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.10.6.Special experimental circumstances Procedures for *in vitro* fertilization and micromanipulation

If embryos are to be cryopreserved following specialised produced by *in vitro* fertilization of oocytes, it is advised that the washed sperm should be used so as to minimize the *risk* of possible pathogen exposure. If embryos are to undergo micromanipulation procedures that involve penetration of the zona pellucida, they must undergo the required washing steps (depending on colony status) before treatment. In the case of *in vitro* fertilisation, to minimise possible pathogen exposure, it is also advised that only washed sperm should be used. Embryos should be washed again before cryopreservation any required *risk management* steps (including washing) should be carried out first, as described in Chapter 4.9.

-----  
 — text deleted

- <sup>1</sup> **Recommendations for the health monitoring of mouse, rat, hamster, guineapig and rabbit breeding colonies.**- Report of the Federation of European Laboratory Animal Science Associations (FELASA), Working Group on Animal Health accepted by the FELASA Board of Management, November 1992.
- <sup>2</sup> Manual of the International Embryo Transfer Society (1998).
- <sup>3</sup> Schiewe M.C., Hollifield V.M., Kasbohm L.A. & Schmidt P.M. (1995) — Embryo importation and cryobanking strategies for laboratory animals and wildlife species. *Theriogenology*, **43**, 97-104.

## CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO  
CERTIFICATION

## Article 5.1.1.

Safety of *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 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 for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Veterinary Authorities* of OIE Members should base their import requirements on the OIE standards.

These requirements should be included in the model certificates approved by the OIE which are included from Chapters 5.10. to 5.12. 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* 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.

The certification requirements should not include conditions for *diseases* that are not transmitted by the *commodity* concerned. There should only be one signing *veterinarian* for one certificate.

When 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 5.1.2.

**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 OIE standards. *Importing countries* should restrict their requirements to those necessary to achieve the national appropriate 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 in the *importing country* and are not subject to any *official control programme*. 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*.
3. The *international veterinary certificate* should not include measures against pathogens or *diseases* which are not OIE listed, unless the *importing country* has demonstrated through import *risk analysis*, carried out in accordance with Section 2., that the pathogen or *disease* poses a significant *risk* to the *importing country*.

Annex XII (contd)

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 the responsibility of *Veterinary Authorities*. However, it can be issued by private sector *veterinarians* at the place of origin of the *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 5.1.3.

**Responsibilities of the exporting country**

1. An *exporting country* should, on request, supply the following to *importing countries*:
  - a. information on the animal health situation and national animal health information systems to determine whether that country is free or has *zones* or *compartments* free from *listed diseases*, including the regulations and procedures in force to maintain its free status;
  - b. regular and prompt information on the occurrence of *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 according to Chapters 3.1. and 3.2.;
  - 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 of oversight and accountability, covering including possible suspension and termination of the ~~appointment~~ authorisation;
  - 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 *Veterinary Authority* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

## Article 5.1.4.

**Responsibilities in case of an incident 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 this *Authority* to notify the *importing country*, so that the imported *commodities* 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~~ If a *disease* condition appears in imported *commodities* 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.

---

-----  
— text deleted



## CHAPTER 5.2.

## CERTIFICATION PROCEDURES

## Article 5.2.1.

**Protection of the professional integrity of the certifying veterinarian**

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the certifying veterinarian must be respected and safeguarded according to Chapters 3.1. and 3.2.

It is essential ~~not~~ to include in ~~the any~~ requirements ~~additional specific matters which cannot~~ only those specific statements that can be accurately and honestly signed by a *veterinarian*. For example, these requirements should not include certification of an area as being free from diseases that are not non-notifiable, diseases or the occurrence of which the signing veterinarian is not necessarily informed about. ~~Equally, It is unacceptable~~ to ask for 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 5.1.1. is not only to inform the signing veterinarian but also to safeguard professional integrity.

## Article 5.2.2.

**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 authorised by the *Veterinary Authority*;
3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying veterinarian should have verified or be in possession of that documentation before signing;
4. have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.

## Article 5.2.3.

**Preparation of international veterinary certificates**

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

Annex XII (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 bear the signature of the certifying veterinarian and the official identifier (stamp) of the issuing *Veterinary Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.
2. Certificates ~~They~~ should be written ~~in~~ using terms that are ~~as~~ simple, unambiguous and as easy to understand as possible, without losing their legal meaning.
3. If so required, certificates ~~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. Certificates ~~They~~ should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).
5. Certificates ~~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, when presented to the certifying veterinarian, certificates ~~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 of a certificate should not be amended except by deletions which must be signed and stamped by the certifying veterinarian.
8. The signature and stamp must be in a colour different from that of the printing of the certificate. The stamp may be embossed instead of being a different colour.
9. Replacement certificates may be issued by a *Veterinary Authority* to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These replacements should be provided by the issuing authority and be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.
10. Only original certificates are acceptable.

## Article 5.2.4.

**Electronic certification**

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

Annex XII (contd)

2. Electronic certificates may be in a different format but should carry the same information as conventional paper 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



## CHAPTER 6.3.

**THE CONTROL OF HAZARDS OF  
ANIMAL HEALTH AND  
PUBLIC HEALTH IMPORTANCE IN ANIMAL FEED**

## Article 6.3.1.

**Introduction**

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

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

## Article 6.3.2.

**Objective and scope**

The objective of this chapter is to provide guidance on animal feeding in relation to animal health and to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety, and related other Codex texts covering animal feeding, e.g. Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001).

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

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

This chapter deals with feed for terrestrial *animals* (except bees).

Annex XIII (contd)

## Article 6.3.3.

**Definitions**

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

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

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

**Contamination:** means the presence of a material or product in a feed or feed ingredient potentially harmful for animal or public health or restricted under current regulations.

## Article 6.3.4.

**General principles**1. Roles and responsibilities

The *Competent Authority* has the legal power to set and enforce regulatory animal feeding requirements, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties to provide it with information and assistance. Refer to Chapters 3.1. and 3.2. of the *Terrestrial Code*.

Those involved in the production and use of animal feed and feed ingredients have the 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 introduction or spread of hazards. Manufacturing equipment, storage and transport facilities should be adequate and maintained in good working order and in a sanitary condition.

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

2. Regulatory safety standards

All feed and feed ingredients should meet regulatory safety standards. 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.

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

Internationally accepted principles and practices on risk analysis (Section 2 of the *Terrestrial Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

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

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 (HACCP) principles should be followed to control hazards that may occur in the manufacture, distribution and feeding of feed and feed additives and feed ingredients.

5. Geographic and environmental considerations

Epidemiological links between potential sources of hazards for animal health or food safety should be considered when assessing water sources, land or facilities for suitability for the production of animal feed and feed ingredients. Animal health considerations include factors such as disease status, location of quarantined premises and existence of *zones/compartments* of specified health status. Food safety considerations include factors such as industrial operations that generate pollutants and waste treatment plants.

6. Zoning and compartmentalisation

Feed is an important component of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 4.3. of the *Terrestrial Code*.

7. Sampling and analysis

Sampling and analysis should be based on scientifically recognised principles and procedures.

8. Labelling

Labelling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and Section 4.2.10 Labelling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), including listing of ingredients and instructions on the handling, storing and use.

9. Design and management of inspection programmes

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

Annex XIII (contd)

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. The *Competent Authority* should verify that process control systems and safety standards achieve all regulatory requirements.

10. Assurance and certification

Feed business operators are responsible for demonstrating the safety of the establishments under their control. *Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory safety standards have been met. For *international trade* in animal product-based feeds, *Veterinary Services* are required to provide *international veterinary certificates*.

11. Hazards associated with animal feed

## a) Biological hazards

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

## b) Chemical hazards

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

## c) Physical hazards

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

12. Contamination

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

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

13. Antimicrobial resistance

Concerning the use of antimicrobials in animal feed refer to Chapters 6.7. to 6.11. of the *Terrestrial Code*.

14. Management of information

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

Annex XIII (contd)

Records should be maintained in a readily accessible form regarding the production, distribution and use of feed and feed ingredients. These records are required to facilitate the prompt trace-back of feed and feed ingredients to the immediate previous source, and trace-forward to the next subsequent recipients, to address identified animal health or public health concerns (see Section 4.3. of CAC/RCP 54-2004).

*Animal identification* and *animal traceability* are tools for addressing animal health (including zoonoses), and food safety risks arising from animal feed (see Chapters 4.1. and 4.2. of the *Terrestrial Code*).

---

-----  
— text deleted



## CONTROL OF HAZARDS OF ANIMAL AND PUBLIC HEALTH IMPORTANCE IN HEAT TREATED PET FOOD

### Article 1

#### Introduction

Pet food is often overlooked as a component of the animal feed and human food supply-chain that has a direct impact on animal health and *welfare* and also on food safety and public health. The importance stems not only from the potential to affect pets and their owners, but also from the potential to affect food producing *animals* through the use of pet food as a protein source in compounded feeds.

### Article 2

#### Objective and scope

The objective of this chapter is to complement Chapter 6.3. and to provide guidance on pet food in relation to animal health, *zoonoses* and food safety. The chapter 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 pet food, including pet treats and pet chews.

For the purpose of this chapter, “pets” are limited to dogs or cats.

### Article 3

#### Definitions

*Dry pet food* – means pet food with a moisture content less than 20 percent, called “kibble” or “crunchy”.

*Pet chews* – means any commercial product prepared and distributed for consumption by dogs or cats made of animal skin, hide, hooves, ears, animal bones, ligaments, snouts, or pizzles<sup>1</sup>.

*Pet food* – means any commercial feed, including snacks and treats, prepared and distributed for consumption by dogs or cats.

*Soft-moist pet food* – means pet food with a moisture content of 20 percent or more and less than 65 percent.

*Wet pet food* – means low acid (pH greater than 4.6) pet food in hermetically sealed containers with a moisture content greater than 65 percent.

### Article 4

#### General principles

##### 1. Roles and responsibilities

The *Competent Authority* and those involved in the production of pet food should follow the recommendations in point 1 of Article 6.3.4.

---

<sup>1</sup> This definition is taken from 2009 *Official Publication* of the Association of American Feed Control Officials Incorporated. Oxford, Indiana, USA. Pages 322-323.

Annex XIV (contd)2. Risk assessment and risk management

*Risk assessment* and *risk management* should follow the recommendations in point 3 of Article 6.3.4. Those involved in the production of pet food should take into account scientific evidence, including the sensitivity of analytical methods and the characterisation of *risks*, when defining limits and tolerances for hazards.

The ingredients in the finished product should have undergone one or more of the time and temperature treatments listed in Table 1.

3. Good Manufacturing Practices

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

Good Manufacturing Practices (GMPs) and/or Hazard Analysis and Critical Control Point<sup>2</sup> (HACCP) principles, where appropriate, should be followed to control hazards that may occur in the manufacture and distribution of pet food.

4. Sampling and analysis

Sampling and analytical protocols should follow the recommendations in point 7 of Article 6.3.4.

5. Labelling

Labelling should follow the recommendations in point 8 of Article 6.3.4.

6. Design and management of inspection programmes

Inspection programme should follow the recommendations in point 9 of Article 6.3.4.

7. Assurance and certification

In addition to point 10 of Article 6.3.4., assurances for pet food products of animal origin may be provided through facility approvals.

8. Hazards which should be considered in the manufacture of *pet food*

a) Biological hazards are described in point 11 a) of Article 6.3.4.

b) Chemical hazards are described in point 11 b) of Article 6.3.4.

c) Physical hazards are described in point 11 c) of Article 6.3.4.

9. Antimicrobials

Concerning the use of antimicrobials in pet food refer to Chapters 6.7. to 6.11. of the *Terrestrial Code*.

10. Management of information

Described in point 14 of Article 6.3.4.

---

<sup>2</sup> Hazard Analysis and Critical Control Point, as defined in the Annex to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

## Article 5

**Groups of pet food**

Pet food groups are described by the percentage of moisture in the finished product. Wet pet food is described as containing greater than 65% moisture in the finished product. Dry pet food contains less than 20% moisture in the finished product; while soft-moist products will contain between 20% and 65% moisture.<sup>3</sup>

## Article 6

**Time and temperature treatments**

Table 1 lists the minimum treatment/temperatures applied in the processing of ingredients of animal origin used in pet foods to ensure the inactivation of biological hazards.

*Table 1. Minimum time and temperature treatments for processing of pet foods containing ingredients of animal origin*

Group	Product subgroup	Minimum time and temperature treatments
A Wet	1) Low-acid <i>pet food</i> in hermetically sealed containers	1) $F_0=3$ $F_c=3$
	2) Refrigerated pet food in non-hermetically sealed containers	2) (under study)
B- Soft Moist	1) Extruded-expanded	1) (under study)
	2) Extruded-non-expanded	2) (under study)
	3) Non-extruded	3) (under study)
C- Dry	1) Extruded-expanded	1) (under study)
	2) Extruded non-expanded	2) (under study)
	3) Non-extruded	3) (under study)

<sup>3</sup> These descriptions are taken from 2009 *Official Publication* of the Association of American Feed Control Officials Incorporated. Oxford, Indiana, USA. Pages 132-134.



## CHAPTER 6.4.

**BIOSECURITY PROCEDURES  
IN POULTRY PRODUCTION**

## Article 6.4.1.

**Introduction**

This chapter provides recommended biosecurity procedures in *poultry* production.

Infectious disease agents of *poultry* are a threat to *poultry* health and, at times, human health and have significant social and economic implications. In *poultry* production, especially under intensive conditions, prevention is the most viable and economically feasible approach to the control of infectious disease agents.

Biosecurity procedures should be implemented with the objective of preventing the introduction and dissemination of infectious disease agents in the *poultry* production chain. The adoption of Good Agricultural Practices and the Hazard Analysis Critical Control Point (HACCP) system will help to achieve these objectives.

## Article 6.4.2.

**Purpose and scope**

This chapter deals with biosecurity procedures in *poultry* production. It should be read in conjunction with the Codex Alimentarius Code of Hygiene Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 Revision 2007).

This chapter provides general recommendations for infectious disease agents of *poultry*. Recommendations on specific *diseases* may be found in relevant *disease* chapters in the *Terrestrial Code*.

This chapter identifies several relevant biosecurity measures. The choice of measures to be implemented will vary according to national conditions, including *poultry disease* status, the risk of introduction and dissemination of infectious disease agents and the cost effectiveness of control measures.

## Article 6.4.3.

**Definitions (for this Chapter only)**

**Breeders:** means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing *day-old birds*.

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

**Live bird markets:** means markets where live birds from various sources are sold for slaughter or further rearing.

## Article 6.4.4.

**Recommendations on the location and construction of poultry establishments**

Annex XV (contd)1. All establishments (poultry farms and hatcheries)

- a) A suitably isolated geographical location is recommended, taking into account the direction of the prevailing winds, location of other *poultry establishments* and the distance from roads used to transport *poultry*.
- b) *Poultry establishments* should be located and constructed to provide adequate drainage away from the site.
- c) *Poultry* houses and hatcheries should be designed and constructed (preferably of smooth impervious materials) so that cleaning and *disinfection* can be carried out effectively. Ideally, the area immediately surrounding the *poultry* houses should be paved with concrete or other impervious material to facilitate cleaning and *disinfection*.
- d) The *establishment* should be surrounded by a security fence to prevent the entry of unwanted animals and people.
- e) A sign indicating restricted entry should be posted at the entrance to the farm.

2. Additional measures for poultry farms

- a) *Establishments* should be designed for use with single species and single purpose. Whenever possible, the 'all-in all-out' single age group principle should be used. If this is not feasible and several *flocks* are maintained on one *establishment*, each *flock* should be managed as a separate *epidemiological unit*.
- b) *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.
- c) Where feasible the floors of *poultry* houses should be constructed using concrete or other impervious materials and designed so that cleaning and *disinfection* can be carried out effectively.
- d) Where feasible, feed should be delivered into the farm from outside the security fence.

3. Additional measures for hatcheries

- a) The design of the hatchery should take account of work flow and air circulation needs, with 'one way flow' movement of eggs and *day-old birds* and one way air flow in the same direction.
- b) The hatchery buildings should include physical separation of areas used for the following:
  - i) personnel changing, showering and sanitary facilities;
  - ii) receipt, storage and transfer of eggs;
  - iii) incubation;
  - iv) hatching;
  - v) sorting, sexing and placing of *day-old birds* in boxes;
  - vi) storage of egg boxes and chick boxes, egg flats, box pads, chemicals and other items;

- vii) washing equipment;
- viii) waste disposal;
- ix) dining facilities for personnel;
- x) office space.

Article 6.4.5.

**Recommendations applicable to the operation of poultry establishments**

1. All establishments (poultry farms and hatcheries)

- a) There should be good communication between all those involved in the *poultry* production chain from breeding to production and consumption to ensure that steps are taken to minimise dissemination of infectious disease agents. Personnel should have access to basic training in biosecurity relevant to *poultry* production and food safety.
- b) Traceability at all levels of the *poultry* production chain should be possible.
- c) Records of production should be maintained. On farm, this includes treatment, vaccination, *flock* history, mortality and *disease surveillance* data. This should be maintained on an individual *flock* basis. In hatcheries, relevant records include fertility, hatchability, vaccination and treatment. Records should be readily available for inspection.
- d) A veterinarian should be responsible for monitoring *poultry* health on the *establishment*.
- e) Access to the *establishment* should be controlled to ensure only authorised persons and *vehicles* enter the site.
- f) *Establishments* should be free from unwanted vegetation and debris.
- g) Procedures for the prevention of entry of wild birds, and the control of vermin such as rodents and arthropods should be implemented on a routine basis.
- h) All personnel and visitors entering an *establishment* should follow a biosecurity procedure. The preferred procedure is for visitors and personnel to shower and change into clean clothes and footwear provided by the *establishment*. Where this is not practical, clean outer garments (coveralls or overalls, hats and footwear) should be provided.

Before entering and after leaving a *poultry* house, personnel and visitors should wash their hands with soap and water and use a properly maintained disinfectant footbath. The disinfectant solution in the footbath should be changed on a regular basis to ensure its efficacy, according to the manufacturer's instructions.

- i) Personnel and visitors should not have had recent contact with other *poultry*, *poultry* waste, or *poultry* processing plant(s). This time period should be based on the level of risk of transmission of infectious disease agents. This will depend on the *poultry* production purpose, biosecurity procedures and disease status (e.g. the time between visiting a breeder *flock* and then a broiler *flock* would be less than the time between visiting a broiler *flock* and then a breeder *flock*).

Annex XV (contd)

- j) Delivery *vehicles* should be cleaned, and *disinfected* before loading each consignment of *hatching eggs*, *day-old birds* or *poultry*.

2. Additional measures for all poultry farms

- a) Animals, other than *poultry* of the appropriate (resident) species and age, should not be permitted access to *poultry* houses. No animals should have access to other buildings (e.g. those used to store feed or eggs).
- b) 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.
- c) Birds used to stock a *poultry* house should preferably be obtained from breeder *flocks* and hatcheries that are free from vertically transmitted infectious disease agents.
- d) Heat treated feeds with the addition of bacteriostatic or bactericidal treatments is recommended (e.g. organic acids). Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended.

Feed should be stored in a manner to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

- e) The litter in the *poultry* house should be kept dry and in good condition.
- f) Dead birds should be removed from *poultry* houses as quickly as possible or at least daily. These should be disposed of in a safe and effective manner.
- g) Personnel involved in the catching of birds should be adequately trained in bird handling and basic biosecurity procedures.
- h) *Poultry* should be transported in well ventilated *containers* and should not be over crowded. Exposure to extreme temperatures should be avoided.
- i) *Containers* should be *cleaned* and *disinfected* between each use.
- j) When a *poultry* 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*.

If litter is not removed and replaced between *flocks* then the litter should be treated in a manner to inactivate infectious disease agents, to prevent the dissemination of infectious disease agents from one *flock* to the next.

After removal of faeces and litter, cleaning and *disinfection* of the building and equipment should be done in accordance with Chapter 4.13.

All litter removed from a *poultry* house should be disposed of in a safe manner to prevent the dissemination of infectious agents.

- k) For *poultry flocks* that are allowed to range outdoors, attractants to wild birds should be minimised e.g. feeders should be kept inside the *poultry* house. *Poultry* should not be allowed access to sources of contamination (e.g. household waste, other farm animals, stagnant water and litter storage areas). The nesting area should be inside the *poultry* house.

Annex XV (contd)

- l) To avoid the development of antimicrobial resistance, antimicrobials should be used according to relevant directions of the *Veterinary Services* and manufacturer's instructions and in accordance with *Terrestrial Code* Chapters 6.7, 6.8., 6.9., 6.10. and 6.11.

3. Additional measures for breeder farms

- a) Nest box litter and liners should be kept clean.
- b) *Hatching eggs* should be collected at frequent intervals, at least daily, and placed in a new or clean and *disinfected* packaging material.
- c) Grossly dirty, broken, cracked, or leaker eggs should be collected separately and should not be used as *hatching eggs*.
- d) *Hatching eggs* should be cleaned and sanitised as soon as possible after collection using an approved sanitising agent, in accordance with the manufacturer's instructions.
- e) *Hatching eggs* or their packaging materials should be marked to assist traceability and veterinary investigations.
- f) The sanitised *hatching eggs* should be stored in a dedicated room as soon as possible after collection. Storage conditions should minimise the potential for microbial contamination and growth and ensure maximum hatchability. The room should be well ventilated, kept clean, and regularly *disinfected* using disinfectants approved for this purpose.

4. Additional measures for hatcheries

- a) Dead in shell embryos should be removed from hatcheries as soon as they are found and disposed of in a safe and effective manner.
- b) All hatchery waste, garbage and discarded equipment should be contained or at least covered while on site and removed from the hatchery and its environs as soon as possible.
- c) After use, hatchery equipment, tables and surfaces should be promptly and thoroughly cleaned and *disinfected* with an approved disinfectant.
- d) Egg handlers, chick sexers and chick handlers should wash their hands with soap and water before commencing work and between working with batches of *hatching eggs* or *day-old birds* from different breeder *flocks*.
- e) *Hatching eggs* and *day-old birds* from different breeder *flocks* should be kept separate during incubation, hatching, sorting and transportation.
- f) *Day-old birds* should be delivered to the farm in new *containers* or in clean, *disinfected containers*.

## Article 6.4.6.

**Prevention of further dissemination of infectious disease agents of poultry**

When a *flock* is determined to be infected, in addition to the general biosecurity measures described previously, management procedures should be adjusted to effectively isolate the infected *flock* from other *flocks* on the *establishment* and other epidemiologically related *establishments*. The following measures are recommended:

Annex XV (contd)

1. Personnel should be trained in the management of infected *flocks* to prevent the dissemination of infectious disease agents to other *flocks* and *establishments*, and to humans (relevant measures include: handling of an infected *flock* separately, last in sequence and the use of dedicated personnel and clothing and equipment).
2. Epidemiological investigations should be carried out to determine the origin and route of transmission of the infectious disease agent.
3. *Poultry* litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent dissemination of infectious disease agents.
4. Depending on the epidemiology of the *disease*, the results of a *risk assessment*, and public and animal health policies, culling may be used to manage infected *flocks*. When infected *flocks* are destroyed or slaughtered they should be processed in a manner to minimise exposure of humans and other *flocks* to the infectious disease agent, and in accordance with recommendations of the *Veterinary Service* and relevant chapters in the *Terrestrial Code*. Based on *risk assessment*, non-infected, high risk *flocks* may be culled. Movement of culled *poultry* should only be allowed for *slaughter* or destruction.

Before restocking, the *poultry* house or *establishment* should be cleaned, *disinfected* and tested to verify that the cleaning has been effective. Special attention should be paid to feed equipment and water systems.

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

5. Depending on the epidemiology of the *disease*, *risk assessment*, vaccine availability and public and animal health policies, vaccination is an option to minimise the dissemination of the infectious disease agent. When used, *poultry* should be vaccinated in accordance with the directions of the *Veterinary Services* and the manufacturer's instructions. Recommendations in the *Terrestrial Manual* should be followed as appropriate.

## Article 6.4.7.

**Recommendations to prevent the dissemination of infectious disease agents from live bird markets**

1. Personnel should be educated on the significance of infectious disease agents and the need to apply biosecurity practices to prevent dissemination of these agents. Education should be targeted to personnel at all levels of operations in these markets (e.g. drivers, owners, handlers, processors). Programmes should be implemented to raise awareness of consumers of the risks associated with activities of live bird markets.
2. Personnel should wash their hands with soap and water before and after handling birds.
3. All *containers* and *vehicles* should be cleaned and *disinfected* every time they leave the market.
4. Live birds that leave the market should be housed separately from other birds for a period of time to minimise the potential dissemination of infectious disease agents of *poultry*.
5. Periodically the market should be emptied, cleaned and *disinfected*. This is of particular importance when an infectious disease agent of *poultry* deemed significant by the *Veterinary Services* has been identified in the market or the region.

Annex XV (contd)

6. Where feasible, *surveillance* should be carried out in these markets to detect infectious disease agents of *poultry*, especially those agents of zoonotic significance. The *surveillance* programme should be determined by the *Veterinary Services*, and in accordance with recommendations in relevant *disease* specific chapters of the *Terrestrial Code*.
  7. Attempts should be made to ensure the possibility of tracing all birds entering and leaving the markets.
-



## CHAPTER 6.5.

PREVENTION, DETECTION AND CONTROL OF  
SALMONELLA IN POULTRY

## Article 6.5.1.

**Introduction**

This Chapter provides recommendations on the prevention, detection and control of *Salmonella* in *poultry*.

Salmonellosis is one of the most common foodborne bacterial *diseases* in the world. The great majority of *Salmonella* infections in humans are foodborne with *Salmonella* Enteritidis and *Salmonella* Typhimurium accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries and therefore, *surveillance* and identification of the prevalent *Salmonella* serotypes in humans and *poultry* should be carried out in order to develop a control programme for the area.

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

## Article 6.5.2.

**Purpose and scope**

This Chapter deals with methods for on farm prevention, detection and control of *Salmonella* in *poultry*, and complements the Codex Alimentarius Code of Hygiene Practice for Meat (CAC/RCP 58-2005) and 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 reducing the presence of foodborne pathogens in eggs and *meat*.

Hygiene and biosecurity procedures to be implemented in *poultry flocks* and hatcheries are described in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production.

The recommendations presented in this Chapter are relevant to the control of all *Salmonella* with special attention to *S. Enteritidis* and *S. Typhimurium*, as these are common *Salmonella* serotypes in many countries. It should be noted that the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Salmonella*.

## Article 6.5.3.

**Definitions (for this Chapter only)**

**Breeders:** means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing ~~day-old chicks~~ day-old birds.

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

Annex XV (contd)

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

**Layers:** means *poultry* during the period of laying eggs for human consumption.

## Article 6.5.4.

**Surveillance of poultry flocks for *Salmonella***

Where justified by *risk assessment*, *surveillance* should be carried out to identify infected *flocks* in order to take measures that will reduce the prevalence in *poultry* and the risk of transmission of *Salmonella* to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broilers *flocks* and higher specificity in breeders and *layer flocks*. In the framework of regulatory programmes for the control of *Salmonella* in *poultry* and salmonellosis in humans, confirmatory testing may be required to ensure that decisions are soundly based.

## Sampling

1. Available methods for sampling

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

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

Dust samples: sampling is done by collecting dust from exhaust fans, screens and other equipment in the *poultry* building.

Faecal samples: multiple fresh faecal/caecal samples collected from different areas in the *poultry* building.

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

Hatchery samples: throughout the hatchery, including the inner liner of the incubators.

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

2. Sample size

Refer to the *Terrestrial Manual* (under development).

3. Laboratory methods

Refer to the *Terrestrial Manual* (under development).

4. Time and frequency of testing

Time and frequency of sampling for each *poultry* type are listed below:

Annex XV (contd)

- a) Breeders and hatcheries
- i) Breeder *flocks* before lay
- Before 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 this chapter.
  - 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) Breeder *flocks* in lay
- At least at monthly intervals during the laying period.
  - Additional testing should be determined by the *Veterinary Services*.
- iii) Hatcheries
- Testing hatcheries may complement on farm testing.
  - The minimal frequency should be determined by the *Veterinary Services*.
- b) Poultry for the production of eggs for human consumption
- i) *Flocks* grown to be layers
- Before the end of the first week of life when the status of the breeding farm and the hatchery is not known or does not comply with this chapter.
  - Within the four weeks before being moved to another house, or before going into production if the 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 flocks*
- At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).
  - One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should be determined by the *Veterinary Services*.

Annex XV (contd)

- c) Poultry for the production of *meat*
  - i) *Flocks* should be sampled at least once.
  - ii) Where sampling occurs on farms and where there is a long period (2 weeks or more) between thinning and final depopulation further testing should be considered.
  - iii) Where sampling occurs on farms, *flocks* should be sampled as late as possible before the first birds are transported to the slaughter house. Where this is done to allow for the implementation of control measures during processing, this must be done at a time that ensures the results are available before slaughter.

Whether sampling occurs on the farm or at the processing plant, there should be an integrated system in place which allows for investigation of the source of positive flocks.

- d) Empty building testing
  - i) Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when *Salmonella* have been detected in the previous *flock*.

As appropriate, sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty building after depopulation, cleaning and *disinfection*.

Results from *surveillance* may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of *Salmonella* to humans:

- a) In breeders, control measures may be implemented to reduce the transmission of *Salmonella* to the next generation, especially for trans-ovarian transmitted serotypes such as *S. Enteritidis*.
- b) In *layer flocks* control measures will reduce and may eliminate contamination of eggs with *Salmonella*.
- c) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article 6.5.5.

### **Prevention and Control measures**

*Salmonella* prevention and control may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective *Salmonella* control.

Additional prevention and control measures include: vaccination, competitive exclusion, *flock* culling, organic acids and product diversion to processing.

Antimicrobials should not be used to control *infection* with *Salmonella* in *poultry* because the effectiveness of the treatment is limited, may mask the infection at sampling, has the potential to produce residues in *meat* and eggs and can contribute to the development of antimicrobial resistance. Antimicrobials may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella*. In special circumstances antimicrobials may be used to salvage animals with high genetic value.

## Annex XV (contd)

1. ~~Day-old chicks~~ Day-old birds used to stock a *poultry* house should be obtained from breeding *flocks* and hatcheries that ~~are free from at least *S. Enteritidis* and *S. Typhimurium* and~~ have been monitored according to this Chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
2. *Layer* and breeder *flocks* should be stocked from *flocks* that ~~are free from at least *S. Enteritidis* and *S. Typhimurium* (under study) and~~ have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
3. Feed contamination with *Salmonella* is known to be a source of *infection* for *poultry*. Therefore, it is recommended to monitor the *Salmonella* status of *poultry* feed, and if found positive to take corrective measures. The use of heat treated feeds or feeds subjected to other bacteriostatic or bactericidal treatment (~~e.g. organic acids~~) is recommended (e.g. organic acids). Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.
4. Competitive exclusion may be used in ~~day-old chicks~~ day-old birds to reduce colonisation by *Salmonella*.

When used, competitive exclusion should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

5. Vaccines are used against *Salmonella* infections caused by different serotypes in various *poultry* species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

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

Vaccination can be used as part of an overall *Salmonella* control programme. It is recommended that vaccination not be used as the sole control measure.

When the status of the breeding farm and the hatchery from which the *flock* originates is not known or does not comply with this Chapter, vaccination of *flocks*, starting with ~~day-old chicks~~ day-old birds, against the *Salmonella* serotypes known to be significant should be considered.

Vaccination against the *Salmonella* serotypes known to be significant should be considered when moving ~~day-old chicks~~ day-old birds to a previously contaminated shed so as to minimise the risk of the birds contracting *Salmonella* infection.

When used, vaccines should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

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

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

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

Annex XV (contd)

7. *S. Enteritidis* is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *S. Enteritidis* from egg-producing flocks through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent *flocks* through breeder *flocks* to layer *flocks*.
8. As far as the veterinary involvement is concerned, the responsible veterinarian should monitor the results of *surveillance* testing for *Salmonella*. This information should be available to the veterinarian before marketing if a veterinary certificate for *flock Salmonella* status is required. When required by the *Competent Authority*, the veterinarian or other authorised person responsible for notification should notify the *Competent Authority* if the presence of *Salmonella* of the relevant serotype is confirmed.

## Article 6.5.6.

**Prevention of *Salmonella* spread from infected flocks**

If a *flock* is found infected with specific *Salmonella* serotypes of concern, the following actions should be taken in addition to general measures detailed in Chapter 6.4. Hygiene and Biosecurity Procedures in Poultry Production:

1. According to the epidemiological situation, investigations should be carried out to determine the origin of the *infection*.
2. Movement of *poultry flocks* at the end of the production cycle should only be allowed for *slaughter* or destruction. Special precautions should be taken in the transport, *slaughter* and processing of the birds, e.g. they could be sent to a separate slaughterhouse or processed at the end of a shift before cleaning and *disinfection* of the equipment.
3. Litter should not be reused. Poultry litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and wildlife to *Salmonella*. Particular care needs to be taken in regard to *poultry* litter/faeces used to fertilise plants intended for human consumption. If litter is not removed then it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.
4. Particular care should be taken in cleaning and *disinfection* of the *poultry* house and equipment.
5. Before restocking the facility, a bacteriological examination should be carried out as detailed in this Chapter and the *Terrestrial Manual*.

Article 6.5.7.**Recommendations for importation of live poultry (other than day-old birds)**

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

1. the *poultry* originated from an *establishment* which participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
2. the *poultry* originated from an *establishment* in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected and have had no contact with birds or other material from *establishments* which do not comply with this chapter;
3. the *poultry* originated from an *establishment* which complies with the recommendations of Chapter 6.4.

Article 6.5.8.**Recommendations for importation of day-old birds**

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

1. the day-old birds showed no clinical signs of salmonellosis on the day of shipment;
2. the day-old birds originated from a breeder establishment and hatchery which participates in a Salmonella surveillance programme in accordance with the recommendations in Article 6.5.4.;
3. the day-old birds originated from a breeder establishment and hatchery in which no evidence of S. Enteritidis and S. Typhimurium has been detected and have had no contact during setting, incubation or hatching with hatching eggs or other material from poultry which do not comply with this chapter;
4. the day-old birds originated from a breeder establishment and hatchery which complies with the recommendations of Chapter 6.4.;
5. the day-old birds were shipped in new and clean containers.

Article 6.5.9.**Recommendations for importation of hatching eggs**

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

1. the hatching eggs originated from a breeder establishment which participates in a Salmonella surveillance programme in accordance with the recommendations in Article 6.5.4.;
2. the hatching eggs originated from a breeder establishment in which no evidence of S. Enteritidis and S. Typhimurium has been detected and have had no contact with poultry or other material from establishments which do not comply with this Chapter;
3. the hatching eggs originated from a breeder establishment which complies with the recommendations of Chapter 6.4.;
4. the hatching eggs were shipped in new and clean packaging materials.

---

-----  
— text deleted



~~CHAPTER 6.6.~~~~SALMONELLA ENTERITIDIS AND  
SALMONELLA TYPHIMURIUM  
IN POULTRY~~~~Article 6.6.1.~~

~~Veterinary Authorities of importing countries should require:~~

~~for breeding birds~~

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

- ~~1. come from an *establishment* which has been regularly monitored for the presence of *Salmonella* in conformity with the provisions of Chapter 6.4. (see Article 6.4.9.);~~
- ~~2. come from a *flock* of birds within the *establishment* in which no evidence of *Salmonella enteritidis* and *Salmonella typhimurium* has been detected and have had no contact with birds or other material from poultry flocks which do not comply with this standard;~~
- ~~3. come from an *establishment* which complies with the hygiene and disease security procedures referred to in Chapter 6.4.~~

~~Article 6.6.2.~~

~~Veterinary Authorities of importing countries should require:~~

~~for day-old birds~~

~~the presentation of an *international veterinary certificate* attesting that the *day-old birds*:~~

- ~~1. showed no clinical sign of salmonellosis on the day of shipment;~~
- ~~2. come from an *establishment* and a hatchery which are regularly monitored for the presence of *Salmonella* in conformity with the provisions of Chapter 6.4. (see Article 6.4.9.);~~
- ~~3. come from a *flock* of birds within the *establishment* in which no evidence of *Salmonella enteritidis* or *Salmonella typhimurium* has been detected and have had no contact during setting, incubation or hatching with *hatching eggs* or other material from poultry flocks which do not comply with this standard;~~
- ~~4. come from an *establishment* and a hatchery which comply with the hygiene and disease security procedures referred to in Chapter 6.4.;~~
- ~~5. were shipped in clean and unused packages.~~

~~Article 6.6.3.~~

~~Veterinary Authorities of importing countries should require:~~

~~for hatching eggs~~

Annex XV (contd)

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

- ~~1. come from an *establishment* which is regularly monitored for the presence of *Salmonella* in conformity with the provisions of Chapter 6.4. (see Article 6.4.9);~~
- ~~2. come from a *flock* of birds within the *establishment* in which no evidence of *Salmonella enteritidis* or *Salmonella typhimurium* has been detected and have had no contact with *hatching eggs* or material from poultry *flocks* which do not comply with this standard;~~
- ~~3. come from an *establishment* which complies with the hygiene and disease security procedures referred to in Chapter 6.4.;~~
- ~~4. were shipped in clean and unused packages.~~

-----  
— text deleted

## CHAPTER 6.7.

INTRODUCTION TO THE RECOMMENDATIONS FOR  
CONTROLLING ANTIMICROBIAL RESISTANCE

## Article 6.7.1.

**Objective**

The purpose of ~~this e~~ Chapters 6.8., 6.9., 6.10. and 6.11. is to provide methodologies for OIE Members to appropriately address the emergence or spread of resistant bacteria from the use of antimicrobial agents in animal husbandry and to contain antimicrobial resistance through controlling the use of antimicrobial agents.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating, controlling and preventing infectious diseases in animals. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is a priority.

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of antimicrobial agents in humans, animals and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to prevent or minimise pressures for the selection of antimicrobial resistance factors in humans and animals. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Members in regard to risks in the animal sector.

The application of *risk management* measures should be based on relevant international standards on ~~microbiological~~ *risk analysis* and supported by sound data and information when available. The methodologies provided in these chapters should be consulted as part of the standard approach to prevent and reduce antimicrobial resistance.

---

-----  
— text deleted



## CHAPTER 7.3.

## TRANSPORT OF ANIMALS BY LAND

**Preamble:** These recommendations apply to the following live domesticated *animals*: cattle, buffaloes, camels, sheep, goats, pigs, *poultry* and equines. They will also be largely applicable to some other *animals* (e.g. deer, other camelids and ratites). Wild, feral and partly domesticated *animals* may need different conditions.

## Article 7.3.1.

The amount of time *animals* spend on a *journey* should be kept to the minimum.

## Article 7.3.2.

1. Animal behaviour

*Animal handlers* should be experienced and competent in handling and moving farm livestock and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns, which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in **herds groups** and follow a leader by instinct.

*Animals* which are likely to harm each other in a group situation should not be mixed.

The desire of some *animals* to control their personal space should be taken into account in designing *loading* and *unloading* facilities, transport *vessels* and *containers*.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans (i.e. tame) have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape and compromise the *welfare* of the *animals*.

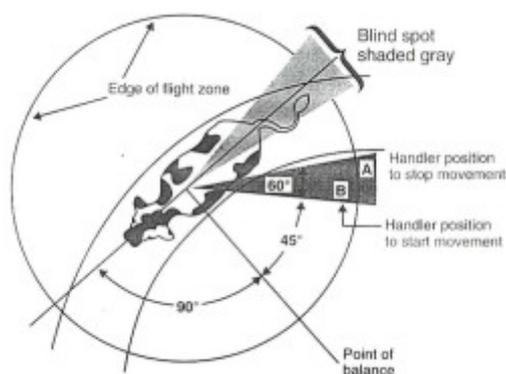
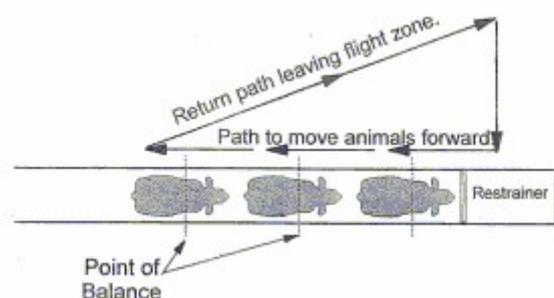
*Animal handlers* should use the point of balance at the *animal's* shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have a wide-angle vision but only have a limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

Although **all most** domestic *animals* have a highly sensitive sense of smell, they may react differently to the smells encountered during travel. Smells which cause negative responses should be taken into consideration when managing *animals*.

Annex XVII (contd)

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noises and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

**An example of a flight zone (cattle)****Handler movement pattern to move cattle forward****2. Distractions and their removal**

Design of new *loading* and *unloading* facilities or modification of existing facilities should aim to minimise the potential for distractions that may cause approaching *animals* to stop, baulk or turn back. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors - move a lamp or change lighting;
- b) dark entrances — illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;
- c) *animals* seeing moving people or equipment up ahead — install solid sides on chutes and races or install shields;
- d) dead ends — avoid if possible by curving the passage, or make an illusory passage;

- e) chains or other loose objects hanging in chutes or on fences — remove them;
- f) uneven floors or a sudden drop in floor levels — avoid uneven floor surfaces or install a solid false floor to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment — install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects — install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of *animals* — redirect or reposition equipment.

#### Article 7.3.3.

### Responsibilities

Once the decision to transport the *animals* has been made, the *welfare* of the *animals* during their *journey* is the paramount consideration and is the joint responsibility of all people involved. The individual responsibilities of persons involved will be described in more detail in this Article.

The roles of each of those responsible are defined below:

1. The owners and managers of the *animals* are responsible for:
  - a) the general health, overall *welfare* and fitness of the *animals* for the *journey*;
  - b) ensuring compliance with any required veterinary or other certification;
  - c) the presence of an *animal handler* competent for the species being transported during the *journey* with the authority to take prompt action; in case of transport by individual trucks, the truck driver may be the sole *animal handler* during the *journey*;
  - d) the presence of an adequate number of *animal handlers* during *loading* and *unloading*;
  - e) ensuring that equipment and veterinary assistance are provided as appropriate for the species and the *journey*.
2. Business agents or buying/selling agents are responsible for:
  - a) selection of *animals* that are fit to travel;
  - b) availability of suitable facilities at the start and at the end of the *journey* for the assembly; *loading*, transport, *unloading* and holding of *animals*, including for any stops at *resting points* during the *journey* and for emergencies.
3. *Animal handlers* are responsible for the humane handling and care of the *animals*, especially during *loading* and *unloading*, and for maintaining a *journey* log. To carry out their responsibilities, they should have the authority to take prompt action. In the absence of a separate *animal handler*, the driver is the *animal handler*.
4. Transport companies, *vehicle* owners and drivers are responsible for planning the *journey* to ensure the care of the *animals*; in particular they are responsible for:

Annex XVII (contd)

- a) choosing appropriate *vehicles* for the species transported and the *journey*;
  - b) ensuring that properly trained staff are available for *loading/unloading* of *animals*;
  - c) ensuring adequate competency of the driver in matters of *animal welfare* for the species being transported in case a separate *animal handler* is not assigned to the truck;
  - d) developing and keeping up-to-date contingency plans to address emergencies (including adverse weather conditions) and minimise stress during transport;
  - e) producing a *journey* plan which includes a *loading* plan, *journey* duration, itinerary and location of resting places;
  - f) *loading* only those *animals* which are fit to travel, for their correct *loading* into the *vehicle* and their inspection during the *journey*, and for appropriate responses to problems arising; if its fitness to travel is in doubt, the *animal* should be examined by a *veterinarian* in accordance with point 3a) of Article 7.3.7.;
  - g) *welfare* of the *animals* during the actual transport.
5. Managers of facilities at the start and at the end of the *journey* and at *resting points* are responsible for:
- a) providing suitable premises for *loading, unloading* and securely holding the *animals*, with water and feed when required, and with protection from adverse weather conditions until further transport, sale or other use (including rearing or slaughter);
  - b) providing an adequate number of *animal handlers* to load, unload, drive and hold *animals* in a manner that causes minimum stress and injury; in the absence of a separate *animal handler*, the driver is the *animal handler*;
  - c) minimising the opportunities for disease transmission;
  - d) providing appropriate facilities, with water and feed when required;
  - e) providing appropriate facilities for emergencies;
  - f) providing facilities for washing and disinfecting *vehicles* after *unloading*;
  - g) providing facilities and competent staff to allow the humane *killing* of *animals* when required;
  - h) ensuring proper rest times and minimal delay during stops.
6. The responsibilities of *Competent Authorities* include:
- a) establishing minimum standards for *animal welfare*, including requirements for inspection of *animals* before, during and after their travel, defining 'fitness to travel' and appropriate certification and record keeping;
  - b) setting standards for facilities, *containers* and *vehicles* for the transport of *animals*;
  - c) setting standards for the competence of *animal handlers*, drivers and managers of facilities in relevant issues in *animal welfare*;
  - d) ensuring appropriate awareness and training of *animal handlers*, drivers and managers of facilities in relevant issues in *animal welfare*;

- e) implementation of the standards, including through accreditation of / interaction with other organisations;
  - f) monitoring and evaluating the effectiveness of standards of health and other aspects of *welfare*;
  - g) monitoring and evaluating the use of veterinary medications;
  - h) giving animal consignments priority at frontiers in order to allow them to pass without unnecessary delay.
7. All individuals, including *veterinarians*, involved in transporting *animals* and the associated handling procedures should receive appropriate training and be competent to meet their responsibilities.
8. The receiving *Competent Authority* should report back to the sending *Competent Authority* on significant *animal welfare* problems which occurred during the *journey*.

#### Article 7.3.4.

### Competence

1. All people responsible for *animals* during *journeys*, should be competent according to their responsibilities listed in Article 7.3.3. Competence may be gained through formal training and/or practical experience.
2. The assessment of the competence of *animal handlers* should at a minimum address knowledge, and ability to apply that knowledge, in the following areas:
  - a) planning a *journey*, including appropriate *space allowance*, and feed, water and ventilation requirements;
  - b) responsibilities for *animals* during the *journey*, including *loading* and *unloading*;
  - c) sources of advice and assistance;
  - d) animal behaviour, general signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and fatigue, and their alleviation;
  - e) assessment of fitness to travel; if fitness to travel is in doubt, the *animal* should be examined by a *veterinarian*;
  - f) relevant authorities and applicable transport regulations, and associated documentation requirements;
  - g) general disease prevention procedures, including cleaning and *disinfection*;
  - h) appropriate methods of animal handling during transport and associated activities such as assembling, *loading* and *unloading*;
  - i) methods of inspecting *animals*, managing situations frequently encountered during transport such as adverse weather conditions, and dealing with emergencies, including humane *killing*;
  - j) species-specific aspects and age-specific aspects of animal handling and care, including feeding, watering and inspection; and
  - k) maintaining a *journey* log and other records.

Annex XVII (contd)

## Article 7.3.5.

**Planning the journey**1. General considerations

- a) Adequate planning is a key factor affecting the *welfare* of *animals* during a *journey*.
- b) Before the *journey* starts, plans should be made in relation to:
  - i) preparation of *animals* for the *journey*;
  - ii) choice of road, rail, roll-on roll-off vessels or *containers*;
  - iii) nature and duration of the *journey*;
  - iv) *vehicle* design and maintenance, including roll-on roll-off vessels;
  - v) required documentation;
  - vi) *space allowance*;
  - vii) rest, water and feed;
  - viii) observation of *animals* en route;
  - ix) control of *disease*;
  - x) emergency response procedures;
  - xi) forecast weather conditions (e.g. conditions being too hot or too cold to travel during certain periods of the day);
  - xii) transfer time when changing mode of transport, and
  - xiii) waiting time at frontiers and inspection points.
- c) Regulations concerning drivers (for example, maximum driving periods) should take into account *animal welfare* whenever possible.

2. Preparation of animals for the journey

- a) When *animals* are to be provided with a novel diet or method of water provision during transport, an adequate period of adaptation should be planned. For all *animals* it is essential that the rest stops during long journeys are long enough to fulfil each *animal's* need for feed and water. Species-specific short period of feed deprivation prior to *loading* may be desirable
- b) *Animals* more accustomed to contact with humans and with being handled are likely to be less fearful of being loaded and transported. *Animal handlers* should handle and load *animals* in a manner that reduces their fearfulness and improves their approachability.
- c) Behaviour-modifying compounds (such as tranquillisers) or other medication should not be used routinely during transport. Such compounds should only be administered when a problem exists in an individual *animal*, and should be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

### 3. Nature and duration of the journey

The maximum duration of a *journey* should be determined according to factors such as:

- a) the ability of the *animals* to cope with the stress of transport (such as very young, old, lactating or pregnant *animals*);
- b) the previous transport experience of the *animals*;
- c) the likely onset of fatigue;
- d) the need for special attention;
- e) the need for feed and water;
- f) the increased susceptibility to injury and *disease*;
- g) *space allowance*, *vehicle* design, road conditions and driving quality;
- h) weather conditions;
- i) *vehicle* type used, terrain to be traversed, road surfaces and quality, skill and experience of the driver.

### 4. Vehicle and container design and maintenance

- a) *Vehicles* and *containers* used for the transport of *animals* should be designed, constructed and fitted as appropriate for the species, size and weight of the *animals* to be transported. Special attention should be paid to avoid injury to *animals* through the use of secure smooth fittings free from sharp protrusions. The avoidance of injury to drivers and *animal handlers* while carrying out their responsibilities should be emphasised.
- b) *Vehicles* and *containers* should be designed with the structures necessary to provide protection from adverse weather conditions and to minimise the opportunity for *animals* to escape.
- c) In order to minimise the likelihood of the spread of infectious *disease* during transport, *vehicles* and *containers* should be designed to permit thorough cleaning and *disinfection*, and the containment of faeces and urine during a *journey*.
- d) *Vehicles* and *containers* should be maintained in good mechanical and structural condition.
- e) *Vehicles* and *containers* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported; the ventilation system (natural or mechanical) should be effective when the *vehicle* is stationary, and the airflow should be adjustable.
- f) *Vehicles* should be designed so that the faeces or urine from *animals* on upper levels do not soil *animals* on lower levels, nor their feed and water. This condition is not applicable for poultry. They are generally transported in plastic cages which are designed to let air flow through in all directions to obtain a better ventilation.
- g) When *vehicles* are carried on board ferries, facilities for adequately securing them should be available.
- h) If feeding or watering while the *vehicle* is moving is required, adequate facilities on the *vehicle* should be available.

Annex XVII (contd)

- i) When appropriate, suitable bedding should be added to *vehicle* floors to assist absorption of urine and faeces, to minimise slipping by *animals*, and protect *animals* (especially young *animals*) from hard flooring surfaces and adverse weather conditions.
5. Special provisions for transport in vehicles (road and rail) on roll-on/roll-off vessels or for containers
- a) *Vehicles* and *containers* should be equipped with a sufficient number of adequately designed, positioned and maintained securing points enabling them to be securely fastened to the *vessel*.
  - b) *Vehicles* and *containers* should be secured to the *vessel* before the start of the sea *journey* to prevent them being displaced by the motion of the *vessel*.
  - c) Roll-on/roll-off *vessels* should have adequate ventilation to meet variations in climate and the thermo-regulatory needs of the animal species being transported, especially where the *animals* are transported in a secondary *vehicle/container* on enclosed decks.
6. Space allowance
- a) The number of *animals* which should be transported on a *vehicle* or in a *container* and their allocation to compartments should be determined before *loading*.
  - b) The space required on a *vehicle* or in a *container* depends upon whether or not the *animals* need to lie down (for example, pigs, camels and *poultry*), or to stand (horses). *Animals* which will need to lie down often stand when first loaded or when the *vehicle* is driven with too much lateral movement or sudden braking.
  - c) When *animals* lie down, they should all be able to adopt a normal lying posture, without being on top of one another, and allowing necessary thermoregulation.
  - d) When *animals* are standing, they should have sufficient space to adopt a balanced position as appropriate to the climate and species transported.
  - e) The amount of headroom necessary depends on the species of *animal*. Each *animal* should be able to assume its natural standing position for transport (including during *loading* and *unloading*) without coming into contact with the roof or upper deck of the *vehicle*, and there should be sufficient headroom to allow adequate airflow over the *animals*. These conditions will not normally apply to *poultry*. However under tropical and subtropical conditions *poultry* benefit from having adequate head room to allow head cooling.
  - f) Calculations for the *space allowance* for each *animal* should be carried out using the figures given in a relevant national or international document. The number and size of pens on the *vehicle* should be varied to where possible accommodate already established groups of *animals* while avoiding group sizes which are too large.
  - g) Other factors which may influence *space allowance* include:
    - i) *vehicle/container* design;
    - ii) length of *journey*;
    - iii) need to provide feed and water on the *vehicle*;

- iv) quality of roads;
- v) expected weather conditions;
- vi) category and sex of the *animals*.

7. Rest, water and feed

- a) Suitable water and feed should be available as appropriate and needed for the species, age, and condition of the *animals*, as well as the duration of the *journey*, climatic conditions, etc.
- b) *Animals* should be allowed to rest at *resting points* at appropriate intervals during the *journey*. The type of transport, the age and species of the *animals* being transported, and climatic conditions should determine the frequency of rest stops and whether the *animals* should be unloaded. Water and feed should be available during rest stops.

8. Ability to observe animals during the journey

- a) *Animals* should be positioned to enable each *animal* to be observed regularly during the *journey* to ensure their safety and good *welfare*.
- b) If the *animals* are in crates or on multi-tiered *vehicles* which do not allow free access for observation, for example where the roof of the tier is too low, *animals* cannot be inspected adequately, and serious injury or *disease* could go undetected. In these circumstances, a shorter *journey* duration should be allowed, and the maximum duration will vary according to the rate at which problems arise in the species and under the conditions of transport.

9. Control of disease

As animal transport is often a significant factor in the spread of infectious *diseases*, *journey* planning should take the following into account:

- a) mixing of *animals* from different sources in a single consignment should be minimised;
- b) contact at *resting points* between *animals* from different sources should be avoided;
- c) when possible, *animals* should be vaccinated against *diseases* to which they are likely to be exposed at their destination;
- d) medications used prophylactically or therapeutically should be approved by the *Veterinary Authority* of the *exporting country* and the *importing country* and should only be administered by a *veterinarian* or other person who has been instructed in their use by a *veterinarian*.

10. Emergency response procedures

There should be an emergency management plan that identifies the important adverse events that may be encountered during the *journey*, the procedures for managing each event and the action to be taken in an emergency. For each important event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

Annex XVII (contd)11. Other considerations

- a) Extreme weather conditions are hazardous for *animals* undergoing transport and require appropriate *vehicle* design to minimise risks. Special precautions should be taken for *animals* that have not been acclimatised or which are unsuited to either hot or cold conditions. In some extreme conditions of heat or cold, *animals* should not be transported at all.
- b) In some circumstances, transportation during the night may reduce thermal stress or the adverse effects of other external stimuli.

Article 7.3.6.

**Documentation**

1. *Animals* should not be loaded until the documentation required to that point is complete.
2. The documentation accompanying the consignment should include:
  - a) *journey* travel plan and emergency management plan;
  - b) date, time and place of *loading* and *unloading*;
  - c) veterinary certification, when required;
  - d) *animal welfare* competencies of the driver (under study);
  - e) *animal identification* to allow *animal traceability* to the premises of departure and, where possible, to the premises of origin;
  - f) details of any *animals* considered at particular risk of suffering poor *welfare* during transport (point 3e) of Article 7.3.7.);
  - g) documentation of the period of rest, and access to feed and water, prior to the *journey*;
  - h) *stocking density* estimate for each load in the consignment;
  - i) the *journey* log - daily record of inspection and important events, including records of morbidity and mortality and actions taken, climatic conditions, rest stops, travel time and distance, feed and water offered and estimates of consumption, medication provided, and mechanical defects.
3. When veterinary certification is required to accompany consignments of *animals*, it should address:
  - a) fitness of *animals* to travel;
  - b) *animal identification* (description, number, etc.);
  - c) health status including any tests, treatments and vaccinations carried out;
  - d) when required, details of *disinfection* carried out.

At the time of certification, the *veterinarian* should notify the *animal handler* or the driver of any factors affecting the fitness of *animals* to travel for a particular *journey*.

## Article 7.3.7.

**Pre-journey period**1. General considerations

- a) *Pre-journey* rest is necessary if the *welfare* of *animals* has become poor during the collection period because of the physical environment or the social behaviour of the *animals*. The need for rest should be judged by a *veterinarian* or other competent person.
- b) *Pre-journey* assembly/holding areas should be designed to:
  - i) securely hold the *animals*;
  - ii) maintain a safe environment from hazards, including predators and *disease*;
  - iii) protect *animals* from exposure to severe weather conditions;
  - iv) allow for maintenance of social groups;
  - v) allow for rest, and appropriate water and feed.
- c) Consideration should be given to the previous transport experience, training and conditioning of the *animals*, if known, as these may reduce fear and stress in *animals*.
- d) Feed and water should be provided *pre-journey* if the *journey* duration is greater than the normal inter-feeding and drinking interval for the *animal*. Recommendations for specific-species are described in detail in Article 7.3.12.
- e) When *animals* are to be provided with a novel diet or method of feed or water provision during the *journey*, an adequate period of adaptation should be allowed.
- f) Before each *journey*, *vehicles* and *containers* should be thoroughly cleaned and, if necessary, treated for animal health and public health purposes, using methods approved by the *Competent Authority*. When cleaning is necessary during a *journey*, this should be carried out with the minimum of stress and risks to the *animals*.
- g) Where an *animal handler* believes that there is a significant risk of *disease* among the *animals* to be loaded or significant doubt as to their fitness to travel, the *animals* should be examined by a *veterinarian*.

2. Selection of compatible groups

Compatible groups should be selected before transport to avoid adverse *animal welfare* consequences. The following recommendations should be applied when assembling groups of *animals*:

- a) *Animals* reared together should be maintained as a group; *animals* with a strong social bond, such as a dam and offspring, should be transported together.
- b) *Animals* of the same species can be mixed unless there is a significant likelihood of aggression; aggressive individuals should be segregated (recommendations for specific species are described in detail in Article 7.3.12.). For some species, *animals* from different groups should not be mixed because poor *welfare* occurs unless they have established a social structure.
- c) Young or small *animals* should be separated from older or larger *animals*, with the exception of nursing mothers with young at foot.

Annex XVII (contd)

- d) *Animals* with horns or antlers should not be mixed with *animals* lacking horns or antlers unless judged to be compatible.
- e) *Animals* of different species should not be mixed unless they are judged to be compatible.

3. Fitness to travel

- a) Each *animal* should be inspected by a *veterinarian* or an *animal handler* to assess fitness to travel. If its fitness to travel is in doubt, the *animal* should be examined by a *veterinarian*. *Animals* found unfit to travel should not be loaded onto a *vehicle*, except for transport to receive veterinary attention.
- b) Humane and effective arrangements should be made by the owner and the agent for the handling and care of any *animal* rejected as unfit to travel.
- c) *Animals* that are unfit to travel include, but may not be limited to:
  - i) those that are sick, injured, weak, disabled or fatigued;
  - ii) those that are unable to stand unaided and bear weight on each leg;
  - iii) those that are blind in both eyes;
  - iv) those that cannot be moved without causing them additional suffering;
  - v) newborn with an unhealed navel;
  - vi) pregnant *animals* which would be in the final 10% of their gestation period at the planned time of *unloading*;
  - vii) females travelling without young which have given birth within the previous 48 hours;
  - viii) those whose body condition would result in poor *welfare* because of the expected climatic conditions.
- d) Risks during transport can be reduced by selecting *animals* best suited to the conditions of travel and those that are acclimatised to expected weather conditions.
- e) *Animals* at particular risk of suffering poor *welfare* during transport and which require special conditions (such as in the design of facilities and *vehicles*, and the length of the *journey*) and additional attention during transport, may include:
  - i) large or obese individuals;
  - ii) very young or old *animals*;
  - iii) excitable or aggressive *animals*;
  - iv) *animals* which have had little contact with humans;
  - v) *animals* subject to motion sickness;

- vi) females in late pregnancy or heavy lactation, dam and offspring;
- vii) *animals* with a history of exposure to stressors or pathogenic agents prior to transport;
- viii) *animals* with unhealed wounds from recent surgical procedures such as dehorning.

#### 4. Specific species requirements

Transport procedures should be able to take account of variations in the behaviour of the species. Flight zones, social interactions and other behaviour vary significantly among species and even within species. Facilities and handling procedures that are successful with one species are often ineffective or dangerous with another.

Recommendations for specific species are described in detail in Article 7.3.12.

#### Article 7.3.8.

### **Loading**

#### 1. Competent supervision

- a) *Loading* should be carefully planned as it has the potential to be the cause of poor *welfare* in transported *animals*.
- b) *Loading* should be supervised and/or conducted by *animal handlers*. The *animals* are to be loaded quietly and without unnecessary noise, harassment or force. Untrained assistants or spectators should not impede the process.
- c) When *containers* are loaded onto a *vehicle*, this should be carried out in such a way to avoid poor *animal welfare*.

#### 2. Facilities

- a) The facilities for loading including the collecting area, races and loading ramps should be designed and constructed to take into account the needs and abilities of the *animals* with regard to dimensions, slopes, surfaces, absence of sharp projections, flooring, etc.
- b) Loading facilities should be properly illuminated to allow the *animals* to be observed by animal handler(s), and to allow the ease of movement of the *animals* at all times. Facilities should provide uniform light levels directly over approaches to sorting pens, chutes, loading ramps, with brighter light levels inside vehicles/containers, in order to minimise baulking. Dim light levels may be advantageous for the catching of *poultry* and some other *animals*. Artificial lighting may be required. Loading ramps and other facilities should have a non-slippery flooring.
- c) Ventilation during loading and the journey should provide for fresh air, the removal of excessive heat, humidity and noxious fumes (such as ammonia and carbon monoxide), and the prevention of accumulations of ammonia and carbon dioxide. Under warm and hot conditions, ventilation should allow for the adequate convective cooling of each animal. In some instances, adequate ventilation can be achieved by increasing the space allowance for *animals*.

Annex XVII (contd)3. Goads and other aids

When moving *animals*, their species-specific behaviour should be used (see Article 7.3.12. If goads and other aids are necessary, the following principles should apply:

- a) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.
- b) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
- c) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.
- d) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.
- e) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.
- f) The use of well trained dogs to help with the *loading* of some species may be acceptable.
- g) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.
- h) Conscious *animals* should not be thrown, dragged or dropped.
- i) Performance standards should be established in which numerical scoring is used to evaluate the use of such instruments, and to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling as a result of their usage.

Article 7.3.9.

**Travel**1. General considerations

- a) Drivers and *animal handlers* should check the load immediately before departure to ensure that the *animals* have been properly loaded. Each load should be checked again early in the trip and adjustments made as appropriate. Periodic checks should be made throughout the trip, especially at rest or refuelling stops or during meal breaks when the *vehicle* is stationary.

- b) Drivers should utilise smooth, defensive driving techniques, without sudden turns or stops, to minimise uncontrolled movements of the *animals*.

## 2. Methods of restraining or containing animals

- a) Methods of restraining *animals* should be appropriate to the species and age of *animals* involved and the training of the individual *animal*.
- b) Recommendations for specific species are described in detail in Article 7.3.12.

## 3. Regulating the environment within vehicles or containers

- a) *Animals* should be protected against harm from hot or cold conditions during travel. Effective ventilation procedures for maintaining the environment within *vehicles* or *containers* will vary according to whether conditions are cold, hot and dry or hot and humid, but in all conditions a build-up of noxious gases should be prevented.
- b) The environment within *vehicles* or *containers* in hot and warm weather can be regulated by the flow of air produced by the movement of the *vehicle*. In warm and hot weather, the duration of *journey* stops should be minimised and *vehicles* should be parked under shade, with adequate and appropriate ventilation.
- c) To minimise slipping and soiling, and maintain a healthy environment, urine and faeces should be removed from floors when necessary and disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.

## 4. Sick, injured or dead animals

- a) A driver or an *animal handler* finding sick, injured or dead *animals* should act according to a predetermined emergency response plan.
- b) Sick or injured *animals* should be segregated.
- c) Ferries (roll-on roll-off) should have procedures to treat sick or injured *animals* during the *journey*.
- d) In order to reduce the likelihood that animal transport will increase the spread of infectious *disease*, contact between transported *animals*, or the waste products of the transported *animals*, and other farm *animals* should be minimised.
- e) During the *journey*, when disposal of a dead *animal* becomes necessary, this should be carried out in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.
- f) When *killing* is necessary, it should be carried out as quickly as possible and assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures. Recommendations for specific species are described in Chapter 7.6. on killing of *animals* for disease control purposes.

## 5. Water and feed requirements

- a) If *journey* duration is such that feeding or watering is required or if the species requires feed or water throughout, access to suitable feed and water for all the *animals* (appropriate for their species and age) carried in the *vehicle* should be provided. There should be adequate space for all *animals* to move to the feed and water sources and due account taken of likely competition for feed.
- b) Recommendations for specific species are described in detail in Article 7.3.12.

Annex XVII (contd)6. Rest periods and conditions

- a) *Animals* that are being transported should be rested at appropriate intervals during the *journey* and offered feed and water, either on the *vehicle* or, if necessary, unloaded into suitable facilities.
- b) Suitable facilities should be used en route, when resting requires the *unloading* of the *animals*. These facilities should meet the needs of the particular animal species and should allow access of all *animals* to feed and water.

7. In-transit observations

- a) *Animals* being transported by road should be observed soon after a *journey* is commenced and whenever the driver has a rest stop. After meal breaks and refuelling stops, the *animals* should be observed immediately prior to departure.
- b) *Animals* being transported by rail should be observed at each scheduled stop. The responsible rail transporter should monitor the progress of trains carrying *animals* and take all appropriate action to minimise delays.
- c) During stops, it should be ensured that the *animals* continue to be properly confined, have appropriate feed and water, and their physical condition is satisfactory.

Article 7.3.10.

**Unloading and post-journey handling**1. General considerations

- a) The required facilities and the principles of animal handling detailed in Article 7.3.8. apply equally to *unloading*, but consideration should be given to the likelihood that the *animals* will be fatigued.
- b) *Unloading* should be supervised and/or conducted by an *animal handler* with knowledge and experience of the behavioural and physical characteristics of the species being unloaded. *Animals* should be unloaded from the *vehicle* into appropriate facilities as soon as possible after arrival at the destination but sufficient time should be allowed for *unloading* to proceed quietly and without unnecessary noise, harassment or force.
- c) Facilities should provide all *animals* with appropriate care and comfort, adequate space and ventilation, access to feed (if appropriate) and water, and shelter from extreme weather conditions.
- d) For details regarding the *unloading* of *animals* at a *slaughterhouse*, see Chapter 7.5. on slaughter of animals for human consumption.

2. Sick or injured animals

- a) An *animal* that has become sick, injured or disabled during a *journey* should be appropriately treated or humanely killed (see Chapter 7.6. on killing of *animals* for disease control purposes). If necessary, veterinary advice should be sought in the care and treatment of these *animals*. In some cases, where *animals* are non-ambulatory due to fatigue, injury or sickness, it may be in the best *welfare* interests of the *animal* to be treated or killed aboard the *vehicle*. Assistance should be sought from a *veterinarian* or other person(s) competent in humane *killing* procedures.

- b) At the destination, the *animal handler* or the driver during transit should ensure that responsibility for the *welfare* of sick, injured or disabled *animals* is transferred to a *veterinarian* or other suitable person.
- c) If treatment or humane *killing* is not possible aboard the *vehicle*, there should be appropriate facilities and equipment for the humane *unloading* of *animals* that are non-ambulatory due to fatigue, injury or sickness. These *animals* should be unloaded in a manner that causes the least amount of suffering. After *unloading*, separate pens and other appropriate facilities should be available for sick or injured *animals*.
- d) Feed, if appropriate, and water should be available for each sick or injured *animal*.

### 3. Addressing disease risks

The following should be taken into account in addressing the greater risk of *disease* due to animal transport and the possible need for segregation of transported *animals* at the destination:

- a) increased contact among *animals*, including those from different sources and with different disease histories;
- b) increased shedding of pathogens and increased susceptibility to infection related to stress and impaired defences against disease, including immunosuppression;
- c) exposure of *animals* to pathogens which may contaminate *vehicles*, *resting points*, *markets*, etc.

### 4. Cleaning and disinfection

- a) *Vehicles*, crates, *containers*, etc. used to carry the *animals* should be cleaned before re-use through the physical removal of manure and bedding by scraping, washing and flushing with water and detergent. This should be followed by *disinfection* when there are concerns about disease transmission.
- b) Manure, litter, bedding and the bodies of any *animals* which die during the *journey* should be disposed of in such a way as to prevent the transmission of *disease* and in compliance with all relevant health and environmental legislation.
- c) Establishments like livestock *markets*, *slaughterhouses*, resting sites, railway stations, etc. where *animals* are unloaded should be provided with appropriate areas for the cleaning and *disinfection* of *vehicles*.

#### Article 7.3.11.

#### **Actions in the event of a refusal to allow the completion of the journey**

1. The *welfare* of the *animals* should be the first consideration in the event of a refusal to allow the completion of the *journey*.
2. When the *animals* have been refused import, the *Competent Authority* of the *importing country* should make available suitable isolation facilities to allow the *unloading* of *animals* from a *vehicle* and their secure holding, without posing a risk to the health of national herd or flock, pending resolution of the situation. In this situation, the priorities should be:
  - a) the *Competent Authority* of the *importing country* should provide urgently in writing the reasons for the refusal;
  - b) in the event of a refusal for animal health reasons, the *Competent Authority* of the *importing country* should provide urgent access to a *veterinarian*, where possible an OIE *veterinarian(s)* appointed by the Director General, to assess the health status of the *animals* with regard to the concerns of the *importing country*, and the necessary facilities and approvals to expedite the required diagnostic testing;

Annex XVII (contd)

- c) the *Competent Authority* of the *importing country* should provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*;
  - d) if the matter cannot be promptly resolved, the *Competent Authorities* of the *exporting* and *importing countries* should call on the OIE to mediate.
3. In the event that a *Competent Authority* requires the *animals* to remain on the *vehicle*, the priorities should be:
- a) to allow provisioning of the *vehicle* with water and feed as necessary;
  - b) to provide urgently in writing the reasons for the refusal;
  - c) to provide urgent access to an independent *veterinarian(s)* to assess the health status of the *animals*, and the necessary facilities and approvals to expedite the required diagnostic testing in the event of a refusal for animal health reasons;
  - d) to provide access to allow continued assessment of the health and other aspects of the *welfare* of the *animals*, and the necessary actions to deal with any animal issues which arise.
4. The OIE should utilise its informal procedure for dispute mediation to identify a mutually agreed solution which will address animal health and any other *welfare* issues in a timely manner.

## Article 7.3.12.

**Species-specific issues**

Camelids of the new world in this context comprise llamas, alpacas, guanaco and vicuna. They have good eyesight and, like sheep, can negotiate steep slopes, though ramps should be as shallow as possible. They load most easily in a bunch as a single *animal* will strive to rejoin the others. Whilst they are usually docile, they have an unnerving habit of spitting in self-defence. During transport, they usually lie down. They frequently extend their front legs forward when lying, so gaps below partitions should be high enough so that their legs are not trapped when the *animals* rise.

Cattle are sociable *animals* and may become agitated if they are singled out. Social order is usually established at about two years of age. When groups are mixed, social order has to be re-established and aggression may occur until a new order is established. Crowding of cattle may also increase aggression as the *animals* try to maintain personal space. Social behaviour varies with age, breed and sex; *Bos indicus* and *B. indicus*-cross *animals* are usually more temperamental than European breeds. Young bulls, when moved in groups, show a degree of playfulness (pushing and shoving) but become more aggressive and territorial with age. Adult bulls have a minimum personal space of six square metres. Cows with young calves can be very protective, and handling calves in the presence of their mothers can be dangerous. Cattle tend to avoid “dead end” in passages.

Goats should be handled calmly and are more easily led or driven than if they are excited. When goats are moved, their gregarious tendencies should be exploited. Activities which frighten, injure or cause agitation to *animals* should be avoided. Bullying is particularly serious in goats and can reflect demands for personal space. Housing strange goats together could result in fatalities, either through physical violence, or subordinate goats being refused access to food and water.

Horses in this context include donkeys, mules and hinnies. They have good eyesight and a very wide angle of vision. They may have a history of *loading* resulting in good or bad experiences. Good training should result in easier *loading*, but some horses can prove difficult, especially if they are inexperienced or have associated *loading* with poor transport conditions. In these circumstances, two experienced *animal handlers* can load an *animal* by linking arms or using a strop below its rump. Blindfolding may even be considered. Ramps should be as shallow as possible. Steps are not usually a problem when horses mount a ramp, but they tend to jump a step when descending, so steps should be as low as possible. Horses benefit from being individually stalled, but may be transported in compatible groups. When horses are to travel in groups, their shoes should be removed. Horses are prone to respiratory *disease* if they are restricted by period by tethers that prevent the lowering and lifting of their heads.

Pigs have poor eyesight, and may move reluctantly in unfamiliar surroundings. They benefit from well lit loading bays. Since they negotiate ramps with difficulty, these should be as level as possible and provided with secure footholds. Ideally, a hydraulic lift should be used for greater heights. Pigs also negotiate steps with difficulty. A good 'rule-of-thumb' is that no step should be higher than the pig's front knee. Serious aggression may result if unfamiliar *animals* are mixed. Pigs are highly susceptible to heat stress. Pigs are susceptible to motion sickness when in transit. Feed deprivation prior to loading may be beneficial to prevent motion sickness.

Sheep are sociable *animals* with good eyesight, a relatively subtle and undemonstrative behaviour and a tendency to "flock together", especially when they are agitated. They should be handled calmly and their tendency to follow each other should be exploited when they are being moved. Crowding of sheep may lead to damaging aggressive and submissive behaviours as *animals* try to maintain personal space. Sheep may become agitated if they are singled out for attention, or kept alone, and will strive to rejoin the group. Activities which frighten, injure or cause agitation to sheep should be avoided. They can negotiate steep ramps.

---

-----  
— text deleted



## CHAPTER 7.4.

## TRANSPORT OF ANIMALS BY AIR

## Article 7.4.1.

## Livestock containers

1. Design

## a) General principles of design

The *container* should:

- conform to the size of the standard pallet of the aircraft that will be used to transport *animals*; the common sizes are: 224 x 318 cm (88 x 125 in.) and 244 x 318 cm (96 x 125 in.);
- not be constructed of material that could be harmful to the *animals* health or *welfare*;
- allow observation of the *animals* and be marked on opposite sides with the International Air Transport Association (IATA) symbols which indicate *animals* and the upright position;
- allow emergency access to *animals*;
- allow the *animal* to stand in its normal position without touching the roof of the *container* or, in the case of open *containers*, the restraining nets, and provide at least 10 cm (4 in.) clearance above the *animal's* head when standing in its normal position; in the case of horses, provide sufficient space above the horses head (21 cm, 8 in. recommended) to allow for the movement required to maintain the horses balance;
- protect the *animals* from adverse weather;
- ensure *animals* stand on a suitable floor to prevent slipping or injury;
- have adequate strength to ensure the safety of the *animals* and to prevent the *animals* from escaping;
- ensure doors can be opened and closed easily, but be secured so that they cannot be opened accidentally;
- be free of any nails, bolts and other protrusions or sharp edges that could cause injuries;
- be designed to minimise the risk of any opening or space entrapping any portion of the *animals* body;
- if reusable, crates should be constructed of impermeable material that is easily cleaned and disinfected;

Annex XVII (contd)

- ensure faeces and urine cannot escape from the crate; this requires a minimum upturn of 20 cm but it must not block any ventilation openings;
- if designated for stacking be stable, not block any ventilation space and prevent urine and faeces from leaking into the *containers* below when stacked;
- allow for a facility for provision of water and possibly food during transportation of longer than 6 hours duration.

## b) Ventilation

The *container* design should:

- provide adequate ventilation taking into consideration the species stocking density, maximum temperature and humidity of the points of departure, destination, and any interim technical stops;
- allow the normal resting or sleeping position to be assumed for certain species and juvenile *animals*;
- ensure there is no dead air space in the *container*;
- provide ventilation openings on the walls equal to at least 16% of the wall area; this may be reduced if the *container* has an open top;
- in the case of two-tiered *containers*, ventilation in the sides should be for cattle equivalent to not less than 20% of the floor area of each deck, and for pigs and sheep up to 40% of the floor area of each deck;
- have ventilation openings on all four sides of the crate except that two walls may have reduced ventilation space and the other walls have increased space where required by the positioning of the crates during transportation and/or the ventilation pattern of the aircraft;
- ensure that any internal supports or dividers do not block the cross ventilation;
- not have a solid wall above the height of the animal's head in normal resting position;
- in those species where the mouth is normally held near the floor, have at least 25 cm (10 in.) of ventilation space at the level of the *animal's* head; this opening should be divided in two with a maximum height for any opening of 13 cm; in all *containers*, there should be a sufficiently large ventilation opening at a height of 25 cm to 30 cm (10 to 11 in.) above floor level on all four sides to allow for circulation;
- have some physical means of ensuring the ventilation space is not blocked, such as the use of cleats (wedges) or allowing space between the outside of the container and the pallet.

2. Species requirements

In general, fractious *animals* or *animals* in late pregnancy should not be transported by air (see Article 7.4.2).

## a) Horses

Should be transported in *containers* and be separated from each other if they are more than 145 cm (57 in.) in height.

Crates used to transport horses should:

- be strong enough to prevent unruly horses from breaking or escaping from the *container* under any circumstances;
- in the case of multi-horse *containers*, have partitions of sufficient strength and size to separate the horses and to support each horse's weight;
- adjust to allow mare and foal to travel together;
- provide the same percentage of open space for ventilation as required in point 1 above, divided between the two side walls; however, if the access doors are constructed in such a manner that they may be left open during the flight, the door space may be included in the ventilation space;
- be constructed to minimise noise;
- allow access to the head during the flight;
- have the front end notched and padded to accept the neck of the *animal*;
- have a secure point for attaching restraining devices;
- have a front and rear barrier that will restrict the movement of the horse and will ensure that liquids are deflected into the *container*;
- ensure horses cannot bite other *animals*;
- be constructed to resist kicking;
- have no fittings or projections in the area likely to be kicked, metal plates should be covered with a protective material;
- ramps shall be non-skid in nature, have foot battens, and be of a maximum slope of 25 degrees when the *container* is on a standard 50 cm (20 in.) dolly;
- not have a step up or down of more than 25 cm (10 in.).

b) Swine

- Crate design and shipment planning should recognize that swine are extremely susceptible to high heat and humidity and that they normally carry their head near the floor.
- In the use of multi-tiered crates, special attention should be paid to ensure air can move through the crate, in accordance with the aircraft's ventilation pattern and capacity to remove heat.
- Crate construction should take into consideration the tendency for mature swine to chew.
- Litter should be dust-free, shavings or other non toxic materials may be used but not sawdust.
- *Containers* for immature swine should only be constructed when flight is imminent, since rapid growth can result in undersized *containers* if the flight is delayed.
- In order to reduce fighting, swine shipped in group pens should be housed together as a group prior to shipment and not be mixed with other swine before *loading* on the aircraft.

Annex XVII (contd)

- Mature boars and incompatible females should be shipped in individual crates.
- Individual crates should be 20 cm (8 in.) longer than the body, 15 cm (6 in.) higher than the loin of the pig and of sufficient width, to allow the pigs to lie on their side.

## c) Cattle

Crates used to transport cattle should:

- if multi-tiered or roofed, have at least 33% of the roof and four walls as open space;
- have at least one ventilation opening 20-25 cm (8-10 in.) above the floor which is of such width that it will not cause injuries to the feet.

Adult bulls should be transported separately unless they have been accustomed to each other. Cattle with and without horns should be separated from each other.

d) Poultry

- Crates/containers containing poultry should be handled and carried carefully with now unnecessary tilting.
- The majority of birds transported by air will be newly hatched chicks. These animals are very vulnerable to sudden changes in temperature.

ee) Other species

- *Animals* that normally exhibit a herding instinct, including buffalo and deer, can be shipped in group *containers* providing the mental and physical characteristics of the species are taken into consideration.
- All crates used to move such *animals* should have a roof or other method of preventing the *animals* from escaping.
- *Animals* in which the horns or antler cannot be removed, should be transported individually.
- Deer should not be transported in velvet nor in rut.

Article 7.4.2.

**Recommendations for pregnant animals**

Heavily pregnant *animals* should not be carried except under exceptional circumstances. Pregnant *animals* should not be accepted when the last service or exposure to a male prior to departure has exceeded the following time given here for guidance only:

Females	Maximum number of days since the last service or successful mating
Horses	300
Cows	250
Deer (axis, fallow and sika)	170
(red deer, reindeer)	185
Ewes (sheep)	115
Nannies (goats)	115
Sows (pigs)	90

Where service dates or date of last exposure to a male successful mating are not available, the *animals* should be examined by a *veterinarian* to ensure that pregnancy is not so advanced that *animals* are likely to give birth during transport or suffer unnecessarily.

Any *animal* showing udder engorgement and slackening of the pelvic ligament should be refused.

#### Article 7.4.3.

#### Stocking density

The current *stocking densities* agreed by the International Air Transport Association (IATA) should continue to be accepted. However, the graphs giving the space requirements should be extended to take into account *animals* larger and smaller than those dealt with currently.

##### 1. General considerations

When calculating stocking rates, the following should be taken into account:

- a) it is essential that accurate weights of *animals* are obtained in view of the limitations imposed by the load capabilities of the aircraft and the space required per *animal*;
- b) in narrow bodied aircraft, there is a loss of floor area in the upper tier of two-tier penning due to the contours of the aircraft;
- c) space available should be calculated on the inside measurements of the crates or penning system used, not on the floor space of the aircraft;
- d) multi-tiered crates, high outdoor temperatures at departure, arrival or stopover points, or extreme length of the trip will require an increase in the amount of space per *animal*; a 10% decrease in *stocking density* is recommended for trips in excess of 24 hours;
- e) special attention should be paid to the transport of sheep in heavy wool which require an increase in space allotted per *animal* and to pigs which have limited ability to dissipate heat;
- f) *animals* confined in groups, especially in pens, should be stocked at a high enough density to prevent injuries at take-off, during turbulence and at landing, but not to the extent that individual *animals* cannot lie down and rise without risk of injury or crushing;

Annex XVII (contd)

- g) in multi-tiered shipments, it should be recognized that the ventilation and cooling capacity of the aircraft is the limiting factor, especially in narrow bodied aircraft. Ventilation capacity varies on each individual aircraft and between aircraft of the same model.

2. Recommendations for stocking densities

The following table gives *stocking density* recommendations for different domestic species. The values are expressed in kilograms and metres.

Species	Weight	Density	Space/ animal	No. of animals per	Animals per single tier pallet		
	kg	kg/m <sup>2</sup>	m <sup>2</sup>	10 m <sup>2</sup>	214x264 cm	214x308 cm	234x308 cm
Calves	50	220	0.23	43	24	28	31
	70	246	0.28	35/6	20	23	25
	80	266	0.30	33	18	21	24
	90	280	0.32	31	17	20	22
Cattle	300	344	0.84	11-12	6	7	8
	500	393	1.27	8	4	5	5
	600	408	1.45	6-7	3-4	4	4-5
	700	400	1.63	6	3	3-4	4
Sheep	25	147	0.17	59	32	37	42
	70	196	0.36	27/8	15	18	20
Pigs	25	172	0.15	67	37	44	48
	100	196	0.51	20	10	12	14

Article 7.4.4.

**Preparation for air transport of livestock**1. Health and customs requirements

The legal requirements including animal health, *welfare* and species conservation, should be ascertained from the country of destination and any in *transit countries* before the *animals* are assembled or the transportation is arranged.

Contact the *Veterinary Authorities* in the country of origin regarding veterinary certification.

Planning of the transportation should take into account weekends, holidays and airport closures.

Verify that any proposed intransit stops or alternates will not jeopardise the importing or in *transit countries* health requirements.

**Waiting time at customs (cargo handling and clearance) should be reduced as much as possible to avoid *welfare* problems.**

## 2. Environment

*Animals* are affected by extremes of temperature. This is especially true of high temperature when compounded by high humidity. Temperature and humidity should therefore be taken into consideration when planning the shipment.

Times of arrival, departure and stopovers should be planned so that the aircraft lands during the coolest hours.

At outside temperatures of below 25°C at the landing point, the aircraft doors should be opened to ensure adequate ventilation. Confirmation should be received from government authorities that animal health legislation does not prevent opening of aircraft doors.

When outside temperatures at any landing point exceed 25°C, prior arrangements should be made to have an adequate air-conditioning unit available when the plane lands.

## 3. Facilities and equipment

Specific arrangements must be made to ensure that holding and *loading* facilities including ramps, trucks, and air-conditioning units are available at departure, all in transit and arrival airports. This should include identification of specific staff who are responsible and the method of contacting them, e.g. telephone number and address.

Specific notification must be given to all those responsible for providing facilities or equipment at the destination and in transit stops immediately before departure.

*Containers* should be loaded so as to ensure access can be made to the *animals* at all times.

## 4. Preparation of animals

Vaccination must be done far enough in advance of the departure date to allow for immunity to develop.

Veterinary certification and serological testing must be arranged several weeks in advance of livestock shipment.

Many *animals* require acclimatisation before they are transported. *Animals* such as swine and wild herbivores must be separated and held in the groups that will occupy *containers*. Mixing of such *animals* immediately before or during transport is extremely stressing and should be avoided.

Incompatible *animals* should be transported singly.

Article 7.4.5.

## **Disinfection and disinfestation**

### 1. Disinfection

a) Those parts of the interior of the aircraft destined for the carriage of *animals* should be thoroughly cleaned of all foreign matters using methods acceptable to aircraft management before being loaded.

b) These parts should be sprayed with a disinfectant:

i) suitable for the *diseases* which could be carried by the *animals*;

Annex XVII (contd)

- ii) that does not cause problems with the aircraft;
- iii) that will not leave a residue hazardous to the *animals* being transported.

If in doubt, the airline should be consulted on the suitability of the disinfectant. A mechanical nebuliser should be used to minimise the amount of disinfectant used.

Suggested disinfectants currently in use are:

- iv) 4% sodium carbonate and 0.1% sodium silicate;
  - v) 0.2% citric acid.
- c) All removeable equipment, penning and *containers* including loading ramps should be thoroughly cleaned and disinfected in accordance with the requirements of both the *exporting* and *importing countries*.
  - d) After *disinfection*, all equipment to be replaced in the aircraft should be washed with clean water to remove any traces of disinfectant to avoid any damage to the aircraft structures.

2. Disinfestation

Where *disinfestation* is required, the country requesting the action should be consulted for appropriate procedures.

The World Health Organisation (WHO) Recommendations on the Disinsectisation of Aircraft (*WHO Weekly Epidem. Rec.*, No. 7, 1985) are recognised as standard.

Article 7.4.6.

**Radiation**

Radioactive materials must be separated from live *animals* by a distance of at least 0.5 metre for journeys not exceeding 24 hours, and by a distance of at least 1.0 metre for journeys longer than 24 hours (reference: Technical instructions on storage and loading-separation of the International Civil Aviation Organisation). Special care should be taken with regard to pregnant *animals*, semen and embryos/ova.

Article 7.4.7.

**Tranquilization**

Experience has shown that there is considerable risk in sedating *animals* transported by air. Tranquilizers reduce the ability of the *animals* to respond to stress during transportation. In addition, the reaction of various species to tranquilization cannot always be foreseen. For these reasons, routine tranquilization is not recommended. Tranquilizers should only be used when a specific problem exists, and should be administered by a *veterinarian* or by a person who has been instructed in their use. Persons using these drugs should understand the full implications of the effects of the drug in air transport, e.g. certain *animals* such as horses and elephants should not go down in *containers*. Drugs should only be administered during the flight with the knowledge and consent of the captain.

In all cases, when tranquilizers are used, a note should be attached to the *container* stating the weight of the individual *animal*, the generic name of the drug used, the dose, the method and time of administration.

## Article 7.4.8.

**Destruction of carcasses**

In the event of any animal *death* on board, the competent authority of the airport of destination should be notified in advance of landing.

Carcasses should be disposed of under the supervision of and to the satisfaction of the *Veterinary Authority* of the country the aircraft is in.

The method of disposal should be based on the risk of introducing a controlled *disease*.

For carcasses which represent a high risk of introducing *disease*, the following is recommended:

1. destruction by incineration, rendering or deep burial under the supervision of the *Veterinary Authority*;
2. if removed from the airport site, transportation in a closed, leakproof *container*.

## Article 7.4.9.

**Emergency slaughter**

Emergency *slaughter* of *animals* in aircraft should, in general, only occur when the safety of the aircraft, crew or other *animals* are involved.

Every aircraft transporting *animals* should have a method of killing the *animals* with minimum pain and someone trained in that method.

In all cases when horses or other large *animals* are to be carried, the method of killing should be discussed with the airline during the planning stages. Suitable methods are:

1. Captive bolt stunner, followed by an injection of a lethal chemical
  - a) Operator should be trained to use the captive bolt stunner on the species or type of *animal* being transported.
  - b) An expert should determine that the type of captive bolt pistol is adequate for all the *animals* being transported.
  - c) Some airlines and countries may prohibit the carriage of captive bolt pistols.
  - d) The user should recognise that the noise associated with the captive bolt may excite other *animals*.
  - e) The requirement that the captive bolt pistol is accurately centered may be difficult to achieve with an excited *animal*.
2. Injection of a chemical
  - a) Various chemicals may be used to sedate, immobilize or kill *animals*.
  - b) Central nervous system depressants such as barbiturate euthanasia solutions must be injected directly into a vein to be effective. This is not normally practical for anyone but an experienced *veterinarian* or an especially trained and experienced attendant, where the *animal* is sufficiently fractious to require euthanasia.

Annex XVII (contd)

- c) Sedatives such as promazine and its derivatives may make the *animal* more fractious (see Article 7.4.7.).
- d) Immobilizing solutions such as succinylcholine are not humane.

3. Firearms

Airlines do not permit the use of firearms which discharge a free bullet because of the danger to the aircraft.

Article 7.4.10.

**Handling of food and waste material**

Waste material which contains anything of animal origin including food, litter, manure, or animal feed should be handled, collected and disposed of in a manner that ensures it will not be fed to livestock. It should be collected in specified areas, and stored and transported in closed, leakproof *containers*.

Some *importing countries* legislation may prohibit or restrict the use of hay or straw during the transportation period. Unloading of hay, straw, other animal feed and litter may be restricted or prohibited by in *transit countries*.

Article 7.4.11.

**Disposal of food and waste material**

Recommended methods of disposal are:

- a) incineration to an ash;
- b) heating at an internal temperature of at least of 100°C for 30 minutes, then disposal in a land fill site;
- c) controlled burial in a land fill site.

---

-----

— text deleted

## CHAPTER 7.5.

## SLAUGHTER OF ANIMALS

## Article 7.5.1.

**General principles**1. Object

These recommendations address the need to ensure the *welfare* of food *animals* during pre-slaughter and slaughter processes, until they are dead.

These recommendations apply to the *slaughter* in *slaughterhouses* of the following domestic *animals*: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and *poultry*. Other *animals*, wherever they have been reared, and all *animals* slaughtered outside *slaughterhouses* should be managed to ensure that their *transport, lairage, restraint* and *slaughter* is carried out without causing undue stress to the *animals*; the principles underpinning these recommendations apply also to these *animals*.

2. Personnel

Persons engaged in the *unloading, moving, lairage, care, restraint, stunning, slaughter* and bleeding of *animals* play an important role in the *welfare* of those *animals*. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the recommendations outlined in the present Chapter and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of *animal welfare*.

3. Animal behaviour

*Animal handlers* should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in **herds groups** and follow a leader by instinct.

*Animals* which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

The desire of some *animals* to control their personal space should be taken into account in designing facilities.

Annex XVII (contd)

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans i.e. tame have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

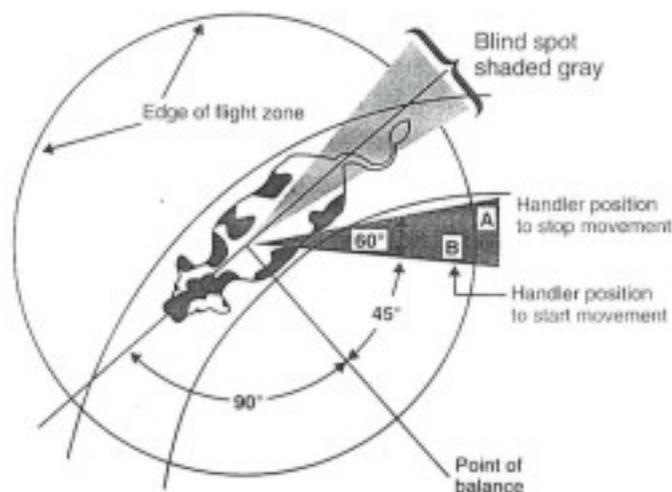
*Animal handlers* should use the point of balance at the *animal's* shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Domestic *animals* have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

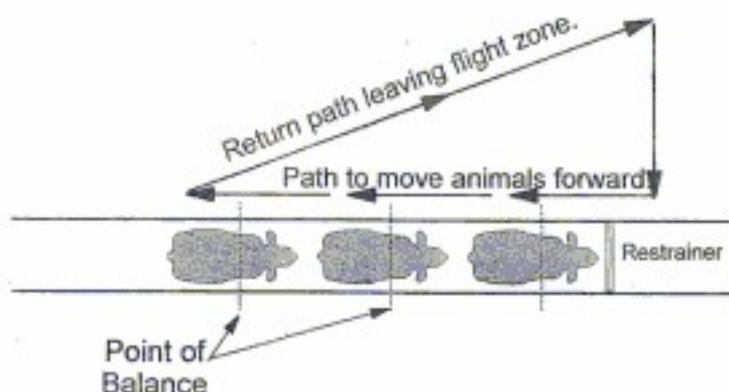
Although **all most** domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

### An example of a flight zone (cattle)



### Handler movement pattern to move cattle forward



#### 4. Distractions and their removal

Distractions that may cause approaching *animals* to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors — move a lamp or change lighting;
- b) dark entrances to chutes, races, stun boxes or conveyor restrainers — illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals*;
- c) *animals* seeing moving people or equipment up ahead — install solid sides on chutes and races or install shields;
- d) dead ends — avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences — remove them;
- f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers — avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface. These lairage conditions may not apply to poultry;
- g) sounds of air hissing from pneumatic equipment — install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects — install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of *animals* — redirect or reposition equipment. These conditions may not apply to poultry.

Annex XVII (contd)

## Article 7.5.2.

**Moving and handling animals**1. General considerations

*Animals* should be transported to *slaughter* in a way that minimises adverse animal health and *welfare* outcomes, and the transport should be conducted in accordance with the OIE recommendations for the transportation of *animals* (Chapters 7.2. and 7.3.).

The following principles should apply to *unloading animals*, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

- a) The conditions of the *animals* should be assessed upon their arrival for any *animal welfare* and health problems.
- b) Injured or sick *animals*, requiring immediate slaughter, should be killed humanely and without delay, in accordance with the recommendations of the OIE.
- c) *Animals* should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of *animals* slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99% of *animals* without their falling. **These conditions may not apply to poultry.**
- d) *Animals* for *slaughter* should not be forced to walk over the top of other *animals*.
- e) *Animals* should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move *animals*, such as crushing or breaking tails of *animals*, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to *animals* and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of *animals*, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small *animals* is permissible.
- f) When using goads and other aids, the following principles should apply:
  - i) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.
  - ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
  - iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.

- iv) Painful procedures (including whipping, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.
- v) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.
- vi) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting such *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.
- vii) Conscious *animals* should not be thrown, dragged or dropped.
- viii) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem.

## 2. Specific considerations for poultry

Stocking density in transport crates should be optimum to suit climatic conditions and maintain species-specific thermal comfort within containers.

Care is especially necessary during *loading* and *unloading* to avoid wings being caught, leading to dislocated or broken wing bones in conscious birds. Such injuries will adversely affect carcass and *meat* quality.

Modular systems that involve tipping of live birds are not conducive to maintaining good *animal welfare*. These systems, when used, should be incorporated with a mechanism to facilitate birds sliding out of the transport system, rather than being dropped or dumped on top of each other from heights of more than a metre.

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in the poorly designed and/or constructed transport systems. Under this situation, operator unloading birds should ensure gentle release of trapped birds.

Drawers in modular systems and crates should be stacked and destacked carefully so as to avoid injury to birds.

All birds should be sufficient space to all lie down at the same time without being on top of each other.

Birds with broken bone(s) and/or dislocated joint(s) should be humanely killed before being hung on shackles for processing.

The number of *poultry* arriving at the processing plant with dislocated joint(s) and/or broken bone(s) should be recorded verifiably. For *poultry*, the percentage of chickens with broken or dislocated wings should not exceed 2%. A frequency of less than 1% should be the goal.

Annex XVII (contd)2. Provisions relevant to animals delivered in containers

- a) *Containers* in which *animals* are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.
- b) *Animals* delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, *animals* should be unloaded from the *containers* individually.
- c) *Animals* which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of *poultry* for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. *Animals* which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

3. Provisions relevant to restraining and containing animals

- a) Provisions relevant to *restraining animals* for *stunning* or *slaughter* without *stunning*, to help maintain *animal welfare*, include:
  - i) provision of a non-slippery floor;
  - ii) avoidance of excessive pressure applied by *restraining* equipment that causes struggling or vocalisation in *animals*;
  - iii) equipment engineered to reduce noise of air hissing and clanging metal;
  - iv) absence of sharp edges in *restraining* equipment that would harm *animals*;
  - v) avoidance of jerking or sudden movement of *restraining* device.
- b) Methods of *restraint* causing avoidable suffering should not be used in conscious *animals* because they cause severe pain and stress:
  - i) suspending or hoisting *animals* (other than *poultry*) by the feet or legs;
  - ii) indiscriminate and inappropriate use of *stunning* equipment;
  - iii) mechanical clamping of the legs or feet of the *animals* (other than shackles used in *poultry* and ostriches) as the sole method of *restraint*;
  - iv) breaking legs, cutting leg tendons or blinding *animals* in order to immobilise them;
  - v) severing the spinal cord, for example using a puntilla or dagger, to immobilise *animals* using electric currents to immobilise *animals*, except for proper *stunning*.

## Article 7.5.3.

**Lairage design and construction**1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of *animals* in relation to the throughput rate of the *slaughterhouse* without compromising the *welfare* of the *animals*.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the *animals*, the *lairage* should be designed and constructed so as to allow the *animals* to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following recommendations may help to achieve this: Some of these conditions may not apply to poultry.

2. Design of lairage

- a) The *lairage* should be designed to allow a one-way flow of *animals* from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.
- b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of *animals* at any time, and to permit the removal of sick or injured *animals* when considered to be appropriate, for which separate appropriate accommodation should be provided.
- c) Each *animal* should have room to stand up and lie down and, when confined in a pen, to turn around, except where the *animal* is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious *animals* should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid *welfare* problems. The *lairage* should have sufficient accommodation for the number of *animals* intended to be held. Drinking water should always be available to the *animals*, and the method of delivery should be appropriate to the type of *animal* held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in *animals*, and should not hinder the movement of *animals*.
- d) Holding pens should be designed to allow as many *animals* as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all *animals* to feed. The feed trough should not hinder the movement of *animals*.
- e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the *animals* and should also allow the *animals* to stand, lie down and access any food or water that may need to be provided.
- f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent *animals* to see each other. For pigs and sheep, passageways should be wide enough to enable two or more *animals* to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the *animals*.
- g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of *animals* to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of *animals* without injury.

Annex XVII (contd)

- h) There should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of *animals* for *stunning* or *slaughter* and to avoid having *animal handlers* trying to rush *animals* from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that *animals* cannot be trapped or trampled.
- i) Ramps or lifts should be used for the *loading* and *unloading* of *animals* where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit *animals* to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent *animals* escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of *animals* without causing distress or injury.

3. Construction of lairage

- a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the *animals*.
- b) Floors should be well drained and not slippery; they should not cause injury to the feet of the *animals*. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where *animals* would have to cross them. Discontinuities or changes in floor patterns or texture which could cause baulking in the movement of *animals* should be avoided.
- c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the *animals* or affect their movement. The fact that *animals* will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.
- d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of *animals* the *lairage* will be expected to hold.
- e) Care should be taken to protect the *animals* from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noises to the areas where *animals* are held and slaughtered.
- f) Where *animals* are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

## Article 7.5.4.

**Care of animals in lairages**

*Animals* in *lairages* should be cared for in accordance with the following recommendations:

1. As far as possible, established groups of *animals* should be kept together. Each *animal* should have enough space to stand up, lie down and turn around. *Animals* hostile to each other should be separated.

Annex XVII (contd)

2. Where tethers, ties or individual stalls are used, they should allow *animals* to stand up and lie down without causing injury or distress.
3. Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the *animals*, and sufficient bedding should be used so that *animals* do not become soiled with manure.
4. *Animals* should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.
5. Suitable drinking water should be available to the *animals* on their arrival and at all times to *animals* in *lairages* unless they are to be slaughtered without delay.
6. If *animals* are not to be slaughtered as soon as possible, suitable feed should be available to the *animals* on arrival and at intervals appropriate to the species. Unweaned *animals* should be slaughtered as soon as possible.
7. In order to prevent heat stress, *animals* subjected to high temperatures, particularly pigs and *poultry*, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of *animals* to thermoregulate (especially *poultry*) should be considered in any decision to use water sprays. The risk of *animals* being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.
8. The *lairage* area should be well lit in order to enable the *animals* to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all *animals*. Subdued lighting, and for example blue light, may be useful in *poultry lairages* in helping to calm birds.
9. The condition and state of health of the *animals* in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian's* responsibility, by another competent person, such as an *animal handler*. *Animals* which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment or the *animals* should be humanely killed immediately if necessary.
10. Lactating dairy *animals* should be slaughtered as soon as possible. Dairy *animals* with obvious udder distension should be milked to minimise udder discomfort.
11. *Animals* which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for their *welfare* and the *welfare* of the newborn. Under normal circumstances, *animals* which are expected to give birth during a *journey* should not be transported.
12. *Animals* with horns, antlers or tusks capable of injuring other *animals*, if aggressive, should be penned separately.
13. *Poultry* awaiting slaughter should be protected from adverse weather conditions and provided with adequate ventilation.
14. Lairage duration for *poultry* should be kept to the minimum and it should not exceed 12 hours.
15. *Poultry* in transport containers should be examined at the time of arrival. Containers should be stacked with sufficient gap between the columns so as to facilitate inspection of birds and movement of air through them.
16. Forced ventilation or other cooling systems may be necessary under certain conditions to avoid build up of temperature and humidity.

Annex XVII (contd)

Recommendations for specific species are described in detail in Articles 7.5.5. to 7.5.8.

## Article 7.5.5.

**Management of foetuses during slaughter of pregnant animals**

Under normal circumstances, pregnant *animals* that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately, and the specific procedures described below are applied. In all cases, the *welfare* of foetuses and dams during *slaughter* should be safeguarded.

Foetuses should not be removed from the uterus sooner than 5 minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-*slaughter* processing of pregnant *animals*, all foetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, foetuses should not be removed from the uterus until at least 15-20 minutes after the maternal neck or chest cut.

If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.

The above recommendations do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at the evisceration of the dam, should not be attempted during normal commercial *slaughter* as it may lead to serious *welfare* complications in the newborn *animal*. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

## Article 7.5.6.

**Summary analysis of handling and restraining methods and the associated animal welfare issues**

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down	Competent animal handlers	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites

## Annex XVII (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handler	Breeding pigs (boars and sows)
	Upright restraint	Beak holding	Captive bolt Electrical-head only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head only	Stress of capture and positioning	Competent animal handler	Ostriches
	Holding body upright- manual	Manual restraint	Captive bolt Electrical-head only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/ slaughter	Competent animal handlers	Sheep, goats, calves, raites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp / crush / squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint – manual or mechanical	Restrainer/ cradle/crush	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint – manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches
Restraining and /or conveying methods	Mechanical - upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical- upright	Mechanical straddle – band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical - upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry

## Annex XVII (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining and/or conveying methods (contd)	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones; Keep restraint as short as possible	Competent animal handlers; proper design and operation of equipment; birds should be hung by both legs	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint Preferable to rotating box with fixed sides Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
Body restraint	Casting/hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, calves, small camelids, pigs
Leg restraints		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

## Article 7.5.7.

**Stunning methods**1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

- a) the *animal* is adequately restrained;
- b) *animals* in *restraint* are stunned as soon as possible;
- c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the *animal*;
- d) the ~~instrument~~ equipment is applied correctly;
- e) stunned *animals* are bled out (slaughtered) as soon as possible;
- f) *animals* are not stunned when *slaughter* is likely to be delayed; and
- g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails. Provision of a manual inspection area and simple intervention like neck dislocation for *poultry* would help prevent potential *welfare* problems.

In addition, such persons should be able to recognise when an *animal* is not correctly stunned and should take appropriate action.

## 2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. The following diagrams illustrate the proper application of the device for certain species.

### Cattle

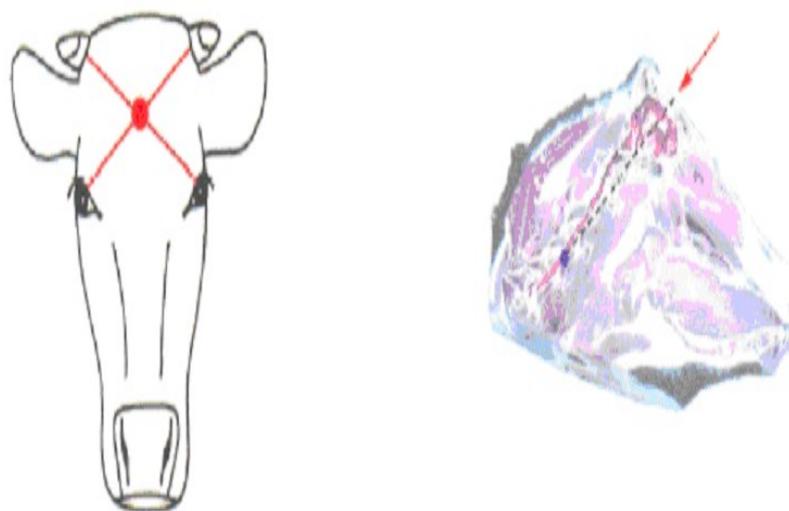


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

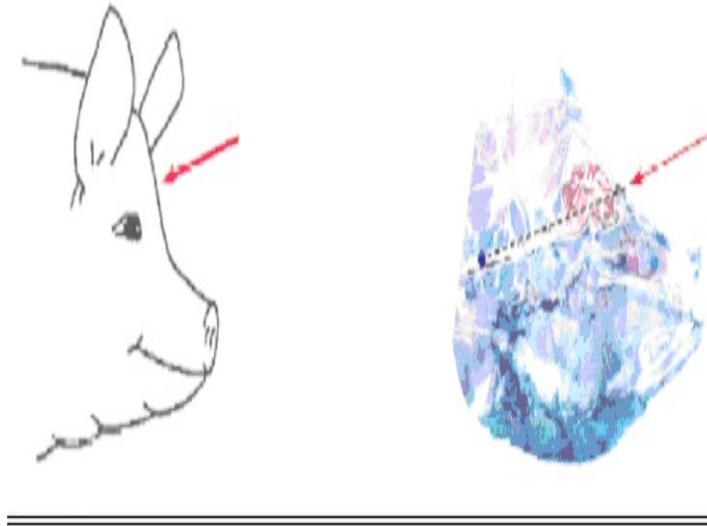
Annex XVII (contd)**Pigs**

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

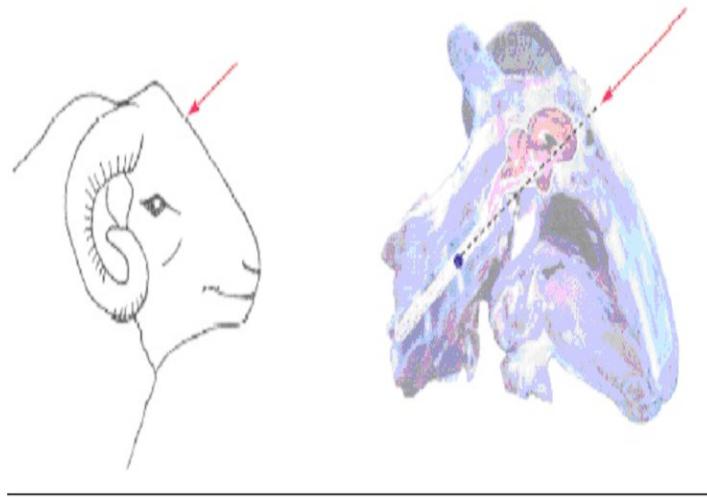
**Sheep**

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

The optimum position for hornless sheep and goats is on the midline.

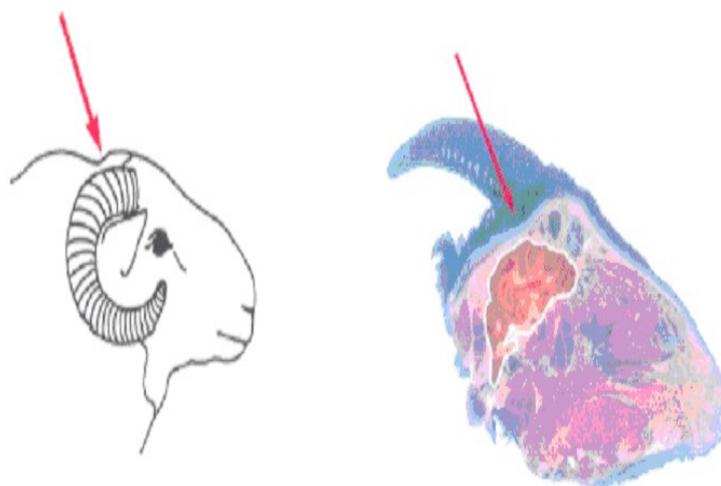
**Goats**

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

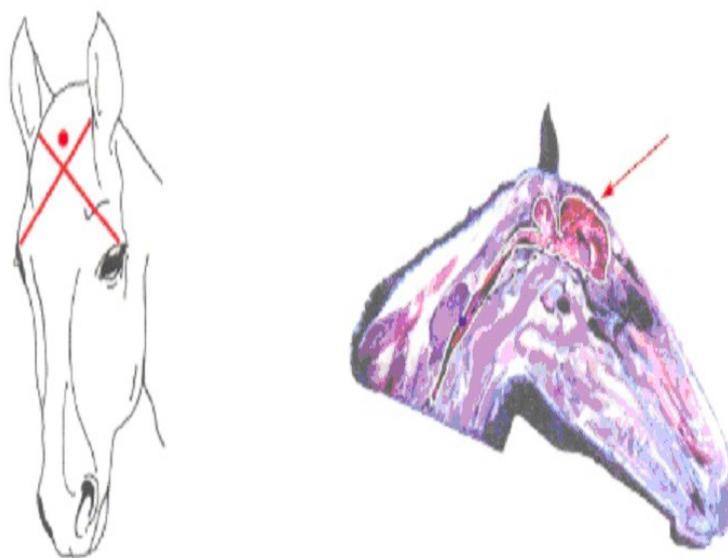
**Horses**

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

Annex XVII (contd)

Signs of correct *stunning* using a mechanical instrument are as follows:

- a) the *animal* collapses immediately and does not attempt to stand up;
- b) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;
- c) normal rhythmic breathing stops; and
- d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

**Poultry**

Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).



Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk))

Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.

Firing of a captive bolt according to manufacturers' instruction should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.

### 3. Electrical stunning

#### a) General considerations

An electrical device should be applied to the *animal* in accordance with the following recommendations.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the *animal* has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the *animal* is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on *animals* as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the *animal* before the actual *stunning* or *killing*.

Annex XVII (contd)

Electrical *stunning* apparatus should be tested prior to application on *animals* using appropriate resistors or dummy loads to ensure the power output is adequate to stun *animals*.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The *stunning* apparatus required for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only *stunning* are show in the following table.

Species	Minimum current levels for head-only stunning
Cattle	1.5 amps
Calves (bovines of less than 6 month of age)	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks. The shackle size should be appropriate to fit the size of the shanks (Meta tarsal bones) of birds.

Birds should be hung on shackles by both legs.

Birds with dislocated or broken legs and wings should not be shackled, instead humanely killed.

The duration between hanging on shackles and *stunning* should be kept to the minimum. In any event, the time between shackling and *stunning* should not exceed one minute.

Waterbaths for *poultry* should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

Annex XVII (contd)

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve electrical conductivity of the **soft** water, it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

While a lower current may also be satisfactory, the current shall in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of *stunning* and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately. **Height of the waterbath stunner should be adjusted according to the size of birds being stunned and slaughtered to ensure even the small birds are immersed in the water bath up to the base of the wings.**

**Minimum currents for stunning poultry when using 50Hz**

Species	Minimum current (milliamperes per bird)
Broilers	100
Layers (spent hens)	100
Turkeys	150
Ducks and geese	130

## Annex XVII (contd)

**Minimum currents for stunning poultry when using high frequencies**

	<b>Minimum currents (milliamperes per bird)</b>	
<b>Frequency (Hz)</b>	<b>Chickens</b>	<b>Turkeys</b>
< 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

**High frequency electrical stunning seldom induces cardiac arrest, and so it is potentially suitable as an alternative to slaughter without stunning.**

4. Gas stunning (under study)a) Stunning of pigs by exposure to carbon dioxide (CO<sub>2</sub>)

The concentration of CO<sub>2</sub> for *stunning* should be preferably 90% by volume but in any case no less than 80% by volume. After entering the *stunning* chamber, the *animals* should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO<sub>2</sub> for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the *animal* prior to loss of consciousness.

The chamber in which *animals* are exposed to CO<sub>2</sub> and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the *animals*. The animal density within the chamber should be such to avoid stacking *animals* on top of each others.

The conveyor and the chamber shall be adequately lit to allow the *animals* to see their surroundings and, if possible, each other.

It should be possible to inspect the CO<sub>2</sub> chamber whilst it is in use, and to have access to the *animals* in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO<sub>2</sub> concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO<sub>2</sub> falls below the required level.

Emergency *stunning* equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be dead or completely stunned.

## b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to *animals*. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

- i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or
- ii) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious *poultry* under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. Inhalation of high concentrations (40% or more) of carbon dioxide can be aversive to birds and ideally the gas mixture should be non-aversive to *poultry*.

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO<sub>2</sub> until the birds are properly stunned. No bird should recover consciousness or sensibility during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Live *poultry* should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all *animals* are properly stunned without unnecessary suffering. Some monitoring points for gas *stunning* could be the following:

- ensure smooth entry and passage of crates or birds through the system
- avoid bunching of birds in crates or conveyors
- gas concentrations should be continuously monitored and maintained during operation
- provide visible and audible alarm systems if gas concentrations are inappropriate to the species
- calibrate of gas monitors and maintain verifiable records
- duration of exposure should be adequate to prevent recovery of consciousness in birds
- provision to monitor and deal with recovery of consciousness
- blood vessels cut should induce *death* in unconscious birds
- all birds should be dead before entering scalding tank
- emergency procedures in the event of system failure.

- i) Gas mixtures used for stunning poultry could include:
  - a minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or

Annex XVII (contd)

- a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
  - a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
  - a minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air; or
  - a minimum of one minute exposure to 30% carbon dioxide in air, followed by a minimum of one minute exposure to at least 60% carbon dioxide in air
- ii) Requirements for effective use are as follows:
- Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.
  - Gas mixtures should be humidified.
  - Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

5. Bleeding

From the point of view of *animal welfare*, *animals* which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no *animals* recover consciousness during bleeding. In any case the following time limits should be applied.

All *animals* should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the *stunning* method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of view of *animal welfare*.

It should be possible for staff to observe, inspect and access the *animals* throughout the bleeding period. Any *animal* showing signs of recovering consciousness should be re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the *animals* for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

<b>Stunning method</b>	<b>Maximum delay for bleeding to be started</b>
Electrical methods and non-penetrating captive bolt	20 seconds
CO <sub>2</sub>	60 seconds (after leaving the chamber)

## Article 7.5.8.

## Summary analysis of stunning methods and the associated animal welfare issues

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate targeting and inappropriate ballistics	Operator competence; achieving outright kill with first shot	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt - penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites, poultry	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt - non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites, poultry	Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available.
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used.
	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	
Gaseous	CO <sub>2</sub> air/O <sub>2</sub> mixture; CO <sub>2</sub> inert gas mixture	Aversiveness of high CO <sub>2</sub> ; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	

## Annex XVII (contd)

## Article 7.5.9.

## Summary analysis of slaughter methods and the associated animal welfare issues

Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut	High level of operator competency. A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	No further procedure should be carried out before the bleeding out is completed (i.e. at least 30 seconds for mammals). The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.
Bleeding with prior stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats	
	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	
	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; inadequate size of stick wound; inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	
	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning

Slaughter methods	Specific method	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord. Acceptable only when slaughtering small numbers of small birds.
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 7.5.10.

#### Methods, procedures or practices unacceptable on animal welfare grounds

1. The restraining methods which work through immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in *animals*. Those methods are not acceptable in any species.
2. The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.
3. The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning* is not acceptable in any species.

-----  
 — text deleted



## CHAPTER 7.6.

**KILLING OF ANIMALS FOR  
DISEASE CONTROL PURPOSES**

## Article 7.6.1.

**General principles**

These recommendations are based on the premise that a decision to kill the *animals* has been made, and address the need to ensure the *welfare* of the *animals* until they are dead.

1. All personnel involved in the humane *killing* of *animals* should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.
2. As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from *animal welfare*, aesthetics of the method of euthanasia, cost of the method, operator safety, biosecurity and environmental aspects, aesthetics of the method of euthanasia and cost of the method.
3. Following the decision to kill the *animals*, *killing* should be carried out as quickly as possible, and normal husbandry should be maintained until the *animals* are killed.
4. The handling and movement of *animals* should be minimised and when done, it should be done in accordance with the recommendations described below.
5. *Animal restraint* should be sufficient to facilitate effective *killing*, and in accordance with *animal welfare* and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.
6. When *animals* are killed for disease control purposes, methods used should result in immediate *death* or immediate loss of consciousness lasting until *death*; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive and should not cause anxiety, pain, distress or suffering in *animals*.
7. For *animal welfare* considerations, young *animals* should be killed before older *animals*; for biosecurity considerations, infected *animals* should be killed first, followed by in-contact *animals*, and then the remaining *animals*.
8. There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to *animal welfare*, operator safety and biosecurity.
9. When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on *animal welfare*, operator safety and biosecurity.
10. These general principles should also apply when *animals* need to be killed for other purposes such as after natural disasters or for culling animal populations.

Annex XVII (contd)

## Article 7.6.2.

**Organisational structure**

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; *animal welfare* considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel competent in the humane *killing of animals* is available. Local level plans should be based on national plans and be informed by local knowledge.

Disease control contingency plans should address the *animal welfare* issues that may result from animal movement controls.

The operational activities should be led by an *official Veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required *animal welfare* and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.

The *official Veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official Veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE *animal welfare* and animal health recommendations.

A specialist team, led by a team leader answerable to the *official Veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

In considering the *animal welfare* issues associated with *killing animals*, the key personnel, their responsibilities and competencies required are described in Article 7.6.3.

## Article 7.6.3.

**Responsibilities and competencies of the specialist team**1. Team leader

- a) Responsibilities
  - i) plan overall operations on affected premises;
  - ii) determine and address requirements for *animal welfare*, operator safety and biosecurity;
  - iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant *animals* on the premises in accordance with national regulations and these recommendations;
  - iv) determine logistics required;

Annex XVII (contd)

- v) monitor operations to ensure *animal welfare*, operator safety and biosecurity requirements are met;
  - vi) report upwards on progress and problems;
  - vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the *animal welfare*, operator safety and biosecurity outcomes.
- b) Competencies
- i) appreciation of normal animal husbandry practices;
  - ii) appreciation of *animal welfare* and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;
  - iii) skills to manage all activities on premises and deliver outcomes on time;
  - iv) awareness of psychological effects on farmer, team members and general public;
  - v) effective communication skills;
  - vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian

- a) Responsibilities
- i) determine and supervise the implementation of the most appropriate *killing* method to ensure that *animals* are killed without avoidable pain and distress;
  - ii) determine and implement the additional requirements for *animal welfare*, including the order of *killing*;
  - iii) ensure that confirmation of the *death* of the *animals* is carried out by competent persons at appropriate times after the *killing* procedure;
  - iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;
  - v) continuously monitor *animal welfare* and biosecurity procedures;
  - vi) in cooperation with the leader, prepare a written report at the conclusion of the *killing*, describing the practices adopted and their effect on *animal welfare*.
- b) Competencies
- i) ability to assess *animal welfare*, especially the effectiveness of *stunning* and *killing* and to correct any deficiencies;
  - ii) ability to assess biosecurity risks.

Annex XVII (contd)3. Animal handlers

- a) Responsibilities
  - i) review on-site facilities in terms of their appropriateness;
  - ii) design and construct temporary animal handling facilities, when required;
  - iii) move and restrain *animals*;
  - iv) continuously monitor *animal welfare* and biosecurity procedures.
- b) Competencies
  - i) animal handling in emergency situations and in close confinement is required;
  - ii) an appreciation of biosecurity and containment principles.

4. Animal killing personnel

- a) Responsibilities

Humane *killing* of the *animals* through effective *stunning* and *killing* should be ensured.
- b) Competencies
  - i) when required by regulations, licensed to use necessary equipment;
  - ii) competent to use and maintain relevant equipment;
  - iii) competent to use techniques for the species involved;
  - iv) competent to assess effective *stunning* and *killing*.

5. Carcass disposal personnel

- a) Responsibilities

An efficient carcass disposal (to ensure *killing* operations are not hindered) should be ensured.
- b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

- a) Responsibilities
  - i) assist when requested.
- b) Competencies
  - i) specific knowledge of his/her *animals* and their environment.

## Article 7.6.4.

**Considerations in planning the humane killing of animals**

Many activities will need to be conducted on affected premises, including the humane *killing* of *animals*. The team leader should develop a plan for humanely *killing animals* on the premises which should include consideration of:

1. minimising handling and movement of *animals*;
2. *killing* the *animals* on the affected premises; however, there may be circumstances where the *animals* may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the recommendations in Chapter 7.5. on the *slaughter* of *animals* should be followed;
3. the species, number, age and size of *animals* to be killed, and the order of *killing* them;
4. methods of *killing* the *animals*, and their cost;
5. housing, husbandry, location of the *animals* as well as accessibility of the farm;
6. the availability and effectiveness of equipment needed for *killing* of the *animals*, as well as the time necessary to kill the required number of *animals* using such methods;
7. the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;
8. biosecurity and environmental issues;
9. the health and safety of personnel conducting the *killing*;
10. any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;
11. the presence of other nearby premises holding *animals*;
12. possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative *welfare* impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the *animals*.

Competences and skills of the personnel handling and *killing animals*.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all *animals* are humanely and quickly killed.

## Annex XVII (contd)

## Article 7.6.5.

**Table summarising killing methods described in Articles 7.6.6.-7.6.18.**

The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an *animal welfare* viewpoint.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt - followed by pithing or bleeding	yes	ineffective stunning	7.6.7.
	adults only	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	7.6.8.
	calves only	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Sheep and goats	all	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO <sub>2</sub> / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO <sub>2</sub>	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
Pigs	all, except neonates	free bullet	no	non-lethal wounding	7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	7.6.8.
	all <sup>1</sup>	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	7.6.11.
	neonates only	CO <sub>2</sub> / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO <sub>2</sub>	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	7.6.15.
Poultry	adults only	penetrating captive bolt	yes	ineffective stunning	7.6.8.

## Annex XVII (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Poultry (contd)	day-olds and eggs only	maceration	no	non-lethal wounding, non- immediacy	7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	7.6.11.
	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	7.6.11.
	all	CO <sub>2</sub> / air mixture Method 1 Method 2	yes no	slow induction of unconsciousness, aversiveness of induction	7.6.12.
	all	nitrogen and/or inert gas mixed with CO <sub>2</sub>	yes	slow induction of unconsciousness, aversiveness of induction	7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	7.6.15.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	7.6.16.

## Article 7.6.6.

**Free bullet**1. Introduction

- a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.
- b) The most commonly used firearms for close range use are:
  - i) humane killers (specially manufactured/adapted single-shot weapons);
  - ii) shotguns (12, 16, 20, 28 bore and .410);
  - iii) rifles (.22 rimfire);
  - iv) handguns (various calibres from .32 to .45).
- c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).
- d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the *animals* (high neck shot) and to cause irreversible concussion and *death* and should only be used by properly trained and competent marksmen.

2. Requirements for effective use

- a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.
- b) The marksman should ensure that the *animal* is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5 –50 cm for a shotgun) but the barrel should not be in contact with the head of the *animals*.
- c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally, the ammunition should expand upon impact and dissipate its energy within the cranium.
- d) Shot *animals* should be checked to ensure the absence of brain stem reflexes.

Annex XVII (contd)3. Advantages

- a) Used properly, a free bullet provides a quick and effective method for *killing*.
- b) It requires minimal or no *restraint* and can be use to kill from a distance by properly trained and competent marksmen.
- c) It is suitable for *killing* agitated *animals* in open spaces.

4. Disadvantages

- a) The method is potentially dangerous to humans and other *animals* in the area.
- b) It has the potential for non-lethal wounding.
- c) Destruction of brain tissue may preclude diagnosis of some *diseases*.
- d) Leakage of bodily fluids may present a biosecurity risk.
- e) Legal requirements may preclude or restrict use.
- f) There is a limited availability of competent personnel.

5. Conclusion

The method is suitable for cattle, sheep, goats and pigs, including large *animals* in open spaces.

**Figure 1.** The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

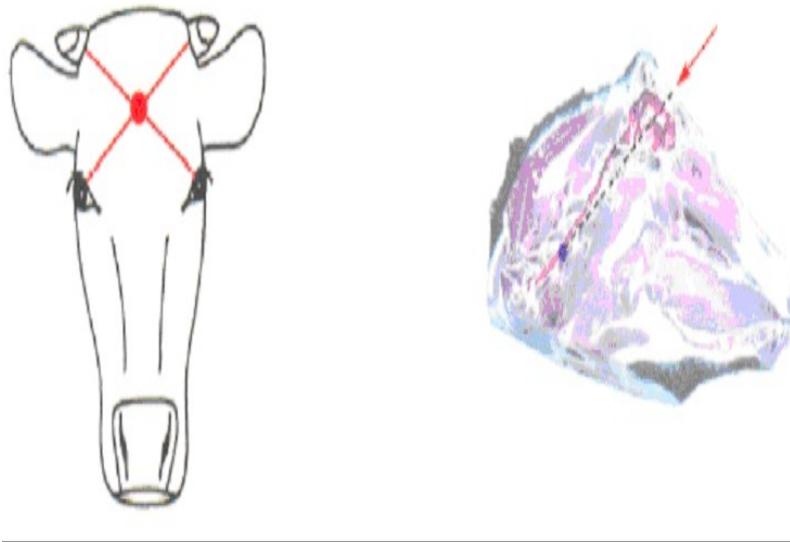


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

**Figure 2.** The optimum position for hornless sheep and goats is on the midline.

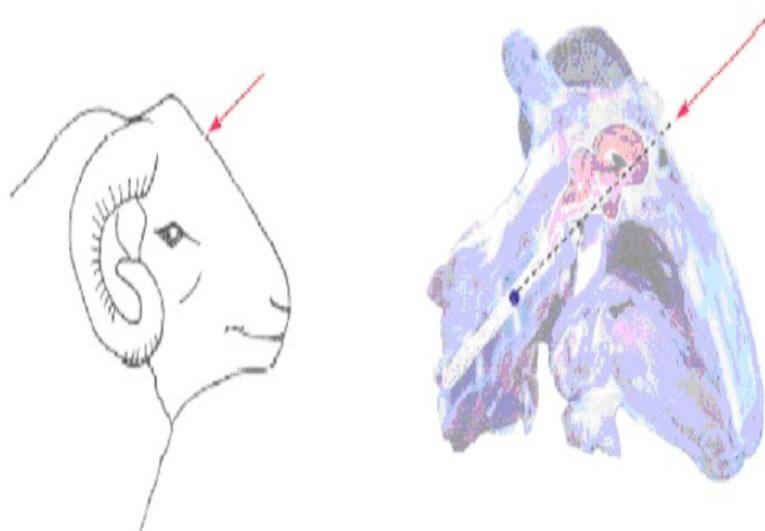


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

**Figure 3.** The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

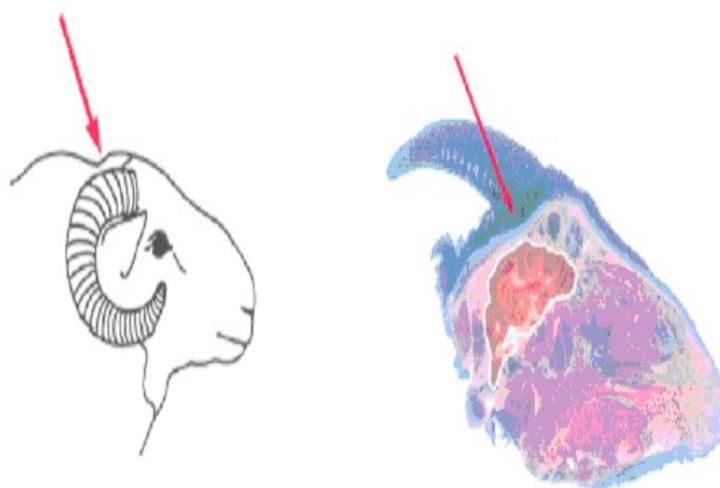


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom ([www.hsa.org.uk](http://www.hsa.org.uk)).

Annex XVII (contd)

**Figure 4.** The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.

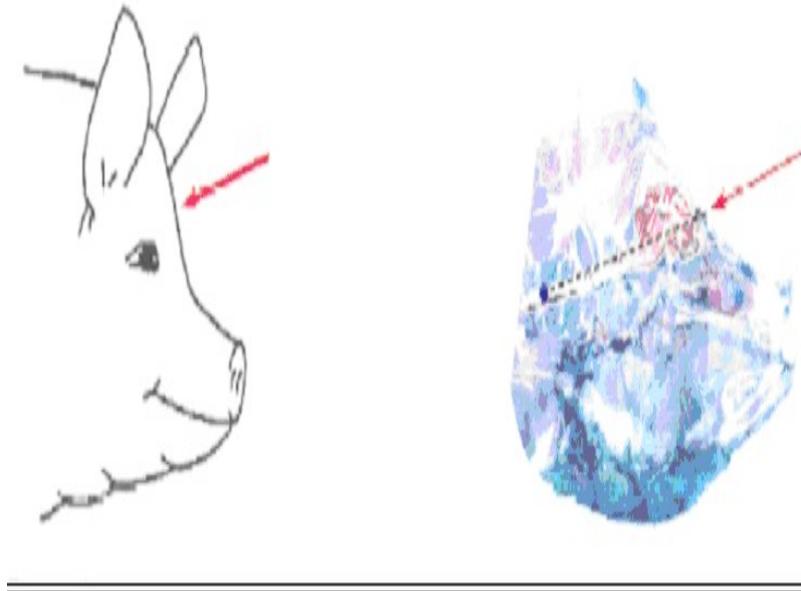


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 7.6.7.

### Penetrating captive bolt

#### 1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the *animal*. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in *death*; however, pithing or bleeding should be performed as soon as possible after the shot to ensure the *death* of the *animal*. Shooting poultry species with the captive bolts results in immediate destruction of the skull and brain, causing *death*.

#### 2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- d) *Animals* should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.

Annex XVII (contd)

- e) The operator should ensure that the head of the *animal* is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).
- g) To ensure the *death* of the *animal*, pithing or bleeding should be performed as soon as possible after *stunning*.
- h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

- a) Mobility of cartridge powered equipment reduces the need to move *animals*.
- b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

- a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.
- b) Post stun convulsions may make pithing difficult and hazardous.
- c) The method is difficult to apply in agitated *animals*.
- d) Repeated use of a cartridge powered gun may result in over-heating.
- e) Leakage of bodily fluids may present a biosecurity risk.
- f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for **poultry**, cattle, sheep, goats and pigs (except neonates), when followed by pithing or bleeding.

Article 7.6.8.

**Non-penetrating captive bolt**1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and *death* in *poultry* and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the *death* of the *animal*.

Annex XVII (contd)2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- d) *Animals* should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
- e) The operator should ensure that the head of the *animal* is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1-4).
- g) To ensure *death* in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.
- h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

- a) The method induces an immediate onset of unconsciousness, and *death* in birds and neonates.
- b) Mobility of equipment reduces the need to move *animals*.

4. Disadvantages

- a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.
- b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.
- c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.
- d) Post stun convulsions may make bleeding difficult and hazardous.
- e) Difficult to apply in agitated *animals*; such *animals* may be sedated in advance of the *killing* procedure.
- f) Repeated use of a cartridge powered gun may result in over-heating.
- g) Bleeding may present a biosecurity risk.

5. Conclusions

The method is suitable for *killing poultry*, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

## Article 7.6.9.

**Maceration**1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and *death* in **day-old newly hatched** *poultry* and embryonated eggs.

2. Requirements

- a) Maceration requires specialised equipment which should be kept in excellent working order.
- b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

3. Advantages

- a) Procedure results in immediate *death*.
- b) Large numbers can be killed quickly.

4. Disadvantages

- a) Specialised equipment is required.
- b) Macerated tissues may present biosecurity or human health risks.
- c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old *poultry* and embryonated eggs.

## Article 7.6.10.

**Electrical – two-stage application**1. Introduction

A two-stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce ‘tonic/clonic’ epilepsy and unconsciousness. Once the *animal* is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in *death*. The second stage (the application of low frequency current across the chest) should only be applied to unconscious *animals* to prevent unacceptable levels of pain.

Annex XVII (contd)2. Requirements for effective use

- a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	220	1.5
Sheep	220	1.0
Pigs over 6 weeks of age	220	1.3
Pigs less than 6 weeks of age	125	0.5

- b) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- c) *Animals* should be restrained, at a minimum free-standing in a pen, close to an electrical supply.
- d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the *animal* to allow the second application to be made.
- e) A *stunning* current should be applied via scissor-type *stunning* tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.
- f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- g) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.
- h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

3. Advantages

- a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.
- b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

- a) The method requires a reliable supply of electricity.
- b) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.
- c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).
- d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

## 5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).



Article 7.6.11.

## Electrical – single application

### 1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the *animal* and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the *animal* will not recover consciousness.

#### a) Requirements for effective use

- i) The stunner control device should generate a low frequency (30–60 Hz) current with a minimum voltage of 250 volts true RMS under load.
- ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- iii) *Animals* should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the *stunning* electrodes and the *animal* is necessary for effective use.
- iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.
- v) Electrodes should be cleaned regularly between *animals* and after use, to enable optimum electrical contact to be maintained.
- vi) Water or saline may be necessary to improve electrical contact with sheep.
- vii) An effective stun and kill should be verified by the absence of brain stem reflexes.

#### b) Advantages

- i) Method 1 stuns and kills simultaneously.
- ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.
- iii) A single team member only is required for the application.
- iv) Non-invasive technique minimises biosecurity risk.

Annex XVII (contd)

## c) Disadvantages

- i) Method 1 requires individual mechanical animal *restraint*.
- ii) The electrodes must be applied and maintained in the correct positions to produce an effective stun and kill.
- iii) Method 1 requires a reliable supply of electricity.

## d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over one week of age).

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled *poultry* through an electrified waterbath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, *poultry* will be simultaneously stunned and killed.

## a) Requirements for effective use

- i) A mobile waterbath stunner and a short loop of processing line are required.
- ii) A low frequency (50-60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.
- iii) *Poultry* need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a waterbath stunner with their heads fully immersed.
- iv) The required minimum currents to stun and kill dry birds are:
  - Quails - 100 mA/bird
  - Chickens – 160 mA/bird
  - Ducks & geese – 200 mA/bird
  - Turkeys – 250 mA/bird.

A higher current is required for wet birds.

- v) An effective stun and kill should be verified by the absence of brain stem reflexes.

## b) Advantages

- i) Method 2 stuns and kills simultaneously.
- ii) It is capable of processing large numbers of birds reliably and effectively.
- iii) This non-invasive technique minimises biosecurity risk.

Annex XVII (contd)

## c) Disadvantages

- i) Method 2 requires a reliable supply of electricity.
- ii) Handling, inversion and shackling of birds are required.

## d) Conclusion

Method 2 is suitable for large numbers of *poultry*.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of *poultry* in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (see Article 7.6.17.).

## a) Requirements for effective use

- i) The stunner control device should generate sufficient current (more than 600 mA/duck and more than 300 mA/bird) to stun.
- ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- iii) Birds should be restrained, at a minimum manually, close to an electrical supply.
- iv) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- v) Birds should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

## b) Advantages

Non-invasive technique (when combined with cervical dislocation) minimises biosecurity risk.

## c) Disadvantages

- i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations.
- ii) The electrodes must be applied and maintained in the correct position to produce an effective stun.
- iii) Birds must be individually restrained.
- iv) It must be followed by a *killing* method.

## d) Conclusion

Method 3 is suitable for small numbers of *poultry*.

Annex XVII (contd)

## Article 7.6.12.

**CO<sub>2</sub> / air mixture (under study)**1. Introduction

Controlled atmosphere *killing* is performed by exposing *animals* to a predetermined gas mixture, either by placing them in a gas-filled container or apparatus (Method 1) or by the gas being introduced into a *poultry* house (Method 2) or by placing transport modules or crates containing birds in a gas tight container and introducing a gas mixture (Method 3). Method 2 should be used whenever possible, as it eliminates *welfare* issues resulting from the need to manually remove live birds. Although Method 3 requires handling and crating of the birds, it benefits overall bird *welfare* as it eliminates chances of causing *death* by smothering or suffocation when compared with Method 1.

Inhalation of carbon dioxide (CO<sub>2</sub>) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, *death*. Exposure to carbon dioxide does not induce immediate loss of consciousness; therefore the aversiveness of various gas mixtures containing high concentrations of CO<sub>2</sub> and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus.

- a) Requirements for effective use in a *container* or apparatus
  - i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.
  - ii) When *animals* are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.
  - iii) *Animals* can also be introduced to low concentrations (as low concentrations are not aversive) and the concentration could be increased afterwards and the *animals* then held in the higher concentration until *death* is confirmed.
  - iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.
  - v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.
- b) Advantages
  - i) CO<sub>2</sub> is readily available.
  - ii) Application methods are simple.

- c) Disadvantages
- i) The need for properly designed *container* or apparatus.
  - ii) The aversive nature of high CO<sub>2</sub> concentrations.
  - iii) No immediate loss of consciousness.
  - iv) The risk of suffocation due to overcrowding.
  - v) Difficulty in verifying *death* while the *animals* are in the container or apparatus.
- d) Conclusion

Method 1 is suitable for use in *poultry*, and neonatal sheep, goats and pigs. But CO<sub>2</sub> is likely to cause a period of distress in the *animals* before they lose consciousness.

### 3. Method 2

In this method, the crates or modules full of birds are loaded into a chamber and gas is introduced into the chamber. As shown in the example below, each containerised gassing unit (CGU) typically consists of a gas-tight chamber designed to accommodate *poultry* transport crates or a module. The chamber is fitted with gas lines and diffusers, with silencers which in turn are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top to permit displaced air to escape during filling the container with gas.

Procedures involved in the operation of CGU includes (a) position the container on a level solid open ground; (b) connect gas cylinder to the container (c) load a module full of birds into the container, (d) shut and secure the door, (e) deliver the gas until 45% by volume of carbon dioxide was achieved at the top of the container, (f) allow time for the birds to become unconscious and die, (g) open the door, allow gas to be dispersed in air, (h) remove the module, (i) check each drawer for survivors; (j) humanely kill survivors, if any; and (k) dispose carcasses appropriately.



Figure source: Department of Clinical Veterinary Science, University of Bristol, United Kingdom.

Annex XVII (contd)

Figure source: Department of Clinical Veterinary Science, University of Bristol, United Kingdom.



Figure source: Department of Clinical Veterinary Science, University of Bristol, Langford, Bristol, United Kingdom.

- a) Requirements for effective use of containerised gassing units (CGU)
- i) The birds should be gently caught and placed in crates or modules of appropriate size and at appropriate stocking densities to allow all birds to sit down.
  - ii) The crates or module full of birds should be placed inside the container and the door shut only when the operator is ready to administer the gas.
  - iii) Ensure the container door is locked and administer the gas until a minimum of 40% carbon dioxide is achieved on top of the crates.
  - iv) Appropriate gas meter should be used to monitor and maintain the level of carbon dioxide continuously during the operation.

## Annex XVII (contd)

- v) Sufficient exposure time should be allowed for birds to die before the door is opened. Cessation of vocalisation and convulsive wing flapping sounds, which can be listened to by standing couple of metres away from the container, can be used to determine the presence of unconsciousness, and *death* will be imminent. Remove the crates or modules out of the container and leave them in atmospheric air.
- vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements under this situation indicate *death*.
- vii) Any survivors should be humanely killed.
- viii) Ducks and geese are resilient to the effects of carbon dioxide and therefore require a minimum of 80% CO<sub>2</sub> and longer exposure time to die.

## b) Advantages

- i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.
- ii) Gradual rising of CO<sub>2</sub> concentration minimises the aversiveness of the induction of unconsciousness with this gas.
- iii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the *poultry* house.
- iv) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.
- v) CO<sub>2</sub> is readily available.
- vi) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.
- vi) The volume of gas required can be readily calculated.
- vii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operators health and safety.
- viii) The system uses skilled catching teams and equipment in daily use by the industry.
- ix) Metal containers can be readily cleansed and disinfected.

## c) Disadvantages

- i) Requires trained operators, trained catchers, transport modules and fork lift but such equipment is usually available and suitable area with hard surface.
- ii) The main limiting factors are speed of catching and availability of gas.
- iii) It is difficult to visually confirm *death* while the birds are still in the container (however, cessation of vocalisations can be used to determine onset of *death*).

## Annex XVII (contd)

## d) Conclusion

- i) Method 3 is suitable for use in *poultry* in a wide range of *poultry* systems which have access to vehicles to carry containers and handling equipment.
- ii) *Animals* should be introduced into the container or apparatus, which is then sealed and filled as quickly as possible thereafter with the required gas concentrations, i.e. more than 40% CO<sub>2</sub> and held in this atmosphere until *death* is confirmed.
- iii) Method 3 is suitable for use in *poultry*, and neonatal sheep, goats and pigs. But CO<sub>2</sub> is likely to cause a period of distress in the *animals* before they lose consciousness.

## 24. Method 2-3

The gas is introduced into a *poultry* house.

## a) Requirements for effective use in a poultry house

- i) Prior to introduction of the CO<sub>2</sub>, the *poultry* house should be appropriately sealed to allow control over the gas concentration. The interval between sealing and gas administration should be kept to the minimum so as to avoid overheating.

Forced ventilation systems, where fitted, will have to be switched off prior to gas administration.

Mains water supply to the house may have to be turned off and water drained to avoid freezing and bursting of water pipes.

Feeders and water troughs will have to be lifted to avoid obstruction and prevent injury to birds.

- ii) Gas delivery pipes or lancets should be positioned appropriately such that birds are not hit directly by the very cold gas delivered at high pressures. It may be necessary that birds are excluded at the front of the delivery pipes for a distance of about 20 meters by partitioning the house with nets, wire mesh or similarly perforated materials.
- iii) The house should be gradually filled with CO<sub>2</sub> so that all birds are exposed to a concentration of >40% until they are dead; a vaporiser may be required to prevent freezing.
- iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

## b) Advantages

- i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.
- ii) CO<sub>2</sub> is readily available.
- iii) Gradual raising of CO<sub>2</sub> concentration minimises the aversiveness of the induction of unconsciousness.

## c) Disadvantages

- i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO<sub>2</sub> in some *poultry* houses.
- ii) It is difficult to verify *death* while the birds are in the *poultry* house.

iii) The extremely low temperature of liquid CO<sub>2</sub> entering the house and formation of solid CO<sub>2</sub> (dry ice) are also bird welfare concerns.

d) Conclusion

Method 2 is suitable for use in *poultry* in closed-environment sheds. This method could be developed for killing pigs. But CO<sub>2</sub> is likely to cause a period of distress in the birds before they lose consciousness.

Article 7.6.13.

## Nitrogen and/or inert gas mixed with CO<sub>2</sub>

### 1. Introduction

CO<sub>2</sub> may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is <2%. Various mixtures of CO<sub>2</sub> and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 3 described under Article 7.6.12. Whole house gassing with mixtures of CO<sub>2</sub> and nitrogen or an inert gas has not been tested owing to the complexity of mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO<sub>2</sub> and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

Pigs and *poultry* appear not to find low concentrations of CO<sub>2</sub> strongly aversive, and a mixture of nitrogen or argon with <30% CO<sub>2</sub> by volume and <2% O<sub>2</sub> by volume can be used for *killing poultry*, neonatal sheep, goats and pigs.

### 2. Method 1

The *animals* are placed in a gas-filled *container* or apparatus

#### a) Requirements for effective use

- i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O<sub>2</sub> and CO<sub>2</sub> concentrations accurately measured during the *killing* procedure.
- ii) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.
- ii) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2% O<sub>2</sub>), and held in this atmosphere until *death* is confirmed.
- iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.
- v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

#### 5. b) Advantages

Low concentrations of CO<sub>2</sub> cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

Annex XVII (contd)4. c) Disadvantages

- i) A properly designed *container* or apparatus is needed.
- ii) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.
- iii) There is no immediate loss of consciousness.
- iv) Exposure times required to kill are considerable.

5. d) Conclusion

The method is suitable for *poultry*, and for neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules full of birds are loaded into a container and gas is introduced into the container (refer to Figures under Article 7.6.12). As shown in the example below, each containerised gassing unit (CGU) typically consists of a gas-tight chamber designed to accommodate *poultry* transport crates or a module. The container or chamber is fitted with gas lines and diffusers, with silencers which in turn are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top to permit displaced air to escape during filling the container with gas.

Procedures involved in the operation of CGU includes (a) position the container on a level solid open ground; (b) connect gas cylinder to the container (c) load a module full of birds into the container, (d) shut and secure the door, (e) deliver the gas until <2% by volume of oxygen was achieved at the top of the container, (f) allow time for the birds to become unconscious and die, (g) open the door, allow gas to be dispersed in air, (h) remove the module, (i) check each drawer for survivors; (j) humanely kill survivors, if any; and (k) dispose carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)

- i) The birds should be gently caught and placed in crates or modules of appropriate size and at appropriate stocking densities to allow all birds to sit down.
- ii) The crates or module full of birds should be placed inside the container and the door shut only when the operator is ready to administer the gas mixture.
- iii) Ensure the container door is locked and administer the gas mixture until <2% residual oxygen is achieved on top of the crates.
- iv) Appropriate gas meter should be used to monitor and maintain the level of oxygen continuously during the operation.
- v) Sufficient exposure time should be allowed for birds to die before the door is opened. Cessation of vocalisation and wing flapping sounds, which can be listened to by standing couple of metres away from the container,, can be used to determine the onset of *death* in birds. Remove the crates or modules out of the container and leave them in atmospheric air.
- vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements under this situation indicate *death*.

vii) Any survivors should be humanely killed.

viii) Ducks and geese do not appear to be resilient to the effects of a mixture 20% carbon dioxide and 80% nitrogen or argon.

b) Advantages

i) The gas mixture is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the *poultry* house.

iii) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

iv) Mixtures containing up to 20% carbon dioxide in argon are readily available as welding gas cylinders.

v) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.

vi) Two CGU can be operated in tandem and throughputs of up to 4,000 chickens per hour are possible.

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoors the gas is dispersed quickly at the end of each cycle by opening the door, improving operators' health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal containers can be readily cleansed and disinfected.

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and fork lift but such equipment is usually available and suitable area with hard surface.

ii) The main limiting factors are speed of catching and availability of gas mixtures.

iii) It is difficult to visually confirm *death* while the birds are still in the container (however cessation of localisations can be used to determine onset of *death*).

d) Conclusion

i) Method 2 is suitable for *poultry*, and for neonatal sheep, goats and pigs.

ii) Method 2 is suitable for use in *poultry* in a wide range of *poultry* systems which have access to vehicles to carry containers and handling equipment.

iii) *Animals* should be introduced into the container or apparatus, which is then sealed and filled as quickly as possible thereafter with the gas mixtures and a residual oxygen of less than 2% should be achieved and maintained, and birds should be held in this atmosphere until *death* is confirmed.

Annex XVII (contd)

## Article 7.6.14.

**Nitrogen and/or inert gases**1. Introduction

This method involves the introduction of *animals* into a container or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

Research has shown that hypoxia is not aversive to pigs and *poultry*, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

- a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O<sub>2</sub> concentration accurately measured.
- b) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.
- c) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2% O<sub>2</sub>), and held in this atmosphere until *death* is confirmed.
- d) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.
- e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid *animals* suffocating by climbing on top of each other.

3. Advantages

*Animals* are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to *animals*.

4. Disadvantages

- a) A properly designed *container* or apparatus is needed.
- b) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.
- c) There is no immediate loss of consciousness.
- d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for *poultry* and neonatal sheep, goats and pigs.

Whole house gassing of *poultry* with nitrogen has been tested in Denmark and Sweden. Nitrogen can also be used in containerised gassing systems however evidence is lacking. Therefore, these two methods of administration could be described as under development.

## Article 7.6.15.

**Lethal injection**1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and *death*. In practice, barbiturates in combination with other drugs are commonly used.

2. Requirements for effective use

- a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.
- b) Prior sedation may be necessary for some *animals*.
- c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.
- d) *Animals* should be restrained to allow effective administration.
- e) *Animals* should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

- a) The method can be used in all species.
- b) *Death* can be induced smoothly.

4. Disadvantages

- a) *Restraint* and/or sedation may be necessary prior to injection.
- b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious *animals*.
- c) Legal requirements and skill/training required may restrict use to veterinarians.
- d) Contaminated carcasses may present a risk to other wild or domestic *animals*.

5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs and *poultry*.

## Article 7.6.16.

**Addition of anaesthetics to feed or water**1. Introduction

An anaesthetic agent which can be mixed with *poultry* feed or water may be used to kill *poultry* in houses. *Poultry* which are only anaesthetised need to be killed by another method such as cervical dislocation.

Annex XVII (contd)2. Requirements for effective use

- a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.
- b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.
- c) Must be followed by *killing* (see Article 7.6.17.) if birds are anaesthetised only.

3. Advantages

- a) Handling is not required until birds are anaesthetised.
- b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

- a) Non-target *animals* may accidentally access the medicated feed or water when provided in an open environment.
- b) Dose taken is unable to be regulated and variable results may be obtained.
- c) *Animals* may reject adulterated feed or water due to illness or adverse flavour.
- d) The method may need to be followed by *killing*.
- e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for *killing* large numbers of *poultry* in houses, provided a back-up method is available to kill birds that are only anaesthetised.

Article 7.6.17.

**Cervical dislocation and decapitation**1. Cervical dislocation (manual and mechanical)

## a) Introduction

Unconscious *poultry* may be killed by either manual cervical dislocation (stretching) or mechanical neck crushing with a pair of pliers. Both methods result in *death* from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

When the number of birds to be killed is small, and other methods of *killing* are not available, or are impracticable, conscious birds of less than 3 kilograms may be killed using cervical dislocation in a way that the blood vessels of the neck are severed. and death is instantaneous.

## b) Requirements for effective use

- i) *Killing* should be performed either by manually or mechanically stretching the neck to sever the spinal cord or by using mechanical pliers to crush the cervical vertebrae with consequent major damage to the spinal cord.

Annex XVII (contd)

- ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.
  - iii) Birds should be monitored continuously until *death* to ensure the absence of brain stem reflexes.
  - c) Advantages
    - i) It is a non-invasive *killing* method.
    - ii) It can be performed manually on small birds.
  - d) Disadvantages
    - i) Operator fatigue.
    - ii) The method is more difficult in larger birds.
    - iii) Requires trained personnel to perform humanely.
    - iv) Human health and safety concerns due to handling of the birds.
    - v) Additional stress to the *animals* from handling.
2. Decapitation
- a) Introduction
    - i) Decapitation results in *death* by cerebral ischaemia using a guillotine or knife.
  - b) Requirements for effective use
    - i) The required equipment should be kept in good working order.
  - c) Advantages
    - i) The technique is effective and does not require monitoring.
  - d) Disadvantages
    - i) The working area is contaminated with body fluids, which increases biosecurity risks.
    - ii) Pain due to loss of consciousness not being immediate.

Article 7.6.18.

## **Pithing and bleeding**

### 1. Pithing

#### a) Introduction

Pithing is a method of *killing animals* which have been stunned by a penetrating captive bolt, without immediate *death*. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

Annex XVII (contd)

- b) Requirements for effective use
  - i) Pithing cane or rod is required.
  - ii) An access to the head of the *animal* and to the brain through the skull is required.
  - iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.
- c) Advantages
 

The technique is effective in producing immediate *death*.
- d) Disadvantages
  - i) A delayed and/or ineffective pithing due to convulsions may occur.
  - ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

- a) Introduction
 

Bleeding is a method of *killing animals* through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and *death*.
- b) Requirements for effective use
  - i) A sharp knife is required.
  - ii) An access to the neck or chest of the *animal* is required.
  - iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.
- c) Advantages
 

The technique is effective in producing *death* after an effective *stunning* method which does not permit pithing.
- d) Disadvantages
  - i) A delayed and/or ineffective bleeding due to convulsions may occur.
  - ii) The working area is contaminated with body fluids, which increases biosecurity risks.

Article 7.6.19. (under study)

Foam as a killing method for poultry1. Introduction

In fire fighting terms, foam is usually defined, on the basis of volume of foam produced to the volume of liquid used as low (20:1), medium (up to 200:1) and high (over 200:1) expansion foam. Medium expansion fire fighting foam made using air bubble has been used to create a blanket over live birds in order to deprive them of oxygen, and causing *death*. It was concluded that birds died due to occlusion of the upper respiratory tract with the foam. A physiological definition of suffocation is the physical separation of the upper respiratory tract from the atmospheric air, and therefore, occlusion of the upper respiratory tract with foam or water would amount to *death* due to suffocation or asphyxiation, which are unacceptable from *animal welfare* point of view.

Therefore, high expansion foam made with 100% carbon dioxide or nitrogen has been tested for killing *poultry*. Research has shown that birds do not show any aversive reactions to high expansion foam with large diameter (10 to 50 mm) made using gases. Therefore, high expansion foam with large diameter and made using industrial gases such as carbon dioxide or nitrogen has potential to be an acceptable method of killing *poultry*.

## 2. Requirements for effective use

- a) Foam expansion ratio should be at least 300:1.
- b) Diameter of foam should be at least 10mm.
- c) Foam should be made using 100% carbon dioxide, nitrogen or inert gases (argon) or mixtures of these gases.
- d) Surfactant used in foam making should be non-irritant, non-corrosive and the surfactant and water mixture should be buffered adequately to avoid causing discomfort to birds.
- e) Foam should be administered into *poultry* houses as rapidly as possible in a calm manner, without causing distress or panic among the birds.

## 3. Advantages

- a) Foam can be administered without entering *poultry* houses.
- b) Administration of a gas in foam will minimise disturbances to live birds.
- c) *Poultry* houses may not have to be sealed for the purpose containing gases.
- d) Standard firefighting foam makers can be deployed.

## 4. Disadvantages

- i) Availability of foam making devices, surfactants and gas in large quantities.
- ii) Surface run-off and its consequences for biosecurity.

## 4. Conclusion

High expansion foam with large diameter and made using industrial gases such as carbon dioxide or nitrogen has potential to be an acceptable method of killing *poultry*.

Article 7.6.20. (under study)

## Use of carbon monoxide for killing *poultry*.

### 1. Introduction

Inhalation of carbon monoxide leads to unconsciousness and *death*. However some argue that convulsions may occur prior to loss of consciousness. It is also lethal at low concentrations and highly explosive at concentrations above 12.5% by volume.

## Annex VII (contd)

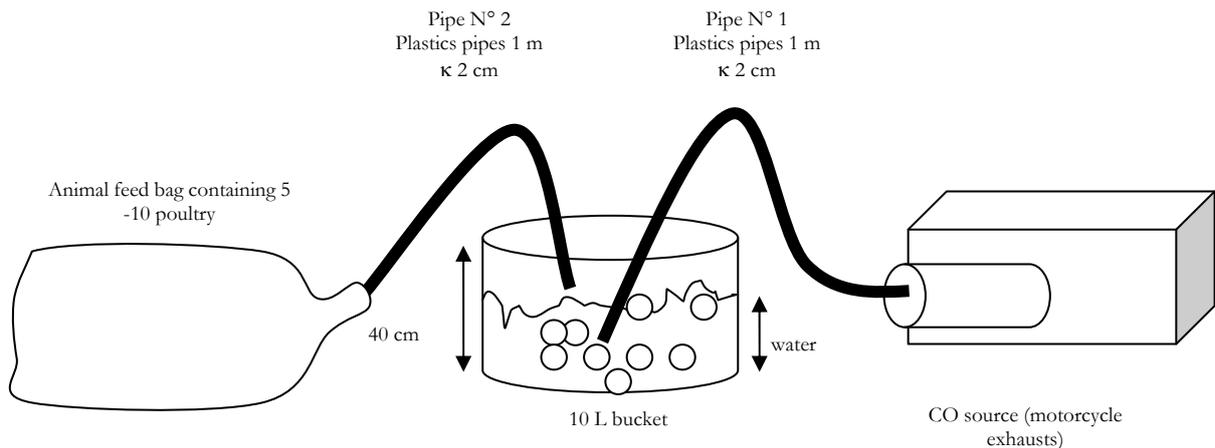
There are two methods of application: Method 1 involves the introduction of *poultry* into a container or apparatus containing carbon monoxide; Method 2 involves administration of carbon monoxide into *poultry* houses.

Carbon monoxide could be delivered from a pure (100%) source or as a mixture of gases generated by using a petrol engine. The concentration required to killing *poultry* has been estimated to be 1.5 to 2.0% in air.

### Method 1:

Exhaust gas from a badly tuned motorcycle engines has been used to generate carbon monoxide, however in low concentrations. An example is presented in the schematic diagram below.

#### Schema of Method 1



### Method 2 : Administration into *poultry* houses

Carbon monoxide can be delivered using a pure source and it is being lighter than air may diffuse very rapidly throughout the house.

## 2. Requirements for effective use

Carbon monoxide concentration should be measured in both Methods.

### a) Method 1:

- i) The time to attain a lethal concentration of this gas in the container (or bag) will depend upon the generator or engine.

- ii) The exhaust gas should be cooled and filtered prior to administration.
- iii) Poultry should be introduced into the container or apparatus after it has been filled with the required gas concentration, and held in this atmosphere until *death* is confirmed.
- iv) Team members should ensure that there is sufficient time allowed for each batch of *poultry* to die before subsequent ones are introduced into the container or apparatus.
- v) Containers or apparatus should not be overcrowded.
- vi) Operators' health and safety should not be compromised.

#### b) Method 2

An exclusion zone of several meters around the vicinity of the house may ensure human safety and the explosive nature of the gas require the presence of fire brigade.

- i) Carbon monoxide should be delivered using a pure source.

### 3. Conclusion

Carbon monoxide is suitable for *poultry*.

#### Article 7.6.21.

Prohibited methods include ventilation shut down as a sole method of killing *poultry*.

---

-----  
 — text deleted  
 -----

<sup>1</sup> The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head/body.



