

**WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
Horizontal chapters		
Restructuring of the Code	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the <i>Codes</i> , notably Glossary, User's Guide, Section 4 on Disease prevention and control and Section 5 on Trade measures, import/export procedures and veterinary certification	Ongoing
	2) Work with BSC for accurate disease description and diagnostic in the <i>Manual</i> and case definitions in the <i>Code</i> and names of diseases and country and zone disease status	Ongoing
	3) Revision and formatting of chapters (articles numbering, tables and figures)	Ongoing
	4) Revision of the Users' Guide	Sent for comments and proposed for adoption May 2020
Glossary	1) 'Epidemiological unit'	Revised definition sent for comments and proposed for adoption May 2020 (Sep 2018/3 rd)
	2) 'Competent Authority', 'Veterinary Authority'. 'Veterinary Services'	Ongoing
	3) Captive wild [animal]', 'feral' and 'wild'	Revised definitions sent for comments (Sep 2018/2 nd)
	4) Review animal welfare terms 'slaughter', 'euthanasia', 'stunning', 'death', 'pain', 'distress' and 'suffering'	Revised and new definitions sent for comments (Sep 2019/1 st)
	5) New definitions for 'animal product', 'product of animal origin' and 'animal by-product'	Preliminary discussion
	6) Review the terms 'notify', 'notifiable disease', 'report' and 'reportable disease'	Preliminary discussion
Horizontal issues not yet in the Code		
Section 3. Veterinary Services	1) New introductory CH in Section 3	Sent for comments (Sep 2019/1 st)
Section 4. Disease control	1) New CH on official control programmes for listed and emerging diseases	Sent for comments and proposed for adoption May 2020 (Feb 2017/ 6 th)
	2) New CH on biosecurity	Preliminary discussion
	3) New CH on application of zoning	Preliminary discussion

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
Section 6. Veterinary public health	1) Control of Shiga toxin-producing <i>E. coli</i> (STEC) in food-producing animals	Preliminary discussion pending FAO/WHO expert consultation
Section 7. Animal welfare	1) New CH on AW and laying hen production systems	Sent for comments and proposed for adoption May 2020 (Sep 2017/3 rd)
Horizontal chapters in need of revision		
Section 1. Animal disease diagnosis, surveillance and notification	1) CH 1.6 on procedures for publication of a self-declaration of disease freedom, recognition of an official animal health status and endorsement of an official control programme by the OIE	Sent for comments and proposed for adoption May 2020 (Feb 2018/4 th)
	2) CH 1.1 on notification of diseases	Sent for comments and proposed for adoption May 2020 (Sep 2018/3 rd)
	3) CH 1.3 on listed diseases: <ul style="list-style-type: none"> • <i>T. lestoquardi</i>, <i>T. luwenshuni</i>, <i>T. uilenbergi</i> and <i>T. orientalis</i> • Chronic wasting disease • MERS-CoV 	Sent for comments (Sep 2019/1 st)
	4) CH 1.3 on listed diseases: <ul style="list-style-type: none"> • Theileriosis • West Nile fever • <i>M. paratuberculosis</i> 	Preliminary discussion
Section 3. Veterinary Services	1) CH 3.4 on veterinary legislation	Revised CH sent for comments and proposed for adoption May 2020 (Sep 2018/3 rd)
	2) CHs 3.1 and 3.2 on Veterinary Services	Revised CHs sent for comments (Sep 2019/1 st)
Section 4. Disease control	1) CH 4.6 on general hygiene in semen collection and processing centres	Ongoing
	2) CH 4.7 on collection and processing of semen	Ongoing
	3) CH 4.4 on zoning and compartmentalisation	Ongoing discussions on protection zone
	4) BVD in collection and processing of <i>in vivo</i> derived embryos	Ongoing
	5) CH 4.14 on disinfection	Preliminary discussion
	6) CH 4.8 on collection and processing of <i>in vivo</i> derived embryos	Preliminary discussion
	7) CH 4.9 on collection and processing of oocytes and <i>in vitro</i> produced embryos from livestock and horses	Preliminary discussion
Section 5. Trade measures	1) CHs 5.4 to 5.7 on measures applicable at departure and on arrival	Preliminary discussion
	2) CH 5.12 on model certificates for competition horses	Preliminary discussion and pending revision of CHs on horse diseases

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
Section 6. Veterinary public health	1) CH 6.3 on meat inspection	Preliminary discussion pending AHG
	2) CH 6.10 on responsible and prudent use of antimicrobial agents in veterinary medicine	Pending expert advice
Section 7. Animal welfare	1) CH 7.5 on slaughter and CH 7.6 on killing of animals	Ongoing and CH 7.5 sent for comments (Sep 2019/1 st)
	2) CH 7.7 on stray dog population control	Pending report of AHG
Diseases not yet in the Code		
Disease-specific chapters	1) New CH on animal trypanosomoses of African origin	Sent for comments (Sep 2019/1 st)
	2) New CH on surra (and revision of CH on Dourine)	Pending expert advice
	3) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter)	Preliminary discussion
Listed disease chapters/articles in need of revision		
Sections 8 to 15	1) CH 10.4 on avian influenza	Sent for comments and proposed for adoption May 2020 (Sep 2018/2 nd)
	2) CH 11.4 on bovine spongiform encephalopathy and CH 1.8 Questionnaire	Sent for comments (Feb 2015/2 nd)
	3) CH 8.8 on foot and mouth disease	Pending outcome of discussion on protection zone (CH 4.4) and of expert advice (Sep 2015/2 nd)
	4) CH 14.7 on peste des petits ruminants (Harmonisation of articles regarding official status recognition by the OIE)	Sent for comments and proposed for adoption May 2020 (Feb 2019/2 nd)
	5) CH 15.2 on classical swine fever	Sent for comments and proposed for adoption May 2020 (Feb 2017/3 rd)
	6) CH 8.15 on Rift Valley fever virus	Sent for comments (Feb 2019/2 nd)
	7) CH 8.16 on rinderpest	Pending work AHG
	8) Revision of safe commodities list to add lactose	Ongoing
	9) CH 12.2 on contagious equine metritis	Pending work of HQs and expert advice
	10) CH12.7 on equine piroplasmiasis	Pending work of HQs and expert advice
	11) CH 12.6 on equine influenza	Sent for comments (Sep 2019/1 st)
	12) CH 11.10 on Theileriosis and new CH 14.X. on infection with <i>Theileria</i> in small ruminants	Ongoing (Sep 2017/1 st)
	13) CH 8.11 on Mycobacterium tuberculosis complex	Ongoing

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	14) CH 12.3 on dourine	Pending expert advice
	15) Revision of Article 15.3.9 on import of semen from countries not free from PRRS	Pending expert advice
	16) CH 14.8 on scrapie	Pending expert advice
	17) CH 10.5 on avian mycoplasmosis	Pending expert advice
	18) CH 9.4 on <i>Aethina Tumida</i> (Small hive beetle)	Preliminary discussion
	19) Pet food (for certification or safe commodities)	Pending expert advice
Follow-up revision of chapters recently adopted		
Recently adopted chapters	1) CH 8.14 on rabies	Pending expert advice
	2) CH 6.2 on the role of Veterinary Services in food safety systems	Pending discussion on definitions of VS, VA and CA

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	<i>ad hoc</i> Group
AMR	Antimicrobial resistance
AW	Animal Welfare
BSC	Biological Standards Commission
CH	Chapter
HQs	Headquarters
MERS-CoV	Middle East Respiratory Syndrome Coronavirus

GLOSSARY

CAPTIVE WILD [ANIMAL]

means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under or requires direct human supervision or control, i.e. such as population management, regular contacts or handling, regular feeding, harvesting and protection from predators or slaughter; including this includes zoo *animals* and pets.

FERAL [ANIMAL]

means an *animal* of a domesticated species that now lives without direct requiring human supervision or control.

WILD [ANIMAL]

means an *animal* that has a phenotype unaffected by human selection and lives independently of direct without requiring human supervision or control.

SLAUGHTER

means any killing procedure that causes the death of an animal by bleeding of animals primarily for human consumption.

EUTHANASIA

means killing the act of inducing death using a method that causes a rapid and irreversible loss of consciousness with the most rapid, painless and distress free method possible minimum pain and distress to animal.

STUNNING

means any mechanical, electrical, chemical or other procedure that causes rapid immediate loss of consciousness with minimal pain and other types of suffering; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; in the absence of *slaughter*, the procedure would allow the *animal* to recover consciousness.

DEATH

means the irreversible permanent loss of all vital functions brain activity demonstrable by the loss of brain stem reflexes. This may be confirmed through a combination of criteria such as dilated pupil and absence of corneal reflex, cardiac activity and breathing.

DISTRESS

means the state of an *animal*, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Annex 18 (contd)

PAIN

means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

SUFFERING

means an unpleasant, undesired state of being that is the outcome of the impact on an animal of noxious negative stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare.

CHAPTER 1.3.

**DISEASES, INFECTIONS AND INFESTATIONS
LISTED BY THE OIE**

Article 1.3.1.

The following are included within the category of multiple species diseases, *infections* and *infestations*:

- Anthrax
- Crimean Congo hemorrhagic fever
- Equine encephalomyelitis (Eastern)
- Heartwater
- Infection with animal trypanosomes of African origin (*T. vivax*, *T. congolense*, *T. simiae* and *T. brucei*)
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with epizootic hemorrhagic disease virus
- Infection with foot and mouth disease virus
- Infection with *Mycobacterium tuberculosis* complex *bovis* and *Mycobacterium caprae* [under study]
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Surra (*Trypanosoma evansi*)
- Tularemia
- West Nile fever.

Article 1.3.2.

The following are included within the category of cattle diseases and *infections*:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine viral diarrhoea

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- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infection with lumpy skin disease virus
- Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Theileriosis
- Trichomonosis
- **Trypanosomosis (tsetse-transmitted).**

[...]

Article 1.3.9.

The following are included within the category of other diseases and *infections*:

- Camelpox
 - **Infection of dromedary camels with Middle East Respiratory Syndrome Coronavirus**
 - Leishmaniosis.
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This draft chapter would replace Chapter 3.1 in the 2019 edition of the *Terrestrial Code*. Considering the significant changes in the text, only a clean version is provided.

DRAFT CHAPTER 3.1.

QUALITY OF VETERINARY SERVICES

Article 3.1.1.

General considerations

The quality of *Veterinary Services* depends on ethical, organisational, legislative and technical factors.

Compliance with standards of quality is critical for *Veterinary Services* to meet their animal health, *animal welfare*, and veterinary public health objectives, and is important for the establishment and maintenance of trust in *international trade*.

Veterinary Services should conform to the fundamental operating principles in Article 3.1.2., regardless of the political, economic or social situation of their country.

The key components of a country's *Veterinary Services* are presented in Articles 3.1.3 to 3.1.12. Four components are focused on governance aspects: Policy and Management, Personnel and Resources, the Veterinary Profession, and Stakeholders; and six components are focused on technical aspects: Animal Health, Animal Production Food Safety, Veterinary Medicinal Products, Laboratories, Animal Welfare and International Trade.

This chapter should be read in conjunction with other chapters in the *Terrestrial Code*, relevant chapters of the *Terrestrial Manual* with regards to quality of *laboratories*, diagnosis and vaccines, as well as relevant Codex Alimentarius texts.

Article 3.1.2.

Fundamental operating principles

Veterinary Services should comply with the following interrelating principles to ensure the quality of their activities:

1. Professional judgement

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

2. Independence and objectivity

Care should be taken to ensure that personnel are free from any undue commercial, financial, hierarchical, political or other pressures which might adversely affect their judgement or decisions. The *Veterinary Services* should, at all times, act in an objective manner.

3. Impartiality

Veterinary Services should be impartial. In particular, all the parties affected by their activities have a right to expect that their services are delivered reasonably and without discrimination.

4. Integrity

Veterinary Services should maintain a consistently high level of integrity. Any fraud, corruption or falsification should be identified and addressed.

Annex 20 (contd)5. Transparency

Veterinary Services should be as transparent as possible in all their governance and technical activities, including but not limited to, disease reporting, policy and programme decision-making, human resources and financial issues.

6. Scientific basis

Veterinary Services should develop and implement their activities on a scientific basis, incorporating relevant inputs from fields such as *risk analysis*, epidemiology and economics.

Article 3.1.3.

Policy and management

Veterinary Services should have the leadership, organisational structure and management systems to develop, implement and update policies, legislation and programmes, incorporating *risk analysis* and sound epidemiological principles. *Veterinary Services'* decision making should be free from undue financial, political and non-scientific influences.

The *Veterinary Authority* should coordinate with other *Competent Authorities* and should undertake active international engagement with OIE and other relevant regional and international organisations.

This component should comprise the following specific elements:

- 1) Comprehensive national *veterinary legislation* in accordance with Chapter 3.4, regularly updated with reference to changing international standards and science.
- 2) Implementation of *veterinary legislation* through a programme of communications and awareness, as well as formal, documented inspection and compliance activities.
- 3) Capability to perform *risk analysis* and cost-benefit analysis to define and adapt policies and programmes.
- 4) Policies or programmes that are well documented, resourced and sustained, appropriately reviewed and updated to improve their effectiveness and efficiency, and addressing emerging issues.
- 5) Quality management systems with quality policies, procedures and documentation suited to the *Veterinary Services'* activities, including procedures for information sharing, complaints and appeals and for internal audits.
- 6) Information management systems for collecting data to monitor and evaluate *Veterinary Services'* activities and to perform *risk analysis*.
- 7) Organisational structures with defined roles and responsibilities for effective internal coordination from central to field levels (chain of command) for activities, which are periodically reviewed and updated as necessary.
- 8) Formal external coordination mechanisms with clearly described procedures or agreements for activities between the *Veterinary Authority*, *Competent Authorities* and stakeholders, incorporating a One Health approach.
- 9) Appropriate levels of official representation at international multilateral fora, with pre-consultation with stakeholders, active participation and sharing of information, and follow up on meeting outcomes.

Article 3.1.4.

Personnel and resources

Veterinary Services should be appropriately staffed, including *veterinarians*, *veterinary paraprofessionals* or other personnel, with appropriate competencies through initial and continuing education to allow for their functions to be undertaken effectively and efficiently.

Annex 20 (contd)

Veterinary Services should have functional and well-maintained physical resources, adequate operational resources for their ongoing and planned activities, and access to extraordinary resources to respond effectively to emergency situations or new emerging issues.

This component should comprise the following specific elements:

- 1) A core of full-time civil service employees with qualified *veterinarians* and *veterinary paraprofessionals*.
- 2) Formal, consistent and merit-based recruitment and promotion procedures.
- 3) Job descriptions, formal performance assessment and management procedures for *veterinarians*, *veterinary paraprofessionals* and other personnel that are defined and being implemented.
- 4) Personnel remuneration, sufficient to minimise the risk of conflicts of interest and to preserve independence.
- 5) *Veterinarians'* and *veterinary paraprofessionals'* education, knowledge, skills and practices, standardised and sufficient to perform relevant activities of the *Veterinary Services*.
- 6) *Veterinary paraprofessionals* are adequately supervised by *veterinarians*.
- 7) All personnel have access to continuing education programmes that are reviewed and updated as necessary.
- 8) Established procedures for *Veterinary Services* to access personnel and other resources, including in emergencies.
- 9) Access to suitable physical resources at all levels (national, state/provincial and local), including, but not limited to, functional buildings, furniture, equipment, communications, information technology, transport and cold chain, which are maintained or renewed as necessary.
- 10) Access to sufficient operational resources for planned and continued activities, as well as for new or expanded operations, including but not limited to, contracts, fuel, per diem, vaccines, diagnostic reagents, personal protective equipment and other consumables.

Article 3.1.5.

The veterinary profession

Veterinarians and *veterinary paraprofessionals* are an essential component of *Veterinary Services*, whether as part of governmental authorities or as private service providers.

The *Veterinary Statutory Body* should regulate *veterinarians* and *veterinary paraprofessionals* to effectively and independently maintain educational and professional standards, including for both official tasks and veterinary clinical services. Mechanisms for coordination between the *Veterinary Authority*, the *Veterinary Statutory Body* and veterinary educational establishments should be in place.

The OIE has produced guidelines on the expected competencies for *veterinarians* and *veterinary paraprofessionals* as well as guidelines on the curricula necessary to deliver those competencies.

This component should comprise the following specific elements:

- 1) An independent *Veterinary Statutory Body*, legally responsible and adequately resourced for:
 - a) licensing and registration of *veterinarians* and *veterinary paraprofessionals* to perform defined activities of veterinary science or animal health;
 - b) setting minimum standards of education required to be registered or licensed as *veterinarians* or *veterinary paraprofessionals*.

Annex 20 (contd)

- c) setting minimum standards of professional conduct and competence of registered *veterinarians* and *veterinary paraprofessionals* and ensuring that these standards are met and maintained;
 - d) investigating complaints and applying disciplinary measures.
- 2) Independence of the *Veterinary Statutory Body* is ensured through transparent governance and funding arrangements including an elected, representative council or equivalent, and financial arrangements for the collection and management of registration fees.
 - 3) Sufficient veterinary clinical services are available of sufficient quality to meet the needs of animal owners, including their access to essential animal disease and injury diagnosis and treatment.

Article 3.1.6.

Stakeholders

A range of individuals or organisations have an interest or concern in the activities of the *Veterinary Services*, for example livestock farmers, processors, traders, feed manufacturers, private *veterinarians* and *veterinary paraprofessionals*, as well as relevant non-governmental organisations (NGOs) and the general public.

Veterinary Services should communicate with these stakeholders in an effective, transparent and timely manner on *Veterinary Services* activities and developments in animal health, animal welfare and veterinary public health. They should also consult effectively with relevant stakeholders on *Veterinary Services* policies and programmes, involving mechanisms that actively seek their views for consideration and response.

Competent Authorities should, where applicable, have the authority and capability to develop or engage in public private partnerships to deliver animal health, animal welfare or veterinary public health outcomes. That is:

- to accredit, authorise or delegate to the private sector;
- the development or participation in collaborative joint programmes with producers or other stakeholders.

The OIE has produced guidelines for both public and private sectors to help advocate for, develop and implement public private partnerships in the veterinary domain.

This component should comprise the following specific elements:

- 1) Good governance relevant to all stakeholder engagement is in place to ensure compliance with Article 3.1.2, incorporating transparency and effective monitoring and evaluation.
- 2) Ongoing, targeted and effective communication with stakeholders in accordance with Chapter 3.3.
- 3) Consultation mechanisms, including written invitation, meetings or workshops with non-government stakeholder representatives, with consultation inputs documented and duly considered.
- 4) Public private partnerships, in the form of official delegation or joint programmes, have the legal authority, formal agreements, and documented procedures, in accordance with Chapter 3.4.

Article 3.1.7.

Animal health

Veterinary Services should organise and implement programmes to prevent, control or eradicate animal diseases, and should be able to identify *animals* to trace and control their movements.

Veterinary Services should organise and implement an effective animal health surveillance system and be prepared to respond effectively to sanitary emergencies.

This component should comprise the following specific elements:

- 1) Effective surveillance for the early detection, monitoring and reporting of animal diseases via an appropriate field animal health network, using laboratory confirmation and epidemiological disease investigation with prompt and transparent reporting, in accordance with relevant chapters, including Chapters 1.1., 1.2., 1.3., 1.4. and 1.5.
- 2) An updated list of *notifiable diseases* that includes relevant *listed diseases*.
- 3) Use of the formal procedures for self-declaration and official recognition by the OIE for both disease freedom and disease control programmes, in accordance with Chapter 1.6.
- 4) Emergency management, including preparedness and response planning, a legal framework, and access to the human, physical and financial resources to respond rapidly to sanitary emergencies in a well-coordinated manner, including for disposal and *disinfection* in accordance with Chapters 4.13. and 4.14.
- 5) *Official control programmes* for priority diseases with scientific and risk-based evaluation of their efficacy and efficiency, in accordance with the relevant chapters of the *Terrestrial Code*.
- 6) A programme for managing the risks to animal health from germplasm, including the collection, processing and distribution of semen, oocytes or embryos, in accordance with the relevant chapters in Section 4.
- 7) A programme for the official health control of bee diseases, in accordance with Chapter 4.15.
- 8) A programme for managing the risks to animal and public health from animal *feed*, including feeding animal materials to susceptible livestock, in accordance with Chapter 6.4.
- 9) A system for *animal identification*, *animal traceability* and movement control for specific animal *populations* as required for traceability or disease control, in accordance with Chapters 4.1. and 4.2.

Article 3.1.8.

Animal production food safety

Veterinary Services should contribute to assuring the safety of food of animal origin for domestic and export markets as part of a food safety system, with effective coordination of official controls between relevant *Competent Authorities*.

This component should comprise the following specific elements:

- 1) Regulation, inspection, authorisation and supervision of establishments and processes for production and processing of food of animal origin (slaughter, rendering, dairy, egg, honey and other animal product processing establishments) for export, national and local markets, including the inspection, sampling and testing of products, in accordance with Chapters 6.1. and 6.2.
- 2) Implementation of procedures for ante-mortem and post-mortem inspection at slaughter facilities, incorporating *risk analysis* and principles of Hazard Analysis and Critical Control Point (HACCP), veterinary supervision, independent inspection, and the collection of information relevant to livestock diseases and zoonoses, in accordance with Chapters 6.2. and 6.3. and the relevant Codex Alimentarius texts.
- 3) Regulation and implementation of controls on animal *feed* safety covering processing, handling, storage, distribution and use of both commercial and on-farm produced animal *feed* and *feed ingredients*, including risks such as microbial, physical, chemical and toxin contamination.
- 4) A residue monitoring programme for veterinary medicines (e.g. antimicrobials and hormones), chemicals, pesticides, radionuclides, heavy metals, etc. and the capacity to respond appropriately to adverse findings.
- 5) Identification and traceability of products of animal origin for the purposes of food safety, animal health or trade, in accordance with Chapter 6.2.

Annex 20 (contd)

- 6) Procedures for corrective actions or sanctions in response to regulatory non-compliance to mitigate risks to the safety of food of animal origin for export or domestic markets in accordance with Article 6.2.3.
- 7) Preparedness and response planning to manage food or *feed* safety incidents of animal origin.

Article 3.1.9.

Veterinary medicinal products

Veterinary Services should regulate all *veterinary medicinal products* such as veterinary medicines, biologicals and medicated *feed*, in order to ensure their quality and safety, as well as their responsible and prudent use, including *monitoring* antimicrobial use and antimicrobial resistance, and minimising the associated risks.

This article should be read in conjunction with the *Terrestrial Manual*, which set standards for the production and control of vaccines and other biological products.

This component should comprise the following specific elements:

- 1) Effective regulatory and administrative control, in accordance with Article 3.4.11., including communications and compliance programmes for:
 - a) the market authorisation of *veterinary medicinal products*, including registration, import, manufacture, quality control, and reducing the risk from illegal imports;
 - b) responsible and prudent use of *veterinary medicinal products*, including the labelling, distribution, sale, dispensing, prescription and administration of these products.
- 2) *Risk management* and *risk communication* for antimicrobial use and antimicrobial resistance, based on *risk assessment*. This includes *surveillance* and control of the use of antimicrobials and the development and spread of antimicrobial resistant pathogens in animal production, animal origin food products, via a One Health approach, and in accordance with Chapter 3.4. and relevant chapters of Section 6.

Articles 3.1.10.

Laboratories

Veterinary Services should have access to quality *laboratory* diagnosis through a sustainable network of *laboratories*, capable of accurately identifying and reporting *infections* and *infestations* or other relevant *hazards*.

Veterinary Services require *laboratory* services for purposes such as early detection, measuring disease prevalence and progress with control, assessing *veterinary medicinal products* quality and protection, antimicrobial resistance *surveillance*, assessing the safety of food or *feed*, or supporting *international trade* (e.g. demonstration of freedom). The *laboratory* services include official government laboratories and other *laboratories* authorised by the *Competent Authorities* to conduct official testing, including private laboratories or those overseas.

This article should be read in conjunction with the *Terrestrial Manual*, which sets *laboratory* diagnostic standards for all OIE *listed diseases* as well as several other diseases of global importance.

This component should comprise the following specific elements:

- 1) access to *laboratory* diagnosis that meets the needs of the *Veterinary Services*, which is efficient and sustainable with an appropriate throughput of samples, in accordance with the *Terrestrial Manual*;
- 2) access to approved *laboratories*, such as national, regional or international reference laboratories, to obtain or confirm a correct diagnosis for *notifiable diseases* and to investigate *emerging diseases* or *hazards*, in accordance with the *Terrestrial Manual*;

- 3) appropriate levels of laboratory biosafety and *biosecurity*;
- 4) formal *laboratory* Quality Management Systems and proficiency testing programmes, in accordance with the *Terrestrial Manual*.

Article 3.1.11.

Animal welfare

Veterinary Services should implement policies, legislation and programmes in accordance with Section 7.

This component should comprise the following specific elements:

- 1) *animal welfare* programmes, supported by suitable legislation, with appropriate stakeholder and public awareness and compliance inspection activities;
- 2) communication, consultation and coordination with stakeholders.

Article 3.1.12.

International trade

Through the implementation of OIE standards, *Veterinary Services* play a critical role in ensuring the safety of *international trade of commodities and veterinary medicinal products*, while avoiding unjustified barriers.

Veterinary Services should implement risk-based measures for import and export following relevant provisions in the *Terrestrial Code* and in accordance with Chapter 5.3. Quality of *Veterinary Services* is essential for these measures to be recognised and trusted.

This component should comprise the following specific elements:

- 1) *Sanitary measures* developed and implemented in accordance with Chapter 2.1. and other relevant chapters of the *Terrestrial Code*.
- 2) Effective implementation of *official veterinary controls* to prevent the entry of diseases and other *hazards* through effective border inspection and quarantine operations, in accordance with Chapter 5.6.
- 3) Effective application of relevant animal health measures at or before departure for exports, during transit through the country, and on arrival for imports, in accordance with Chapters 5.4., 5.5. and 5.7.
- 4) Effective development and implementation of international veterinary certification for *animals*, animal products, services and processes for export under their mandate, in accordance with importing country requirements and relevant chapters in Section 5.
- 5) Effective development, implementation and maintenance of equivalence and other types of sanitary agreements with trading partners, where applicable, in collaboration with national stakeholders, and in accordance with Chapter 5.3.
- 6) Regular and timely official notification to the OIE, WTO, trading partners and other relevant organisations of changes in animal disease status, regulations and *sanitary measures* and systems, in accordance with the procedures established by these organisations, including Chapters 1.1. and 1.3.
- 7) Where applicable, effective implementation and maintenance of disease-free *zones, compartments* or other high health status *subpopulations* for the purposes of trade, in collaboration with producers and other stakeholders, and in accordance with relevant chapters in Sections 4 and 5.
- 8) Active participation in the OIE and Codex Alimentarius standard setting processes.

This draft chapter would replace Chapter 3.2 in the 2019 edition of the *Terrestrial Code*. Considering the significant changes in the text, only a clean version is provided.

DRAFT CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

Article 3.2.1.

General considerations

This chapter covers the evaluation of a country's *Veterinary Services*, including the various objectives and types of evaluation that may be considered.

Member Countries may develop their own mechanisms and methods for the evaluation of their *Veterinary Services*. The evaluation of the quality of *Veterinary Services* should be in accordance with Chapter 3.1.

The OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) provides a thorough, benchmarked methodology for the consistent, comprehensive evaluation of *Veterinary Services*. The OIE PVS Tool is aligned with the OIE standards, in particular, with the quality standards for *Veterinary Services* defined in Chapter 3.1. Based on the OIE PVS Tool, the OIE has developed a capacity building platform, the PVS Pathway, for the sustainable improvement of a country's *Veterinary Services'* compliance with OIE standards.

Article 3.2.2.

Objectives of the Evaluation of Veterinary Services

The evaluation of *Veterinary Services* has the following objectives:

- 1) to provide an independent, objective perspective on the performance of *Veterinary Services*;
- 2) to verify performance, provide confidence, enhance reputation and avoid complacency, and as part of a process of continuous improvement;
- 3) to demonstrate compliance of the *Veterinary Services* with Chapter 3.1.;
- 4) to better advocate for, allocate and prioritise resources;
- 5) to generate trust between trading partners in the quality and integrity of *Veterinary Services*.

The evaluation of *Veterinary Services* can be performed by the country itself (self-evaluation), by another country or countries, or by OIE experts under the auspices of the OIE as part of the PVS Pathway.

Article 3.2.3.

Self-evaluation of the Veterinary Services of a Member Country

- 1) Member Countries should undertake a self-evaluation of their *Veterinary Services* periodically as part of their quality management system.
- 2) Self-evaluation may be undertaken by *Competent Authorities* for the whole or part of the *Veterinary Services*.
- 3) Self-evaluation at the sub-national level such as of individual provinces or states can usefully supplement national level evaluation.
- 4) The use of the OIE PVS Tool is encouraged.

Annex 21 (contd)

Article 3.2.4.

Evaluation of the Veterinary Services of a Member Country by another Member Country

- 1) Every Member Country should recognise the right of another Member Country to request an evaluation of its *Veterinary Services* to facilitate decision-making on trade.
- 2) The evaluation should be in accordance with Chapter 3.1.
- 3) The evaluation process may be desktop or field based, and cover whole or part of the *Veterinary Services*, depending on its objective.
- 4) A Member Country which intends to conduct an evaluation of another Member Country's *Veterinary Services* should give them notice in writing. This should define the purpose and scope of the evaluation and detail the information required.
- 5) Prior to the evaluation, the parties should agree on the objective, scope and approach of the evaluation, including any requirements of confidentiality.
- 6) The evaluation should be conducted in accordance with the Fundamental Operating Principles set-out for *Veterinary Services* in Article 3.2.2 in a timely and efficient manner, ensuring the level of evaluation activity is undertaken only to the extent necessary.
- 7) The evaluation should start with a review of available information including existing PVS Pathway or other reports, analysis of publicly available or previously provided information, or historical performance such as relating to safe trade or transparency.
- 8) The outcome of the evaluation conducted by another Member Country should be provided in writing to the evaluated country as soon as possible. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify any points of the evaluation on request.
- 9) The use of the OIE PVS Tool is encouraged.

Article 3.2.5.

Evaluation of the Veterinary Services of a Member Country by OIE experts, under the auspices of the OIE

- 1) The OIE has established procedures for the evaluation of the *Veterinary Services* of a Member Country using the OIE PVS Tool, following a voluntary request from the Member Country.
 - 2) The report of such an evaluation belongs to the *Veterinary Authority* of the Member Country. The OIE encourages Member Countries to make their reports publicly available.
 - 3) Member Countries are encouraged to use these reports in a transparent way to achieve some or all of the objectives listed in Article 3.2.2.
 - 4) Support for further use of the evaluation report in national planning and targeted capacity building is available from the OIE as part of its PVS Pathway.
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DRAFT CHAPTER 3.X.

**INTRODUCTION TO RECOMMENDATIONS
ON VETERINARY SERVICES**

Article 3.X.1.

Veterinary Services are critical to global and national health security, food security and food safety, agricultural and rural development, poverty alleviation, safe *international trade*, *wildlife* and environmental protection; as such they are considered a global public good. To achieve these goals, *Veterinary Services* require good governance, including effective policy and management, personnel and resources, veterinary professionals and interaction with stakeholders.

Member Countries have the sovereign right to structure and manage the delivery of animal health, *animal welfare* and veterinary public health in the veterinary domain in their countries as they see fit. The veterinary domain covers a broad scope of possible activities. Section 3 focuses on aspects of the *Veterinary Services* that enable the OIE standards to be met even when under the responsibility of one or more *Competent Authorities*.

Member Countries should implement the OIE standards across their whole territory and should meet their obligations at the international level through representation by their respective OIE Delegate. The *Veterinary Authority*, including the OIE Delegate, should coordinate with other *Competent Authorities* to ensure international standards and responsibilities are met.

Veterinary Services have responsibility for implementing the activities necessary for the Member Country to comply with OIE standards. These activities can be delivered by a combination of individuals or organisations, public or private that are responsible to one or more *Competent Authorities*. *Veterinary Services* also include the personnel of the *Competent Authorities* themselves. The term *Veterinary Services* refers to the combination of a number of separate actors, with different organisational affiliations.

Section 3 provides standards to assist the *Veterinary Services* of Member Countries in meeting their objectives of improving terrestrial animal health and *animal welfare* and veterinary public health, as well as to establish and maintain confidence in their *international veterinary certificates*.

DRAFT CHAPTER 7.5.

ANIMAL WELFARE DURING SLAUGHTER

Article 7.5.1.

Introduction

Providing good welfare to the animals at *slaughter* is ethically and economically beneficial. The implementation of animal welfare measures contributes to the improvement of workers' safety and product quality, and is essential for food safety [Blokhuis *et al.*, 2008; Lara and Rostagno, 2018].

Article 7.5.2.

Scope

This chapter identifies potential *animal welfare hazards* during *slaughter* and provides recommendations for arrival and *unloading, lairage*, handling, *restraint, stunning* and bleeding of animals in *slaughterhouses/abattoirs*. It provides animal-based measures to assess the level of welfare and recommends remedial actions to be applied, when necessary.

This chapter applies to the *slaughter* in *slaughterhouses/abattoirs* of the following domestic animals: cattle, buffalo, bison, sheep, goats, horses, pigs, rabbits and *poultry*, hereafter referred as “animals”. Recommendations consider whether animals arrive at the *slaughterhouse/abattoir* in *containers* or are free-moving.

This chapter should be read with the guiding principles for *animal welfare* provided in Chapter 7.1. and relevant provisions of Chapters 6.2. and 6.3.

The principles underpinning these recommendations may also apply to the *slaughter* of other species and those slaughtered in other places.

Article 7.5.3.

Definition for the purpose of this chapter

Bleeding means the act of severing major blood vessels that supply the brain, to ensure *death*.

Article 7.5.4.

Animal welfare hazards

Hazards to *animal welfare* during each of the pre-slaughter stages have an additive effect on the stress of the animals [Moberg and Mench, 2000].

At the *slaughterhouse/abattoirs*, animals are exposed to *animal welfare hazards* including fasting and water deprivation, mixing of unfamiliar *animals*, handling by humans, exposure to a novel environment (e.g. noise, lighting, flooring), forced physical exercise, limited space allowance, extreme weather conditions and inadequate *stunning* and bleeding. These *hazards* can have negative impacts on the welfare of the animals that can be assessed through animal-based measures. *Animal welfare hazards* can be minimised by appropriate design of premises and choice of equipment, and through good management, training and competency of personnel.

Article 7.5.5.

Criteria (or measures)

The welfare of animals at *slaughter* should be assessed using outcome-based measures. Although consideration should be given to the resources provided as well as the design and management of the system, animal-based criteria are preferential.

Annex 23 (contd)

The routine use of these outcome-based measures and the appropriate thresholds should be adapted to the different situations in which animals are managed at a *slaughterhouse/abattoir*. It is recommended that target values or thresholds for *animal welfare* measurables be based on current scientific knowledge and appropriate national, sectorial or regional standards.

Article 7.5.6.

Management

The *slaughterhouse/abattoir* operator is responsible for the development and enforcement of a dedicated operating plan that should consider the following:

- design of premises and choice of equipment;
- training and competency of personnel;
- throughput (number of animals slaughtered per hour);
- maintenance and cleaning procedures;
- contingency plans.

Article 7.5.7.

Training and competency of personnel

Animal handlers and other personnel have a crucial role to play in ensuring good *animal welfare* conditions from the time of arrival of the animals at the *slaughterhouse/abattoir* through to their *death*. Training for all personnel should emphasise the importance of *animal welfare* and their responsibility in contributing to the welfare of the animals that come through the *slaughterhouse/abattoir*.

Animal handlers should understand the behavioural patterns of animals and their underlying principles to carry out the required tasks whilst ensuring good *animal welfare*. They should be experienced and competent in handling and moving the animals and able to identify signs of pain and suffering. Personnel in charge of *restraint* and of *stunning* and bleeding operations should be familiar with the relevant equipment, their key working parameters and procedures. Personnel *stunning*, shackling and bleeding animals should be able to identify effective *stunning* of the animal and signs of recovery of consciousness, and should be able to take corrective actions, if necessary [EFSA, 2013a; EFSA 2013b].

Competencies may be gained through a combination of formal training and practical experience. These competencies should be assessed by the *Competent Authority* or by an independent body recognised by the *Competent Authority*.

Article 7.5.8.

Design of premises and choice of equipment

The design of premises and the choice of equipment used in a *slaughterhouse/abattoir* have an important impact on the welfare of animals. They should consider the animals' needs, in terms of their physical comfort including thermal conditions, protection from injury, protection from sudden or excessive noise, ability to perform natural and social behaviours as well as watering and feeding needs. Premises should be designed to eliminate distractions that may cause approaching animals to stop, baulk or turn back.

The design of the *slaughterhouse/abattoir* and choice of equipment should take into consideration the species, categories, quantities, and size or weight of the animals. *Restraint*, *stunning* and bleeding equipment is critical for the welfare of an animal at the time of *slaughter*. Appropriate back-up equipment should be available for immediate use in case of failure of the *stunning* equipment initially used.

Article 7.5.9.

Throughput (number of animals slaughtered per hour)

The throughput of the *slaughterhouse/abattoir* should never exceed the maximum specification of the design of the facilities or equipment and may be reduced depending on the welfare outcomes.

Personnel allocation should be adequate for the anticipated throughput and be sufficient to implement the *slaughterhouse/abattoir* operating plan as well as ante and post-mortem inspections.

Article 7.5.10.

Maintenance and cleaning procedures

All equipment should be clean and well maintained in order to ensure *animal welfare* and safety of personnel.

Maintenance and cleaning of *unloading, lairage* and moving facilities contributes to ensuring that animals are handled smoothly, preventing pain and fear.

Maintenance and cleaning of *restraining, stunning* and bleeding equipment is essential to ensure reliable and efficient *stunning* and *slaughter*, thereby minimising pain, fear and suffering.

Article 7.5.11.

Contingency plans

Contingency plans should be in place at the *slaughterhouse/abattoir* to protect the welfare of the animals in the event of an emergency. The contingency plans should consider the most likely emergency situations given the species slaughtered and the location of the *slaughterhouse/abattoir*.

Contingency plans should be documented and communicated to all responsible parties.

Article 7.5.12.

Arrival of free-moving animals

On arrival at the *slaughterhouse/abattoir*, animals will already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may affect the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare outcomes, and in accordance with Chapters 7.2. and 7.3.

1. Animal welfare concerns:

Delay in *unloading* of animals is the main *animal welfare* concern at arrival [NAMI, 2017].

Animals in *vehicles* have smaller space allowances than on farm, undergo water and *feed* deprivation, and may be exposed to thermal stress due to adverse weather conditions. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading* animals will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention will not be identified and therefore the duration of their suffering will be increased.

2. Animal-based and other measurables include:

It can be difficult to assess animal-based measures while animals are in the *vehicle*. Some measurables that may be assessed include animals with injuries, or those that are sick or have died. Panting, shivering and huddling may indicate thermal stress. Drooling and licking may indicate prolonged thirst.

Animals dead on arrival or condemned on arrival should be recorded and monitored as an indicator of *animal welfare* prior to and during transport.

Annex 23 (contd)

Time from arrival to *unloading* and the environmental temperature and humidity can be used to establish relevant thresholds for corrective action.

3. Recommendations:

Animals should be unloaded promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *lairage* area.

Consignments of animals assessed to be at greater risk of *animal welfare hazards* should be unloaded first. When no space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade or additional ventilation during waiting periods, or animals transported to an alternative nearby location where such provision is available.

4. Species-specific recommendations:

Pigs are especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in *unloading* this species.

Article 7.5.13.

Displacements of free-moving animals

This article addresses the handling of animals during *unloading* and *lairage*, and in the killing area.

1. Animal welfare concerns:

During *unloading*, animals are exposed to similar *hazards* to those encountered when being loaded (see Chapters 7.2. and 7.3). Inappropriate equipment in the *vehicle* or the *slaughterhouse/abattoir*, such as a lack of lateral protection when *unloading*, excessively steep ramps or an absence of foot battens, may result in animals slipping, falling or being trampled, causing injuries. These *hazards* can also be associated with inappropriate handling and forced physical movement of animals that are unable to move independently as a result of weakness or injuries. Exposure to novel environments (e.g. noise, lighting, flooring) will cause fear and reluctance to move, or turning back.

2. Animal-based and other measurables include:

- a) animals running, slipping and falling;
- b) animals with broken limbs;
- c) animals turning-back, reluctant to move;
- d) animals that are unable to move by themselves;
- e) animals that strike against the facilities;
- f) frequency of use of excessive force by personnel;
- g) frequency of use of electrical prods.

Animals are safely handled when these measures are below an acceptable threshold.

3. Recommendations:

Ramps should be positioned so that the animals can be handled safely. There should be no gap between the *vehicle* and the ramp, the gradient should not be too steep, and side barriers should be in place.

Preventive measures such as foot battens, rubber mats and deep groove flooring can help animals to avoid slipping.

Annex 23 (contd)

The *unloading* area and raceways should be well lit so that animals can see where they are going.

The design of *unloading* areas and raceways should aim to minimise the potential for distractions that may cause animals to stop, baulk or turn back when being unloaded (e.g. shadows, changes in flooring, moving objects). For details refer to Chapters 7.2. and 7.3.

Animals that are injured, sick or unable to rise require immediate action and, when necessary, should be euthanised without moving them and without delay. Refer to Articles 7.5.19. and 7.5.20.

Personnel should be calm and patient, assisting the animals to move using a soft voice and slow movements. They should not shout, kick, or use any other means that is likely to cause fear or pain to the animals. Under no circumstances should *animal handlers* resort to violent acts to move animals (see Article 7.5.20.).

Mechanical aids and electric goads should be used in a manner to encourage and direct movement of the animals without causing distress and pain. Preferred mechanical aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles.

Mechanical aids and electric goads should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.

Electric goads should only be used in extreme cases and not on a routine basis to move animals.

The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants, and never to 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.

The manual lifting of animals should be avoided; if it is necessary, animals should not be grasped or lifted in a manner which causes pain or suffering and physical damage (e.g. bruising, fractures, dislocations). (See Article 7.5.20.).

4. Species-specific recommendations:

None identified.

Article 7.5.14.

Lairage of free-moving animals

1. Animal welfare concerns:

Animals during *lairage* may be exposed to several *animal welfare hazards* including:

- a) food and water deprivation leading to prolonged hunger and thirst,
- b) absence of protection against extremes in climate leading to thermal stress,
- c) sudden or excessive noises, including from personnel, leading to fear,
- d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour,
- e) poor design and maintenance leading to distress and injuries,
- f) mixing of unfamiliar animals leading to aggressive behaviour,
- g) limited access to resources (e.g. drinkers, bedding) leading to aggressive behaviour.

Annex 23 (contd)2. Animal-based and other measurables include:

- a) thermal stress (e.g. panting, sweating, shivering, huddling behaviour),
- b) space allowance,
- c) excessive soiling with faeces,
- d) injuries (e.g. lameness, open wounds, fractures),
- e) illness (e.g. limping, diarrhoea, coughing),
- f) aggressive behaviours (e.g. mounting, fighting).

3. Recommendations:

Animals should have constant access to clean water. Water supply points should be designed according to the species and age of the animal, with environmental conditions that allow for effective consumption. The number and location of the water supply points should minimise competition.

Animals should be provided with *feed* in *lairage* if the duration between loading and expected time for *slaughter* exceeds 24 hours.

The *lairage* should provide animals with protection against adverse weather conditions.

Animals should be protected from excessive noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

Lairage areas should be free from sharp edges and other *hazards* that may cause injury to animals.

The *lairage* should provide enough space for all animals to lie down at the same time, to move freely and to move away in case of aggressive behaviours.

Lairage areas should have adequate lighting levels to allow inspection of the animals.

Animals from different groups (or different species) should not be mixed.

4. Species-specific recommendations:

None identified.

Article 7.5.15.

Restraint for stunning or bleeding (free-moving animals)1. Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* or bleeding equipment. Incorrect *restraint* may not only lead to ineffective *stunning* or bleeding, but also cause pain and distress.

Other *hazards* include:

- a) slipping or falling of animals entering the restraining area;
- b) struggling or escape attempts caused by insecure *restraint*;
- c) injuries and pain caused by excessive force of *restraint*;
- d) fear caused by prolonged *restraint*, which may exacerbate insecure or excessive *restraint*.

Annex 23 (contd)

In addition, *slaughter* without *stunning* increases the risk of pain and fear due to the need for robust *restraint* of conscious animals for neck cutting, especially if animals are turned on their sides or backs [von Holleben *et al.*, 2010; Pleiter, 2010].

2. Animal-based and other measurables include:

- a) animal slipping or falling;
- b) struggling;
- c) escape attempts;
- d) vocalisation (cattle and pigs);
- e) reluctance to enter the restrainer;
- f) frequency of use of electric goads.

3. Recommendations:

The restrainer should be narrow enough that the animals cannot move either backwards or forwards or turn around.

The restrainer being used should be appropriate to the size of the animals and the restrainer should not be loaded beyond its design capacity.

When restrainers are used that hold an animal with its feet off the floor, the animal must be held in a balanced, comfortable, upright position.

When a restrainer is used to rotate an animal from an upright position, the body and head must be securely held and supported to prevent struggling and slipping within the device.

Restrainers should not have sharp edges.

Non-slip flooring should be used to prevent animals from slipping or falling.

Distractions (e.g. movements of equipment or people) should be minimised to prevent balking and improve ease of entry into the restrainer.

No animals should enter the restrainer until equipment and personnel are ready to slaughter that animal.

No animals should be released from the restrainer until the operator has confirmed loss of consciousness.

4. Species-specific recommendations:

Gondolas for gas *stunning* of pigs should not be overloaded and pigs should be able to stand without being on top of each other.

Head *restraint* is recommended for cattle.

Article 7.5.16.

Stunning of free-moving animals1. Animal welfare concerns:

The main *animal welfare* concern associated with *stunning* is 'ineffective *stunning*' which results in pain, distress or fear during induction of unconsciousness and possible recovery before *death*.

The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere.

Annex 23 (contd)

Mechanical *stunning* is divided into penetrating and non-penetrating applications. Both applications aim to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly *et al.*, 1987; EFSA, 2004]. The main hazards preventing effective mechanical stunning are incorrect shooting position and incorrect direction of the impact. These may cause ineffective stunning and pain or short-lasting unconsciousness. Low bolt velocity, narrow bolt diameter or short length of bolt leading to shallow penetration, may also affect the effectiveness of *stunning*. In non-penetrating applications, high bolt velocity may cause fracture of the skull and ineffective *stunning* [Gibson *et al.*, 2014].

Electrical *stunning* involves application of an electric current to the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, dirty or corroded electrode, low voltage/current or high frequency [EFSA, 2004].

Controlled atmosphere *stunning* methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere *stunning*. The main *hazards* causing increased distress during induction of unconsciousness are irritant or aversive gas mixtures, low gas temperature and humidity. The main *hazards* causing ineffective controlled atmosphere *stunning* are incorrect gas concentration and short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].

2. Animal-based and other measurables include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before neck cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No single indicator should be relied upon alone.

Mechanical stunning:

An effective stun is characterised by the presence of all the following signs: immediate collapse; apnoea; tonic seizure; absence of corneal reflex; absence of eye movements.

The presence of any of the following signs may indicate an ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

Electrical stunning:

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs may indicate an ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

Gas stunning:

An effective stun is characterised by the presence of all the following signs: loss of posture; apnoea; absence of corneal reflex; absence of muscle tone.

The presence of any of the following signs may indicate an ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3. Recommendations:

Animals should be stunned as soon as they are restrained.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective stunning or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Annex 23 (contd)

Stunning equipment should be cleaned, maintained and stored following manufacturer's recommendations.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for *stunning*, such as:

a) Mechanical:

- position and direction of the shot [AVMA, 2016];
- grain of the cartridge or air pressure appropriate to the type of animal (captive bolt) [Gibson 2014];
- length and diameter of the bolt (captive bolt);
- calibre and type of gun and ammunition (free bullet).

b) Electrical:

- shape, size and placement of the electrodes [AVMA, 2016];
- pressure between electrode and head;
- electrical parameters (current, voltage and frequency);
- visual or auditory warning system to alert the operator to proper or improper function.

c) Controlled atmosphere:

- concentrations and exposure time;
- temperature and humidity.

4. Species-specific recommendations:

Non-penetrating captive bolt should not be used in mature cattle and pigs [Finnie, 1993 and Finnie *et al.*, 2003].

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of animals.

Article 7.5.17

Bleeding of free-moving animals

1. Animal welfare concerns:

The main *animal welfare* concern at the time of bleeding following *stunning* is the recovery of consciousness due to prolonged stun-to-stick interval or due to incomplete severance of the main blood vessels.

Bleeding without prior *stunning* increases the *risk* of animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience pain [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animal can feel fear, pain and distress [Gregory, 2004; Johnson *et al.*, 2015].

Absence of or ineffective *stunning* may result in animals being released from the *restraint*, shackled, and further processed while they are still conscious or have the potential to recover consciousness.

Annex 23 (contd)2. Animal-based and other measurables include:

The main animal-based measurable is the blood flow (rate and duration).

For animal-based and other measurables of return of consciousness after stunning see Article 7.5.16.

In cases of bleeding without *stunning* the animal-based and other measurables that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal reflex; absence of rhythmic breathing. In addition, cessation of bleeding can be used as an indicator of *death*.

3. Recommendations:

- a) continuous and rapid blood flow should be assured after bleeding;
- b) cessation of blood flow should be assured before further processing;
- c) bleeding knife should be sharpened for each animal.

In addition, the following should be considered:

Slaughter with stunning:

- a) the stun-to-stick interval should be short enough to ensure that the animal will die before recovering consciousness;
- b) unconsciousness should be confirmed before bleeding.

Slaughter without stunning:

- a) bleeding should be carried out by a single incision; any second intervention should be recorded and analysed to improve procedures.

4. Species-specific recommendations

None identified.

Article 7.5.18.

Slaughter of pregnant free-moving animals1. Animal welfare concerns:

Foetuses in the uterus cannot achieve consciousness [EFSA, 2017; Diesch *et al.*, 2005]. However, if removed from the uterus the foetus may perceive pain or other negative impacts.

2. Animal-based and other measurables include:

None identified.

3. Recommendations:

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/abattoir* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately.

The foetus should be left undisturbed in utero for at least 30 minutes after the *death* of the dam [EFSA, 2017; Anon, 2017].

In cases where the foetus is removed before 30 minutes has elapsed *euthanasia* should be carried out immediately.

4. Species-specific recommendations:

None identified.

Article 7.5.19.

Emergency killing of free-moving animals

This article addresses animals that show signs of severe pain or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of pain or suffering.

1. Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue pain and suffering. This is more likely in animals of low economic value.

2. Animal-based and other measurables include:

Animals requiring emergency *killing* are unable to walk independently or present severe injuries such as fractures, large open wounds, or prolapses. They may also present clinical signs of serious illness or being in a state of extreme weakness. New-born animals or animals that gave birth within the last 48 hours may also belong in this category.

3. Recommendations:

Animals should not be moved unless it can be done without causing further pain or suffering.

Animal handlers should euthanise the animal as soon as possible.

Emergency *killing* should be systematically recorded and analysed in order to improve procedures and prevent recurrences.

4. Species-specific recommendations:

None identified.

Article 7.5.20.

Methods, procedures or practices unacceptable on animal welfare grounds for free-moving animals

None of the following practices for handling animals are acceptable and should not be used:

- 1) crushing or breaking tails of animals;
- 2) applying pressure using an injurious object or applying an irritant substance to sensitive areas such as eyes, mouth, ears, anogenital region or belly;
- 3) hitting animals with instruments such as large sticks, sticks with sharp ends, metal piping, stones, fencing wire or leather belts;
- 4) throwing or dropping animals;
- 5) grasping, lifting or dragging animals only by some body parts such as their tail, head, horns, ears, limbs, wool or hair.

Annex 23 (contd)

None of the following practices for restraining animals are acceptable and should not be used:

- 1) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*;
- 2) breaking legs, cutting leg tendons or blinding animals;
- 3) severing the spinal cord, by using a puntilla or dagger;
- 4) applying electrical current that does not span the brain;
- 5) suspending or hoisting conscious animals by the feet or legs;
- 6) severing brain stem by piercing through the eye socket or skull bone.

Breaking the neck while the animal is still conscious during bleeding animals is also an unacceptable practice.

Article 7.5.XX.

Articles on animals arriving in containers [to be developed]

[....]

References

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CHAPTER 8.Y.

INFECTION WITH ANIMAL TRYPANOSOMES OF AFRICAN ORIGIN

Article 8.Y.1.

General provisions

- 1) Animal trypanosomes of African origin is a disease complex caused by several protozoan parasites of the genus *Trypanosoma*, transmitted mainly cyclically by the genus *Glossina* (tsetse flies), but also mechanically by several biting flies (e.g. tabanids, *Stomoxys* spp). The disease can be caused by many different trypanosomes and can affect various mammals such as horses, donkeys, camels, goats, sheep, pigs, dogs, cats and non-human primates. From the socio-economic point of view is particularly deleterious in cattle. Some trypanosomes of African origin (i.e. *T. brucei gambiense*, *T. brucei rhodesiense*) also affect humans and are responsible for a disease almost always fatal if untreated (sleeping sickness also known as human African trypanosomosis).
- 2) *Infection* with several trypanosome species in the same animal could exist although they may not always be evidenced.
- 3) For the purposes of this chapter, 'susceptible animals' means domestic and *wild animals* from the following families: bovidae, suidae, equidae, camelidae, canidae, felidae and non-human primates.
- 4) For the purposes of the *Terrestrial Code*, *infection* with animal trypanosomes of African origin is defined as an *infection* of susceptible animals with one or more Salivarian trypanosomes of the subgenus *Duttonella* (only *T. vivax*), *Nannomonas* (only *T. congolense* and *T. simiae*) and *Trypanozoon* (*T. brucei* spp excluding *T. evansi* and *T. equiperdum*), hereafter referred to as 'pathogenic agent'.
- 5) *Infection* of susceptible animals with *T. evansi* or *T. equiperdum* is covered by Chapter 8.X. and Chapter 12.3., respectively.
- 6) Other trypanosomes including *T. uniforme*, *T. godfreyi* and *T. suis*, which are rarely reported, of limited distribution and impact, do not play a significant role in the epidemiology of the disease; however, they should be considered in the *surveillance* system due to their interference (hidden *infection*) with the diagnosis of animal trypanosomes of African origin.
- 7) The following defines the occurrence of *infection* with animal trypanosomes of African origin:
 - a) the pathogenic agent has been observed in a sample from a susceptible animal; or
 - b) presence of genetic material specific to the pathogenic agent has been detected in a sample from a susceptible animal showing clinical signs consistent with *infection* with animal trypanosomes of African origin or which has an epidemiological link to a confirmed case; or
 - c) antibodies have been detected in a sample from a susceptible animal showing clinical signs consistent with *infection* with animal trypanosomes of African origin or which has an epidemiological link to a confirmed case in any susceptible animal species.
- 8) For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with animal trypanosomes of African origin in susceptible animals shall be 90 days.
- 9) Standards for diagnostic tests are described in the *Terrestrial Manual*.

Annex 24 (contd)

Article 8.Y.2.

Safe commodities

When authorising import or transit of the following *commodities* from susceptible animal, *Veterinary Authorities* should not require conditions related to animal trypanosomes of African origin regardless of the status of the *exporting country or zone*:

- 1) pasteurised *milk* and pasteurised *milk products*;
- 2) hair, wool and fibre;
- 3) gelatine;
- 4) horns, hooves and claws;
- 5) *meat products*;
- 6) hides and skins (except raw).

Article 8.Y.3.

Country or zone free from infection with animal trypanosomes of African origin

A *country or zone* may be considered free from *infection* with animal trypanosomes of African origin when:

- 1) the *infection* is notifiable in the entire country;
- 2) measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of *commodities* into the *country or zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;
- 3) and either:
 - a) the relevant provisions in point 2 of Article 1.4.6. have been complied with; or
 - b) for at least the past two years:
 - i) *surveillance* in accordance with Articles 8.Y.13. to 8.Y.16. has been in place in the entire country;
 - ii) there has been no *case of infection* with animal trypanosomes of African origin in the *country, zone or compartment*.

A *country or zone* free from *infection* with animal trypanosomes of African origin neighbouring to an infected *country or zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 8.Y.13. to 8.Y.16.

Article 8.Y.4.

Compartment free from infection with animal trypanosomes of African origin

The establishment and bilateral recognition of a *compartment* free from *infection* with animal trypanosomes of African origin should follow the provisions laid down in this chapter and in Chapters 4.4. and 4.5.

Susceptible animals in the free *compartment* should be protected against the *vectors* by the application of an effective *biosecurity* management system.

Article 8.Y.5.

Recovery of free status

Should a *case* of *infection* with animal trypanosomes of African origin occur in a previously free country or *zone*, its status may be recovered after the following:

- 1) infected *animals* have been isolated and then immediately treated, slaughtered, or killed and appropriately disposed of;
- 2) *animals* in contact with infected *animals* have been put immediately under *vector*-protection and tested;
- 3) and for six consecutive months, either:
 - a) after the last *case* was slaughtered or killed, the *animals* in contact have undergone monthly repeated serological and agent detection tests with negative results in both tests; or
 - b) when treatment is applied to the infected *animals*, both treated and in contact *animals* have undergone monthly repeated serological and agent detection tests with negative results in both tests;
- 4) *surveillance* in accordance with Articles 8.Y.13. to 8.Y.16. has been carried out with negative results;
- 5) appropriate *biosecurity* is in place, that may include *vector* control or *vector* protection in the affected area.

Otherwise, Article 8.Y.3. applies.

Article 8.Y.6.

Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African originFor susceptible animals

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

- 1) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of shipment;
- 2) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;
- 3) did not transit through an *infected zone* during transportation to the *place of shipment* or were protected from any source of animal trypanosomes of African origin during transportation to the *place of shipment*.

Article 8.Y.7.

Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African originFor semen

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

- 1) the donor males:
 - a) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;

Annex 24 (contd)

- b) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 8.Y.8.

Recommendations for importation from countries or zones infected with animal trypanosomes of African origin

For semen

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

- 1) the donor males:
 - a) were kept in isolation in a *vector-protected artificial insemination centre* for at least 90 days prior to semen collection;
 - b) were subjected, with negative results, to an agent identification test and an ELISA test for antibody detection adapted to the epidemiological situation on samples collected at entrance of the *vector-protected artificial insemination centre* and at least 90 days after the first test;
 - c) showed no clinical signs of *infection* with animal trypanosomes of African origin during the isolation period and on the day of collection;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 8.Y.9.

Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin

For *in vivo* derived embryos and for *in vitro* produced embryos

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

- 1) the donor females:
 - a) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;
 - b) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;
- 2) the semen used for the production of embryos complied with the provisions of Article 8.Y.7. or Article 8.Y.8.;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 8.Y.10.

Recommendations for importation from countries or zones infected with animal trypanosomes of African origin

For *in vivo* derived embryos and for *in vitro* produced embryos

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

Annex 24 (contd)

- 1) the donor females:
 - a) were kept in isolation in a *vector-protected collection centre* for at least 90 days prior to the collection;
 - b) were subjected, with negative results, to an agent identification test and an ELISA test for antibody detection adapted to the epidemiological situation on samples collected at entrance to the *vector-protected collection centre* and at least 90 days after the first test;
 - c) showed no clinical signs of *infection* with animal trypanosomes of African origin on the day of collection;
- 2) the semen used for the production of embryos complied with the provisions of Article 8.Y.7. or Article 8.Y.8.;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 8.Y.11.

Recommendations for importation from countries, zones or compartments free from infection with animal trypanosomes of African origin

For meat

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

- 1) were kept since birth in a free country, *zone* or *compartment* or were imported from a free country, *zone* or *compartment*;
- 2) have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.Y.12.

Recommendations for importation from countries or zones infected with animal trypanosomes of African origin

For meat

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat*:

- 1) comes from *animals* which have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results; and
- 2) either:
 - a) has been kept at a temperature lower than + 4°C for a minimum period of five days; or
 - b) has been subjected to any procedure of equivalent efficacy recognised by the *Veterinary Authority*.

Article 8.Y.13.

Introduction to surveillance

Articles 8.Y.13. to 8.Y.16. define the principles and provide guidance on *surveillance* for *infection* with animal trypanosomes of African origin, complementary to Chapter 1.4. and to Chapter 1.5.

The purposes of *surveillance* could be the demonstration of the absence of *infection*, the early detection of *cases*, or the measurement and monitoring of the *prevalence* and distribution of the *infection* in a country, *zone* or *compartment*.

Annex 24 (contd)

Vectors are an essential component of the epidemiology of animal trypanosomes of African origin. Therefore, the *surveillance* system should include a *vector surveillance* component to detect the presence and estimate the abundance of tsetse flies. When appropriate, it should also allow the estimation of the *vector infection* rate with animal trypanosomes of African origin. *Vector surveillance* may also aim the estimation of mechanical *vectors* abundance.

The impact and epidemiology of animal trypanosomes of African origin widely differs between different regions of the world and therefore, it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data explaining the epidemiology of the disease in the concerned country or *zone* and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

Wildlife should be considered in the *surveillance* system because they can serve as reservoirs of *infection* and as indicators of *risk* to humans and domestic *animals*. *Surveillance* in *wildlife* presents challenges that may differ significantly from those in domestic *animals*.

Article 8.Y.14.

General conditions and methods for surveillance

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular, it should include:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of disease;
 - b) a procedure for the rapid diagnosis in the field or for the collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data.
- 2) The *surveillance* programme for animal trypanosomes of African origin should, at least:
 - a) in a free country, *zone* or *compartment*, have an *early warning system* which obliges farmers and workers, who have regular contact with susceptible animals as well as diagnosticians, to report promptly any suspicion of animal trypanosomes of African origin to the *Veterinary Authority*.

An effective *surveillance* system will periodically identify suspected *cases* that require follow-up and investigation to confirm or exclude whether the cause of the condition is animal trypanosomes of African origin. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* should be investigated immediately, and samples should be taken and submitted to a *laboratory*;

- b) include the conduct random or targeted serological or parasitological *surveillance* appropriate to the status of the country or *zone*.

Article 8.Y.15.

Surveillance strategies

The target population should include domestic and *wild* susceptible animals of epidemiological significance within the country or *zone*. Active and passive *surveillance* for animal trypanosomes of African origin should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using parasitological, serological, clinical and entomological methods appropriate for the status of the country or *zone*.

In a free country or *zone*, it is appropriate to focus *surveillance* in an area neighbouring to a border of an infected country or *zone*, considering relevant ecological or geographical features likely to interrupt the transmission of animal trypanosomes of African origin.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with animal trypanosomes of African origin in accordance with Chapter 1.4. and Chapter 1.5., and with the prevailing epidemiological situation.

If a Member Country wishes to declare freedom from *infection* with animal trypanosomes of African origin in a specific *zone*, the design of the *surveillance* strategy should be targeted to the susceptible population within the *zone*.

For random surveys, the sample size selected for testing should be large enough to detect evidence of *infection* if it was to occur at a predetermined minimum rate. The sample size and expected *prevalence* determine the level of confidence in the results of the survey. The Member Country should justify the choice of the minimum expected *prevalence* and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *infection* history and the different species in the target population.

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

The principles involved in *surveillance* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* of animal trypanosomes of African origin should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated.

The results of random or targeted surveys are important in providing reliable evidence that no *infection* with animal trypanosomes of African origin is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results considering the movement history of the *animals* being sampled.

An active programme of *surveillance* of susceptible populations to detect evidence of *infection* with animal trypanosomes of African origin is essential to establish the *animal health status* of a country or *zone*.

1. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs of *infection* with animal trypanosomes of African origin in susceptible animals, particularly during a newly introduced *infection*. However, neither clinical nor post-mortem signs of *infection* with animal trypanosomes of African origin are pathognomonic. Therefore, diagnosis must rely on direct or indirect laboratory tests that confirm the presence of trypanosomes.

2. Parasitological surveillance

Suspected *cases* of animal trypanosomes of African origin detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

Parasitological *surveillance* can be conducted to:

- a) confirm clinically suspected *cases*;
- b) identify parasite at the subgenus level;
- c) confirm active *infection* after positive serological results.

3. Molecular techniques

Molecular techniques increase the sensitivity of the detection of active *infections*. They can also be applied to identify the parasite and to better characterise the genotype of circulating parasitic in a country or *zone*.

Annex 24 (contd)

Molecular techniques can be used to:

- a) detect an active *infection*;
- b) characterise the parasite at the species, subspecies, group and population level.

4. Serological surveillance

- a) Serological testing of susceptible animals is one of the most effective methods for detecting the exposure to animal trypanosomes of African origin. The host species tested should reflect the epidemiology of the *disease*. Management variables that may influence likelihood of *infection*, such as the use of insecticides or animal treatment, should be considered.
- b) Due to cross reactions with *T. evansi*, *T. equiperdum*, *T. cruzi* and *Leishmania* spp, the presence of these pathogenic agents should be considered when interpreting the results of the serological *surveillance* system.
- c) Serological *surveillance* can be used to:
 - i) demonstrate individual or population freedom;
 - ii) evidence subclinical or latent *infection* by animal trypanosomes of African origin;
 - iii) determine by seroprevalence the magnitude of *infection* by animal trypanosomes of African origin in the host population.
- d) Positive test results can have four possible causes:
 - i) active *infection*;
 - ii) *infection* (after effective treatment or self-cure);
 - iii) maternal antibodies;
 - iv) cross reactions with *T. evansi*, *T. equiperdum*, *T. cruzi* and *Leishmania* spp.

5. Sentinel animals

Sentinel *surveillance* may provide evidence of freedom from *infection* or provide data on *prevalence* and *incidence* as well as the distribution of disease or *infection*. Sentinel *surveillance* may consist of:

- a) the identification and regular testing of one or more of sentinel animal units of known health or immune status in a specified geographical location to detect the occurrence of *infection* with animal trypanosomes of African origin;
- b) the investigation of clinical suspect cases targeting highly susceptible animals such as dogs, donkeys or horses.

6. Vector surveillance

For the purposes of this chapter, *vector surveillance* aims at determining different levels of *risk* by identifying the various *vector* species presence and abundance in an area or demonstrating the absence of *vectors*.

Demonstration of absence of tsetse flies may support the claim of freedom from *infection* with animal trypanosomes of African origin that are cyclically transmitted.

The most effective way of gathering *vector surveillance* data should consider the biology and behavioural characteristics of the local *vector* species and include traps, fly rounds, sticky targets or other collection tools. *Vector surveillance* should be based on scientific sampling techniques. The choice of the number and type of collecting tools to be used and the frequency of their use should consider the size and ecological characteristics of the area to be surveyed.

When sentinel *animals* are used, *vector surveillance* should be conducted at the same locations.

Article 8.Y.16.

Additional surveillance procedures for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with animal trypanosomes of African origin.

Populations under this *surveillance* programme should include:

- 1) *establishments* in the proximity of the *outbreak*;
 - 2) *establishments* epidemiologically linked to the *outbreak*;
 - 3) *animals* moved from or used to re-populate affected *establishments*.
-

CHAPTER 8.15.

INFECTION WITH RIFT VALLEY FEVER VIRUS

Article 8.15.1.

General provisions

- 1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.
- 2) For the purposes of this chapter:
 - a) 'epizootic area' means a part of a country or zone in which an epizootic of RVF occurs, and which does not correspond to the definition of zone;
 - b) 'epizootic of RVF' means a sudden and unexpected change in the distribution or increase in incidence of, or morbidity or mortality of RVF;
 - c) 'inter-epizootic period' means a period with low levels of vector activity and low rates of RVF virus (RVFV) transmission;
 - d) 'susceptible animals' means ruminants and dromedary camels.
- 3) Humans and many animal species are susceptible to *infection*. For the purposes of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants susceptible animals with Rift Valley fever virus (RVFV).
- 4) The following defines the occurrence of *infection* with RVFV:
 - a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant susceptible animal; or
 - b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from a ruminant susceptible animal epidemiologically linked to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV; or
 - c) antibodies to RVFV antigens which are not the consequence of *vaccination*, have been identified in a sample from a ruminant susceptible animal with either epidemiological links to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV.
- 5) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days.
- 6) In areas where RVFV is present, epizootics of RVF may occur following favourable climatic, environmental conditions and availability of susceptible host and competent *vector* populations. Epizootics are separated by inter-epizootic periods. The transition from an inter-epizootic period to an epizootic complies with point 1) d) of Article 1.1.3. in terms of notification.
- 7) For the purposes of this chapter:
 - a) 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of zone;

Annex 25 (contd)

- b) 'epizootic of RVF' means the occurrence of *outbreaks* at an incidence substantially exceeding that during an inter-epizootic period ~~or the occurrence of indigenous human cases;~~
- c) 'inter-epizootic period' means the period of variable duration, often long, with intermittent low level of vector activity and low rate of virus transmission, which is often not detected;
- d) ~~ruminants include dromedary camels.~~
- 7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south western Arabian Peninsula. However, ~~vectors, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the infection.~~
- 78) When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.15.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant susceptible animal population of the *exporting country*.
- 89) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.15.2.

Safe commodities

When authorising import or transit of the following *commodities* and any products made from them, *Veterinary Authorities* should not require any RVF-related conditions, regardless of the RVF status of the ruminant susceptible animal population of the *exporting country*.

- 1) hides and skins;
- 2) wool and fibre.

Article 8.15.3.

Country or zone free from RVF

A country or a *zone* may be considered free from RVF when *infection* with RVFV is notifiable in the entire country and either:

- 1) it meets the requirements for historical freedom in point 1 a) of Article 1.4.6.; or
- 2) meets the following conditions:
 - a) an on-going pathogen-specific *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with RVFV in ruminants susceptible animals in the country or *zone* for a minimum of ten years; and
 - b) during that period no indigenous human cases have occurred in the country or *zone*.

A country or *zone* free from RVF will not lose its free status through the importation of ruminants susceptible animals that are seropositive, so long as they are either permanently identified as such or destined for immediate *slaughter*.

Article 8.15.4.

Country or zone infected with RVFV during the inter-epizootic period

A country or zone infected with RVFV, during the inter-epizootic period, is one that does not comply with Article 8.15.3, in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.

Article 8.15.5.

Country or zone infected with RVFV during an epizootic

A country or zone infected with RVFV, during an epizootic, is one in which outbreaks of RVF are occurring at an incidence substantially exceeding that of the inter-epizootic period; or one in which indigenous human cases of RVF are occurring even in the absence of detection of animal cases.

Article 8.15.6.

Strategies to protect from vector attacks during transport

Strategies to protect animals from vector attacks during transport should take into account the local ecology and potential insecticide resistance of the vectors, and potential risk management measures include:

- 1) treating animals and vehicles/vessels with insect repellents and insecticides prior to and during transportation;
- 2) loading, transporting and unloading animals at times of low vector activity;
- 3) ensuring vehicles/vessels do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect-proof netting;
- 4) using historical and current information to identify low risk ports and transport routes.

Article 8.15.7.

Recommendations for importation from countries or zones free from RVF**For ruminants susceptible animals**

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

- 1) were kept in a country or zone free from RVF since birth or for at least 14 days prior to shipment;

AND

- 2) either:
 - a) were vaccinated at least 14 days prior to leaving the free country or zone; or
 - b) did not transit through an epizootic area experiencing an epizootic during transportation to the place of shipment; or
 - c) were protected from vector attacks when transiting through an epizootic area experiencing an epizootic.

Article 8.15.8.

Recommendations for importation from countries or zones infected with RVFV during the inter-epizootic period**For ruminants susceptible animals**

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

Annex 25 (contd)

- 1) showed no clinical signs of RVF on the day of shipment;
- 2) met one of the following conditions:
 - a) were vaccinated against RVF at least 14 days prior to shipment ~~with a modified live virus vaccine~~; or
 - b) were held for at least 14 days prior to shipment in a *vector-protected quarantine station*, which is located in an area of demonstrated low *vector* activity. During this period the animals showed no clinical sign of RVF;

AND

- 3) either:
 - a) did not transit through an ~~area experiencing an epizootic area~~ during transportation to the *place of shipment*; or
 - b) were protected from *vector* attacks when transiting through an ~~area experiencing an epizootic area~~.

Article 8.15.98.

Recommendations for importation from countries or zones infected with RVFV during an epizooticFor ruminants susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the susceptible animals †

- 1) showed no clinical signs of RVF on the day of shipment;
- 2) did not originate ~~from an in the epizootic area of the epizootic~~;
- 3) were vaccinated against RVF at least 14 days prior to shipment;
- 4) were held for at least 14 days prior to shipment in a *vector-protected quarantine station*, which is located in an area of demonstrated low *vector* activity outside ~~the of an epizootic area of the epizootic~~. During this period the animals showed no clinical signs of RVF;
- 5) either:
 - a) did not transit through an epizootic area experiencing an epizootic during transportation to the *place of shipment*; or
 - b) were protected from *vector* attacks when transiting through an epizootic area experiencing an epizootic.

Article 8.15.109.

Recommendations for importation from countries or zones ~~not free from infected with RVFV~~For semen and *in vivo* derived embryos of ruminants susceptible animals

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

- 1) showed no clinical signs of RVF within the period from 14 days prior to and 14 days following collection of the semen or embryos;

AND

- 2) either:
- a) were vaccinated against RVF at least 14 days prior to collection; or
 - b) were demonstrated to be seropositive on the day of collection; or
 - c) testing of paired samples has demonstrated that seroconversion did not occur within 14 days of between semen or embryo collection and 14 days after.

Article 8.15. ~~1110~~.

Recommendations for importation of fresh meat and meat products from ruminants susceptible animals from countries or zones not free from infected with RVFV

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

- 1) the entire consignment of *meat* comes from:
 - 1a) ruminants which susceptible animals that showed no clinical signs of RVF within 24 hours before slaughter;
 - 2b) ruminants which susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;
 - 3c) carcasses which that were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;
- 2) the necessary precautions were taken to avoid contact of the products with any potential source of RVFV.

Article 8.15.10bis.

Recommendations for importation of meat products from susceptible animals from countries or zones infected with RVFV

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat products* comes from *meat* that complies with Article 8.15.10.

Article 8.15. ~~1211~~.

Recommendations for importation from countries or zones not free from infected with RVFV

For milk and milk products

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

- 1) was subjected to pasteurisation; or
- 2) was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Annex 25 (contd)

Article 8.15.1312.

Surveillance

Surveillance should be carried out in accordance with Chapter 1.4.

- 1) During an epizootic, *surveillance* should be conducted to define the extent of the affected area.
- 2) During the inter-epizootic period, *surveillance* and monitoring of climatic factors predisposing an epizootic should be carried out in countries or *zones* infected with RVFV.
- 3) Countries or *zones* adjacent to a country or *zone* in which epizootics have been reported should determine their RVF status through an on-going *surveillance* programme.

To determine areas of low *vector* activity (see Articles 8.15.87. and 8.15.98.) *surveillance* for arthropod *vectors* should be carried out in accordance with Chapter 1.5.

Examination of *vectors* for the presence of RVFV is an insensitive *surveillance* method and is therefore not recommended.

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions

The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Oral exposure to contaminated *feed* is the main route of transmission of classical BSE. Given that cattle have been experimentally infected by the oral route with L-type BSE, atypical BSE is also potentially capable of being recycled in a cattle population if cattle are orally exposed to contaminated *feed*.

BSE primarily affects cattle. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal is not practiced.

For the purposes of the *Terrestrial Code*:

- 1) BSE is an invariably fatal neurological prion disease of cattle caused by PrP^{BSE}, including both classical (C-type BSE) and atypical strains (H- and L-type BSE). The term 'BSE' includes both classical and atypical forms, unless otherwise specified.
- 2) The occurrence of a BSE case is defined by the immunohistochemical (IHC) or immunochemical detection of PrP^{BSE} in brain tissue of a bovid, with discrimination between atypical and classical BSE strains based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.

For the purposes of this chapter:

- 3) 'Cattle' means a bovid of the species *Bos taurus* or *Bos indicus*.
- 4) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino-acids.

When *commodities* are imported in accordance with this chapter, the BSE risk of the *importing country* or *zone* of destination is not affected by the BSE risk of the *exporting country, zone* or *compartment* of origin.

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

Article 11.4.1bis.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any conditions related to BSE, regardless of the BSE risk posed by the cattle population of the *exporting country, zone* or *compartment*.

- 1) *milk* and *milk products*;
- 2) *semen* and *in vivo* derived cattle embryos collected and handled in accordance with the relevant chapters of the *Terrestrial Code*;

Annex 26 (contd)

- 3) hides and skins;
- 4) gelatine and collagen;
- 5) tallow with maximum level of insoluble impurities of 0.15% in weight;
- 6) tallow derivatives;
- 7) dicalcium phosphate (with no trace of protein or fat).

Other *commodities* of cattle can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

The BSE risk of the cattle population of a country, zone or compartment

The BSE risk of the cattle population of a country, *zone* or *compartment* is determined on the basis of the following criteria:

- 1) a *risk assessment*, in accordance with the provisions of Chapter 1.8. that evaluates the likelihood of BSE being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.

A *risk assessment* for the purpose of BSE consists of:

- a) Entry assessment

An entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, *zone* or *compartment* via imported *commodities*.

- b) Exposure assessment

An exposure assessment evaluates the likelihood of cattle being exposed to BSE, either through imported *commodities* or as a result of the presence of BSE agents in the indigenous cattle population of the country, *zone* or *compartment*.

- c) Consequence assessment

A consequence assessment evaluates the likelihood of cattle becoming infected with BSE together with the likely extent of any subsequent recycling and amplification.

- d) Risk estimation

Risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal, with indigenous cases arising as a consequence;

- 2) the ongoing implementation of a *surveillance* programme for classical BSE in the cattle population;
- 3) the history of occurrence and management of BSE *cases*.

Article 11.4.3.

Negligible BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* can be considered to be negligible if the following conditions are met for at least eight years:

Annex 26 (contd)

- 1) A *risk assessment* as described in Article 11.4.2. has been conducted, and the Member Country has demonstrated through documented evidence that the likelihood of BSE agents being recycled in the cattle population has been negligible as the result of:

EITHER:

- a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;

OR

- b) effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.

- 2) The *surveillance* provisions as described in Article 11.4.18. have been implemented.

- 3) EITHER:

- a) there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter;

OR

- b) if there has been an indigenous case of classical BSE

EITHER:

- i) all cases were born at least eight years ago;

OR

- ii) where a case was born within the preceding eight years, subsequent investigations have confirmed that the likelihood of BSE being recycled within the cattle population has continued to be negligible.

- 4) Any cases of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal *feed* chain.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1) to 4) above. Documented evidence should be resubmitted annually for points 1) to 4) above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.3bis.

Recovery of negligible BSE risk status

When an indigenous case of classical BSE is reported in an animal born within the preceding eight years in a country or *zone* recognised as having a negligible BSE risk status, the negligible BSE risk status is suspended and the recommendations for controlled BSE risk status apply, pending the outcome of subsequent investigations confirming that the likelihood of BSE being recycled within the cattle population continues to be negligible. The country or *zone* will regain negligible BSE risk status only after the submitted evidence has been accepted by the OIE.

Annex 26 (contd)

Article 11.4.4.

Controlled BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* can be considered to be controlled provided the conditions of Article 11.4.3. are met, but at least one of the conditions has not been met for at least eight years.

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1) to 4) of Article 11.4.3. Documented evidence should be resubmitted annually for points 1) to 4) of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.5.

Undetermined BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled risk.

Article 11.4.6.

Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that cattle selected for export came from a country, *zone* or *compartment* posing a negligible BSE risk.

Article 11.4.7.

Recommendations for importation of cattle from a country, zone or compartment posing a controlled BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that cattle selected for export:

- 1) came from a country, *zone* or *compartment* posing a controlled BSE risk;

AND EITHER:

- 2) were born in the country, *zone* or *compartment* during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

- 3)

- a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and
- b) are demonstrated as having not been fed protein meal derived from ruminants.

Article 11.4.8.

Recommendations for importation of cattle from a country, zone or compartment posing an undetermined BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that cattle selected for export:

Annex 26 (contd)

- 1) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime;
- 2) are demonstrated as having not been fed protein meal derived from ruminants.

Article 11.4.9.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the *fresh meat* and *meat products* were derived:

- 1) came from a country, *zone* or *compartment* posing a negligible BSE risk;
- 2) have been subjected to an ante-mortem inspection with favourable results.

Article 11.4.10.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a controlled BSE risk

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

- 1) the cattle from which the *fresh meat* and *meat products* were derived came from a country, *zone* or *compartment* posing a controlled BSE risk;
 - 2) they have been subjected to an ante-mortem inspection with favourable results;
- AND EITHER:
- 3) they were born in the country, *zone* or *compartment* during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

- 4) the *fresh meat* and *meat products*:
 - a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to *slaughter*; and
 - b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - i) the *commodities* listed in points 1) a) and 1) b) of Article 11.4.14.;
 - ii) mechanically separated meat from the skull and from the vertebral column from cattle over 30 months of age.

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

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

Annex 26 (contd)

- 1) the cattle from which the *fresh meat* and *meat products* were derived:
 - a) are demonstrated as having not been fed protein meal derived from ruminants;
 - b) were subjected to an ante-mortem inspection with favourable results;
 - c) were not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to *slaughter*;
- 2) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the *commodities* listed in points 1) a) and 1) b) of Article 11.4.14.;
 - b) mechanically separated meat from the skull and from the vertebral column from cattle over 30 months of age.

Article 11.4.12.

Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the protein meal was derived came from a country, *zone* or *compartment* posing a negligible BSE risk.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from cattle

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

EITHER:

- 1) the blood and blood products came from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

- 2) the blood and blood products came from a country, *zone* or *compartment* posing a controlled BSE risk and the cattle from which the blood and blood products were derived were born in the country, *zone* or *compartment* during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

- 3) the blood and blood products were:
 - a) collected from cattle not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to *slaughter*;
 - b) collected in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

- 1) Unless covered by other articles in this chapter, the following *commodities* originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, and any *commodity* contaminated by them, should not be traded for the preparation of food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:
 - a) distal ileum from cattle of any age;
 - b) skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of *slaughter* over 30 months of age.
- 2) Protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using *commodities* listed in points 1) a) or 1) b) of this article, which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, should not be traded.
- 3) Cattle-derived protein meal, or any *commodities* containing such products, which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, should not be traded.

These points do not apply to cattle in a country or *zone* with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4.bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) is derived from cattle which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in points 1) a) and 1) b) of Article 11.4.14.

Article 11.4.16.

Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) is a co-product of bone gelatine.

Article 11.4.17.

Procedures for reduction of BSE infectivity in protein meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of protein meal containing ruminant proteins.

- 1) The raw material should be reduced to a maximum particle size of 50 mm before heating.

Annex 26 (contd)

- 2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.18.

Surveillance

- 1) *Surveillance* for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the *Veterinary Authority* for subsequent investigation and diagnosis. The credibility of the *surveillance* programme is supported by:
- a) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsman, *veterinarians*, transporters and *slaughterhouse/abattoir* workers;
 - b) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;
 - c) appropriate *laboratory* investigations in accordance with the *Terrestrial Manual* and follow-up field investigation as necessary of all clinical suspects.
- 2) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:
- a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive vocalization, panic-stricken response and excessive alertness;
 - b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;
 - c) generalized non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form may be observed with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress over a few weeks to several months, but in rare occasions cases can develop acutely and progress rapidly. The final stages are characterised by recumbency, coma and death.

Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.

Annex 26 (contd)

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations may observe individual animals displaying clinical signs suggestive of BSE. The rate at which they are likely to occur cannot be reliably predicted as they will vary depending on the epidemiological situation in a particular country. In addition, in those countries where cattle are intensively reared and subjected to regular observation, it is likely that such animals will be more readily seen. Behavioural changes, that may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In more extensive systems however, where cattle are not monitored as closely, situations may inevitably arise where an animal might be considered as a clinical suspect, yet if it was not observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for *surveillance*.

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions and safe commodities

The recommendations in this chapter are intended to ~~mitigate~~ manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle (~~*Bos taurus* and *B. indicus*~~) only. BSE manifests in two main forms: classical BSE and atypical BSE. For the purpose of official BSE risk status recognition, BSE excludes 'atypical' Atypical BSE is as a condition that occurs at a very low rate believed and is assumed to occur spontaneously in any all cattle populations. Oral exposure to contaminated feed is the main route of transmission of classical BSE. Given that cattle have been experimentally infected by the oral route with L-type BSE, atypical BSE is also potentially capable of being recycled in a cattle population if cattle are orally exposed to contaminated feed.

BSE primarily affects cattle. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal is not practiced.

For the purposes of the *Terrestrial Code*:

- 1) BSE is an invariably fatal neurological prion disease of cattle caused by PrP^{BSE}, including both classical (C-type BSE) and atypical strains (H- and L-type BSE). The term 'BSE' includes both classical and atypical forms, unless otherwise specified.
- 2) The occurrence of a BSE case is defined by the immunohistochemical (IHC) or immunochemical detection of PrP^{BSE} in brain tissue of a bovid, with discrimination between atypical and classical BSE strains based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.

For the purposes of this chapter:

- 3) 'Cattle' means a bovid of the species *Bos taurus* or *Bos indicus*.
- 4) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino-acids.
- 2) ~~When authorising import or transit of other commodities listed in this chapter, Veterinary Authorities should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the exporting country, zone or compartment.~~
- 3) ~~When authorising import of commodities according to the conditions prescribed in this chapter, the risk status of an importing country is not affected by the BSE risk status of the exporting country, zone or compartment.~~

When commodities are imported in accordance with this chapter, the BSE risk of the importing country or zone of destination is not affected by the BSE risk of the exporting country, the zone or compartment of origin.

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

Article 11.4.1bis.**Safe commodities**

- 4) ~~When authorising the importation or transit of the following commodities and any products made from these commodities and containing no other tissues from cattle, Veterinary Authorities should not require any BSE related conditions related to BSE, regardless of the BSE risk posed by status of the cattle population of the exporting country, zone or compartment.~~

Annex 27 (contd)

- 1a) milk and milk products;
- 2b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the relevant Chapters recommendations of the Terrestrial Code International Embryo Transfer Society;
- 3e) hides and skins;
- 4d) gelatine and collagen prepared ~~exclusively from hides and skins;~~
- 5e) tallow with maximum level of insoluble impurities of 0.15% in weight;
- 6) ~~and tallow derivatives made from this tallow;~~
- 7f) dicalcium phosphate (with no trace of protein or fat);₂
- g) ~~deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante- and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.4.14.;~~
- h) ~~blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.~~

Other commodities of cattle can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

The BSE risk status of the cattle population of a country, zone or compartment

The BSE risk status of the cattle population of a country, zone or compartment ~~is~~ should be determined on the basis of the following criteria:

- 1) ~~the outcome of a risk assessment, in accordance with, based on the provisions of Chapter 1.8. of the Terrestrial Code, that evaluates the likelihood of BSE being recycled within the cattle population by identifying all potential factors associated with the for BSE occurrence of BSE and their historic perspective. Member Countries should review the risk assessment annually to determine whether the situation has changed.~~

A risk assessment for the purpose of BSE consists of:

- a) Entry assessment

An entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, zone or compartment via imported commodities.

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

- i) ~~the presence or absence of the BSE agent in the indigenous ruminant population of the country, zone or compartment and, if present, evidence regarding its prevalence;~~
- ii) ~~production of meat and bone meal or greaves from the indigenous ruminant population;~~
- iii) ~~imported meat and bone meal or greaves;~~
- iv) ~~imported cattle, sheep and goats;~~

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- v) imported animal feed and feed ingredients;
- vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.4.14. and may have been fed to cattle;
- vii) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of *surveillance* and other epidemiological investigations into the disposition of the commodities identified above should be taken into account in carrying out the assessment.

b) Exposure assessment

An exposure assessment evaluates the likelihood of cattle being exposed to BSE, either through imported commodities or as a result of the presence of BSE agents in the indigenous cattle population of the country, zone or compartment.

If the entry assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:

- i) recycling and amplification of the BSE agent through consumption by cattle of *meat and bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- ii) the use of ruminant carcasses (including from fallen stock), by products and *slaughterhouse/abattoir* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- iii) the feeding or not of ruminants with *meat and bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;
- iv) the level of *surveillance* for BSE conducted on the cattle population up to that time and the results of that *surveillance*;

c) Consequence assessment

A consequence assessment evaluates the likelihood of cattle becoming infected with BSE together with the likely extent of any subsequent recycling and amplification.

d) Risk estimation

Risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal, with indigenous cases arising as a consequence;

- 2) the ongoing implementation of a *surveillance* programme for classical BSE in the cattle population;
- 3) the history of occurrence and management of BSE cases.
- 2) ongoing awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.4.20. to 11.4.22.;
- 3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
- 4) the examination carried out in accordance with the *Terrestrial Manual* in a laboratory of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.

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~~When the risk assessment demonstrates negligible risk, the Member Country should conduct Type B surveillance in accordance with Articles 11.4.20. to 11.4.22.~~

~~When the risk assessment fails to demonstrate negligible risk, the Member Country should conduct Type A surveillance in accordance with Articles 11.4.20. to 11.4.22.~~

Article 11.4.3.

Negligible BSE risk

~~Commodities from~~ The BSE risk of the cattle population of a country, zone or compartment pose a can be considered to be negligible risk of transmitting the BSE agent if the following conditions are met for at least eight years:

- 1) ~~A~~ a risk assessment, as described in point 1) of Article 11.4.2., has been conducted, and the Member Country has demonstrated through documented evidence that the likelihood of BSE agents being recycled in the cattle population has been negligible as the result of: in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;

EITHER:

- a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;

OR

- b) effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.

- 2) ~~The Member Country has demonstrated that Type B surveillance provisions as described in accordance with Articles 11.4.20-18. have been implemented; to 11.4.22. is in place and the relevant points target, in accordance with Table 1, has been met;~~

- 3) EITHER:

- a) there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter; and has been completely destroyed, and

- i) ~~the criteria in points 2) to 4) of Article 11.4.2. have been complied with for at least seven years; and~~
- ii) ~~it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither meat and bone meal nor greaves derived from ruminants has been fed to ruminants;~~

OR

- b) if there has been an indigenous case of classical BSE, every indigenous case was born more than 11 years ago; and

EITHER:

- i) all cases were born at least eight years ago;

OR

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- ii) where a case was born within the preceding eight years, subsequent investigations have confirmed that the likelihood of BSE being recycled within the cattle population has continued to be negligible.
 - ~~i) the criteria in points 2) to 4) of Article 11.4.2. have been complied with for at least seven years; and~~
 - ~~ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat and bone meal* nor *greaves* derived from ruminants has been fed to ruminants;~~
 - ~~iii) all BSE cases, as well as:

 - ~~– 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~~
 - ~~– 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,~~
 if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.~~
- 4) Any cases of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal *feed* chain.

The Member Country or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and *feed* controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1) to 4) above. Documented evidence should be resubmitted annually for points 1) to 4) above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.3bis.**Recovery of negligible BSE risk status**

When an indigenous case of classical BSE is reported in an animal born within the preceding eight years in a country or *zone* recognised as having a negligible BSE risk status, the negligible BSE risk status is suspended and the recommendations for controlled BSE risk status apply, pending the outcome of subsequent investigations confirming that the likelihood of BSE being recycled within the cattle population continues to be negligible. The country or *zone* will regain negligible BSE risk status only after the submitted evidence has been accepted by the OIE.

Article 11.4.4.

Controlled BSE risk

~~Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent if the following conditions are met:~~

- ~~1)- a risk assessment, as described in point 1) of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;~~

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2) ~~the Member Country has demonstrated that Type A surveillance in accordance with Articles 11.4.20. to 11.4.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B surveillance may replace Type A surveillance once the relevant points target is met;~~

3) EITHER:

a) ~~there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross-contamination, that neither meat and bone meal nor greaves derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:~~

- ~~i) the criteria in points 2) to 4) of Article 11.4.2. have not been complied with for seven years;~~
- ~~ii) it cannot be demonstrated that controls over the feeding of *meat and bone meal* or *greaves* derived from ruminants to ruminants have been in place for eight years;~~

OR

b) ~~there has been an indigenous case of BSE, the criteria in points 2) to 4) of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross-contamination, that neither *meat and bone meal* nor *greaves* derived from ruminants has been fed to ruminants;~~

~~and all BSE cases, as well as:~~

- ~~– 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~~
- ~~– 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,~~

~~if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.~~

The BSE risk of the cattle population of a country, *zone* or *compartment* can be considered to be controlled provided the conditions of Article 11.4.3. are met, but at least one of the conditions has not been met for at least eight years.

~~The Member Country or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and *feed* controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.~~

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1) to 4) of Article 11.4.3. Documented evidence should be resubmitted annually for points 1) to 4) of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.5.

Undetermined BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* is considered to be poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements for negligible or controlled risk of another category.

Article 11.4.6.

Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

For all commodities from cattle not listed in point 1) of Article 11.4.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, zone or compartment complies with the conditions in Article 11.4.3.

Article 11.4.7.6.

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case

For cattle selected for export

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that cattle selected for export the animals came from a country, zone or compartment posing a negligible BSE risk.

- 1) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3 b) iii) of Article 11.4.3.;
- 2) were born after the date from which the ban on the feeding of ruminants with meat and bone meal and groaves derived from ruminants had been effectively enforced.

Article 11.4.8.7.

Recommendations for the importation of cattle from a country, zone or compartment posing a controlled BSE risk

For cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that cattle selected for export:

- 1) came from a the country, zone or compartment posing a controlled BSE risk; complies with the conditions referred to in Article 11.4.4.;

AND EITHER:

- 2) cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3 b) of Article 11.4.4.;
- 3) cattle selected for export were born after the date from which the ban on the feeding of ruminants with meat and bone meal and groaves derived from ruminants was effectively enforced.

were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

3)

a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and

b) are demonstrated as having not been fed protein meal derived from ruminants.

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Article 11.4.9.8.

Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE riskFor cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that cattle selected for export:

- 1) ~~the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced;~~
- 2) ~~all BSE cases, as well as:~~
 - a) ~~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~~
 - b) ~~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,~~
~~if alive in the country, zone or compartment, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;~~
- 3) ~~cattle selected for export:~~
 - a) ~~are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;~~
 - b) ~~were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was effectively enforced.~~
- 2) are demonstrated as having not been fed protein meal derived from ruminants.

Article 11.4.10.9.

Recommendations for the importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE riskFor fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the fresh meat and meat products were derived:

- 1) came from a the country, zone or compartment posing a negligible BSE risk; complies with the conditions in Article 11.4.3.;
- 2) ~~the cattle from which the fresh meat and meat products were derived passed~~ have been subjected to an ante- and post-mortem inspections with favourable results;
- 3) ~~in countries with negligible BSE risk where there have been indigenous cases, the cattle from which the fresh meat and meat products were derived were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced.~~

Article 11.4.14-10.

Recommendations for the importation of fresh meat and meat products from a country, zone or compartment posing a controlled BSE risk

~~For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)~~

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

- ~~1) the country, zone or compartment complies with the conditions referred to in Article 11.4.4.;~~
- ~~2) the cattle from which the *fresh meat and meat products* were derived passed ante- and post-mortem inspections;~~
- ~~3) cattle from which the *fresh meat and meat products* destined for export were derived were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;~~
- ~~4) the *fresh meat and meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

 - ~~a) the tissues listed in points 1) and 2) of Article 11.4.14.,~~
 - ~~b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.~~~~

1) the cattle from which the *fresh meat and meat products* were derived came from a country, zone or compartment posing a controlled BSE risk;

2) they have been subjected to ante-mortem inspection with favourable results;

AND EITHER:

3) they were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

4) the *fresh meat and meat products*:

a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to *slaughter*, and

b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

i) the *commodities* listed in points 1) a) and 1) b) of Article 11.4.14.;

ii) mechanically separated meat from the skull and from the vertebral column from cattle over 30 months of age.

Article 11.4.12-11.

Recommendations for the importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

~~For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)~~

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

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- 1) the cattle from which the *fresh meat* and *meat products* were derived originate:
 - a) are demonstrated as having ~~have~~ not been fed protein meal ~~meat and bone meal or greaves~~ derived from ruminants;
 - b) were subjected to an ~~passed~~ ante- and post-mortem inspections with favourable results;
 - c) were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter, ~~were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;~~
- 2) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the commodities ~~tissues~~ listed in points 1) a) and 1) b) 3 of Article 11.4.14.;
 - b) ~~nervous and lymphatic tissues exposed during the deboning process,~~
 - e) mechanically separated meat from the skull and from the vertebral column from cattle over 30 ~~42~~ months of age.

Article 11.4.13-12.

Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk on ruminant derived meat and bone meal or greaves

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the cattle from which the protein meal was derived came from a country, zone or compartment posing a negligible BSE risk.

- 1) ~~Ruminant-derived meat and bone meal or greaves, or any commodities containing such products, which originate from a country, zone or compartment defined in Article 11.4.3., but where there has been an indigenous case of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with meat and bone meal and greaves derived from ruminants had been effectively enforced.~~
- 2) ~~Ruminant-derived meat and bone meal or greaves, or any commodities containing such products, which originate from a country, zone or compartment defined in Articles 11.4.4. and 11.4.5. should not be traded between countries.~~

Article 11.4.13.

Recommendations for importation of blood and blood products derived from cattle

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

EITHER:

- 1) the blood and blood products came from a country, zone or compartment posing a negligible BSE risk;

OR

- 2) the blood and blood products came from a country, zone or compartment posing a controlled BSE risk and the cattle from which the blood and blood products were derived were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

- 3) the blood and blood products were:

- a) collected from cattle not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter;
- b) collected in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of ~~on~~ commodities with the greatest BSE infectivity that should not be traded

- 1) Unless covered by other articles in this chapter, the following commodities ~~From cattle of any age originating from a country, zone or compartment posing a controlled or undetermined BSE risk, defined in Articles 11.4.4. and 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:

 - a) tonsils and distal ileum from cattle of any age;
 - b) skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of slaughter over 30 months of age.~~
- 2) Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities listed in points 1) a) or 1) b) of this article, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, (unless covered by other Articles in this chapter) should also not be traded.
- 3) Cattle-derived protein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.
- 2) From cattle that were at the time of slaughter over 30 months of age originating from a country, zone or compartment defined in Article 11.4.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
- 3) From cattle that were at the time of slaughter over 12 months of age originating from a country, zone or compartment defined in Article 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

These points do not apply to cattle in a country or zone with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.15.

Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 4) ~~the commodities came from a country, zone or compartment posing a negligible BSE risk;~~

OR

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- 2) ~~they originate from a country, zone or compartment posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante- and post-mortem inspections; and that~~
- a) ~~vertebral columns from cattle over 30 months of age at the time of slaughter and skulls have been excluded;~~
 - b) ~~the bones have been subjected to a process which includes all of the following steps:~~
 - i) ~~degreasing,~~
 - ii) ~~acid demineralisation,~~
 - iii) ~~acid or alkaline treatment,~~
 - iv) ~~filtration,~~
 - v) ~~sterilisation at $\geq 138^{\circ}\text{C}$ for a minimum of 4 seconds,~~
- ~~or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).~~

Article 11.4.1615.

Recommendations for the importation of tallow (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) ~~came from a country, zone or compartment posing a negligible BSE risk; or~~
- 2) ~~it originates from a country, zone or compartment posing a controlled BSE risk, is derived from cattle which have been subjected to an passed ante- and post-mortem inspections with favourable results, and has not been prepared using the commodities tissues listed in points 1) a) and 1) b) 2 of Article 11.4.14.~~

Article 11.4.1716.

Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) ~~came from a country, zone or compartment posing a negligible BSE risk; or~~
- 2) ~~it originates from a country, zone or compartment posing a controlled or undetermined BSE risk and is a coby-product of bone gelatine produced according to Article 11.4.15.~~

Article 11.4.18.

Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) ~~the tallow derivatives originate from a country, zone or compartment posing a negligible BSE risk; or~~
- 2) ~~they are derived from tallow meeting the conditions referred to in Article 11.4.16.; or~~
- 3) ~~they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.~~

Article 11.4.1917.

Procedures for the reduction of BSE infectivity in protein meal ~~meat and bone meal~~

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of protein meal ~~meat and bone meal~~ containing ruminant proteins.

- 1) The raw material should be reduced to a maximum particle size of 50 mm before heating.
- 2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.2018.

Surveillance ~~Surveillance~~: introduction

- 1) Surveillance for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the Veterinary Authority for subsequent investigation and diagnosis. The credibility of the surveillance programme is supported by:
 - a) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, veterinarians, transporters and slaughterhouse/abattoir workers;
 - b) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;
 - c) appropriate laboratory investigations in accordance with the Terrestrial Manual and follow-up field investigation as necessary of all clinical suspects.
- 2) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:
 - a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive vocalization, panic-stricken response and excessive alertness;
 - b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;
 - c) generalized non-specific signs such as reduced milk yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form may be observed with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress over a few weeks to several months, but in rare occasions cases can develop acutely and progress rapidly. The final stages are characterised by recumbency, coma and death.

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Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations may observe individual animals displaying clinical signs suggestive of BSE. The rate at which they are likely to occur cannot be reliably predicted as they will vary depending on the epidemiological situation in a particular country. In addition, in those countries where cattle are intensively reared and subjected to regular observation, it is likely that such animals will be more readily seen. Behavioural changes, that may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In more extensive systems however, where cattle are not monitored as closely, situations may inevitably arise where an animal might be considered as a clinical suspect, yet if it was not observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for surveillance.

- 1) ~~Depending on the risk category of a country, zone or compartment with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:~~
 - a) ~~detecting BSE, to a pre-determined design prevalence, in a country, zone or compartment;~~
 - b) ~~monitoring the evolution of BSE in a country, zone or compartment;~~
 - c) ~~monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;~~
 - d) ~~supporting a claimed BSE status;~~
 - e) ~~gaining or regaining a higher BSE status.~~
- 2) ~~When the BSE agent is present in a country or zone, the cattle population will comprise the following sectors, in order of decreasing size:~~
 - a) ~~cattle not exposed to the infective agent;~~
 - b) ~~cattle exposed but not infected;~~
 - c) ~~infected cattle, which may lie within one of three stages in the progress of BSE:~~
 - i) ~~the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;~~
 - ii) ~~some will progress to a stage at which BSE is detectable by testing before clinical signs appear;~~
 - iii) ~~the smallest number will show clinical signs.~~
- 3) ~~The BSE status of a country, zone or compartment cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 11.4.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.~~
- 4) ~~With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:~~
 - a) ~~cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);~~
 - b) ~~cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter or downer cattle);~~

- e) ~~cattle over 30 months of age which are found dead or killed on farm, during transport or at an slaughterhouse/abattoir (fallen stock);~~
 - d) ~~cattle over 36 months of age at routine slaughter.~~
- 5) ~~A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, zone or compartment. This approach is consistent with Articles 11.4.20. to 11.4.22.~~
- 6) ~~When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.~~

Article 11.4.21.

Surveillance: description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

~~Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all Member Countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.~~

~~This subpopulation is the one exhibiting the highest prevalence of 'classical' BSE. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 11.4.2.), implemented by the Veterinary Services, are essential for the credibility of the surveillance system.~~

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

~~These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.~~

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)

~~These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.~~

4. Cattle over 36 months of age at routine slaughter

~~Experience in Member Countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).~~

Annex 27 (contd)

Article 11.4.22.

Surveillance activities

~~In order to implement efficiently a surveillance strategy for BSE, a Member Country should use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, zone or compartment.~~

~~The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, zone or compartment.~~

~~A surveillance strategy should be designed to ensure that samples are representative of the herd of the country, zone or compartment, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for seven years.~~

~~The point targets and surveillance point values in this chapter were obtained by applying the following factors to a statistical model:~~

- ~~1) the design prevalence for Type A or Type B surveillance;~~
- ~~2) a confidence level of 95%;~~
- ~~3) the pathogenesis, and pathological and clinical expression of BSE:

 - ~~a) sensitivity of diagnostic methods used;~~
 - ~~b) relative frequency of expression by age;~~
 - ~~c) relative frequency of expression within each subpopulation;~~
 - ~~d) interval between pathological change and clinical expression;~~~~
- ~~4) demographics of the cattle population, including age distribution and population size;~~
- ~~5) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;~~
- ~~6) percentage of infected animals in the cattle population which are not detected.~~

~~Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:~~

- ~~7) cattle population numbers stratified by age;~~
- ~~8) the number of cattle tested for BSE stratified by age and by subpopulation.~~

~~This chapter utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.~~

~~Within each of the subpopulations above in a country, zone or compartment, a Member Country may wish to target cattle identifiable as imported from countries or zones not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE.~~

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, *animals* from the other subpopulations should be tested.

1- Type A surveillance

The application of Type A *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2- Type B surveillance

The application of Type B *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.4.3.) to confirm the conclusions of the *risk assessment*, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through *surveillance* targeted to maximise the likelihood of identifying failures of such measures.

Type B *surveillance* may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 11.4.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

3- Selecting the points target

The *surveillance* points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment.

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,600	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500

Annex 27 (contd)

90,001-100,000	19,900	9,950
80,001-90,000	17,700	8,850
70,001-80,000	15,500	7,750
60,001-70,000	13,300	6,650
50,001-60,000	11,000	5,500
40,001-50,000	8,800	4,400
30,001-40,000	6,600	3,300
20,001-30,000	4,400	2,200
10,001-20,000	2,100	1,050
9,001-10,000	1,900	950
8,001-9,000	1,600	800
7,001-8,000	1,400	700
6,001-7,000	1,200	600
5,001-6,000	1,000	500
4,001-5,000	800	400
3,001-4,000	600	300
2,001-3,000	400	200
1,001-2,000	200	100

4. Determining the point values of samples collected

Table 2 can be used to determine the point values of the *surveillance* samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of *surveillance* described in Chapter 1.4. and the epidemiology of BSE.

Because precise aging of the *animals* that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the *cattle herd* of the country, *zone* or *compartment*. In addition, Member Countries should sample at least three of the four subpopulations.

Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.

Surveillance subpopulation			
¹ Routine slaughter	² Fallen stock	³ Casualty slaughter	⁴ Clinical suspect
Age \geq 1 year and $<$2 years			
0.04	0.2	0.4	N/A
Age \geq 2 years and $<$4 years (young adult)			
0.1	0.2	0.4	260
Age $>$ 4 years and $<$7 years (middle adult)			
0.2	0.9	1.6	750
Age \geq 7 years and $<$9 years (older adult)			
0.1	0.4	0.7	220
Age \geq 9 years			
0.0	0.1	0.2	45

If a country, zone or compartment determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for seven years (the 95th percentile of the incubation period).

Article 11.4.23.

BSE risk assessment: introduction

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

4. Entry assessment

Entry assessment consists of assessing the likelihood that a BSE agent or has been introduced via the importation of the following commodities potentially contaminated with a BSE agent:

- a) meat and bone meal or greaves;
- b) live animals;
- e) animal feed and feed ingredients;
- e) products of animal origin for human consumption.

Annex 27 (contd)

2- Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure BSE agent to cattle, through a consideration of the following:

- a) epidemiological situation concerning BSE agents in the country or zone;
- b) recycling and amplification of the BSE agent through consumption by cattle of *meat and bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- c) the origin and use of ruminant carcasses (including fallen stock), by products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; thorough epidemiological investigations of any indigenous case born after the date of the implementation of feed bans should be conducted.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 11.4.24.

The potential for the entry of the BSE agent through the importation of meat and bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article 11.4.27. indicates that *meat and bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight 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 ruminants.

Assumption: That *meat and bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat and bone meal*, *greaves*, or feedstuffs containing either been imported within the past eight 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 likelihood of entry of BSE agent. *Meat and bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry than that from low risk countries. *Meat and bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown likelihood of entry.

Evidence required:

- 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
- Where *meat and bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past eight years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat and bone meal*, *greaves* or feedstuffs containing them.
- Documentation, from 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.

- Documentation describing the fate of imported *meat and bone meal* and *greaves*.

Article 11.4.25.

The potential for the entry of the BSE agent through the importation of live animals potentially infected with BSE

Assumptions:

- Countries which have imported ruminants from countries infected with 'BSEs are more likely to experience 'BSE'.
- Cattle pose the only known risk although other species are under study.
- ~~Animals~~ Cattle imported for breeding may pose a greater risk than ~~animals~~ imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than ~~animals~~ imported for *slaughter*.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

~~Question to be answered:~~ Have live *animals* been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:

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

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported *animals*, including their age at *slaughter*.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Annex 27 (contd)

Article 11.4.26.

The potential for the entry of the BSE agent through the importation of products of animal origin potentially infected with BSE*Assumptions:*

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with 'BSEs are more likely to experience 'BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: What products of animal origin have been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.4.14.);
- country 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 animals in the country 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 animals 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;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.27.

The potential for the exposure of cattle to the BSE agent through consumption of meat and bone meal or greaves of ruminant origin*Assumptions:*

- That the consumption by bovines of *meat and bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially available products of animal origin used in animal feeds may contain *meat and bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

~~Question to be answered: Has *meat and bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (see Articles 11.4.3. and 11.4.4.)?~~

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

Article 11.4.28.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production*Assumptions:*

- BSE has a long *incubation period* and insidious onset of signs, so cases may escape detection.
- Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.4.19.
- BSE agent is present at much higher titres central nervous system, and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

~~Question to be answered: How has animal waste been processed over the past eight years?~~

~~Rationale: If potentially infected *animals* 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 utilised in the production of any animal feeds, the risk of cross-contamination exists.~~

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

Annex 27 (contd)

- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat and bone meal* and *greaves*.
- 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.
- Documentation describing monitoring and enforcement of the above.

Article 11.4.29.

Conclusions of the risk assessment

~~The overall risk of BSE in the cattle population of a country or zone 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 or zone is free from BSE risk, it should have demonstrated that appropriate measures have been taken to manage any risks identified.~~

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1. ~~See point 4 of Article 11.4.21.~~
 2. ~~See point 3 of Article 11.4.21.~~
 3. ~~See point 2 of Article 11.4.21.~~
 4. ~~See point 1 of Article 11.4.21.~~

CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS

[...]

Article 12.6.6.

Recommendations for the importation of domestic equids for unrestricted movement

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

- 1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

- 2) came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and
- 3) were ~~immunised~~ vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* and considered effective against the epidemiologically relevant virus strains, ~~between 21 and 90 days before shipment either with a primary course or a booster; information on their vaccination status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12;~~ in accordance with one of the following procedures:
 - a) between 14 and 90 days before shipment either with a primary course or a booster; or
 - b) between 14 and 180 days before shipment, if they are older than four years of age, previously having received at least four doses of the same vaccine at intervals not greater than 180 days.

Information on the vaccination status should be included in the international veterinary certificate or the passport in accordance with Chapter 5.12, as relevant.

~~For additional security, c~~Countries that are free of from EI or undertaking an eradication programme may also request that the domestic equids were ~~tested negative for EIV by~~ subjected to an agent identification test for EI described in the *Terrestrial Manual* with negative results, ~~conducted on samples collected on two occasions, at 7 to 14 days~~ four to six days after commencement of pre-export isolation and ~~less than 5~~ prior to four days ~~before of~~ shipment.

[...]