CHAPTER 1.2.

CRITERIA FOR LISTING DISEASES

Article 1.2.1.

[presented as clean text for Member comments]

The criteria for the inclusion of a disease in the OIE List are as follows:

1. International spread of the agent (via live animals, their products or fomites) has been proven on three or more occasions.

   AND

   i) A number of countries with populations of susceptible animals are free of the disease/infection or face impending freedom (based on the animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4.)

   OR

   ii) OIE annual reports indicate that a number of countries with susceptible populations have reported absence of the disease for several consecutive years (based on the animal health surveillance information notified in WAHIS)

   AND

   i) Transmission to humans has been proven, and human infection is associated with severe consequences (death or serious illness)

   OR

   ii) The disease/infection has been shown to cause significant production losses in domestic animals at the level of a country or a zone, excepting the situation where there is an efficient and affordable vaccine and vaccination is carried out by most Members

   OR

   iii) The disease/infection has been shown to, or scientific evidence indicates that it would, have a significant negative effect on wild animal populations
Annex 29 (contd)

AND

i) A repeatable and reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

OR

2. The disease is an emerging disease with apparent zoonotic properties, rapid spread, or possible significant production losses and a case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

Article 1.2.2.

The following diseases are included in the OIE List.

In case of modifications of this list of animal diseases adopted by the General Assembly, the new list comes into force on 1 January of the following year.

1. The following diseases are included within the category of multiple species diseases:

- Anthrax
- Aujeszky's disease
- Bluetongue
- Brucellosis (Brucella abortus)
- Brucellosis (Brucella melitensis)
- Brucellosis (Brucella suis)
- Crimean Congo haemorrhagic fever
- Echinococcosis/hydatidosis
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- New world screwworm (Cochliomyia hominivorax)
- Old world screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Surra (*Trypanosoma evansi*)
- Trichinelliosis
- Tularemia
- Vesicular stomatitis
- West Nile fever.

2. The following *diseases* are included within the category of cattle *diseases*:
   - Bovine anaplasmosis
   - Bovine babesiosis
   - Bovine genital campylobacteriosis
   - Bovine spongiform encephalopathy
   - Bovine tuberculosis
   - Bovine viral diarrhoea
   - Contagious bovine pleuropneumonia
   - Enzootic bovine leukosis
   - Haemorrhagic septicaemia
   - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
   - Lumpy skin disease
   - Theileriosis
   - Trichomonosis
   - Trypanosomosis (tsetse-transmitted).
Annex 29 (contd)

3. The following diseases are included within the category of sheep and goat diseases:
   - Caprine arthritis/encephalitis
   - Contagious agalactia
   - Contagious caprine pleuropneumonia
   - Enzootic abortion of ewes (ovine chlamydiosis)
   - Maedi–visna
   - Nairobi sheep disease
   - Ovine epididymitis (*Brucella ovis*)
   - Peste des petits ruminants
   - Salmonellosis (*S. abortusovis*)
   - Scrapie
   - Sheep pox and goat pox.

4. The following diseases are included within the category of equine diseases:
   - African horse sickness
   - Contagious equine metritis
   - Dourine
   - Equine encephalomyelitis (Western)
   - Equine infecti-us anaemia
   - Equine influenza
   - Equine piroplasmosis
   - Equine rhinopneumonitis
   - Equine viral arteritis
   - Glanders
   - Venezuelan equine encephalomyelitis.

5. The following diseases are included within the category of swine diseases:
   - African swine fever
   - Classical swine fever
6. The following diseases are included within the category of avian diseases:

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*Mycoplasma gallisepticum*)
- Avian mycoplasmosis (*Mycoplasma synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 10.4.
- Infectious bursal disease (Gumboro disease)
- Newcastle disease
- Pullorum disease
- Turkey rhinotracheitis.

7. The following diseases are included within the category of lagomorph diseases:

- Myxomatosis
- Rabbit haemorrhagic disease.

8. The following diseases are included within the category of bee diseases:

- Acarapisosis of honey bees
- American foulbrood of honey bees
- European foulbrood of honey bees
- Small hive beetle infestation (*Aethina tumida*)
Annex 29 (contd)

- *Tropilaelaps* infestation of honey bees
- Varroosis of honey bees.

9. The following *diseases* are included within the category of other *diseases*:

- Camelpox
- Leishmaniosis.
General principles

1. Respect of the hierarchy of Acts

Veterinary legislation should scrupulously respect the separation between the primary legislation, represented by primary acts (laws), and the secondary legislation derived from regulations or rule books as laid down in the Constitution or fundamental texts of the country.

2. Legal basis

The competent authorities should have the necessary primary and secondary legislation adopted for their activities at all levels of their functional or territorial organisation.

3. Inventory of the veterinary legislation

The competent authorities should establish and maintain a complete and up to date inventory of veterinary legislation.

The use of computerised databases is recommended, on the condition that their completeness, currency, accessibility and continuity can be guaranteed.

4. Communication

The competent authorities should ensure communication of veterinary legislation and subsequent documentation to stakeholders.

5. Codification

Veterinary legislation should be collected and codified so as to make it readily accessible and intelligible and provide the capability for updating and modification as appropriate.

6. Participation in the process of developing legislation

The drafting of new and updated veterinary texts should involve the competent authorities that are responsible for the scientific and technical content, together with the necessary legal expertise to ensure that the resulting texts are legally sound.

Conversely, the competent authorities should be consulted on all proposals to develop or modify texts that have a bearing on veterinary legislation.

7. Consistency of the legislation

Veterinary legislation should be consistent with civil, penal and administrative laws and the associated procedures as appropriate.
The form of veterinary legislation

1. **Normative character**

   Veterinary legislation should be normative and should be drafted in a manner that prevents ambiguity in interpretation.

2. **Style and precision**

   The syntax and vocabulary should be clear and consistent so as to avoid any ambiguity.

   Precision and accuracy should take precedence over style even if this results in repetition and a cumbersome style.

3. **Definitions**

   Definitions should refer to the precise subjects and texts to which they pertain.

   Definitions in secondary legislation should not create any conflict or ambiguity with definitions in primary legislation.

4. **Competent authority**

   The definition of ‘competent authority’ or ‘competent authorities’ should be consistent with the OIE standards in order to assure an efficient chain of command and reliability in the provision of veterinary certification.

5. **Objectives of veterinary legislation**

   Veterinary legislation should include a clear statement of scope.

   The legislation should as a minimum include instruments to enable protection of relevant guidelines in order to protect:

   a. animal health and food security;
   b. food safety;
   c. public health (zoonotic diseases) and security (stray animals);
   d. animal welfare, as defined by the OIE.

6. **Penalties and sanctions**

   Veterinary legislation should provide for penalties and sanctions at the level required for proper implementation of the overall strategy, as follows:

   a. penalty sanctions, to be applied by the competent jurisdictions according to current penalty procedures;
   b. administrative sanctions that are designed for immediate application in the case of activities posing a risk to animal health, animal welfare or public health.
Veterinary legislation should distinguish between significant penalties established in primary legislation and those less strong that depend on secondary legislation.

Veterinary legislation should include additional specific sanctions which would be applied on the basis of a decision from the court, notably a ban on the use of animals or the conduct of activities posing a risk to public or animal health or animal welfare.

7. **Powers of the competent authority**

Where official veterinary matters are the responsibility of more than one administration (multiple competent authorities), a reliable system of coordination and cooperation between the different authorities should be put in place.

The competent authorities should be organised in such a way as to provide for taking action quickly and coherently when such action is key to success, notably in case of implementation of animal health emergency measures or veterinary public health crises.

The legislation should provide for a chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined).

For this purpose, the responsibilities and power of the competent authorities, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined.

If they are not under the responsibility of a unique competent authority, the responsibility for each element of the public veterinary domain should be attributed to a specific competent authority.

8. **Interventions by inspectors**

The competent authority should appoint technically qualified inspectors to take any actions needed for implementation or verification of compliance with the veterinary legislation.

The veterinary legislation should ensure that:

a. inspectors have the legal authority to intervene in accordance with the legislation and the penal procedures in force in the State;

b. the field of competence and the role of each inspector are prescribed according to their technical qualifications;

c. inspectors are protected against legal action and physical harm.

9. **Powers**

The rights of inspectors should be explicitly and thoroughly listed to protect the rights of stakeholders against any abuse of authority.

The powers of inspectors and rules of inspections should be prescribed, notably the authorisation and conditions for obtaining access to professional and private premises and to vehicles.

Inspectors should have powers and procedures to:

a. gain access to documents;

b. take samples;
c. retain (set aside) animals and goods, pending a decision on final disposition.

10. **Obligations**

The obligation of inspectors to respect confidentiality should be defined.

When attributing a field of competence or sector of responsibility, the competent authority should respect the principles of independence and impartiality prescribed in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) (see Article 3.1.2.).

11. **Administrative and enforcement actions**

For the purposes of administrative and enforcement actions the following elements should be prescribed in the veterinary legislation:

a. seizure of animals, products and food of animal origin;

b. suspension of one or more activities of an inspected establishment;

c. the temporary, partial or complete closure of inspected establishments;

d. suspension or withdrawal of authorisations or approvals.

Means of compulsion enabling inspection to be performed should be provided for.

The rights of appeal against an action or a decision of an inspector should be established according to the laws of the State.

12. **Financing**

Veterinary legislation should provide for the sources, levels and conditions of financing required for the execution of all the activities of the competent authority, notably inspection, sampling and analysis and the procedures of authorisation or approval in all domains covered by the veterinary legislation.

Article 3.3.3.

**Veterinary and para-veterinary professions**

1. **Veterinary medicine**

In order to ensure the quality of veterinary medicine, the veterinary legislation should:

a. provide an official definition of veterinary medicine;

b. define the prerogatives of the professionals involved in the practice of veterinary medicine;

c. define the minimum initial and continuous educational requirements for the professionals;

d. prescribe the conditions for recognition of diplomas for veterinarians and para-veterinarians;

e. define the conditions for the exercise of veterinary and para-veterinary professions;

f. define the professional responsibilities of veterinarians and persons working under their control;
g. prescribe the situations where persons other than qualified veterinarians can undertake activities that are normally to be carried out by veterinarians e.g. in exceptional circumstances such as epizootics.

2. The control of the professions

In order to control the veterinary and para-veterinary professions, the veterinary legislation should:

a. describe the general system of control in terms of the political, administrative and geographic configuration of the State;

b. provide for the possibility of the delegation of powers to a professional organisation such as a veterinary statutory body;

c. where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation;

d. prescribe the disciplinary powers that apply to the relevant professions.

Article 3.3.4.

Laboratories in the veterinary field

1. Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

a. reference laboratories, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;

b. laboratories designated by the State for carrying out the analysis of official samples;

c. laboratories recognised by the State as fit to conduct compulsory analyses by the private sector.

The veterinary legislation should define the conditions for the classification, approval, operations and supervision of laboratories at each level.

2. Laboratory reagents

Veterinary legislation should address the elements listed below:

a. procedures for authorising the reagents that are used to perform official analyses;

b. surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation;

c. quality assurance of reagents by manufacturers.
Delegation of powers

1. General principles

The veterinary legislation should provide for the possibility of the competent authorities delegating specific tasks related to official activities.

The specific tasks delegated, the body(ies) to which the tasks are delegated and the conditions of supervision by the competent authority should be defined.

2. Animal health delegation

The veterinary legislation should provide for the possibility of the competent authority delegating specific tasks in the sector of animal health to individual professional veterinarians who are not civil servants.

For that purpose the veterinary legislation should:

a. define the field of activities and the specific tasks covered by the delegation;

b. provide for the control, supervision and financing of the delegation;

c. define the procedures for making delegations;

d. define the competencies to be held by persons receiving delegation;

e. define the conditions of withdrawals of delegations.

3. Delegation of functions relating to veterinary certification

Veterinary legislation should conform with Section 5 of the Terrestrial Code concerning certification procedures, especially on the:

a. conditions of appointment or recognition of certifying officials;

b. role and responsibilities of the certifying officials;

c. conditions of certification;

d. means of supervision and financing of certification;

e. define the conditions of withdrawal of the delegation.

4. Delegation of functions relating to the identification of animals and traceability

a. Veterinary legislation should provide for the possibility of delegating operations, under the supervision of the competent authority, to the operators that are best placed to carry out and manage the identification systems.

b. Veterinary legislation should define the conditions of withdrawal of the delegation.
5. **Relationships with stakeholders**

To ensure transparency and facilitate implementation of the veterinary legislation, the competent authority should establish relationships with stakeholders, including by:

a. taking steps to ensure that stakeholders participate in the development of significant legislation and required follow up;

b. supporting, as appropriate, participation of stakeholders in international discussions fora such as OIE and Codex Alimentarius Commission.

Article 3.36.

**Health provisions relating to animal production**

1. **Identification and traceability**

Veterinary legislation should address the following elements:

a. the objectives and scope of animal identification;

b. the possibility to make animal identification compulsory for certain species, regions or function;

c. the power of the competent authority to control movements of animals and record changes of ownership;

d. identification includes the marking of animals or groups of animals and the recording of corresponding data;

e. the use of identification data for veterinary matters;

f. the equipment and methods to be used and the qualifications of operators for the marking or tracing of animals as appropriate to each situation;

g. the type of data to be recorded and the responsibilities of each party, notably those of animal keepers;

h. for the conduct of checks and corrections, as may be required to ensure the reliability of information in the database, notably in respect of animals that have died or have been slaughtered for any reason;

i. respect for constitutional liberties by restricting the use, security and confidentiality of data.

2. **Animal markets and other gatherings**

Veterinary legislation should address the following elements:

a. registration of all permanent or temporary animal markets and other animal gatherings;

b. health measures to prevent disease transmission, including procedures for cleaning and disinfection, and animal welfare measures;

c. provision for compulsory veterinary checks at animal gatherings.
3. **Animal reproduction**

   Except where the animals or reproductive material are only used in a single holding, the veterinary legislation should address the elements listed below:

   a. the health regulation of animal reproduction as appropriate;
   
   b. health regulations may be implemented at the level of animals, genetic material, establishments or operators.

4. **Animal feed**

   Veterinary legislation should address the elements listed below:

   a. standards for the production and composition of animal feed;
   
   b. registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations;
   
   c. recall from the market of any product likely to present a hazard to human health or animal health.

5. **Animal by-products (i.e. products not used for human consumption)**

   Veterinary legislation should address the elements listed below:

   a. definition of the animal by-products subject of the legislation;
   
   b. rules for collection, processing methods and authorised uses of animal by-products;
   
   c. registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations;
   
   d. definition of the rules to be applied by animal owners as appropriate.

6. **Disinfection**

   Veterinary legislation should address the following elements:

   a. the regulation of products and methods that are used for disinfection relating to animal diseases;
   
   b. the use of disinfection at all critical points, notably during the transportation of animals.

   Article 3.3.7.

**Animal diseases**

1. **Surveillance**

   Veterinary legislation should address the following elements:

   a. collection, transmission and utilisation of epidemiological data relevant to listed diseases;
   
   b. an early warning system.
2. **Disease prevention**

Veterinary legislation should address the following elements:

a. specific rules for each listed disease;

b. support to stakeholders in proposing joint programmes;

c. the direct control by the competent authority of some disease prevention programmes;

d. compulsory programmes for some disease prevention when necessary.

3. **Disease control**

a. Veterinary legislation should address the following elements:

i. different lists of diseases, with provision (as appropriate) for:
   - emergency measures in accordance with established contingency plans;
   - measures for prevention, control or eradication, including carcass disposal;
   - surveillance measures;

ii. the specification of mandatory control measures for certain diseases;

iii. arrangements for the declaration of animal diseases including on the grounds of suspicion;

iv. immediate technical measures including on the grounds of suspicion;

v. measures for official disease surveillance;

vi. conditions for confirmation of diseases;

vii. precautionary measures.

b. Veterinary legislation should provide for the following general measures:

i. definition of areas in which health measures are applied;

ii. official publicising of measures;

iii. listing of all measures requiring a legal basis;

iv. measures to be implemented by the public force;

v. epidemiological investigations;

vi. provisions for wild or protected animals;

vii. conditions for restocking;

viii. commercial restrictions.
Annex 30 (contd)

c. Contingency plan should be developed for certain diseases and, in addition to the general measures, should provide for:

   i. administrative and logistic organisation;

   ii. exceptional powers of the competent authority;

   iii. special and temporary measures to address all identified risks to human or animal health.

d. Veterinary legislation should provide for the financing of animal disease control measures, notably:

   i. operational expenses;

   ii. production losses;

   iii. owners compensation in the event of killing or slaughtering of animals, seizure or destruction of carcasses, meat, animal feed or other things.

4. Emerging disease

   Measures allowing for investigation of and response to emerging diseases.

   Article 3.3.8.

Animal welfare measures

1. General provisions

   Veterinary legislation should address the elements listed below:

   a. general principles to ensure the protection of animals against cruelty, abuse, abandonment and avoidable suffering, in line with the OIE Terrestrial Code;

   b. legal definition of cruelty as an offense, subject to penal action;

   c. direct intervention of the competent authority in the case of neglect by animal keepers;

   d. accepted practices for livestock, pets, animals used in scientific experiments, sport and leisure, and for wild animals, notably in relation to:

      i. transport and handling;

      ii. animal production and housing;

      iii. slaughtering and killing;

      iv. scientific experiments;

      v. use in games, shows, exhibitions and zoos;

   e. certain activities relating to animals may be restricted to the holders of appropriate qualifications or approvals.
2. Free-roaming and stray domestic animals

Veterinary legislation should address the elements listed below:

a. prohibition of abandonment of animals and of allowing animals to stray;

b. establishments where stray animals can be held and the conditions governing their operation;

c. the circumstances and the conditions of capture and of holding of stray animals;

d. the outcomes for these animals, including arrangements for veterinary interventions (including euthanasia in compliance with OIE standards), and for the transfer of ownership.

Article 3.3.9.

Veterinary products

1. Objectives

Veterinary legislation should address the following elements:

a. avoiding the presence of harmful residues in the food chain;

b. ensuring that the use of veterinary products does not give rise to human health risks.

2. General measures

Veterinary legislation should address the elements listed below:

a. definition of veterinary products, including any specific exclusions;

b. regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary products.

3. Raw materials and veterinary products

Veterinary legislation should address the elements listed below:

a. quality standards for raw materials used in the manufacture or composition of veterinary products and arrangements for checking quality;

b. establishment of the withdrawal periods and maximum residue limits for veterinary products as appropriate;

c. requirements for any substances that may interfere with the conduct of veterinary checks.

4. Authorisation of veterinary products

a. Veterinary legislation should ensure that only authorised veterinary products may be placed on the market.
Annex 30 (contd)

b. Special provisions should be made for:
   
   i. veterinary products that do not present any risk of residues or interference with the conduct of disease prevention and control programmes;
   
   ii. medicated feed;
   
   iii. products prepared by veterinarians or pharmacists;
   
   iv. emergencies and temporary situations.

c. Veterinary legislation should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.

d. In defining the procedures for seeking and granting authorisations, the legislation should:
   
   i. describe the functioning of the competent authority concerned;
   
   ii. establish rules providing for the transparency of decisions.

e. Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

5. Quality of veterinary products

To give effect to the objectives identified above, veterinary legislation should address the elements listed below:

a. the conduct of clinical and non clinical trials to verify all claims made by the manufacturer, including analysis and dosage methods;

b. conditions for the conduct of trials;

c. qualifications of experts involved in trials;

d. surveillance for adverse effects arising from the use of veterinary products.

6. Establishments producing, storing and selling veterinary products

Veterinary legislation should address the following elements:

a. registration or authorisation of all operators importing, storing, processing, selling or otherwise distributing veterinary products or raw materials for use in making veterinary products;

b. definition of the responsibilities of operators;

c. good manufacturing practices as appropriate;

d. arrangements for informing the competent authority on adverse effects of products and on traceability and recalling procedures about traceability of products and adverse effects.
7. **Commerce, distribution, use and traceability of veterinary products**

Veterinary legislation should address the following elements:

a. control over the circulation and distribution of veterinary products and arrangement for traceability and condition of use;

b. establishment of rules of prescription and provision of veterinary products to the end user;

c. restricting to authorised professionals all commerce in veterinary products that are subject to prescription;

d. the supervision by an authorised professional of organisations approved for holding and use of veterinary products;

e. the regulation of advertising claims and other marketing and promotional activities.

Article 3.3.10.

**Safeguards for the food production chain and traceability**

1. **Objectives**

Veterinary legislation should address the following elements:

a. the control of the manufacturing process at all relevant levels in the food production chain;

b. requirements to assure food safety for the purpose of (i).

In addition, procedures may be implemented to allow food production appropriate to the economic situation.

2. **General**

Veterinary legislation should address the following elements in order to ensure the food safety of animal products:

a. recording all significant health events that occur during primary production;

b. prohibition of the marketing of infected products or products likely to be contaminated or hazardous for the consumer or for animal health;

c. inspection for food safety and food composition;

d. inspection of premises;

e. controls over the implementation of the legislation at all stages of the production, processing and distribution of food of animal origin;

f. establish that operators of food production premises have the primary responsibility for food safety;

g. obligations for producers to withdraw from the marketplace all products likely to be hazardous for human or animal health.
Annex 30 (contd)

3. **Products of animal origin intended for human or animal consumption**

Veterinary legislation should address the following elements:

a. arrangements for inspection;

b. the conduct of inspection on the basis of veterinary expertise;

c. relevant health standards;

d. application of health identification marks, which are visible to the intermediary or final user.

The competent authority should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

4. **Premises and establishments pertaining to the food chain**

Veterinary legislation should address the following elements as appropriate:

a. recording the coordinates of operators working within the food chain;

b. the implementation by operators of procedures based on HACCP principles;

c. prior authorisation of operators whose activities are likely to constitute a significant risk to human or animal health.

Article 3.3.11.

**International movements and trade**

1. **Importation**

Veterinary legislation should address the following elements:

a. the coordinates of importers and, as appropriate, their approval by the competent authority of the importing country;

b. the establishment by the competent authority of:

   i. the list of goods to be subject to veterinary checks;

   ii. the importation check points officially designated for each kind of goods;

   iii. the kinds and procedures of checks to be performed;

   iv. the standards with which animals and commodities proposed for importation must comply;

     c. prevention of entry of listed goods and consignments into the country unless such goods have been subjected to the required veterinary checks;

   d. objectivity and independence of inspectors.
2. **Exports**

Veterinary legislation should specify the conditions governing the provision of veterinary certification and any prohibitions, in conformity with relevant provisions of the OIE and of the Codex Alimentarius Commission.

It should also include provisions ensuring national involvement to relevant activities of the work of the OIE and the Codex Alimentarius and, if necessary, interministerial coordination allowing the harmonization of the positions taken by the country in these international organizations.

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CHAPTER 6.8.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIALS AGENTS USED IN FOOD PRODUCING ANIMALS ANIMAL HUSBANDRY

Article 6.8.1.

Purpose

The purpose of these recommendations is to describe an approach to the monitoring of the quantities of antimicrobial agents used in food producing animals animal husbandry.

These recommendations are intended for use by OIE Members to collect objective and quantitative information to evaluate usage patterns by animal species, antimicrobial class, potency and type of use.

In order to evaluate antimicrobial exposure in food producing animals, quantitative information should be collected to monitor usage patterns by animal species, antimicrobial agents/class, type of use and route of administration.

Article 6.8.2.

Objectives

The information provided in these recommendations is essential for antimicrobial resistance risk analyses and planning purposes and should be read in conjunction with Terrestrial Code Chapters 6.7 and 6.10. This information is necessary can be helpful in for interpreting antimicrobial resistance surveillance data and can assist in the ability to responding to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information will also help to give an indication of trends in the use of antimicrobial agents in animals over time and potential associations with antimicrobial resistance in animals.

This information may also assist in risk management to in evaluating the effectiveness of efforts to ensure prudent use and mitigation strategies (for example, by identifying changes in veterinary prescribing practices for animals) and to indicate where change alteration of antimicrobial usage prescribing practices might be appropriate. The publication of some or all of these data may be helpful for risk communication purposes.

The continued collection of this basic information will also help to give an indication of trends in the use of animal antimicrobials over time and the role of these trends in the development of antimicrobial resistance in animals.

For all OIE Members, the minimum basic information collected should be the annual weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production. In addition, the type of use (therapeutic or growth promotion) and route of administration (parenteral or oral administration) should be recorded.

Members may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for relative risk analysis and help to promote optimal usage of antimicrobials.
Development and standardisation of antimicrobial monitoring systems

Systems to monitor antimicrobial usage consist of the following elements:

1. Sources of antimicrobial data
   a) Basic sources

   Sources of data will vary from country to country. Such sources may include customs, import and export data, manufacturing and manufacturing sales data.

   b) Direct sources

   Data from animal veterinary medicinal product drug registration authorities, wholesalers, retailers, pharmacists, veterinarians, feed stores, feed mills and organised pharmaceutical industry associations in these countries can might be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by pharmaceutical manufacturers to the regulatory authority one of the requirements of antimicrobial registration.

   c) End-use sources (veterinarians and food animal producers)

   This may be appropriate when basic or direct sources cannot be used for the routine collection of this the information and or when more accurate and locally specific information is required (such as off label use).

   Periodic collection of this type of information may be sufficient.

   It may be important when developing writing recommendations on antimicrobial resistance usage to take into account factors such as seasonality and disease conditions, species and age affected, agricultural systems and animal movement (e.g. extensive range conditions and feedlots), dose rate, duration and length of treatment with antimicrobials.

   Collection, storage and processing of data from end-use sources should be carefully designed, well managed and are likely to be inefficient and expensive processes unless carefully designed and well managed, but should have the capability to produce advantage of producing accurate and targeted information.

   d) Other sources

   Non-conventional sources including internet sales data related to antimicrobial agents could be collected where available.

   Members may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food producing animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for risk analysis purposes and help to promote optimal usage of antimicrobials.
2. **Types and reporting formats of antimicrobial usage data**

   **Categories of data**

   a) **Type of Requirements for antimicrobial use data on antimicrobial use**

   The **minimal** data collected at **minimum** should be the **annual** weight in kilograms of the active ingredient of the antimicrobial(s) used in food animal production per year. This should be related to the scale of production (see point 3 below). It is possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, export/import data or any combination of these.

   The total number of food producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.

   Information on dose regimes and duration of administration are elements to include when estimating antimicrobial usage in food producing animals.

   b) **Reporting formats of antimicrobial use data**

   The antimicrobial agents/classes/sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity and antimicrobial resistance data.

   Nomenclature of antimicrobials should comply with international standards where available.

   For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For antibiotics, antimicrobial agents expressed in International Units, the calculation required to convert these units to mass of active entity should be stated.

   The reporting of antimicrobial use data may be further organised by species, by route of administration (specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical) and by type of use (therapeutic/non-therapeutic).

   Regarding data coming from end-use sources, further breakdown of data for analysis of antimicrobial use at the regional, local, herd and individual veterinarian/veterinary practice levels may be possible.

   If a Member has the infrastructure for capturing basic animal antimicrobial use data for a specific antimicrobial, then additional information can be considered to cascade from this in a series of subdivisions or levels of detail. Such a cascade of levels should include the following:

   i) The absolute amount in kilograms of active antimicrobial used per antimicrobial family per year, or for a specific antimicrobial chemical entity when this information is required.

   ii) Therapeutic and growth promotion use in kilograms of the specific active antimicrobial.

   iii) Subdivision of antimicrobial use into therapeutic and growth promotion use by animal species.

   iv) Subdivision of the data into the route of administration, specifically in feed, in water, injectable, oral, intramammary, intra-uterine and topical.

   v) Further subdivision of these figures by season and region by a Member may be useful. *(Note: This may be especially management conditions, or where animals are moved from one locality to another during production.)*
Further breakdown of data for analysis of antimicrobial use at the regional, local, and individual veterinarian levels may be possible, using veterinary practice computer management software as part of specific targeted surveys or audits. Analysis of this information with the local or regional context could be useful for individual practitioners and practices where specific antimicrobial resistance has been identified and feedback is required.

b) Classes of antimicrobials

Nomenclature of antimicrobials should comply with international standards where available. Decisions need to be made on what classes of antimicrobials should be considered and what members of various antimicrobial classes should be included in the data collection programme. These decisions should be based on currently known mechanisms of antimicrobial activity and resistance of the particular antimicrobial and its relative potency.

c) Species and production systems

Countries should keep a register of all animal use of antimicrobials for individual food animal species (cattle, sheep, goats, pigs, poultry, horses and fish) and for specific diseases. This will help to identify possible nonauthorised usage.

3. Other important information

Breakdown of farm livestock into species and production categories, including total live weights, would be most useful in any risk analysis or for comparison of animal antimicrobial use with human medical use within and between countries. For example, the total number of food animals by category and their weight in kilograms for food production per year (meat, dairy and draught cattle, and meat, fibre and poultry and dairy sheep) in the country would be essential basic information.

Interpretation

According to the OIE risk assessment guideline (refer to Chapter 6.10.), factors such as the number/percentage of animals treated, treatment regimes, type of use and route of administration are key elements to consider.

When comparing antimicrobial use data over time, changes in the size and composition of animal populations should also be taken into account.

The interpretation and communication of results should take into account factors such as seasonality and disease conditions, animal species and age affected, agricultural systems (e.g. extensive range conditions and feedlots), animal movements, dose regimes and duration of treatment with antimicrobial agents.
Objective

This chapter provides criteria for the:

1. development of national antimicrobial resistance surveillance and monitoring programmes,
2. harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes,

in food producing animals (e.g. avian, bovine, caprine, equine, ovine, porcine) and in products of animal origin intended for human consumption.

Purpose of surveillance and monitoring

Active (targeted) surveillance and monitoring are as core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). Regional cooperation between Members conducting antimicrobial resistance surveillance should be encouraged.

Surveillance and monitoring of antimicrobial resistance is necessary to:

1. a) follow trends in antimicrobial resistance trends in bacteria;
2. b) detect the emergence of new antimicrobial resistance mechanisms;
3. c) provide the data necessary for conducting risk analyses with as relevance to for animal human and human animal health;
4. d) provide a basis for policy recommendations for animal and human public health;
5. e) provide information on for antimicrobial prescribing practices and useful for development of prudent use recommendations.

National antimicrobial resistance monitoring and surveillance programmes may include the following components:

a) scientifically based surveys (including statistically based programmes);
b) routine sampling and testing of animals on the farm, at market or at slaughter;
c) an organised sentinel programme, sampling animals, herds, flocks, and vectors;
d) analysis of veterinary practice and diagnostic laboratory records.
Annex 31 (contd)

3. Countries should conduct active surveillance and monitoring. Passive surveillance and monitoring may offer additional information.

4. Targeted surveillance is conducted through an active sampling scheme designed to meet programme objectives. Passive surveillance is conducted when samples are submitted to a laboratory for testing from sources outside the programme.

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance at regular or targeted intervals or ongoing monitoring of the prevalence of resistance in prevalence changes of resistant bacteria from animals, food, environmental and human origin, constitutes a critical part of animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of antimicrobials used in therapy.

Monitoring of bacteria from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, should also be considered.

National antimicrobial resistance monitoring and surveillance programmes may include the following components:

a) scientifically-based surveys (including statistically-based programmes);

b) routine sampling and testing of food producing animals on the farm, at live animal market or at slaughter;

c) an organised sentinel programme, for example targeted sampling of food producing animals, herds, flocks, and vectors (e.g. birds, rodents);

d) analysis of veterinary practice and diagnostic laboratory records.

2. Sampling strategies

a) General

i) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:

- the sample is representativeness of the population of interest;
- the robustness of the sampling method.

ii) The following criteria are to be considered:

- sample size;
- sample source (e.g. food producing animal, food, animal feed);
- animal species;
- category of animal within species (e.g. age group, production type);
Sample size

The sample size should be large enough to allow detection of existing and emerging antimicrobial resistance phenotypes, not excessively large to avoid waste of resources.

Table 1. Sample size estimates for prevalence of antimicrobial resistance in a large population

<table>
<thead>
<tr>
<th>Expected prevalence</th>
<th>90% Level of confidence</th>
<th>95% Level of confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>90% Desired precision</td>
<td>95% Desired precision</td>
</tr>
<tr>
<td></td>
<td>10% 5% 1% 10% 5% 1%</td>
<td></td>
</tr>
<tr>
<td>10%</td>
<td>24  97  2,429 35 138 3,445</td>
<td></td>
</tr>
<tr>
<td>20%</td>
<td>43 173  4,310 61 246 6,109</td>
<td></td>
</tr>
<tr>
<td>30%</td>
<td>57 227  5,650 81 323 8,003</td>
<td></td>
</tr>
<tr>
<td>40%</td>
<td>65 260  6,451 92 369 9,135</td>
<td></td>
</tr>
<tr>
<td>50%</td>
<td>68 270  6,718 96 384 9,512</td>
<td></td>
</tr>
<tr>
<td>60%</td>
<td>65 260  6,451 92 369 9,135</td>
<td></td>
</tr>
<tr>
<td>70%</td>
<td>57 227  5,650 81 323 8,003</td>
<td></td>
</tr>
<tr>
<td>80%</td>
<td>43 173  4,310 61 246 6,109</td>
<td></td>
</tr>
<tr>
<td>90%</td>
<td>24  97  2,429 35 138 3,445</td>
<td></td>
</tr>
</tbody>
</table>


Sample sources

Members should examine their livestock production systems and decide, after risk analysis, the relative importance of antimicrobial resistance and its impact on animal and human health.
Annex 31 (contd)

a) Animal feed

Members should consider including animal feeds in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella*.

b) Food producing animals

Each OIE Member should examine its livestock production systems and decide, after *risk analysis*, the relative importance of antimicrobial resistance and its impact on animal and human health.

Categories of food producing animals livestock that should be considered for sampling include cattle and calves, slaughter pigs, broiler chickens, layer hens and/or other poultry and farmed fish considered for sampling should be relevant to the country’s production system livestock and include.

bc) Food and animal feed

Members should consider including relevant food products originating from food producing animals in surveillance and monitoring programmes as foodborne transmission of antimicrobial resistance is commonly considered to be an important principal route for the transfer of antimicrobial resistance from animals to humans. Plants and vegetables of different types may be exposed to manure or sewage from livestock and may thereby become contaminated with resistant bacteria of animal origin. Animal feed, including imported feed, may also be considered in surveillance and monitoring programmes.

<table>
<thead>
<tr>
<th>Table 1. Sample size estimates for prevalence of antimicrobial resistance in a large population</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expected prevalence</strong></td>
</tr>
<tr>
<td>10%</td>
</tr>
<tr>
<td>10%</td>
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<tr>
<td>20%</td>
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<tr>
<td>60%</td>
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<tr>
<td>70%</td>
</tr>
<tr>
<td>80%</td>
</tr>
<tr>
<td>90%</td>
</tr>
</tbody>
</table>

Calculations based on Epi Info v6.04b to e Upgrade, October 1997, Centers for Disease Control (public domain software available at http://www.cdc.gov/epo/epi/epiinfo.htm)

45. **Type of sample specimens to be collected**

Feed samples should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to pathogen surveillance programmes.
Faecal samples should be collected in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from poultry) all from livestock, and whole caeca should be collected from poultry. In cattle and pigs, a faecal sample size at least of 5 g provides a sufficient sample for isolation of the bacteria of concern.

Sampling of the carcasses at the abattoir provides information on slaughter practices, slaughter hygiene and the level of microbiological faecal contamination and cross-contamination of meat during the slaughter process. Further sampling of the product at retail sales level from the retail chain may provide additional information on microbiological contamination, prevalence changes before the food reaches the consumer.

Existing food processing microbiological monitoring and ‘hazard analysis and critical control points’ (HACCP) programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after slaughter.

Table 2 provides examples of sampling sources, sample types and monitoring outcomes.

<table>
<thead>
<tr>
<th>Source</th>
<th>Sample type</th>
<th>Outcome</th>
<th>Additional information required/additional stratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herd/Flock of origin</td>
<td>Faecal</td>
<td>Prevalence of resistance in bacteria originating from animal populations (of different production types)</td>
<td>Per age categories, production types, etc. Antibiotic use over time</td>
</tr>
<tr>
<td>Abattoir</td>
<td>Faecal</td>
<td>Prevalence of resistance in bacterial populations originating from animals at slaughter age</td>
<td></td>
</tr>
<tr>
<td>Caeca/Intestine</td>
<td>As above</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcass</td>
<td></td>
<td>Hygiene, contamination during slaughter</td>
<td></td>
</tr>
<tr>
<td>Processing, packing</td>
<td>Meat Food</td>
<td>Hygiene, contamination during processing and handling</td>
<td></td>
</tr>
<tr>
<td>Point of sales (Retail)</td>
<td>Meat Food</td>
<td>Prevalence of resistance in bacteria originating from food, exposure data for consumers</td>
<td></td>
</tr>
<tr>
<td>Vegetables</td>
<td></td>
<td>Prevalence of resistance in bacteria originating from vegetables, exposure data for consumers</td>
<td></td>
</tr>
<tr>
<td>Various origins</td>
<td>Animal feed</td>
<td>Prevalence of resistance in bacteria originating from animal feed, exposure data for animals</td>
<td></td>
</tr>
</tbody>
</table>

Bacterial isolates

The following categories of bacteria could be monitored:
Annex 31 (contd)

a) Animal bacterial pathogens

Monitoring of antimicrobial resistance in animal pathogens is important, both to:

i) detect emerging resistance that may pose a concern for animal human and human animal health;

ii) guide veterinarians in their prescribing decisions.

Information on the occurrence of antimicrobial resistance in animal pathogens is in general derived from routine clinical material sent to veterinary diagnostic laboratories. These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.

b) Zoonotic bacteria

i) Salmonella

Salmonella should be sampled from animal feed, food producing animals, cattle, pigs, broilers and other poultry, and animal derived food products. For the purpose of consistency and harmonisation, samples should be preferably taken at the abattoir, facilitating sampling and reducing the concurrent costs, samples should preferably be taken at the abattoir.

Surveillance and monitoring programmes may also include bacterial isolates obtained from designated national laboratories originating from other sources.

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised accepted procedures.

Serovars of public health epidemiological importance such as S. Typhimurium and S. Enteritidis should be included. The inclusion selection of other relevant serovars will depend on the epidemiological situation in each country.

All Salmonella isolates should be serotyped and, where appropriate, phage-typed according to standard methods used at the nationally designated laboratories. For those countries that have the capabilities, Salmonella could be genotyped using genetic fingerprinting methods.

Validated antimicrobial susceptibility testing methods should be used.

ii) Campylobacter

Campylobacter jejuni and C. coli should be isolated from food producing animals and associated food products (primarily from poultry), can be isolated from the same samples as commensal bacteria. Isolation and identification of these bacteria should follow nationally or internationally standardised accepted procedures. Campylobacter isolates should be identified to the species level.

Validated antimicrobial susceptibility testing methods should be used.

Agar or broth micro-dilution methods are recommended for Campylobacter susceptibility testing. Internal and external quality control programmes should be strictly adhered to.

Validated methods with appropriate reference strains are expected to become available in the near future.
iii) Enterohaemorrhagic *Escherichia coli*

Enterohaemorrhagic *Escherichia coli* (EHEC), such as the serotype O157, which is pathogenic to humans but not to *animals*, may be included in resistance surveillance and monitoring programmes.

Validated antimicrobial susceptibility testing methods should be used.

c) Commensal bacteria

*Escherichia coli* and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal feed, food producing animals and animal-derived food products, are common commensal bacteria.

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir considered to constitute a reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria, causing disease in *animals* or *humans*. It is considered that these bacteria should be isolated from healthy *animals*, preferably at the abattoir, and be monitored for antimicrobial resistance.

Validated antimicrobial susceptibility testing methods should be used.

<table>
<thead>
<tr>
<th>Source</th>
<th>Sample type</th>
<th>Outcome</th>
<th>Additional information required/additional stratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herd of origin</td>
<td></td>
<td>Prevalence of resistance in bacteria originating from animal populations (of different production types)</td>
<td>Per age categories, production types, etc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Relationship resistance—antibiotic use</td>
<td>Antibiotic use over time</td>
</tr>
<tr>
<td>Abattoir</td>
<td>Faecal</td>
<td>Prevalence of resistance in bacterial populations originating from animals at slaughter age</td>
<td></td>
</tr>
<tr>
<td>Intestine</td>
<td></td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td>Carcass</td>
<td></td>
<td>Hygiene, contamination during slaughter</td>
<td></td>
</tr>
<tr>
<td>Processing, packing</td>
<td>Meat products</td>
<td>Hygiene, contamination during processing and handling</td>
<td></td>
</tr>
<tr>
<td>Retail</td>
<td>Meat products</td>
<td>Prevalence of resistance in bacteria originating from food, exposure data for consumers</td>
<td></td>
</tr>
<tr>
<td>Various origin</td>
<td>Animal feed</td>
<td>Prevalence of resistance in bacteria originating from animal feed, exposure data for animals</td>
<td></td>
</tr>
</tbody>
</table>
47. **Storage of bacterial strains**

If possible, isolates should be preserved at least until reporting is completed. Preferably, isolates should be permanently stored. Bacterial strain collections, established by storage of all isolates from certain years, will provide the possibility of conducting retrospective studies.

48. **Antimicrobials to be used in susceptibility testing**

Clinically important antimicrobial agents/classes used in human and veterinary medicine should be included in antimicrobial resistance surveillance programmes monitored. Members should refer to Chapter 1.1.6. of the *Terrestrial Manual* and the OIE list of antimicrobials of veterinary importance for monitoring purposes. However, the number of tested antimicrobials may have to be limited according to financial resources.

49. **Type of data to be recorded and stored**

Data on antimicrobial susceptibility data should be reported quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively. Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with Chapter 1.1.6. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing.

50. **Recording, storage and interpretation of results**

a) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.

b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation of the data in response to various kinds of questions, including those arising in the future.

b) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (compatibility/comparability of automatic recording of laboratory data and transfer of these data between and within resistance monitoring programmes) is envisaged. Results should be collected in a suitable national database. They should be recorded quantitatively:

i) as distributions of minimum inhibitory concentrations (MICs) in milligrams per litre;

ii) or inhibition zone diameters in millimetres.

b) The information to be recorded should include, where possible, at least the following aspects:

i) sampling programme;

ii) sampling date;

iii) animal species/livestock category;

iv) type of sample;

v) purpose of sampling;

vi) type of antimicrobial susceptibility testing method used;
vii) geographical origin \textit{geographical information system data where available} of herd, flock or animal;

viii) age of animal factors (e.g. age, condition, health status, identification, sex).

e) The reporting of laboratory data should include the following information:

i) identity of laboratory,

ii) isolation date,

iii) reporting date,

iv) bacterial species,

and, where relevant, other typing characteristics, such as:

v) serotype/serovar,

vi) phage-type,

vii) antimicrobial susceptibility result/resistance phenotype,

viii) molecular genotype.

f) The proportion of isolates regarded as resistant should be reported, including the defined interpretive criteria breakpoints used.

g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate susceptible or resistant. These clinical breakpoints, often referred to as clinical or pharmacological breakpoints, may be elaborated on a national basis and may vary between Members.

h) The system of reference used should be recorded. The antimicrobial susceptibility testing standards and guidelines used should be recorded.

i) For surveillance purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant.

j) Ideally, if available, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded. The phenotype of the isolates (resistance pattern) should be recorded.

114. Reference laboratory and annual reports

a) Members should designate a national reference centre that assumes the responsibility to:

i) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;

ii) coordinate and collect information from participating surveillance laboratories at a central location within the country;

iii) produce an annual report on the antimicrobial resistance situation of in the country.
Annex 31 (contd)

b) The national reference centre should have access to the:
   
i) raw data;

   ii) complete results of quality assurance and inter-laboratory calibration activities;

   iii) inter-laboratory proficiency testing results;

   iv) information on the structure of the monitoring system;

   v) information on the chosen laboratory methods.

<table>
<thead>
<tr>
<th>Target animals</th>
<th>Respiratory pathogens</th>
<th>Enteric pathogens</th>
<th>Udder pathogens</th>
<th>Other pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>Pasturella spp.</td>
<td>Escherichia coli</td>
<td>Staphylococcus</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>aureus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Haemophilus somnus</td>
<td>Salmonella spp.</td>
<td></td>
<td>Streptococcus</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>suis</td>
</tr>
<tr>
<td>Pigs</td>
<td>Actinobacillus pleuropneumoniae</td>
<td>Escherichia coli</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Strep tococcus suis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Brachyspira spp.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Salmonella spp.</td>
</tr>
<tr>
<td>Poultry</td>
<td></td>
<td></td>
<td></td>
<td>Escherichia coli</td>
</tr>
<tr>
<td>Fish</td>
<td></td>
<td></td>
<td></td>
<td>Vibrio spp.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aeromonas spp.</td>
</tr>
</tbody>
</table>

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GUIDANCE FROM THE ANIMAL WELFARE WORKING GROUP TO AD HOC GROUPS ON THE DEVELOPMENT OF ANIMAL WELFARE STANDARDS

When ‘welfare codes’ were first developed in the 1970s and 1980s, they tended to contain truisms such as ‘Animals should have adequate space’ and ‘Noise levels should not be excessive’. Although such statements can be useful to identify important variables in the course of providing more specific advice, they do not provide any implementable information or any means of determining whether a given practice or facility is in compliance. In contrast, an OIE animal welfare standard should contain recommendations that can be implemented, and criteria that can be used to tell whether a given practice or facility is in compliance with the standard.

Outcome-based or animal-based criteria should be used where possible because they are generally related most directly to animal welfare, and because they can be applied to a wide range of production systems. Such criteria can be qualitative (all animals should be able to lie down at the same time without lying on top of each other) or quantitative (no more than 1% of animals should be dead on arrival).

In some cases, input-based or resource-based criteria may also be acceptable and can supplement outcome-based criteria where there is a good scientific basis for doing so may be possible. For example if welfare is likely to be reduced by a certain factor in a wide range of systems. Again these can be qualitative (no animal should be hoisted while conscious) or quantitative (ammonia level in the air should not exceed 25 ppm).

In other cases, ‘conditional’ criteria can be used. These generally specify what actions should be taken under certain conditions. These can include both qualitative and quantitative elements, respectively, as in: (1) If more than 2% of birds arrive at the slaughter plant with broken wings, catching crews should be re-trained to catch birds in ways that are less likely to cause injuries. (2) If more than 2% of birds arrive at the slaughter plant with broken wings, catching crews should be re-trained to catch birds in ways that are less likely to cause injuries.

For certain variables, it is possible to identify ‘critical levels’ beyond which welfare is expected to be affected. Such levels are normally determined by scientific research. For example, welfare in many species is noticeably affected if ammonia levels in the air exceed 25 ppm.

For other variables (percent lame, percent dead during transport) there are no critical levels but it may be possible to set or recommend ‘performance targets’. In the case of performance targets, an ad hoc committee may be able to agree that a certain level of performance should be achieved broadly, for example, that no more than 1% of animals should fall while being moved in a slaughter facility. In other cases, there may be so much variation between breeds or locations that a standard merely identifies variables that should be used to assess performance, and calls for national or breed-specific targets to be set. In such cases it is helpful to provide examples of performance targets from other standards that are broadly applicable under different conditions.

June 25, 2010
CHAPTER 12.1.

AFRICAN HORSE SICKNESS

Article 12.1.1.

General provisions

For the purposes of the Terrestrial Code, the infective period for African horse sickness virus (AHSV) shall be 40 days for domestic horses. Although critical information is lacking for some species, this chapter applies to all equidae.

All countries or zones neighbouring adjacent to, or considered to be at risk from, a country or zone not having free status should determine their AHSV status from an ongoing surveillance programme. Throughout the chapter, surveillance is in all cases understood as being conducted as described in Chapter 1.4. Article 12.1.11. to 12.1.13.

The following defines a case of African horse sickness (AHS):

1. AHSV has been isolated and identified from an equid or a product derived from that equid; or

2. viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed case; or

3. serological evidence of active infection with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of vaccination have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed case.

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

Article 12.1.2.

AHSV free country or zone

1. A country or zone may be considered free from AHSV when African horse sickness (AHS) is notifiable in the whole country, systematic vaccination is prohibited, importation of equidae and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:

   a) historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or zone, or

   b) the country or zone has not reported any case of AHS for at least 2 years and is not adjacent to a country or zone not having a free status; or

   c) a surveillance programme has demonstrated no evidence of AHSV in the country or zone for at least 12 months and includes a complete season of vector activity; or

   d) the country or zone has not reported any case of AHS for at least 40 days and a surveillance programme has demonstrated no evidence of Culicoides likely to be competent AHSV vectors for at least 2 years in the country or zone.
Annex 33 (contd)

2. An AHS free country or zone adjacent to an infected country or infected zone should include a zone in which surveillance is conducted in accordance with Articles 12.1.11. to 12.1.13. Animals within this zone should be subjected to continuing surveillance. The boundaries of this zone should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to AHS transmission.

2. An AHSV free country or zone will not lose its free status through the importation of vaccinated or seropositive equidae and their semen, oocytes or embryos from infected countries or infected zones, provided these imports are carried out in accordance with this chapter.

4. To qualify for inclusion in the existing list of AHSV free countries or zones, a Member should:
   a) have a record of regular and prompt animal disease reporting;
   b) send a declaration to the OIE stating:
      i) the section under paragraph 1 on the base of which the application is based is made;
      ii) no systematic vaccination against AHS has been carried out during the past 12 months in the country or zone;
      iii) equidae are imported in accordance with paragraph 3 above;
   c) supply documented evidence that:
      i) surveillance for both AHS and AHSV infection in accordance with Articles 12.1.11. to 12.1.13 is in operation applied;
      ii) regulatory measures for the early detection, prevention and control of AHS have been implemented.

5. The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 4b(ii) and iii) and 4c) above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that:
   4a) there has been no outbreak of AHS during the past 12 months in the country or zone;
   4b) no evidence of AHSV infection has been found during the past 12 months in the country or zone.

AHSV seasonally free zone

1. An AHSV seasonally free zone is a part of an infected country or an infected zone in which for part of a year, ongoing surveillance and monitoring consistently demonstrated neither evidence of AHSV transmission nor the evidence of the presence of adult Culicoides likely to be competent AHSV vectors.

2. AHS is notifiable in the whole country.
For the application of Articles 12.1.6., 12.1.8. and 12.1.9., the seasonally free period is:

a) taken to commence the day following the last evidence of AHSV transmission and of the cessation of activity of adult Culicoides likely to be competent AHSV vectors as demonstrated by an ongoing surveillance programme, and

b) taken to conclude either:

i) at least 40 days before the earliest date that historical data show AHSV activity has recommenced; or

ii) immediately when current climatic data or data from a surveillance and monitoring programme indicate an earlier resurgence of activity of adult Culicoides likely to be competent AHSV vectors.

An AHSV seasonally free zone will not lose its free status through the importation of vaccinated or seropositive equidae and their semen, oocytes or embryos from infected countries or infected zones, provided these imports are carried out in accordance with this chapter.

Article 12.1.4.

AHSV infected country or zone

For the purpose of this chapter, an AHSV infected country or infected zone is one that does not fulfil the requirements to qualify as either AHSV free country or zone or AHSV seasonally free zone in which the conditions of Article 12.1.2. or Article 12.1.3. do not apply.

Article 12.1.4 bis.

Establishment of a containment zone within an AHS free country or zone

In the event of limited outbreaks within an AHS free country or zone, including within a protection zone, a single containment zone, which includes all cases and should be large enough to contain any potentially infected vectors, can be established for the purpose of minimizing the impact on the entire country or zone. For this to be achieved, the Veterinary Authority should provide documented evidence that:

1. the outbreaks are limited based on the following factors:
   a) immediately on suspicion, a rapid response including notification has been made;
   b) standstill of movements of equidae has been imposed, and effective controls on the movement of equidae and their products mentioned specified in this chapter are in place;
   c) epidemiological investigation (trace-back, trace-forward) has been completed;
   d) the infection has been confirmed;
   e) the primary outbreak and likely source of the outbreak has been identified;
   f) all cases have been shown to be epidemiologically linked;
   g) no new cases have been found in the containment zone within a minimum of two infectious periods as defined in Article 12.1.1.
Annex 33 (contd)

2. the equidae within the containment zone should be clearly identifiable as belonging to the containment zone;

3. increased passive and targeted surveillance in accordance with Articles 12.1.11. to 12.1.13. in the rest of the country or zone and has not detected any evidence of infection;

4. animal health measures that effectively prevent the spread of AHS to the rest of the country or zone, taking into consideration the establishment of a protection zone within the containment zone, the seasonal vector conditions and existing physical, geographical and ecological barriers;

5. ongoing surveillance is in place in the containment zone;

The free status of the areas outside the containment zone is suspended pending the establishment of the containment zone in accordance with points 1 to 5 above. The free status of the areas outside the containment zone could be reinstated irrespective of the provisions of Article 12.1.4.tris, once the containment zone is recognised by the OIE.

The recovery of the AHS free status of the containment zone should follow the provisions of Article 12.1.4.tris.

Article 12.1.4.tris

Recovery of free status

When an AHS outbreak occurs in an AHS free country or zone, the following provisions apply waiting period required to regain the status of AHS free country or zone:

1. If emergency vaccination is not carried out, the conditions of Article 12.1.2. paragraph 1b), 1c) or 1d) apply; or

2. if emergency vaccination is carried out, a waiting period of 24 months after the last case and completion of the emergency vaccination has elapsed, during which surveillance applied in accordance with Articles 12.1.11. to 12.1.13. has shown no evidence of AHSV infection.

Article 12.1.5.

Recommendations for importation from AHSV free countries that are neither neighbouring nor considered to be at risk from an AHSV infected country or infected zones for equidae

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

1. showed no clinical sign of AHS on the day of shipment;

2. have not been vaccinated against AHS within the last 40 days;

3. were kept in an AHSV free country or zone since birth or for at least 40 days prior to shipment;
4. **either:**
   a) did not transit through an *infected country or infected zone during transportation to the place of shipment*; or
   b) were protected from attacks by *Culicoides* at all times when transiting through an *infected country or infected zone*.

**Article 12.1.6.**

**Recommendations for importation from AHSV-free countries or free zones or from AHSV seasonally free zones (during the seasonally free period) that are neighbouring or are considered to be at risk from an AHSV-infected country or infected zone for equidae**

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

1. showed no clinical signs of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. **and either**
   a) were kept in an AHSV-free country, free zone or seasonally free zone during the seasonally free period since birth or for at least 40 days prior to shipment; or
   b) in a country or zone considered to be at risk, were held in quarantine isolation in a vector-protected establishment for at least 40 days prior to shipment and protected at all times from attacks by *Culicoides*; and
   c) for a period of at least 28 days and a serological test according to the *Terrestrial Manual* to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the quarantine station; or
   d) for a period of at least 40 days and serological tests according to the *Terrestrial Manual* to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the quarantine station; or
   e) for a period of at least 14 days and an agent identification test according to the *Terrestrial Manual* were carried out with a negative result on a blood sample collected on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the vector-protected establishment—quarantine station; or
   f) were protected from attacks by *Culicoides* at all times during transportation (including to and at the place of shipment) when transiting through an infected zone.
Annex 33 (contd)

Article 12.1.7.

Recommendations for importation from AHSV infected countries or zones for equidae

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

1. showed no clinical sign of AHS on the day of shipment;
2. have not been vaccinated against AHS within the last 40 days;
3. were held continuously during the quarantine period of at least 40 days, in isolation in a vector-proof protected establishment quarantine station and protected at all times from attacks by Culicoides, and
   a) for a period of at least 28 days and a serological test according to the Terrestrial Manual to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the vector-proof protected establishment quarantine station, or
   b) for a period of at least 40 days and serological tests according to the Terrestrial Manual to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after introduction into the vector-proof protected establishment quarantine station, or
   c) for a period of at least 14 days and an agent identification test according to the Terrestrial Manual were carried out with a negative result on a blood sample collected on two occasions with an interval of not less than 14 days between collection, the first sample being collected at least 7 days after introduction into the vector-proof protected establishment quarantine station.
4. were protected from attacks by Culicoides at all times during transportation (including transportation to and at the place of shipment).

Article 12.1.8.

Recommendations for the importation of equid semen

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
2. had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
3. were either:
   a) kept in an AHSV free country or free zone or from an AHSV seasonally free zone (during the seasonally free period) for at least 40 days before commencement of, and during collection of the semen, or
   b) kept in an AHSV free vector-proof protected artificial insemination centre throughout the collection period, and subjected to either:
i) a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or

ii) agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days, during semen collection for this consignment.

Article 12.1.9.

**Recommendations for the importation of in vivo derived equid embryos/oocytes**

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

1. the donor animals:
   a) showed no clinical sign of AHS on the day of collection of the embryos/oocytes and for the following 40 days;
   b) had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
   c) were either:

      i) kept in an AHSV free country or free zone or from an AHSV seasonally free zone (during the seasonally free period) for at least 40 days before commencement of, and during collection of the embryos/oocytes, or

      ii) kept in an AHSV free vector proof protected collection centre throughout the collection period, and subjected to either:

         ▪ a serological test according to the *Terrestrial Manual* to detect antibody to the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of embryos/oocytes; or

         ▪ agent identification tests according to the *Terrestrial Manual* carried out with negative results on blood samples collected at commencement and conclusion of, and at least every 7 days during embryos/oocytes collection for this consignment;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant;

3. semen used to fertilize the oocytes, complies at least with the requirements in Article 12.1.8.

Article 12.1.10.

**Protecting animals from Culicoides attack**

1. **Vector-protected establishment or facility**

   The means of protection of the establishment or facility should at least comprise the following:

   a) Appropriate physical barriers at entry and exit points, for example double-door entry-exit system.
Annex 33 (contd)

b) openings of the building are vector screened with mesh of appropriate gauge aperture size (under study) impregnated regularly with an approved insecticide according to manufacturers’ instruction;

c) vector surveillance and control within and around the building;

d) measures to limit breeding sites for vectors in vicinity of the establishment or facility;

e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the establishment or facility and transport of horses to the place of loading.

2. During transportation

When transporting equids through AHSV infected countries or AHSV infected zones, Veterinary Authorities should require strategies to protect animals from attacks by Culicoides during transport, taking into account the local ecology of the vector.

a) Transport by road:

Potential risk management strategies include a combination of:

1. treating animals with chemical repellents prior to and during transportation, in sanitized vehicles treated with appropriate residual contact insecticide;

2. loading, transporting and unloading animals at times of low vector activity (i.e. bright sunshine and low temperature);

3. ensuring vehicles do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

4. darkening the interior of the vehicle, for example by covering the roof and/or sides of vehicles with shade cloth;

5. monitoring for vectors at common stopping and offloading points to gain information on seasonal variations;

6. using historical, ongoing and/or AHS modelling information to identify low risk ports and transport routes.

b) Transport by air:

Prior to loading the equids, the crates, containers or jetstalls are sprayed with an insecticide approved in the country of dispatch.

Crates, containers or jet stalls in which equidae are being transported and the cargo hold of the aircraft must be sprayed with an approved insecticide just after the doors to the aircraft are closed and prior to takeoff, or immediately prior to the closing of the aircraft doors after loading.

In addition, during any stop over in countries or zones not free of AHS, prior to, or immediately after the opening of any aircraft door and until all doors are closed prior to takeoff, netting of appropriate aperture gauge size (under study) impregnated with an approved insecticide must be placed over all crates, containers or jetstalls.
Surveillance: introduction

Articles 12.1.11. to 12.1.13. define the principles and provide guidance on the surveillance for AHS, complementary to Chapters 1.4. and, for vectors, complementary to Chapter 1.5., applicable to Members seeking to determine their AHSV status. This may be for the entire country or zone. Guidance for Members seeking free status following an outbreak and for the maintenance of AHS status is also provided.

AHS is a vector-borne infection transmitted by a limited number of species of Culicoides insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of disease risk that incorporates vector competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic incubation period. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context.

According to this chapter, a Member demonstrating freedom from AHSV infection for the entire country or a zone should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter. This requires the support of a laboratory able to undertake identification of AHSV infection through the virus detection and antibody tests described in the Terrestrial Manual.

Susceptible captive wild, feral and wild equid populations should be included in the surveillance programme.

For the purposes of surveillance, a case refers to an equid infected with AHSV.

The purpose of surveillance is to determine if a country or zone is free from AHSV or if a zone is seasonally free from AHSV. Surveillance deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of infection with AHSV in the absence of clinical signs.

The following defines the occurrence of AHSV infection:

1. AHSV has been isolated and identified as such from an equid or a product derived from that equid, or
2. viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a confirmed or suspected case, or
3. serological evidence of active infection with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of vaccination have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a suspected case.

Article 12.1.12.

Surveillance: general conditions and methods

1. A surveillance system should be under the responsibility of the Veterinary Authority. In particular the following should be in place:
Annex 33 (contd)

a) a formal and ongoing system for detecting and investigating outbreaks of disease;

b) a procedure for the rapid collection and transport of samples from suspect cases of AHS to a laboratory for AHS diagnosis as described in the Terrestrial Manual;

c) a system for recording, managing and analysing diagnostic, epidemiologic and surveillance data.

2. The AHS surveillance programme should:

a) in a country/zone, free or seasonally free, include an early warning system for reporting suspicious cases. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the Veterinary Authority. An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is AHS. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of AHS should be investigated immediately and samples should be taken and submitted to a laboratory. This requires that sampling kits and other equipment are available for those responsible for surveillance;

b) conduct random or targeted serological and virological surveillance appropriate to the infection status of the country or zone in accordance with Chapter 1.4.

Article 12.1.13.

Surveillance strategies

The target population for surveillance aimed at identification of disease and/or infection should cover susceptible equids within the country or zone. Active and passive surveillance for AHSV infection should be ongoing. Surveillance should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the infection status of the country or zone.

A Member should justify the surveillance strategy chosen as appropriate to detect the presence of AHSV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clinical signs (e.g. horses). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. donkeys).

In vaccinated populations serological and virological surveillance is necessary to detect the AHSV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member wishes to declare freedom from AHSV infection in a specific zone, the design of the surveillance strategy would need to be aimed at the population within the zone.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size, expected prevalence and diagnostic sensitivity of the tests determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence, in particular, needs to be based on the prevailing or historical epidemiological situation.
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 vaccination/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 needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles for surveillance for disease/infection are technically well defined. Surveillance programmes to prove the absence of AHSV infection/circulation, need to be carefully designed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of AHS in equids particularly during a newly introduced infection. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucosal membranes and dyspnoea.

AHS suspects detected by clinical surveillance should always be confirmed by laboratory testing.

2. Serological surveillance

Serological surveillance of equid populations is an important tool to confirm absence of AHSV transmission in a country or zone. The species tested should reflect the local epidemiology of AHSV infection, and the equine species available. Management variables that may reduce the likelihood of infection, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the surveillance system.

Samples should be examined for antibodies against AHSV using tests prescribed in the Terrestrial Manual. Positive AHSV antibody tests results can have four possible causes:

a) natural infection with AHSV;

b) vaccination against AHSV;

c) maternal antibodies;

d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other purposes for AHSV surveillance. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of AHSV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no AHSV infection is present in a country or zone. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.
Annex 33 (contd)

Serological surveillance in a free zone should target those areas that are at highest risk of AHSV transmission, based on the results of previous surveillance and other information. This will usually be towards the boundaries of the free zone. In view of the epidemiology of AHSV, either random or targeted sampling is suitable to select herds and/or animals for testing.

Serological surveillance in a free country or zone should be carried out over an appropriate distance from the border with an infected country or infected zone, based upon geography, climate, history of infection and other relevant factors. The surveillance should be carried out over a distance of at least 100 kilometres from the border with that country or zone, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHSV free country or zone may be protected from an adjacent infected country or infected zone by a protection zone.

Serological surveillance in infected zones will identify changes in the boundary of the zone, and can also be used to identify the AHSV types circulating. In view of the epidemiology of AHSV infection, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of AHSV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological surveillance using tests described in the Terrestrial Manual can be conducted:

a) to identify virus circulation in at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to better characterize the genotype of circulating virus in a country or zone.

4. Sentinel animals

Sentinel animals are a form of targeted surveillance with a prospective study design. They comprise groups of unexposed equids that are not vaccinated and are managed at fixed locations and observed and sampled regularly to detect new AHSV infections.

The primary purpose of a sentinel equid programme is to detect AHSV infections occurring at a particular place, for instance sentinel groups may be located on the boundaries of infected zones to detect changes in distribution of AHSV. In addition, sentinel equid programmes allow the timing and dynamics of infections to be observed.

A sentinel equid programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of AHSV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.
Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting AHSV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid confounding factors sentinel groups should comprise animals selected to be of similar age and susceptibility to AHSV infection. The only feature distinguishing groups of sentinels should be their geographical location. Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling should reflect the equid species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of infection. Monthly sampling intervals are frequently used. Sentinels in declared free zones add to confidence that AHSV infections are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV circulating in a country or zone is provided by isolation and identification of the viruses. If virus isolation is required sentinels should be sampled at sufficiently frequent intervals to ensure that some samples are collected during the period of viraemia.

5. Vector surveillance

AHSV is transmitted between equine hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential vector species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of vector surveillance is to define high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector abatement measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local vector species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to equids.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types of traps to be used in vector surveillance and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of vector surveillance sites at the same locations as sentinel animals is advisable.

The use of a vector surveillance system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low vector infection rates mean that such detections can be rare. Other surveillance strategies are preferred to detect virus circulation.

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Annex 33 (contd)

CHAPTER 1.6.

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

Article 1.6.6.

Questionnaire on African horse sickness

AHS FREE COUNTRY

Report of a Member which applies for recognition of status, under Chapter 12.1. of
the Terrestrial Animal Health Code (2010), as a AHS free country

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

1. Introduction

   a. Geographical factors. Provide a general description of the country including physical, geographical
      and other factors that are relevant to AHS introduction. Provide a map identifying the factors
      above.

   b. Equine sector. Provide a general description of the equine sector and their relative economic
      importance in the country. Outline any recent significant changes observed within the sector
      grouping(s) (if relevant documents are available, please attach).

      i. Sport and race horses

      ii. Breeding stock equidae

      iii. Working and production equidae (including horses for slaughter)

      iv. Leisure equidae

      v. Captive wild, wild and feral equidae.

2. Description of equid population

   a. Demographics of domestic equidae. What is the equidae population by species within the various
      sectors? Provide a description of the methods of animal identification, holding and individual animal
      registration systems if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps
      as appropriate.

   b. Wildlife demographics. What captive wild, wild or feral equidae are present in the country? Provide
      estimates of population sizes and geographic distribution. What are the measures in place to prevent
      contact between domestic and captive wild, wild or feral equidae?
3. **Veterinary system**
   
a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.

b. Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how Veterinary Services supervise and control all AHS related activities. Provide maps and tables wherever possible.

c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS surveillance and control (include a description of training and awareness programmes on AHS).

d. Role of private veterinary profession in AHS surveillance and control.

e. Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS pathway.

4. **AHS eradication**
   
a. History. Provide a description of the AHS history in the country if applicable, date of first detection, origin of infection, date of eradication (date of last case), and serotypes present.

b. Strategy. Describe how AHS was controlled and eradicated (e.g. isolation of cases, stamping-out policy, zoning), provide time frame for eradication.

c. Vaccines and vaccination. What type of vaccine was used? What equine species were vaccinated? Were vaccinated animals marked or was vaccination recorded in a unique identification document?

d. Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.

e. Animal identification. Are equidae identified (individually or at a group level)?

f. Movements of equidae. How are movements of equidae controlled in the country? Provide evidence on the effectiveness of equidae identification and movement controls. Please provide information on pastoralism, transhumance and related movements.

g. Leisure and competition movements of equidae. How are movements of competition and leisure equidae controlled in the country. Please provide information on systems including any use of registration. Provide information on any events that include international movements of equidae.

h. Describe the market systems for equidae, in particular, if markets require the international movement of equidae.

5. **AHS diagnosis**
   
Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

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

i. Details on the types of tests undertaken.

ii. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.

iii. Give details of participation in inter-laboratory validation tests (ring tests).

iv. Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance

Provide documentary evidence that surveillance for AHS in the country complies with the provisions of Articles 12.1.11. to 12.1.13. of the Terrestrial Code, and Chapter 2.5.1. of the Terrestrial Manual. In particular, the following points should be addressed:

a. Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect cases, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis).

b. Surveillance. Are the following undertaken?

i. Serological surveillance

ii. Virological surveillance

iii. Sentinel animals

iv. Vector surveillance.

If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are wildlife species included? Provide a summary table indicating detailed results, for at least the past 2 years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of equidae examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the surveillance system.

7. AHS prevention

a. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that have been taken into account (e.g. size, distance from adjacent border to infected equidae)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

If the AHS free country borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent and/or vectors, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.
b. Import control procedures

From what countries or zones does the country authorize the import of equidae or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such equidae and products, and subsequent internal movement? What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equidae and their products for at least the past 2 years, specifying country or zone of origin and volume.

i. Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the Competent Authority. Describe the communication systems between the Competent Authority and the border inspection posts, and between border inspection posts.

ii. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

- Equidae,

- genetic material (semen, ova and embryos of the equine species),

- equine derived (by-)products and biological.

iii. Describe the action available under legislation, and actually taken, when an illegal introduction is detected. Provide information on detected illegal introduction.

8. Control measures and contingency planning

a. Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the Competent Authority for dealing with suspected or confirmed cases of AHS.

b. In the event of a suspected or confirmed AHS outbreak:

i. is quarantine imposed on premises with suspicious cases, pending final diagnosis?

ii. are movement restrictions applied on suspicion?

iii. describe the sampling and testing procedures used to identify and confirm presence of the causative agent;

iv. describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;

v. describe the control and/or eradication procedures (e.g. vaccination, modified stamping-out);

vi. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including conditions for restocking;
vii. give details of any compensation made available when equidae are killed, for disease control/eradication purposes.

9. Compliance with the Terrestrial Code

a. In addition to the documentary evidence that the provisions of Article 12.1.2 are properly implemented and supervised, the Delegate of the country must submit a declaration stating:

i. The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made;

ii. there has been no outbreak of AHS during the past 12 months;

iii. no systematic vaccination against AHS has been carried out during the past 12 months;

b. and that vaccinated equidae were imported in accordance with Chapter 12.1.

10. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 12.1.2. of the Terrestrial Code and provide detailed information as specified in sections 4(a), b), c and 6, and highlight any measures introduced to prevent a recurrence of the infection under section 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

AHS FREE ZONE

Report of a Member which applies for recognition of status, under Chapter 12.1. of the Terrestrial Animal Health Code (2010), as a AHS free zone

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

1. Introduction

a. Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above. The boundaries of the zone must be clearly defined, including a protection zone, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone (and of the protection zone) established in accordance with Chapter 4.3.

b. Equine sectors. Provide a general description of the equine sector and their relative economic importance in the country and the zone. Outline any recent significant changes observed within the sector grouping(s) (if relevant documents are available, please attach).

i. Sport and race horses

ii. Breeding stock equidae

iii. Working and production equidae (including horses for slaughter)
iv. Leisure equidae

v. Captive wild, wild and feral equidae.

2. Description of equidae population

a. Demographics of domestic equidae. What is the equidae population by species within the various sectors in the country and the zone? Provide a description of the methods of animal identification, holding and individual animal registration systems in the country and the zone if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.

b. Wildlife demographics. What captive wild, wild or feral equidae are present in the country and the zone? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and captive wild, wild or feral equidae?

3. Veterinary system

a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.

b. Veterinary Services. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 3.1 and 3.2 of the Terrestrial Code and 1.1.3 of the Terrestrial Manual and describe how Veterinary Services supervise and control all AHS related activities in the country and in the zone. Provide maps and tables wherever possible.

c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS surveillance and control (include a description of training and awareness programmes on AHS).

d. Role of private veterinary profession in AHS surveillance and control.

4. AHS eradication

a. History. Provide a description of the AHS history in the country and zone, if applicable, date of first detection, origin of infection, date of eradication in the zone (date of last case), and serotypes present.

b. Strategy. Describe how AHS was controlled and eradicated in the zone (e.g. isolation of cases, stamping-out policy, zoning), provide time frame for eradication.

c. Vaccines and vaccination. What type of vaccine was used in the zone and the rest of the country? What equine species were vaccinated? Were vaccinated animals marked or was vaccination recorded in a unique identification document?

d. Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.

e. Animal identification. Are equidae identified (individually or at a group level)?

f. Movements of equidae. How are movements of equidae controlled in, and between zones of the country? Provide evidence on the effectiveness of equidae identification and movement controls in the zone. Please provide information on pastoralism, transhumance and related movements.
Annex 33 (contd)

g. Leisure and competition movements of equidae. How are movements of competition and leisure equidae controlled in the country and the zone? Please provide information on systems including any use of registration. Provide information on any events that include international movements of equidae.

h. Describe the market systems for equidae in the country and the zone, in particular, if markets require the international movement of equidae.

5. AHS diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the Terrestrial Manual are applied in the country and the zone. In particular, the following points should be addressed:

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

b. Provide an overview of the AHS approved laboratories, in particular to address the following points:

   i. Details on the types of tests undertaken.

   ii. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.

   iii. Give details of participation in inter-laboratory validation tests (ring tests).

   iv. Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance

Provide documentary evidence that surveillance for AHS in the zone complies with the provisions of Articles 12.1.11. to 12.1.13. of the Terrestrial Code, and Chapter 2.5.1. of the Terrestrial Manual. In particular, the following points should be addressed:

a. Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect cases, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis) from the zone.

b. Surveillance. Are the following undertaken?

   i. Serological surveillance

   ii. Virological surveillance

   iii. Sentinel animals

   iv. Vector surveillance.
If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are wildlife species included? Provide a summary table indicating detailed results, for at least the past 2 years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted surveillance and numbers of equidae examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the surveillance system.

7. **AHS prevention**

a. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and/or zones that have been taken into account (e.g. size, distance from adjacent border to infected equidae)? Describe coordination, collaboration and information sharing activities with neighbouring countries and zones.

If the AHS free zone is established in an AHS infected country or borders an infected country or infected zones, describe the animal health measures implemented to effectively prevent the introduction of the agent and/or vectors, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.

b. Import control procedures. From what countries or zones does the country authorize the import of equidae or their products into the free zone? What criteria are applied to approve such countries or zones? What controls are applied on entry of such equidae and products, and subsequent internal movement? What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equidae and their products to the free zone for at least the past 2 years, specifying country or zone of origin and volume.

i. Provide a map with the number and location of ports, airports and land crossings in the zone. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the Competent Authority. Describe the communication systems between the Competent Authority and the border inspection posts, and between border inspection posts.

ii. Describe the regulations, procedures, type and frequency of checks at the points of entry into the zone and/or their final destination, concerning the import and follow-up of the following:

- equidae,
- genetic material (semen, ova and embryos of the equine species),
- equine derived (by-)products and biologicals.

iii. Describe the action available under legislation, and actually taken, when an illegal introduction into the zone is detected. Provide information on detected illegal introductions into the zone.

8. **Control measures and contingency planning**

a. Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the Competent Authority for dealing with suspected or confirmed cases of AHS in the country and the zone (including the protection zone if applicable).
Annex 33 (contd)

b. In the event of a suspected or confirmed AHS outbreak in the zone:
   i. is quarantine imposed on premises with suspicious cases, pending final diagnosis?
   ii. are movement restrictions applied on suspicion?
   iii. describe the sampling and testing procedures used to identify and confirm presence of the causative agent;
   iv. describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;
   v. describe the control and/or eradication procedures (e.g. vaccination, modified stamping-out);
   vi. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including conditions for restocking;
   vii. give details of any compensation made available when equidae are killed, for disease control/eradication purposes.

9. Compliance with the Terrestrial Code
   a. In addition to the documentary evidence that the provisions of Article 12.1.2 are properly implemented and supervised, the Delegate of the country must submit a declaration stating:
      i. The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made
      ii. there has been no outbreak of AHS during the past 12 months in the zone;
      iii. no systematic vaccination against AHS has been carried out during the past 12 months in the zone;
   b. and that vaccinated equidae were imported into the zone in accordance with Chapter 12.1.

10. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 12.1.2. of the Terrestrial Code and provide detailed information as specified in sections 4 (a), (b), (c) and 6 and highlight any measures introduced to prevent a recurrence of the infection under Section 7 of this questionnaire.

- text deleted
REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON ZOONOTIC PARASITES

Paris (France), 5–7 October 2010

The OIE ad hoc Group on Zoonotic Parasites (the ad hoc Group) met at the OIE Headquarters in Paris from 5 to 7 October 2010.

The members of the ad hoc Group and other participants are listed at Annex I. The Agenda and Terms of Reference adopted are given at Annex II and Annex III, respectively.

Dr Vallat, Director General of the OIE, joined the ad hoc Group meeting and thanked members for their support of the OIE and their work that will improve both animal health and public health. Dr Vallat noted that zoonotic parasites are involved in important public health problems worldwide and that the OIE will continue to increase its contribution to improving public health through the development of standards for zoonotic parasitic diseases.

Dr Vallat proposed that the ad hoc Group develop the existing OIE Terrestrial Animal Health Code (Terrestrial Code) chapters for trichinellosis and echinococcosis/hydatidosis, and develop a new chapter for porcine cysticercosis, also an OIE-listed disease. Dr Vallat suggested that it could be important for Members to have guidelines for good on-farm practices to prevent and control key non OIE-listed parasites such as Taenia saginata as these parasites, although not always a significant public health concern can result in significant economic losses due to condemnation of affected tissues. Dr Vallat encouraged the ad hoc Group to discuss these proposals as they develop their work plan during their meeting.

Dr Vallat informed the ad hoc Group that zoonotic aquatic parasites may also be of interest, and the OIE would explore this area if relevant in future work.

1. Trichinellosis

The ad hoc Group reviewed the current Terrestrial Code Chapter 8.13. Trichinellosis and decided to draft a new chapter as much of the existing text was out of date.

The ad hoc Group did not include articles on the establishment of a Trichinella-free country or zone as they considered that this was not feasible, since a number of wildlife species are known to be reservoirs of Trichinella, and it would be very difficult to reliably document their Trichinella-free status in a geographical area (country or zone), as well as to document the maintenance of such a status over time. The ad hoc Group discussed extensively the issue of whether to recommend conducting on-going surveillance of wildlife as a component of control programmes. The ad hoc Group considered that it was not practical to conduct on-going surveillance of wildlife in the area around a Trichinella-free pig farm. The ad hoc Group considered that in this case, providing that appropriate barriers to the entry of rodents and wildlife are in place and maintained, surveillance of wildlife is not warranted.
Annex 34 (contd)

The ad hoc Group did not make any recommendations for risk management of horses at the farm level because horses entering the food chain come from a wide range of sources, including farmed and non-farmed, and it was not feasible to make recommendations that would cover all possibilities. In relation to horses, public health protection could be assured by post mortem sampling and testing or by inactivation of the parasite by treatment of the meat.

The ad hoc Group noted that trichinellosis is prevalent in farmed crocodiles and recommended that the OIE address the associated public health issue.

The ad hoc Group also noted that trichinellosis affects many other species (both domestic and wild), and that exposure to meat from those species (for example, consumption by hunters of raw or undercooked meat from wild animals) could pose additional public health risks. The Group did not have time to discuss trichinellosis in wildlife in any detail. The revised Chapter 8.13. Trichinella Infection is presented in Annex IV.

2. Echinococcosis/hydatidosis

The ad hoc Group reviewed the current Terrestrial Code Chapter 8.4. Echinococcosis/hydatidosis and decided to draft a new chapter as the current text was scant and there was a need for more advice to Members.

The ad hoc Group noted the development the EG95 vaccine against hydatid infection in sheep, which has been shown to be highly effective in field trials. The ad hoc Group encouraged the commercialisation of this vaccine as an important adjunct to strategies to control hydatid disease in many parts of the world.

The ad hoc Group highlighted the importance of cooperation between the Veterinary Authority, the public health sector and other relevant entities such as wildlife services and local authorities responsible for abattoir waste management in the control of this disease, because management of the human/domestic animal/wildlife interface is key in the mitigation of public health risk.

The revised Chapter 8.4. Echinococcosis/hydatidosis is presented in Annex V.

3. Porcine cysticercosis

Due to lack of time, the ad hoc Group was not able to draft new text on porcine cysticercosis but members agreed to do some preparatory work prior to the next meeting.

4. Bovine cysticercosis

The ad hoc Group discussed briefly the feasibility of developing recommendations for bovine cysticercosis, and agreed that this was possible. However, they requested guidance from the OIE Terrestrial Animal Health Standards Commission as to the format and mode of publication/placement of an appropriate document.

5. Other zoonotic parasites of farmed animals

Agenda Item 3 was carried over to the next ad hoc Group meeting.

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../Annexes
Annex 34 (contd)

Annex 1

MEETING OF THE OIE AD HOC GROUP ON ZOONOTIC PARASITES

Paris (France), 5−7 October 2010

List of participants

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Annex 34 (contd)

Annex 1 (contd)

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MEETING OF THE OIE AD HOC GROUP ON ZOONOTIC PARASITES

Paris (France), 5–7 October 2010

Agenda

Welcome

1. Confirmation of Terms of Reference.

2. Discussion of working documents and other relevant documents provided by ad hoc Group Members.

3. Prepare a report to the APFSWG for consideration at its meeting on 2-4 November 2010 covering:
   a) Proposals for revision of the text of Terrestrial Code chapters on echinococcus/hydatidosis (Chapter 8.4.) and trichinellois (Chapter 8.13.) and for a new chapter on porcine cysticercosis, dealing with the management of these pathogens in animals in order to manage risks to human health.
   b) The need for guidance to OIE Members on bovine cysticercosis, including the feasibility and form of such guidance.
   c) The need for guidance to OIE Members on any other zoonotic parasite of farmed animals, including the feasibility and form of such guidance.
MEETING OF THE OIE AD HOC GROUP ON ZOONOTIC PARASITES

Paris (France), 5–7 October 2010

Adopted Terms of Reference

Background

The 3rd OIE Strategic Plan (2001–2005) recommended that "OIE should be more active in the area of public health and consumer protection," and noted that this should include "zoonoses and diseases transmissible to humans through food, whether or not animals are affected by such diseases", with the object of improving the safety of the food production to consumption continuum worldwide. In 2002, the Director General of the OIE established a permanent Working Group on Animal Production Food Safety (APFSWG) to coordinate the food safety activities of the OIE.

Since 2008 the OIE Terrestrial Animal Health Code (Terrestrial Code) has included a section on Veterinary Public Health, containing animal production food safety standards with a primary focus on measures applicable to food-borne/zoonotic hazards arising at the production level of the food chain.

In a OIE discussion paper ‘Animal production food safety: priority pathogens for standard setting by the OIE’, Taenia solium, T. saginata, Echinococcus granulosus and Trichinella spiralis were identified as zoonotic pathogens with a very significant impact on human health, particularly in Africa, South America and the Middle East. Echinococcosis/hydatidosis, trichinellosis and porcine cysticercosis are OIE listed diseases. The Terrestrial Code contains some recommendations on trade measures for Echinococcosis/hydatidosis and trichinellosis but no information on appropriate measures at the animal level to avoid human infection with these zoonotic pathogens. The Terrestrial Code does not contain any recommendations on porcine cysticercosis.

In 2005, the WHO/FAO/OIE published guidelines on the control of Echinococcus¹, Trichinella spiralis² and Taenia solium³. The Control of Neglected Zoonotic Diseases⁴ publication also includes some information on cysticercosis and Echinococcosis.

It is timely for the OIE to consider developing specific guidance to help Members manage the risks associated with these pathogens at the production level in order to prevent human illness.

Relevant considerations:

- The OIE has a mandate to develop international standards for animal production food safety, with a primary focus on measures applicable to zoonotic pathogens, for which measures can most effectively be implemented at the animal production level.

Annex 34 (contd)

Annex III (contd)

- Standards for zoonotic pathogens at the animal production level should take into account:
  - feasible and cost effective means of controlling the pathogen at the animal level;
  - feasible and cost effective measures for animals and animal products that are internationally traded;
  - existing Codex standards and guidelines of the WHO and FAO.

- The Terrestrial Code contains general recommendations on veterinary public health and specific recommendations on controlling salmonellosis in poultry.

- The existing recommendations in the Terrestrial Code (2010) on Echinococcosis/hydatidosis (Chapter 8.4.) and trichinellosis (Trichinella spiralis) (Chapter 8.13.). There is no Terrestrial Code chapter on porcine cysticercosis.

- The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (2010) recommendations on the diagnosis of animal infection with Echinococcosis/hydatidosis (Chapter 2.1.4.), trichinellosis (Chapter 2.1.16.) and cysticercosis (Chapter 2.9.5.).

- The ad hoc Group is required to prepare a report to the APFSWG for consideration at its meeting on 2–4 November 2010 covering:
  - Proposals for revision of the text of Terrestrial Code chapters on echinococcosis/hydatidosis (Chapter 8.4.) and trichinellosis (Chapter 8.13.) and for a new chapter on porcine cysticercosis, dealing with the management of these pathogens in animals in order to manage risks to human health.
  - The need for guidance to OIE Members on bovine cysticercosis, including the feasibility and form of such guidance. Note: Bovine cysticercosis was delisted in 2005 as it did not meet the criteria for listing and therefore it would not be appropriate to develop a Terrestrial Code chapter on this pathogen.
  - The need for guidance to OIE Members on any other zoonotic parasite of farmed animals, including the feasibility and form of such guidance.

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5 'The disease is not of cattle health concern. Although it is a zoonosis, the consequences in humans do not meet the criteria for inclusion and the disease can be excluded from the list' - extract from the report of the OIE ad hoc Group on Disease Listing (2005).
C H A P T E R  8 . 1 3 .

T R I C H I N E L L A  I N F E C T I O N

Article 8.13.1.

Introduction

Trichinellosis is a cosmopolitan zoonosis caused by eating raw or undercooked meat from Trichinella-infected food animals or game. The parasite lives in the small intestine (adults) and muscles (larvae) of many mammalian, avian and reptile host species, including humans, pigs, rodents, horses, bears and walruses. Within the genus Trichinella, twelve genotypes have been identified, eight of which have been designated species. Trichinella genotypes may vary considerably between localities, districts, regions and countries.

Trichinellosis can be a fatal disease in humans and is clinically inapparent in animals.

Breaking the transmission cycle to humans currently relies on the provision of Trichinella-free meat for human consumption. This is achieved by post mortem inspection and inactivation of the parasite in domestic or wild sourced meat. Processing of meat which ensures inactivation of Trichinella includes cooking, freezing and curing of meat (using specified time-temperature combinations). In addition, appropriate measures should be taken to prevent the exposure of food animals to infected meat including uncooked food waste, rodents and other wildlife.

Game meats should always be considered a potential source of infection, and should be tested or cooked properly. Trichinella found in game meats may be resistant to freezing (depending on the genotype present) and therefore untested, frozen game poses a public health risk.

Testing methods for the detection of Trichinella infection in pigs and other animal species include either directly demonstrating the parasite in muscle samples or indirectly demonstrating the parasite by detecting specific circulating antibodies to Trichinella spp., although the latter method is not always reliable, because of certain situations where cross-reactive antibodies are present due to co-infections with other nematode parasites or infection is in the early stages and detectable antibodies are not yet present.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 8.13.2.

Purpose and scope

This chapter deals with methods for on farm prevention of Trichinella infection in pigs and for safe trade of fresh meat and meat products derived from pigs and equines. This chapter complements the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

Article 8.13.3.

Prevention of trichinellosis in pigs

This article applies to pigs kept under confined conditions.

1. Constructing buildings and environmental barriers

   a) Buildings used to house pigs should be constructed to prevent entry of rodents (e.g. openings, such as those for air ventilation or water pipes should be covered with wire or specific devices) and wildlife.
Annex 34 (contd)

Annex IV (contd)

b) Areas within 100 metres of pig buildings should be free from rubbish and rodent harbourage.

c) A 2 metre perimeter consisting of gravel or vegetation mowed to a height of less than 10 cm should be maintained around all pig buildings.

2. Feed and feed storage

a) Feed should be stored and contained in closed silos or bins, which do not allow rodents to enter.

b) Purchased feed should be obtained from an approved facility, which produces feed following approved Good Manufacturing Practices.

c) Waste food containing meat products should be cooked to inactivate trichinae and in accordance with the provisions in the Terrestrial Manual (under development).

3. Rodent control

An ongoing approved programme for the control of rodents should be implemented.

4. Farm hygiene

a) Dead animals should be removed from pig buildings immediately after detection to prevent exposure to other pigs and rodents, and disposed of as soon as possible in accordance with the provisions of Chapter 4.12. Disposal of animals.

b) Garbage dumps should not be located near pig farm(s) in order to minimise the risk of infected rodents entering the farm(s).

5. Identification and traceability

An animal identification and traceability system should be implemented in accordance with the provisions of Chapters 4.1. and 4.2.

6. Introduction of animals

a) It is preferable to obtain new animals from Trichinella-free farms or compartments; or

b) if new animals are obtained from farms of unknown Trichinella status, they should be held in isolation and tested serologically to ensure the absence of antibodies to Trichinella (refer to the Terrestrial Manual). Adult pigs should be tested serologically on arrival and again five weeks after arrival. Weaner pigs should be tested serologically once five weeks after arrival.

If seropositive animal(s) are detected, all newly introduced pigs should be placed in quarantine and retested serologically. If positive, the animal(s) should be slaughtered and the meat processed or rendered according to national regulations on the handling of unsafe meat. The meat should also be tested directly by the pepsin digestion procedure (refer to Terrestrial Manual) to monitor the reliability of the serological test procedure and the validity of the test results.

Article 8.13.4.

Recommendations for pigs exposed to outdoor environments

While confinement production systems can be managed in a manner to reduce or eliminate the risk of exposure of pigs to Trichinella, pigs exposed to outdoor environments, or under conditions that facilitate contact with wildlife will always be at risk of Trichinella infection.
Pigs raised under these conditions should be tested at slaughter by detection methods, in accordance with the provisions in the *Terrestrial Manual*.

Recommendations in Article 8.13.3. for the prevention of *Trichinella* in pigs kept under confined conditions should also be applied wherever possible.

**Article 8.13.5.**

**Official recognition for *Trichinella*-free pig farm(s) or compartment(s)**

The *Veterinary Authority* may officially recognise pig farm(s) or compartment(s) already complying with Article 8.13.3. as *Trichinella*-free if the following additional requirements are met:

a) muscle samples from all pigs sent for slaughter during the 12 months preceding recognition of the pig farms within the compartment as *Trichinella*-free should have been tested by a digestion method and found to be negative for *Trichinella* (refer to the *Terrestrial Manual*);

b) at least two visits, at a minimum of 6 months apart, should have been made in the 12 months preceding recognition of the pig farms in the compartment as *Trichinella*-free and annually thereafter to verify compliance with good management practices described in Article 8.13.3;

c) a serological survey of the on farm pig population in the compartment should be conducted annually with a sample size providing at least a 95% confidence interval for detecting *Trichinella* (refer to the *Terrestrial Manual*);

d) documentation of all management practices undertaken on farm.

If a positive animal is detected by a digestion method, or serology which is confirmed by digestion, the pig farm(s) or compartment(s) will lose its *Trichinella*-free status. An investigation should be carried out by the *Veterinary Services* to identify the origin of the infection and appropriate remedial actions to be implemented.

Isolates that are obtained from an infected pig should be sent to an OIE Reference Laboratory for genotyping in order to provide epidemiological information.

**Article 8.13.6.**

**Recommendations for the importation of fresh meat or meat products of domestic pigs**

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

1. comes from domestic pigs that have been slaughtered in an approved *abattoir*, AND

2. was subjected to post mortem sampling and the samples were subjected to a digestion assay for *Trichinella* with negative results, in accordance with the provisions in the *Terrestrial Manual*; OR

3. comes from domestic pigs that originated from a *Trichinella*-free farm(s) or compartment(s) in accordance with the recommendations in Article 8.13.5.; OR

4. has been processed to ensure the inactivation of the larvae of the parasite *Trichinella* in accordance with the recommendations in Article 8.13.10. (under development).

**Article 8.13.7.**

**Recommendations for the importation of fresh meat or meat products of wild pigs**

*Veterinary Authorities* of importing countries should require the presentation of an *international veterinary certificate* attesting that the entire consignment of meat:
Annex 34 (contd)

Annex IV (contd)

1. comes from wild pigs that have been inspected in accordance with the provisions in Chapter 6.2.; AND

2. was subjected to a digestion assay for *Trichinella* with negative results, in accordance with the provisions in the *Terrestrial Manual*; OR

3. has been processed to ensure the inactivation of the larvae of the parasite *Trichinella*, in accordance with the recommendations in Article 8.13.10. (under development).

   Article 8.13.8.

**Recommendations for the importation of fresh meat or meat products of domestic equines**

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

1. comes from domestic equines that have been slaughtered in an approved abattoir; AND

2. was subjected to post mortem sampling and the samples were subjected to a digestion assay for *Trichinella* with negative results, in accordance with the provisions in the *Terrestrial Manual*; OR

3. has been processed to ensure the inactivation of all the larvae of the parasite *Trichinella* in accordance with the recommendations in Article 8.13.10. (under development).

   Article 8.13.9.

**Recommendations for the importation of fresh meat or meat products of wild equines**

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

1. comes from wild equines that have been inspected in accordance with the provisions in Chapter 6.2; AND

2. was subjected to a digestion assay for *Trichinella* with negative results, in accordance with the provisions in the *Terrestrial Manual*; OR

3. has been processed to ensure the inactivation of all the larvae of the parasite *Trichinella*, in accordance with the recommendations in Article 8.13.10. (under development).

   Article 8.13.10.

**Inactivation of muscle larvae**

(under development)
CHAPTER 8.4.

ECHINOCOCCOSIS / HYDATIDIOSIS

Introduction

*Echinococcus* is a genus of parasitic zoonotic cestodes (tapeworms) found worldwide in which the adult stages occur in the intestines of canids and felids, and the larval stages in tissues of various organs of other mammalian hosts, including humans. Transmission of parasites from this genus occurs in a predator/prey interaction between canids and less commonly to felids (definitive hosts) and a range of domestic and wildlife species of herbivores (intermediate hosts). Intermediate hosts may also include omnivores (humans and pigs). Infection with the larval stage (hydatid) of the parasite in the intermediate host, referred to as hydatidosis or hydatid disease, is associated with major economic losses and causes severe clinical disease in humans.

Echinococcosis is a zoonotic infection caused by larval (metacestode) stages of cestodes belonging to the genus *Echinococcus*. At present, four zoonotic species of *Echinococcus* are recognised, namely *Echinococcus granulosus*, *E. multilocularis*, *E. oligarthrus* and *E. vogeli*. *E. shiquicus* has recently been identified but its zoonotic status is not known.

The two most important causes of human hydatid disease are *Echinococcus granulosus*, that has a global distribution and *E. multilocularis* which occurs in wide areas of the Northern Hemisphere. There are at least ten genetic variants of *E. granulosus* of which seven (sheep strain G1, Tasmanian sheep strain G2, buffalo strain G3, cattle strain G5, camel strain G6, pig strain G7 and cervid strain G8) have been shown to be infective for humans. (NOTE: A recent proposal divides *E. granulosus* into several species, i.e., *E. granulosus* s.s. [G1-3], *E. equinus*, *E. ortleppi*, *E. canadensis* [G6-G10] and *E. felidis*). However, a broad consensus on this has not yet developed, and for the purposes of this chapter, the target species are *E. granulosus* and *E. multilocularis*, the most important causes of hydatid disease in important livestock.

Hydatidosis is not a foodborne disease in the classical sense. Infection occurs by ingestion of eggs via contact with infected dogs and/or by consumption of food (mainly vegetables) or water contaminated with infected (egg-contaminated) dog faeces. Prevention of human infection is achieved by preventing infection of dogs and intermediate hosts (mainly ruminants and especially sheep).

The long term goal should be the prevention of human and ruminant infection through prevention and control programmes.

Purpose and scope

This chapter deals with methods for the prevention of *Echinococcus* infection in dogs, hydatidosis in livestock and slaughterhouse/abattoir security.

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

Owned dog: means a dog with a person that claims responsibility.

Responsible dog ownership: means the situation whereby a person (as defined above) accepts and commits to perform various duties according to the legislation in place and focused on the satisfaction of the behavioural, environmental and physical needs of a dog and to the prevention of risks (aggression, disease transmission or injuries) that the dog may pose to the community, other animals or the environment.

Stray dog: means any dog not under direct control by a person or not prevented from roaming. Types of stray dog:
1. free-roaming owned dog not under direct control or restriction at a particular time;
2. free-roaming dog with no owner;
3. feral dog: domestic dog that has reverted to the wild state and is no longer directly dependent upon humans for successful reproduction.

Prevention of Echinococcus infection in canids

Both owned dogs, stray dogs and wild canids are important in the transmission of hydatid disease to humans and livestock because of the close inter-relationship between humans, dogs and livestock. The prevention of Echinococcus infection in dogs is the key element in breaking the transmission pattern of this parasite and is a fundamental aspect in the success of a hydatid control programme.

1. **Owned dogs**
   To prevent echinococcosis in owned dogs, the following measures should be undertaken:
   - dogs should be dewormed at least every 4-6 weeks with praziquantel (5 mg/kg);
   - dogs should not be fed raw offal from any animal species;
   - dogs should not be allowed to roam freely;
   - dogs should not have access to dead animals or offal of any animal species, including wildlife species. All dead animals and offal should be disposed of in accordance with provisions in Chapter 4.12. Disposal of animals;
   - dogs should be prevented access to carcasses, offal and waste at slaughterhouses/abattoirs;
   - people, and especially farmers and farm workers should be made aware of the risk factors of transmission and the importance of the disease in animals and humans, the role of dogs and wild canids in transmission, the need to implement control measures, and the importance of responsible dog ownership.

2. **Stray dog populations**
   To prevent echinococcosis in stray dog populations, the following measures should be undertaken:
   - compliance with relevant aspects of Chapter 7.7. Stray dog population control;
   - where possible, dogs should be dewormed at least every 4-6 weeks with praziquantel (5 mg/kg);
   - stray dogs should not be fed raw offal from any species;
stray dogs should be prevented access to carcasses, offal and waste at slaughterhouses/abattoirs;

stray dogs should not have access to dead animals or offal of any animal species, including wildlife species;

community health education programmes should be carried out regarding the risk factors of transmission and the importance of the disease in animals and humans, the role of dogs (including stray dogs) and wild canids in transmission, the need to implement control measures, and the importance of responsible dog ownership.

3. **Wild canid populations**

To prevent echinococciosis in wild canid populations, the following measures should be undertaken:

- wild canids should be prevented access to dead animals or offal of any animal species;
- wild canids should be prevented access to carcasses, offal and waste at slaughterhouses/abattoirs;
- wild canids should be prevented from entering areas of human habitation and farms, and contaminating the environment with eggs of *Echinococcus*;
- community health education programmes should be carried out regarding the role of wild canids in the transmission of hydatid disease to humans and animals.

In addition, the Veterinary Authority or other Competent Authority should ensure that slaughterhouses/abattoirs have in place measures that prevent access of dogs and wild canids to animal carcasses, offal and waste.

Article 8.4.5.

### Surveillance for the prevention of hydatid disease

1. **In slaughterhouses/abattoirs**

   The Veterinary Authority should carry out surveillance for hydatid infection in livestock species in slaughterhouses/abattoirs. When hydatid infection is detected an investigation should be carried out by the Veterinary Authority to identify the origin of the infection and appropriate remedial actions to be implemented.

2. **In dogs**

   Surveillance of *Echinococcus* infection in dogs using the copro-antigen test is a useful tool for monitoring the effectiveness of prevention programmes. The Veterinary Authority should use the copro-antigen test for surveillance in dogs. Positive results indicate failure of a control programme. In such a case, the Veterinary Authority should identify aspects of the prevention programme that should be reviewed and those for which remedial actions should be implemented.

   An animal identification and traceability system should be implemented in accordance with the provisions of Chapters 4.1 and 4.2.
Recommendations for the importation of dogs, cats and wild canids

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the animal has been treated, in accordance with the manufacturer’s instructions, between 24 and 48 hours prior to export with a praziquantel-based product (5mg/kg) that is effective against *Echinococcus granulosus* and *E. multilocularis*.
The OIE Working Group on Animal Production Food Safety (the Working Group) held its tenth meeting at the OIE Headquarters on 2 to 4 November 2010.

The members of the Working Group and other participants are listed at Annex I. The adopted agenda is provided at Annex II.

Dr Bernard Vallat, OIE Director General, met with the Working Group for a brief update on OIE developments relevant to the work of this Working Group, and welcomed the members of Working Group and thanked them for their support of OIE in this important area of work. Dr Vallat noted that the WHO World Health Assembly in May 2010 approved an amendment to the official OIE/WHO Agreement, introducing food safety as a topic of common interest and possible common activities for both organisations, and providing a legal basis for the joint development of common OIE/Codex standards. Dr Vallat noted that the Codex Alimentarius (CAC), Committee on General Principles will consider the proposal for the joint development of common OIE/Codex standards when it meets in April, 2012. He asked the Working Group to continue to provide advice on the areas where development of common OIE/Codex standards could be desirable.

Dr Vallat noted that there is interest on the part of Delegates in the scientific linkages between animal welfare, animal health and food safety. This is a complex matter as, although there are linkages, animal welfare and food safety are not linked in a simple and direct manner and this topic warrants study. He advised that he would support collaborative work between the two permanent OIE Working Groups (Animal Welfare and Animal Production Food Safety) on this topic as this could be useful to inform the standard setting work of the OIE in both animal welfare and animal production food safety.

Dr Vallat drew to the attention of the Working Group the work of the ad hoc Group on Zoonotic Parasites, which arose from the Discussion Paper on Priority Pathogens for future standard setting, produced under the APFSWG auspices. He asked the Working Group to review this work and, if in agreement with the ad hoc Group’s approach, to forward the report to the OIE Terrestrial Animal Health Standards Commission (Code Commission) for consideration at its February 2011 meeting.
Annex 35 (contd)

Dr Vallat noted that the OIE started working on the topic of veterinary education in 2009 and that this work is ongoing, with an ad hoc Group and a second global conference on veterinary education being organized in Lyon within the framework of the ‘Veterinary Year 2011’. This conference will feature 1 ½ days dedicated to the work of the OIE on 13-14 May 2011. Dr Vallat encouraged the Working Group and particularly, FAO to become involved in the OIE work on veterinary education, with particular attention to veterinary competencies in food inspection and safety.

On the important contribution of aquaculture to food security, Dr Vallat informed the Working Group that the OIE would hold the first Global Conference on the contribution of aquatic animal health programmes to food security in Panama, 28-30 June, 2011 and encouraged the Working Group to consider the future need for animal production food safety standards for products of aquatic animals at the production level.

Finally, on the subject of capacity building, Dr Vallat noted the on-going work of the OIE in conducting seminars for OIE National Focal Points, under the authority of the national Delegate, in all five regions. Funding was available to ensure that these seminars would be repeated (using new content) on a 2-yearly basis. Dr Vallat also highlighted the role of the OIE focal points for the coordination of national activities, e.g. through their relationship with INFOSAN networks and welcomed input from the Working Group for new content of these seminars and suggestions for mechanisms for improving collaboration between focal points and other organisations/experts dealing with food safety.

Dr Vallat informed the Working Group that it was possible at any time to convene specific ad hoc Groups or to work with OIE Reference Laboratories or Collaborating Centres, as appropriate, if the Working Group sees any need for additional expertise.

1. **Update on OIE / Codex / FAO / WHO activities**

   1.1. OIE

   **The ad hoc Group on the OIE Handbook on Import Risk Analysis**

   The revised Volume I (Introduction and qualitative risk analysis) of the OIE Handbook on Import Risk Analysis for Animals and Animal Products has been finalised with publication planned for December 2010. Volume II (quantitative risk assessment) has not been revised, but will be reprinted. In addition, these publications will be available by downloading, free of charge, from the OIE website and by purchase in hard copy.

   **Brucellosis**

   The 2010 meeting of the ad hoc Group on Brucellosis to review the OIE Terrestrial Animal Health Code (Terrestrial Code) chapters on brucellosis was postponed until early 2011.

   **One Health Concept**

   The Working Group briefly reviewed the Tripartite Concept Note, which addresses the need and mechanisms for collaboration between the OIE, FAO and WHO on the interface between wildlife, livestock, human health and the environment. Noting that the framework for collaboration covers food safety, the Working Group concluded that, for the moment, it has nothing to add, but would keep the matter under review.

   **Pet food**

   The Working Group noted that the modification of the terms of reference of the ad hoc Group on Pet Food to address only OIE listed diseases. As the ad hoc Group is no longer addressing food safety, the Working Group decided to remove this item from its agenda.
**Food safety and aquatic animal products**

The Working Group briefly reviewed the Discussion paper on ‘Infectious agents of potential public health concern in aquaculture’ prepared by members of the Aquatic Animal Health Standards Commission. The Working Group noted that the paper addressed occupational health issues and that there are very few bacterial or viral pathogens of aquatic animals that systematically cause food borne illness in humans.

Dr Bruno informed the Working Group that in July 2010 the CAC adopted a Code of Practice for Pathogenic *Vibrio* spp. in Seafood and an Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in molluscan shellfish and that the Codex Committee on Fish and Fishery Products at its next session will consider a list of methods for the determination of biotoxins for the Standard for Raw and Bivalve Molluscs.

The Working Group considered that no further work is needed at this time on food safety standards for products of aquatic animals, but would monitor developments in this area.

**1.2. Codex**

Dr Bruno provided an update on the work of Codex. Detailed information is provided in Annex III.

**1.3. FAO**

Dr de Balogh was unable to attend the meeting but provided an update on the work of FAO which is provided in Annex IV.

**1.4. WHO**

Dr Magnino provided an update on the work of WHO. Detailed information is provided in Annex V.

The Working Group encouraged the Director General to continue to support communication and collaboration between the Secretariats of OIE and CAC, and the relevant units at the FAO and WHO, to ensure close co-ordination of the relevant work of these organisations.

**2. Priority pathogens for future standard setting at the OIE**

The Working Group considered the comments of OIE Members and the Code Commission on the OIE Discussion paper ‘Priority pathogens for future standard setting at the OIE’.

The Working Group discussed the need for and feasibility of developing OIE advice on the control of *Salmonella* spp. in food producing animals other than poultry (i.e. pigs, cattle, small ruminants) and Verotoxigenic *E.coli* (VTEC) in food-producing animals with the purpose of reducing foodborne illness. In this regard the Working Group requested that the OIE undertake a review of the scientific literature on these pathogens. The proposed terms of reference for this work are presented in Annex VI.

The Working Group undertook to examine the review at its meeting in 2011 and to decide on the need for and feasibility of development of OIE standards for these pathogens.

**3. Ad hoc Group on Zoonotic Parasites**

The Working Group discussed the report of the *ad hoc* Group on Zoonotic Parasites and supported the proposed new chapters and the work direction.
Annex 35 (contd)

The Working Group agreed that the Code Commission should consider the recommendations of the ad hoc Group in February 2011.

4. Terrestrial Code chapters on salmonellosis and biosecurity procedures in poultry production

Dr Mylrea, Charge de mission, International Trade Department, updated the Working Group on the on-going work on Terrestrial Code Chapter 6.5, ‘Prevention, Detection and Control of Salmonella in Poultry’ and Chapter 6.4, ‘Biosecurity Procedures in Poultry Production’. These texts had been revised by the ad hoc Group on Salmonellosis and circulated to OIE Members with the September 2010 Report of the Code Commission.

Concerning on-going work in Codex Committee on Food Hygiene on Campylobacter and Salmonella in chicken meat refer to Annex III.

The Working Group supported this work and congratulated the ad hoc Group on its work.

5. Antimicrobial resistance

Dr Erlacher-Vindel, Deputy Head of the OIE Scientific Department, joined the Working Group for this item. Dr Erlacher-Vindel summarised the current work of the OIE related to antimicrobial resistance in terrestrial animals. She noted that the OIE had convened an ad hoc Group to update the OIE standards on antimicrobial resistance (Terrestrial Code and Terrestrial Manual) and the OIE list of critically important veterinary antimicrobial agents. The first meeting of the ad hoc Group, in collaboration with WHO and FAO, was held on 2–4 November 2011 with the objective of revising the Terrestrial Code Chapter 6.8, ‘Monitoring of the quantities of antimicrobials used in animal husbandry’. If time allows, the Group will also update Chapter 6.7, ‘Harmonisation of national antimicrobial resistance surveillance and monitoring programmes’. The report of the ad hoc Group will be submitted to the Scientific Commission for Animal Diseases and the Code Commission at their meetings in February 2011. The OIE is taking care to ensure coordination between this ad hoc Group and the ad hoc Group developing text on the prudent use of antimicrobial agents in aquatic animals.

The ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance has finalised its work on the draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance which will be considered for adoption at the 34th Session of the CAC in 2011 (refer to Annex III).

Dr Erlacher-Vindel noted that the OIE was providing seminars for national OIE Focal Points on Veterinary Products in the five OIE regions.

Dr Kahn, Head OIE International Trade Department, updated the Working Group on activities related to antimicrobial resistance in aquatic animals. The ad hoc Group on Responsible Use of Antimicrobials in Aquatic Animals held its second meeting the 4–6 October 2010 and reviewed Member comments on the draft Aquatic Animal Health Code (Aquatic Code) Chapter 6.3 ‘Responsible and prudent use of antimicrobial agents in veterinary medicine’. This chapter will be proposed for adoption at the 79th General Session in May 2011 and was circulated for Member comment in the October 2010 report of the Aquatic Animals Commission. The ad hoc Group is also developing a new draft Aquatic Code Chapter 6.X. ‘Harmonisation of National Antimicrobial Resistance Surveillance’ and ‘Monitoring Programmes for Aquatic Animals’ and a new draft Chapter 6.X. ‘Monitoring of the Quantities of Antimicrobials Used in Aquatic Animals’.

The Working Group endorsed the OIE work on antimicrobial resistance and encouraged the OIE to continue to engage closely with CAC, FAO and WHO on the important topic.
6. **Biotechnology**

Dr Erlacher-Vindel joined the Working Group for this item and summarised the activities related to biotechnology. The updated chapter 1.1.7A of the *Terrestrial Manual* on ‘The application of Biotechnology to the Development of Veterinary Vaccines’ was adopted at the 78th OIE General Session in May 2010. The need for a new chapter on Diagnostic Tests related to new and emerging technologies was discussed by the Biological Standards Commission at their October 2010 meeting. However, the final decision on whether an *ad hoc* Group should be convened on this issue will be taken at the next meeting in 2011.

7. **OIE Regional training workshops for national Focal Points for Animal Production Food Safety**

Dr Kahn informed the Working Group that seminars for Animal Production Food Safety national Focal Points had been conducted in 2009/2010 in: Europe (22 - 24 April 2009, Sofia, Bulgaria); Africa (24 - 26 September 2009, Yaoundé, Cameroun); Middle East (2-4 February 2010, Kuwait City); Americas (9-11 March 2010, Buenos Aires, Argentina); and Far East, Asia Pacific (12-14 October 2010, Singapore).

Dr Kahn thanked Dr Slorach for his participation in these seminars and informed the Working Group that the OIE had secured resources to undertake a second global round of training for OIE national Focal Points.

The Working Group welcomed this initiative and endorsed the terms of reference for the national Animal Production Food Safety Focal Points.

The Working Group made the following recommendations:

i) in order to stimulate active participation in OIE activities related to animal production food safety, OIE Members that have not already appointed a national Focal Point for Animal Production Food Safety should do so as soon as possible;

ii) OIE Members should participate more actively in the development of new and revised standards by commenting on the draft texts on animal production food safety circulated by the OIE Specialist Commissions. The Focal Points for Animal Production Food Safety should assist the Delegates in this work;

iii) each national Focal Point for Animal Production Food Safety should communicate with the Codex Contact Point and other relevant contact points in food safety and SPS domains in their country in order to better co-ordinate the standard setting activities of the OIE and CAC at the national level;

iv) OIE should copy the information on animal production food safety issues sent to Delegates to the national Focal Points for animal production food safety.

8. **OIE’s work on private standards**

Dr Kahn updated the Working Group on the outcomes of two meetings of the *ad hoc* Group on Private Standards (16 February and 10 September 2010) and Resolution 26 of the 78th OIE General Session (May 2010) on the issue of private standards.

Dr Messuti expressed his satisfaction that, according to the Resolution, a successful collaborative meeting was held in September 2010 between some of the key global private standard setting organisations and the OIE to try to ensure that the international standards of the OIE for animal health are referenced by these organisations.
Annex 35 (contd)

Dr Bruno informed the Working Group that an FAO document on private standards was presented at the 33rd CAC in 2010 and is available at: ftp://ftp.fao.org/codex/cac/cac33/cac33_13e.pdf

The Working Group noted this update and requested that the OIE continue to provide updates on developments in this area.

9. Scientific evidence on the relationship between animal welfare and animal production food safety

Dr Slorach informed the members of the Working Group of his contacts with the Chair of the OIE Animal Welfare Working Group (AWWG) on this topic and noted that food safety was not within the mandate of the AWWG, which is primarily responsible for the development of OIE standards and recommendations on animal welfare.

The Working Group discussed how to proceed on this topic and the scope of the work that it might undertake. The Working Group proposed to work in collaboration with the AWWG to draft terms of reference for a literature review on the scientific evidence for relationships that may exist between the welfare of food producing animals and food safety. This information would be useful to inform the standard setting work of the OIE in both animal welfare and food safety.

The Working Group proposed to work together with the AWWG in reviewing the outcome of the literature review and deciding the next steps.

10. Importance of animal production food safety for food security

The Working Group discussed this topic at length and agreed that measures to improve food safety contribute significantly to improved productivity. Apart from the obvious need to produce food that is safe and nutritious, appropriate measures result in more efficient production and therefore help to improve food security.

The Working Group noted work that is being undertaken by FAO and other relevant organisations on this topic (http://www.fao.org/docrep/x0262e/x0262e14.htm#TopOfPage).

The Working Group decided to keep this matter under review.

11. Animal production food safety in veterinary education

Dr Kahn informed the Working Group on the work of the OIE ad hoc Group on Veterinary Education. Following the successful First OIE Global Conference on Veterinary Education (Paris, December 2009), the OIE convened an ad hoc Group comprising veterinary deans from the five OIE regions, the President of the World Veterinary Association, and representatives of major donors (the EC and the World Bank). The Group held its first meeting in June 2010 and produced a report, which was endorsed by the Terrestrial Code Commission at its meeting in September 2010. The ad hoc Group made recommendations on the key competencies of a ‘day 1 veterinary graduate’ with regard to the OIE recommendations for performance of veterinary services. The ad hoc Group will meet again in December 2010 to consider Member comments.


The Working Group briefly reviewed the recommendations of the ad hoc Group and endorsed the overall approach.

Professor Aidaros and Dr Thwala both expressed very strong support for the OIE’s work in the field of veterinary education and encouraged the OIE to provide recommendations on the minimum requirements in the core curriculum for veterinary education which may improve education in some developing countries.
Dr Vallat in his welcome had encouraged the involvement of the Working Group and FAO in particular in future work on veterinary education.

The Working Group offered their expertise for future work on veterinary education with respect to competencies in animal production food safety and looked forward to future outcomes in this area.

12. Work Programme for 2011

The Working Group proposed work programme for 2011 is presented at Annex VII.

13. Next meeting

The Working Group plans to hold its next meeting in early November 2011.

.../Appendices
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Annex 35 (contd)

Appendix I (contd)

**OTHER PARTICIPANTS**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Address</th>
<th>Phone</th>
<th>Email</th>
</tr>
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<tbody>
<tr>
<td>Dr Annamaria Bruno</td>
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<tr>
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**OBSERVERS**

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<thead>
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<td>Tel.: (39) 06570 56254</td>
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**OIE HEADQUARTERS**

<table>
<thead>
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<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Dr Bernard Vallat</td>
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</tr>
<tr>
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TENTH MEETING OF THE OIE
ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP
Paris, 2–4 November 2010

Adopted agenda

Welcome from the OIE Director General

Adoption of the Agenda

Report of the previous Working Group Meeting

1. Update on OIE / Codex / FAO / WHO activities
   1.1. OIE
   1.2. Codex
   1.3. FAO
   1.4. WHO

2. Priority pathogens for future standard setting at the OIE

3. Ad hoc Group on Zoonotic Parasites

4. Terrestrial Code chapters on salmonellosis and biosecurity procedures in poultry production

5. Antimicrobial resistance

6. Biotechnology

7. OIE Regional training workshops for national Focal Points for Animal Production Food Safety

8. OIE’s work on private standards

9. Scientific evidence on the relationship between animal welfare and animal production food safety

10. Importance of animal production food safety for food security

11. Animal production food safety in veterinary education

12. Work Programme for 2011

13. Next meeting
ACTIVITIES OF THE CODEX ALIMENTARIUS COMMISSION

CODEX SESSIONS SINCE THE LAST MEETING OF THE OIE APFSWG (3-5 NOVEMBER 2009)

- The 31st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (Düsseldorf, Germany, 2-6 November 2009)⁶
- The 41st Session of the Codex Committee on Food Hygiene (San Diego, United States of America, 16-20 November 2009)⁷
- The 63rd Session of the Executive Committee of the Codex Alimentarius Commission (Geneva, Switzerland, 8-11 December 2009)⁸
- The 11th Session of the Codex Committee on Milk and Milk Products (Auckland, New Zealand, 1-5 February 2010)⁹
- The 18th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (Surfers Paradise, Australia, 1-5 March 2010)¹⁰
- The 31st Session of the Codex Committee on Methods of Analysis and Sampling (Budapest, Hungary, 8-12 March 2010)¹¹
- The 42nd Session of the Codex Committee on Food Additives (Beijing, China, 15-19 March 2010)¹²
- The 26th Session of the Codex Committee on General Principles (Paris, France, 12-16 April 2010)¹³
- The 42nd Session of the Codex Committee on Pesticide Residues (Xian, China, 19-24 April 2010)¹⁴
- The 4th Session of the Codex Committee on Contaminants in Foods (Izmir, Turkey, 26-30 April 2010)¹⁵
- The 38th Session of the Codex Committee on Food Labelling (Quebec City, Canada, 3-7 May 2010)¹⁶
- The 64th Session of the Executive Committee of the Codex Alimentarius Commission (Geneva, Switzerland, 29 June – 2 July 2010)¹⁷
- The 33rd Session of the Codex Alimentarius Commission (Geneva, Switzerland, 5-9 July 2010)¹⁸
- The 19th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (Burlington, United States of America, 30 August – 3 September 2010)¹⁹
- The 11th Session of the FAO/WO Coordinating Committee for North America and the South West Pacific (Nuku’alofa, Tonga, 28 September – 1 October 2010)²⁰

⁷ http://www.codexalimentarius.net/download/report/734/al33_13e.pdf
⁸ http://www.codexalimentarius.net/download/report/735/al33_03e.pdf
¹⁰ http://www.codexalimentarius.net/download/report/733/al33_30e.pdf
¹³ http://www.codexalimentarius.net/download/report/740/al33_33e.pdf
¹⁵ http://www.codexalimentarius.net/download/report/739/al33_41e.pdf
¹⁶ http://www.codexalimentarius.net/download/report/742/al33_22e.pdf
¹⁷ http://www.codexalimentarius.net/download/report/743/al33_03ae.pdf
¹⁹ http://www.codexalimentarius.net/download/report/761/REP11_RXe.pdf
Annex 35 (contd)

Appendix III (contd)

- The 11th Session of the FAO/WO Coordinating Committee for Europe (Warsaw, Poland, 5-8 October 2010)
- The 4th Session of the ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (Muju, Republic of Korea, 18-22 October 2010)
- The 25th Session of the Codex Committee on Processed Fruits and Vegetables (Bali, Indonesia, 25-29 October 2010)

In particular, the OIE APFSWG may wish to note the following:

The 33rd Session of the Codex Alimentarius Commission, among others:

- Adopted 25 new or revised Codex standards or related texts or amendments to these texts and many new or revised provisions for additives and MRLs for pesticides;
- Agreed to consider further the MRLs for ractopamine at its next session;
- Approved a number of new work proposals or discontinuation of work, and revoked several standards and related texts;
- Agreed to establish a new Task Force on Animal Feeding and made other recommendations to address issues related to animal feeding;
- Noted the status of implementation of the Strategic Plan 2008-2013 of the Codex Alimentarius Commission;
- Considered the impact of private standards and agreed to forward this question to regional Coordinating Committees; and
- Confirmed the host governments of Codex subsidiary bodies and adjourned sine die the Committee on Milk and Milk Products

The following is a summary of the main outputs of the work and discussion of Codex Committees and Task Forces relevant to the OIE APFSWG:

The 41st Session of the Codex Committee on Food Hygiene, expressed appreciation to the OIE for their information and contribution to the work of the Committee and noted the need for continued collaboration in areas of mutual interest. Finalised work on the Code of Hygienic Practice for Vibrio spp. in Seafood; the Annex on Control Measures for Vibrio parahaemolyticus and Vibrio vulnificus in Molluscan Shellfish; and the Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene. The CCFH agreed to continue working on the Proposed Draft Guidelines for the Control of Campylobacter and Salmonella spp. in Chicken Meat and to ask the Commission to approve new work on the revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1995) and the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

The 11th Session of the Codex Committee on Milk and Milk Products, finalised work on the amendment to the Codex Standard for Fermented Milks (CODEX STAN 243-2003), pertaining to Drinks based on Fermented Milk and the revised Model Export Certificate for Milk and Milk Products (CAC/GL 67-2008) to the 33rd Session of the Commission for adoption. The CCMMMP recommended discontinuing work on the elaboration of a standard for processed cheese and to adjourn the Committee sine die until such a time as the Commission would require it to undertake new work.

The 18th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems, finalised work on the Principles and guidelines for the conduct of assessment of foreign official inspection and certification systems (Annex to the Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997)) and agreed to further work on the principles and guidelines for the national food control systems.

The 26th Session of the **Codex Committee on General Principles**, finalised work on the revised *Code of ethics for international trade in food including concessional and food aid transactions*; the amendments to the *Guidelines to Chairpersons of Codex Committees and Ad Hoc Intergovernmental Task Forces* and the *Guidelines to Host Governments of Codex Committees and Ad Hoc Intergovernmental Task Forces*. The CCGP concluded that there was no merit in having a general Codex definition of the term “competent authority” and agreed to see government comments on the discussion paper on Joint Codex/OIE standards to request comments from members for discussion at the next session.

The 4th Session of the **Codex Committee on Contaminants in Foods**, finalised work, among others, on the Maximum Level for Melamine in Food (*powdered infant formula and foods other than infant formula*) and Feed.

The 19th Session of the **Codex Committee on Residues of Veterinary Drugs in Foods**, finalised work on the MRLs for narasin in pig tissues and tilmicosin in chicken and turkey tissues and agreed to consider the MRLs for tilmicosin in cattle tissues at its next session. The CCRVDF agreed to consider the development of a policy for extrapolation of MRLs to additional species and tissues and to revise the *Risk Analysis Principles applied by the CCRVDF* and the *Risk Assessment Policy for the Setting of MRLs for Veterinary Drugs* with special emphasis on the revision of Section 3.2 “Evaluation of risk management options” and the development of risk management and risk communication recommendations for veterinary drugs with no ADI and/or MRLs. The CCRVDF further agreed to start developing risk management recommendations for veterinary drugs for which no ADI and/or MRL was recommended by JECFA due to specific human health concern; and a risk analysis policy for setting appropriate limits for veterinary drugs in honey.

The 4th Session of the **ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance** finalised its work on the draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance which were forwarded to the 34th Session of the Codex Alimentarius Commission for adoption. With the completion of this work, the Task Force had completed the task assigned to it by the Commission. The Task Force was also informed on recent activities of FAO, WHO and OIE on antimicrobial resistance.

**FORTHCOMING CODEX MEETINGS (relevant to the OIE APFSWG)**

- The 42nd Session of the Codex Committee on Food Hygiene (Kampala, Uganda, 29 November – 3 December 2010)
- The 5th Session of the Codex Committee on Contaminants in Foods (the Hague, the Netherlands, 21 – 25 March 2011)
- The 31st Session of the Codex Committee on Fish and Fishery Products (Tromso, Norway, 11-16 April 2011)
- The 34th Session of the Codex Alimentarius Commission (Geneva, Switzerland, 4-9 July 2011)
- The 19th Session of the Codex Committee on Food Import and Export Inspection and Certifications Systems (Australia, 17-21 October 2011)

The 42nd Session of the **Codex Committee on Food Hygiene** will consider the following proposed drafts: Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat; Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food; and Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods. International Organizations, including OIE, have been invited to present relevant work to the Committee.
Annex 35 (contd)

Appendix III (contd)

The 31st Session of the **Codex Committee on Fish and Fishery Products** will continue working on sections of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and on a number of standards for fish and fish products, including standards for: fish sauces; smoked fish, smoke-flavoured fish and smoke-dried fish; quick frozen scallop adductor muscle meat; and fresh/live and frozen abalone (*Haliotis* spp.). The CCFFP will also consider: the need to revise the *Model (sanitary) certificate for fish and fishery products* (CAC/GL 48-2004) to align it with the *Generic Model Official Certificate* (CAC/GL 28-2001); a list of methods for determination of biotoxins in the *Standard for raw and live bivalve molluscs* (CODEX STAN 292-2008); a Code of practice for processing scallop meat; and the procedure for the inclusion of additional species in standards for fish and fishery products.

The 18th Session of the **Codex Committee on Food Import and Export Inspection and Certification Systems** will continue working on the Principles and Guidelines for National Food Control Systems. International Organizations, including OIE, have been invited to present relevant work to the Committee.

___________
### Part 1 – Standards and Related Texts Adopted at Step 8

<table>
<thead>
<tr>
<th>Standards and Related Texts</th>
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<tr>
<td>Standard for Bitter Cassava</td>
<td>ALINORM 08/31/REP, Para. 38</td>
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<tr>
<td>Section 6 “Marking or Labelling” (Standard for Bitter Cassava)</td>
<td>ALINORM 10/33/35 Appendix II</td>
</tr>
<tr>
<td>Standard for Apples</td>
<td>ALINORM 10/33/35 Appendix III</td>
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<tr>
<td>Code of Practice for Fish and Fishery Products (Sections on Lobsters and Crabs and Relevant Definitions)</td>
<td>ALINORM 10/33/18 Appendix II</td>
</tr>
<tr>
<td>Standard for Sturgeon Caviar</td>
<td>ALINORM 10/33/18 Appendix V</td>
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<tr>
<td>List of Methods for Dietary Fibre</td>
<td>ALINORM 10/33/26 Appendix II</td>
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<tr>
<td>Amendment to the <em>Codex Standard for Fermented Milks</em> (CODEX STAN 243-2003), pertaining to Drinks based on Fermented Milk</td>
<td>ALINORM 10/33/11 Appendix II</td>
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<td>Food Additive Provisions of the <em>General Standard for Food Additives</em> (GSFA)</td>
<td>ALINORM 10/33/12 Appendix III</td>
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<tr>
<td>Revised <em>Code of Ethics for International Trade in Foods</em> (CAC/RCP 20-1985) including Concessional and Food Aid Transactions</td>
<td>ALINORM 10/33/33 Appendix II</td>
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<td>Maximum Residue Limits for Pesticides</td>
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### Part 2 – Standards and Related Texts Adopted at Step 5/8 (with omission of Step 6 and 7)

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<tr>
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<tr>
<td>Code of Hygienic Practice for Pathogenic <em>Vibrio</em> spp. in Seafood</td>
<td>ALINORM 10/33/13 Appendix III</td>
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<td>Annex on Control Measures for <em>Vibrio parahaemolyticus</em> and <em>Vibrio vulnificus</em> in Molluscan Shellfish</td>
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<td>Principles and Guidelines for the Conduct of Assessment of Foreign Official Inspection and Certification Systems (Annex to the <em>Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems</em> (CAC/GL 26-1997))</td>
<td>ALINORM 10/33/30 Appendix II</td>
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### Appendix III (contd)

#### Standards and Related Texts

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<tr>
<td>Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods</td>
<td>ALINORM 10/33/23 Appendix III</td>
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<td>Food Additive Provisions of the <em>General Standard for Food Additives</em> (GSFA)</td>
<td>ALINORM 10/33/12 Appendix III</td>
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<td>Guidelines on Substances Used as Processing Aids</td>
<td>ALINORM 10/33/12 Appendix VIII</td>
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<td>Amendments to the <em>International Numbering System for Food Additives</em> (CAC/GL 36-2009)</td>
<td>ALINORM 10/33/12 Appendix IX</td>
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<td>Specifications for the Identity and Purity of Food Additives arising from the 71st Meeting of JECFA</td>
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<td>Maximum Residue Limits for Pesticides</td>
<td>ALINORM 10/33/24 Appendix III</td>
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<tr>
<td>Maximum Levels for Melamine in Food (<em>Powdered Infant Formula and Foods other than Infant Formula</em>) and Feed</td>
<td>ALINORM 10/33/41 Appendix IV</td>
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<tr>
<td>Maximum Levels for Total Aflatoxins in Shelled, Ready-to-Eat Brazil Nuts and Shell, Destined for Further Processing Brazil Nuts</td>
<td>ALINORM 10/33/41 Appendix V</td>
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<tr>
<td>Revision of Code of Practice for the Prevention and Reduction of Aflatoxin in Tree Nuts (Additional Measures for Brazil Nuts)</td>
<td>ALINORM 10/33/41 Appendix VI</td>
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<tr>
<td>Principles and Criteria for Legibility of Nutrition Labelling</td>
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#### Part 3 – Other Standards and Related Texts Submitted for Adoption

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<tr>
<td>Revised Food Additive Listings in Standards for Milk and Milk Products</td>
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<tr>
<td>Revised <em>Model Export Certificate for Milk and Milk Products</em> (CAC/GL 67-2008)</td>
<td>ALINORM 10/33/11 Appendix V</td>
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<tr>
<td>Revised Section on Contaminants in Standards for Milk and Milk Products</td>
<td>ALINORM 10/33/11 para. 105</td>
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<td>Methods of Analysis in Codex Standards at Different Steps, including Methods of Analysis for Natural Mineral Waters</td>
<td>ALINORM 10/33/23 Appendix II</td>
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<td>Amendment to the name and descriptors of food categories 06.0, 06.2 and 06.2.1 of the GSFA</td>
<td>ALINORM 10/33/12 para. 16</td>
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<tr>
<td>Deletion of note 180 “expressed as beta-carotene” in all adopted and proposed provisions for carotenoids (INS 160a(i), (iii), c, f) and carotene, beta- (vegetable) (INS 160a(ii)) of the GSFA</td>
<td>ALINORM 10/33/12 para. 61</td>
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### Amendment of the provision for ascorbyl esters (INS 304, 305) in food category 13.2 “Complementary foods for infants and young children” of the GSFA

Reference: ALINORM 10/33/12 para. 90

### Amendment to notes 130 and 131 associated with the provisions for phenolic antioxidants, i.e. butylated hydroxyanisole (BHA, INS 320), butylated hydroxytoluene (BHT, INS 321); propyl gallate (INS 310) and tertiary butylhydroquinone (TBHQ, INS 319) of the GSFA

Reference: ALINORM 10/33/12 para. 91

### Amendment to the text of note 136 of the GSFA

Reference: ALINORM 10/33/12 para. 92

### Amendment to Section 2 “Table of functional classes, definitions and technological purposes” of CAC/GL 36-1989

Reference: ALINORM 10/33/12 para. 129

### Amendment to Section 2.1 “General Definitions of the Code of Practice for Fish and Fishery Products”

Reference: ALINORM 10/33/18 Appendix III

### Maximum Level for tin in Canned Fruits and Vegetables in the Codex Standard for Contaminants and Toxins in Food and Feed

Reference: ALINORM 10/33/41 Appendix II

### Deletion of Section 8 and related text from the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999)

Reference: ALINORM 10/33/22 Appendix IX

### Alignment of the General Standard for the Labelling of Prepackaged Food (CODEX STAN 1-1985) with the Codex International Numbering System in CAC/GL 36-1989

Reference: ALINORM 10/33/22 Appendix XI

### LIST OF DRAFT STANDARDS AND RELATED TEXTS APPROVED AS NEW WORK BY THE THIRTY-THIRD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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<thead>
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<th>Standard and Related Texts</th>
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<tr>
<td>CCFFV</td>
<td>Standard for Pomegranate</td>
<td>ALINORM 10/33/35 Appendix VIII</td>
<td>N01-2010</td>
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<tr>
<td>CCNFSDU</td>
<td>Amendment of the Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)</td>
<td>ALINORM 10/33/26 Appendix V</td>
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<tr>
<td>CCNFSDU</td>
<td>Revision of the Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991)</td>
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<td>CCFH</td>
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<td>CCFA</td>
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<td>ALINORM 10/33/12 Appendix VII</td>
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<td>General Standard for Food Additives</td>
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<td>Revision of the Standard for Food Grade Salt</td>
<td>ALINORM 10/33/12 Appendix XII</td>
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<td>Priority List of Chemicals Scheduled for Evaluation and Re-evaluation by JMPR</td>
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<td>CCPR</td>
<td>The Pilot Project in which JMPR would conduct an Independent, Parallel Review along with</td>
<td>ALINORM 10/33/24 para. 202</td>
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<td>a Global Joint Review Team and recommend MRLs before National Governments establish MRLs</td>
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<td>Maximum Levels for Deoxynivalenol (DON) and its Acetylated Derivatives in Cereals and</td>
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<td>CCCF</td>
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<td>CCFL</td>
<td>Establishment of Claims for Sugars, Salt/ Sodium and Trans-fatty Acids</td>
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<td>Establishing a Definition for Nutrient Reference Values</td>
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FAO places high priority on support to strengthening food safety systems. The four key elements of the strategy are focused on the following areas:

a) Provision of scientific advice to Codex Alimentarius Commission and FAO member countries to support the review and development of food safety and quality standards;

b) Provision of support for strengthening institutional, policy and legislative frameworks for food safety management and the basis of integrated food chain approach;

c) Provision of guidance and assistance to promote the application of risk analysis at country level, including strengthening laboratory services;

d) Promoting the application of preventive food safety management systems by food business operators along the food chain and also support the development of geographic indication and traditional food production.

Assuring food safety requires action to address traditional hazards – microbial and chemical in nature, as well as the capacity to respond to emerging hazards which may be due to more virulent strains of micro-organisms, changes in food processing technologies, a fraudulent practice. In addition to hosting the Secretariat of the Codex Alimentarius Commission (CAC), FAO implements a well-established programme to develop capacity in developing countries to improve food quality and safety and equipping individuals with the requisite knowledge and skills. Furthermore, an important new FAO programme is the Emergency Prevention System for Food Safety (EMPRES Food Safety): an early warning system for food safety emergencies at global, regional and local levels that identifies potential and imminent threats to human health and advises countries on preparedness and risk mitigation strategies.

Animal diseases that are known to spread primarily through human activities can be controlled through increased awareness, education and the application of biosecurity measures along the production and marketing chain. For the purpose of controlling zoonotic and non-zoonotic infectious diseases, the FAO Animal Production and Health Division defines biosecurity as the implementation of measures that reduce the risk of the introduction and spread of disease agents on farms and along marketing chains. As part of the response to the H5N1 highly pathogenic avian influenza (HPAI) crisis, FAO, OIE and the World Bank jointly prepared a reference document: “Biosecurity for highly pathogenic avian influenza: Issues and options” in 2008, which outlined an approach for developing biosecurity for HPAI. Apprehension about the pandemic H1N1 2009 crisis and its impact on human health, global trade and food security has led FAO, OIE and the World Bank to give high priority to the development of biosecurity measures for pig production and the preparation in 2010 of the reference document “Good practices for biosecurity in the pig sector: Issues and options in developing and transition countries”.

FAO within the framework of its Emergency Center for Transboundary Animal Diseases (ECTAD) have been and will be implementing a number of projects and activities to improve biosecurity in all poultry production systems, including the use of participatory approaches to identify, test and implement biosecurity measures in small scale production systems in Egypt and Nigeria and capacity building for mainly commercial producers, sellers and local authorities managing markets, through a series of regional workshops in East, Central and West Africa plus Egypt and in Asia (Bangladesh, Indonesia). Biosecurity related issues are also key entry points to strengthen public-private partnerships in the livestock production sector. In its project on “Developing and Maintaining Public-Private Partnerships for the Prevention and Control of Highly Pathogenic Avian Influenza H5N1 and other Emerging Infectious Animal Diseases” FAO has been involving actors from both state public services and the private commercial sector in the development of solutions to strengthen biosecurity on commercial farms in countries were HPAI is now endemic.
Fisheries and Aquaculture: Aquatic Biosecurity

The scope of biosecurity risks in aquaculture include transboundary aquatic animal diseases (TAADs), food safety hazards and fishborne zoonosis, public health risks from the use of veterinary medicinal products, invasive aquatic alien species, issues pertaining to aquatic GMOs and climate-change scenarios affecting biosecurity. The application of risk analysis as an important decision-making tool to improve aquatic biosecurity is being promoted.

Emergencies: The Food Chain Crisis Management Framework (FCC)

The FCC is a system-wide, inter-departmental, collaborative and integrated approach to carry out prevention, early warning and response to food chain crises while utilizing all available skills and expertise within FAO at headquarters and decentralized offices, under common governance and through common coordination mechanisms. The FCC provides for horizon scanning of emerging threats to the food chain and enhances surveillance of these threats, provides risk analysis and a response to food chain emergencies. It designs and implements programmes addressing emergency preparedness to food chain crises through national capacity-building, enhancing prevention, devising programmes which will address immediate, medium and longer-term impacts on human health, food security and livelihoods at global, regional and national levels.

Guide to good farming practices for animal production food safety

Finally there has been an agreement reached between FAO and OIE on the copyright wording of the Guide to good farming practices for animal production food safety. It has been published on the website: http://www.fao.org/docrep/012/i0482t/i0482t00.pdf

There have been numerous requests for printed copies that due to limitation of funds are not available so far.

One Health Concept

FAO continues to be very much engaged in further developing the One Health concept and is implementing activities as a follow up of the Stone Mountain meeting held May 2010 near Atlanta, USA.

FAO tools under development relevant to the WG

FAO is finalizing the development of a tool to determine constraints for specific production chains and develop stakeholder negotiation platforms. Pilot exercises have been held in Ethiopia for the dairy chain, Morocco for the small ruminant chain and in Vietnam for the pork production chain.

Brucellosis tool-box including defining the steps for the progressive control of brucellosis

Tool for determining different control methods for salmonellosis

FAO has developed table and field simulation exercises jointly with WHO and STOPAI for highly pathogenic avian influenza. These exercises are presently expanded to address communication, coordination and collaboration between different sectors to address other zoonotic diseases
Antimicrobial resistance (AMR)

FAO together with OIE and WHO are working on antimicrobial resistance

**Joint FAO/WHO collaboration on study of AMR risks in the poultry chain in East Africa:** Poultry production is increasingly important for household nutrition, food security and income in East African countries. Globally, foodborne AMR is an emerging public health threat but there is a lack of information on the significance and magnitude of the problem in most developing countries. FAO and WHO are collaborating with the Kenya Medical Research Institute (KEMRI) in a poultry value chain study to establish the prevalence and patterns of resistance of AMR strains of *Salmonella*, *Campylobacter* and indicator organisms (*E. coli* and *Enterococcus* spp); and associated public health risks at all stages from primary production to consumption - in a pilot study in Kenya. The ongoing study will also determine the animal husbandry, product processing and handling factors influencing emergence and spread of AMR.

The main outputs/outcomes from the 1 year study will be the dissemination of guidance to support development of national policies and regulation to address AMR risk, and on surveillance of antimicrobials usage and AMR. Guidance on prudent use of antimicrobials and biosecurity in poultry production will also be developed and disseminated.

**Microbiological contamination risks**

The above project will also establish the patterns of contamination of *Salmonella* and *Campylobacter*, the most significant foodborne disease pathogens associated with poultry production, processing and marketing stages and identify the critical stages of the Kenyan value chain at which control measures to minimise contamination risks can be most effectively applied. Guidance aimed at improving production and management, processing and handling practices will be developed and disseminated.

**Meat hygiene/safety**

Presently FAO is supporting and developing national capacities for regulation of slaughterhouses. The recently completed Somalia Livelihoods Project under which FAO supported the construction of export abattoirs in Somalia, supporting national policy and regulation development, inspection and certification systems, and the training of veterinarians, meat inspectors and slaughterhouse operators. The project contributed to improving compliance with animal health and food safety requirements and contributed to increased incomes for pastoral communities and the increased export trade (up to $250 million annually) with the Middle East has made a significant contribution to the Somali economy.

**Food security**

FAO considers food safety and integral part of food security. The challenge is how to ensure adequate food safety under different prevailing situations.

The FAO flagship publication “the State of Food and Agriculture” (SOFA) 2010 was dedicated to livestock. The publication also extensively addresses the role of livestock in poverty alleviation and food security (http://www.fao.org/publications/sofa/en/).

Presently the FAO publication “The World of Livestock” is being compiled and it will be specifically dedicated to livestock and food security. This publication will be published in 2011.
Animal welfare

FAO is involved in a wide range of activities on animal welfare but unfortunately is not a member of the OIE working group addressing animal welfare.

Animal Health Clubs

FAO is supporting the establishing of Animal Health Clubs in schools in Sierra Leone as a model for other countries to promote animal health and food safety in communities where extension and veterinary services are very weak or absent.

Rabies and animal production

FAO is assessing the role of rabies for food security especially in Latino-America.
ACTIVITIES OF THE WORLD HEALTH ORGANISATION (WHO)

A new Director for the Department of Food Safety and Zoonoses of WHO

Dr Maged Younes has been recently (1 November 2010) appointed as Director of the Department of Food Safety and Zoonoses (FOS) at WHO HQ in Geneva.

Dr Jørgen Schlundt, former Director of FOS, left WHO after over 10 years of work in the organization, and took up the position of Deputy Director of the National Food Safety Institute, at the Danish Technical University in Copenhagen, starting 1 August 2010.

After the departure of Dr Schlundt, Dr Danilo Lo Fo Wong has been Acting Director of FOS from 1 August to 31 October 2010.

* * *

Resolution on Food Safety at the 63rd World Health Assembly, May 2010

The WHO top governing body, the World Health Assembly, approved in May 2010 the Resolution “Advancing Food Safety Initiatives” (http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R3-en.pdf).

In the resolution, the WHO Member States requested action from the Director-General of WHO in a number of areas, five of which are briefly outlined here:

1. “To strengthen the emergency function of the International Food Safety Authorities Network (INFOSAN) as a critical component of WHO’s preventive and emergency operations...”

2. To develop INFOSAN... and establish an international initiative for collaboration of laboratory partners in support of surveillance for foodborne diseases, food contamination... including mechanisms for data sharing”

3. “To continue to provide global leadership... for the scientific estimations of... foodborne disease burden from all causes”

4. “To develop guidance on the public health aspects arising from zoonotic diseases that originate at the human-animal interface... prevention, detection and response”

5. “To provide adequate and sustainable support for the joint expert bodies of FAO and WHO, the Codex Alimentarius Commission and the INFOSAN... to support the development of international food standards that protect health... and communicate more effectively on food safety issues at the national and international levels”

In addition, the Resolution requested Member States “to continue to develop and maintain sustainable preventive measures, including food safety-education programmes aimed at reducing the burden of foodborne diseases...”

* * *
Annex 35 (contd)

Appendix V (contd)

Amendment of the Agreement between OIE and WHO

The 63rd World Health Assembly held at WHO Headquarters in Geneva in May 2010 approved an amendment to the Agreement between OIE and WHO, providing a legal basis for the collaboration of the two organizations in the joint development of international standards relating to relevant aspects in animal production which impact on food safety, in collaboration with other appropriate international agencies. The text of the amendment is provided in Annex 2 of the 63rd World Health Assembly and can be found at http://apps.who.int/gb/ebwha/pdf_files/WHA63-REC1/WHA63_REC1-P4-en.pdf.

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Global Foodborne Infections Network (GFN)

The Global Foodborne Infections Network (GFN) began as WHO Global Salm-Surv (WHO GSS) in 2000 as a capacity-building programme to build integrated laboratory-based surveillance for Salmonella around the world. During the following years, the programme continued to extend its focus to a number of additional foodborne and zoonotic pathogens, as well as a broader scope in diagnostic and analytical methods. Currently, GFN has over 1,600 members from 179 Member States and territories. GFN has held over 70 international training courses in Chinese, English, French, Portuguese, Spanish, and Russian for microbiologists and epidemiologists from more than 130 countries. The GFN External Quality Assurance System (EQAS) is one of the world’s largest proficiency test with close to 200 laboratories from more than 80 countries participating annually. The GFN Country Databank is a global passive surveillance system that collects annual Salmonella summary data from national reference laboratories. More than 80 countries have provided data to the GFN Country Databank on over 1.5 million human isolates and close to 400,000 isolates from non-human sources to help provide a global overview of the epidemiology of Salmonella. To date, more than 30 GFN projects have resulted in over 25 peer-reviewed articles in the international literature.

GFN recently held a strategic planning meeting, with representatives from OIE and FAO, to review the past 10 years of activities and to plan the new five-year strategy for 2011 to 2015. The revised mission of GFN is to enable countries to detect, control, and prevent foodborne and other enteric infections by building capacity for integrated surveillance and fostering collaboration among human health, veterinary, food and other relevant sectors. The underlying goals that were defined are:

1) to foster partnerships relevant to regional and country goals,

2) to raise awareness of GFN outputs and activities and its benefits of integrated surveillance to countries,

3) to strengthen national and regional capacities for surveillance, investigation, and prevention of foodborne and other enteric infections, and

4) to generate country and regional data that contributes to a global understanding of foodborne and other enteric infections.

For more information: www.who.int/gfn

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Antimicrobial Resistance: Critically Important Antimicrobials for Human Health and WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR)

WHO initiated its work in the area of Critically Important Antimicrobials for Human Health through the organization of an expert consultation in Canberra in 2005 with the overall scope to develop a list of critically important antimicrobial agents for human medicine (WHO, 2005). The resulting list has subsequently been re-examined and updated during two expert meetings, both held in Copenhagen in 2007 (2nd edition) and in 2009 (3rd edition).
All three editions are available at: www.who.int/foodborne_disease/resistance/cia/en

The WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (WHO-AGISAR, http://www.who.int/foodborne_disease/resistance/agisar/en/index.html) was established in December 2008 to support WHO's effort to minimize the public health impact of antimicrobial resistance associated with the use of antimicrobials in food animals. In particular, the Advisory Group will assist WHO on matters related to the integrated surveillance of antimicrobial resistance and the containment of food-related antimicrobial resistance. One of the main objectives of WHO-AGISAR is to promote harmonization of methods as well as data and experience sharing in the area of foodborne antimicrobial resistance at global level.

The first meeting of WHO-AGISAR was held in Copenhagen, Denmark in 2009 and the second in Guelph, Canada, 5-7 June 2010. The four WHO-AGISAR subcommittees (antimicrobial usage monitoring, antimicrobial resistance monitoring, capacity building and data management) are in the process of developing practical tools/guidelines/protocols on usage monitoring, antimicrobial resistance monitoring and integrated data management to support WHO Member States in their efforts to implement a national program for integrated surveillance of antimicrobial resistance. Both meetings were attended by OIE representatives.

WHO-AGISAR contribute to enhancing the capacity of Member States, particularly developing countries, through training courses (using the Global Foodborne Infections training platform), focused research projects (currently in Costa Rica and Cameroon) and sentinel studies (currently pilot projects on integrated surveillance of antimicrobial resistance are conducted in China, Columbia and Kenya).

The 2011 World Health Day will be devoted to Antimicrobial Resistance, and in that occasion the public health aspect of the impact of the use of antimicrobials in the agriculture sector will be addressed.

* * *

Development of the web-based decision support tool for the control of Salmonella and Campylobacter in chicken by JEMRA (Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment)

In response to the request from the Codex Committee on Food Hygiene (CCFH) who is developing the guidelines for the control of Salmonella and Campylobacter in poultry, FAO and WHO have been working on the development of the web-based decision support tool for the control of Salmonella and Campylobacter in poultry. This tool aims to provide risk managers with a means of selecting appropriate control measures based on risk and also demonstrating their impact relative to other control measures. The tool was reviewed by a group of experts during April-May 2010 and their recommendations are now being implemented. The revised version of the tool will be presented at the end of November 2010 at the 42nd session of the CCFH in Kampala, Uganda. Details on the development of the tool are available at ftp://ftp.fao.org/codex/ccfh42/fb42_03e.pdf.

Once the tool is completed, FAO/WHO are planning to initiate the development of case studies using the tool and to conduct pilot tests of the tool in interested member countries for better understanding and utilization of the tool. In addition, FAO/WHO is investigating the possibility of developing a database which consists of information relevant to each step of the process and the users can refer to if they do not have their own data to be put into the tool. It is proposed that this database would be a living database whereby generators of relevant data would be encouraged to input their data to the database as it becomes available.

* * *

The Foodborne Disease Burden Epidemiology Reference Group (FERG)

From 8-12 November 2010, the WHO will host the fourth formal meeting of the Foodborne Disease Burden Epidemiology Reference Group (FERG) in connection with the fourth international Foodborne Diseases Stakeholder Event in Geneva (http://www.who.int/foodsafety/foodborne_disease/ferg4_stakeholder/en/index.html). For the second time, the FERG will review preliminary burden of disease results in the areas of enteric, parasitic and chemical causes
Annex 35 (contd)

Appendix V (contd)

of foodborne diseases. Specifically, they will discuss *inter alia* interim results of diarrhoeal disease morbidity and mortality in persons older than 5 years, as well as the burden of cystic echinococcosis, neurocysticercosis, and aflatoxicosis. The results of a study commissioned by FERG on the global burden of alveolar echinococcosis have been recently presented in a paper published in PLoS Neglected Tropical Diseases (http://www.plosntds.org/article/info%3Adoi%2F10.1371%2Fjournal.pntd.0000722). WHO will also nominate the candidate countries for foodborne disease burden studies. WHO will prepare the reports which will be publicly available in due course. For more information please contact foodsafety@who.int.

* * *

The International Food Safety Authorities Network (INFOSAN)

INFOSAN is a joint FAO/WHO initiative which includes the participation of 177 member states. The aim of the network is to promote the rapid exchange of information during food safety related events, share information on important food safety related issues of global interest, promote partnership and collaboration between countries, and help countries strengthen their capacity to manage food safety emergencies. To accomplish this, INFOSAN works with a number of partners at the international and regional level. INFOSAN receives information from its members and monitors for food safety related events of potential international concern to alert to its network members. In addition, INFOSAN publishes INFOSAN Information Notes periodically on topics of interest and concern to its members. The Network will have its first global meeting in Abu Dhabi, UAE in December 2010. The proposed meeting is intended to provide a forum to discuss the requirements of the network and develop a plan for enhancing the system and building partnerships. For more information, please contact: http://www.who.int/foodsafety/fs_management/infosan/en/index.html
Terms of reference for literature reviews to be prepared by an OIE expert(s) on:

Non-poultry Salmonella

The Working Group is considering the need for, and the possibility of, developing suitable OIE advice on the control of *Salmonella* in food producing animals (i.e. pigs, cattle, small ruminants) other than poultry with the purpose of reducing foodborne risks to human health.

In this regard the Working Group requests a review of the scientific literature and other authoritative sources on:

1. The occurrence of foodborne salmonellosis from these species;
2. Measures that have been taken at the production level (farm-level) to reduce the incidence of non-poultry *Salmonella*, and an assessment of their outcomes;
3. Measures taken at slaughter and primary processing that have been used to reduce the risk of negative health effects in humans due to foodborne *Salmonella* in non-poultry species, and an assessment of their outcome.

Detailed information on sampling, testing or diagnostic procedures is not required at this stage.

The literature review should include an analysis of information from WHO and other publically available data.

Verotoxigenic *E. coli* (VTEC)

The Working Group is considering the need for, and the possibility of, developing suitable OIE advice on the control of Verotoxigenic *E.coli* (VTEC) in food producing animals with the purpose of reducing foodborne risks to human health.

In this regard the Working Group requests a review of the scientific literature and other authoritative sources on:

1. The occurrence of foodborne Verotoxigenic *E.coli* (VTEC) from these species;
2. Measures that have been taken at the production level (farm-level) to reduce the incidence of Verotoxigenic *E.coli* (VTEC), and an assessment of their outcomes;
3. Measures taken at slaughter and primary processing that have been used to reduce the risk of negative health effects in humans due to food-borne Verotoxigenic *E.coli* (VTEC), and an assessment of their outcome.

Detailed information on sampling, testing or diagnostic procedures is not required at this stage.

The literature review should include an analysis of information from the WHO and other publically available data.
WORK PROGRAMME FOR 2011

The Working Group agreed that its work programme for 2011 would include:

1. Horizontal issues

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

   b) The ad hoc Group on Vaccines in Relation to New and Emerging Technologies – animals and animal products derived from biotechnological interventions – review texts for potential food safety implications of biotechnology vaccines when this work is undertaken. Follow any developments in nanotechnology relevant to the work of the Working Group;

   c) Consideration of the scientific evidence on the relationship between animal welfare and animal production food safety, in collaboration with the OIE Animal Welfare Working Group;

   d) Animal production food safety in veterinary education;

   e) Food safety issues arising from the ongoing work on the emerging zoonoses at the human animal ecosystem interface (‘One Health’);

   f) Generic certification, in particular electronic certification;

   g) Development of a Terrestrial Code chapter on Good Farming Practices in co-operation, as appropriate, with FAO;

   h) Monitoring developments concerning the relationship between animal production food safety and food security.

2. Disease-specific issues

   a) Chapters of the OIE Terrestrial Code on brucellosis. A further ad hoc Group meeting is to be held in 2011;

   b) Future work on salmonellosis and campylobacteriosis in poultry - taking into account developments in Codex;

   c) Draft Terrestrial Code chapters on trichinella infection and porcine cysticercosis;

   d) Follow up of literature review on non-poultry Salmonella;

   e) Follow up of literature review on Verotoxigenic E.coli (VTEC).

3. Relationship between OIE and Codex:

   a) Encourage enhanced OIE input into Codex texts and vice versa;

   b) Encourage continued close collaboration between the Codex secretariat and the OIE Headquarters;

   c) Identification of areas where development of joint or common OIE/Codex standards could be desirable.
Terms of reference for a literature review of the scientific evidence for relationships that may exist between the welfare of food-producing animals and food safety

This review is intended to form the basis of work to be carried out in collaboration between the OIE Working Groups on Animal Production Food Safety (APFSWG) and Animal Welfare (AWWG).

- The review should examine and report on the scientific evidence that exists for relationships between the welfare of food-producing animals (both terrestrial and aquatic) and food safety.

- The review should cover primary production, both intensive and extensive, transport and slaughter and any other areas that may be of particular relevance.

- The review should use the results of the literature searches already carried out at OIE and any other information available from other sources.

- A clear identification of the databases searched, the search strategy used, and the inclusion / exclusion criteria adopted to carry out the literature review and draw conclusions should be provided.

- The review should highlight animal welfare measures which can improve food safety and areas where there may be potential for conflict between animal welfare measures and food safety.

- The review should be completed by 1 July 2011.

SAS 25.01.2011
The OIE ad hoc Group on Laboratory Animal Welfare (the ad hoc Group) met at the OIE Headquarters on 14-16 December 2010. Dr D. Bayvel chaired the meeting.

The members of the ad hoc Group and other participants at the meeting are listed at Appendix I. The adopted Agenda is provided as Appendix II and a Glossary in Appendix III.

Meeting with Dr Bernard Vallat, Director General

Dr Vallat participated in the ad hoc Group meeting on Wednesday 15 December 2010.

Dr Vallat thanked the members of the ad hoc Group and emphasised the importance of their work, which will help to safeguard the future of scientific research and teaching on medical and veterinary science and related issues. Animal welfare standards are of critical importance to help to guarantee the continued use of animals in research and teaching and thereby to help assure human health and animal health and welfare globally. Dr Vallat congratulated the Group on the adoption of Chapter 7.8. in 2010 and noted that the relatively small number of comments received from Members subsequent to the 78th General Session reflects a general level of satisfaction with the text. However, there is more work to be done – particularly in raising OIE Delegates’ awareness of this important issue and in encouraging them to liaise with competent authorities where the Veterinary Services are not responsible for the legislation covering the use of animals in research and teaching.

At Dr Bayvel’s request, Dr Bayne summarised the work done by the ad hoc Group on the need for specialised training of veterinarians in laboratory animal medicine. Dr Bayvel also referred to the other two strategic priority areas i.e. air transport, and a strategy to reduce the use of animals in regulatory testing.

Dr Vallat agreed that it would be valuable to develop specific guidance for the use of institutes and airlines facing the sensitive topic of air transport of animals for use in scientific research and confirmed his support for continued work by the ad hoc Group on the topics identified.

Dr Vallat supported in principle the development of a model veterinary certificate to address the specific health and welfare issues associated with the international transport of laboratory animals and noted the request to invite Dr William White to the next meeting of the ad hoc Group to assist with this work.
Regarding veterinary training, Dr MacArthur Clark suggested that the OIE consider closer collaboration with organisations such as the International Association of Colleges of Laboratory Animal Medicine (IACLAM) and the Institute for Laboratory Animal Research (ILAR), for example, to ensure the harmonization of post graduate education for veterinarians working with animals for research and education. It was agreed that the World Veterinary Year is a good window to promote the key role of veterinarians in respect of laboratory animal health and welfare; and the importance of standards for scientific institutes using animals and of professional training for veterinarians. Dr Vallat encouraged the ad hoc Group to liaise with the ad hoc Group on Veterinary Education, particularly as some countries have already banned the use of animals for teaching purposes at veterinary schools.

On the subject of animal use in regulatory testing, Dr Vallat agreed with the ad hoc Group that the OIE could encourage the use of alternatives to animals in regulatory testing, including through promoting the 3 Rs. Dr Vallat mentioned the OIE’s close working relationship with VICH and the US Food and Drug Administration, and encouraged the Group to continue its liaison with VICH. Dr Vallat also expressed support for future liaison between the OIE and the ISO, noting that a formal agreement between the two organisations is under development.

Finally, Dr Bayvel thanked Dr Vallat for his ongoing support for the work of the ad hoc Group and added that some countries would be contacted by the ad hoc Group for comments on Chapter 7.8 as they have already expressed an interest to do so.

1. **Feedback from the Chair on the Report of the Third Meeting of the OIE ad hoc Group on Laboratory Animal Welfare**

Dr Bayvel reviewed the report of the Third Meeting of the OIE ad hoc Group on Laboratory Animal Welfare and noted that Chapter 7.8 was adopted at the 78th General Session in May 2010. He also mentioned that he was awarded with a Meritorious Service Award, which he accepted on behalf of both the ad hoc Group and OIE Animal Welfare Working Group Members.

Dr Bayvel reiterated the need to raise awareness on the importance of using animals in research and education. He noted that in some OIE Member countries the Veterinary Services are not the competent authority for laboratory animal welfare. He also mentioned that OIE Delegates and the animal welfare focal points are key elements to establishing a network to inform stakeholders about OIE animal welfare standards.

2. **Feedback from the Chair on the Report of the Ninth Meeting of the Animal Welfare Working Group**

The ad hoc Group acknowledged the report of the ninth Animal Welfare Working Group (AWWG) meeting. Dr Bayvel indicated that Air Transport was identified as the main priority topic to be addressed by the ad hoc Group. He updated the group regarding the existing ad hoc Groups on Production Systems and confirmed that it is proposed that the chapter on Broiler Chicken Production Systems be adopted at the next General Session. Dr Kahn mentioned the difficulties faced in developing standards that can be accepted by all 177 OIE Members, given the variations that exist between developing countries, where standards may be minimal, and the high standards of other countries, for example in the European Union. Dr Bayvel referred to a document written by Dr Fraser entitled “Guidance from the Animal Welfare Working Group to ad hoc Groups on the development of animal welfare standards” (Appendix IV).

Continuing with the AWWG report, Dr Bayvel noted that a joint meeting with the Animal Welfare Collaborating Centres (CCs) was held, and listed the attendees at that meeting. He also mentioned that this experience would be repeated, if possible, at the next AWWG meeting to be held at OIE Headquarters in June 2011, or by means of a teleconference. Dr Bayvel also described the system of rotation for AWWG observers. It was confirmed that IFAP has ceased to operate.

Dr Bayvel mentioned the Third OIE Global Conference on Animal Welfare to be held in January 2013 in Asia. Dr Kahn confirmed the location and commented that the existence of a Regional Strategy on Animal Welfare (RAWS) and countries keen to host this event helped the OIE to decide to hold the conference in the Asia, Far East and Oceania (AFEO) Region.
Dr Bayvel confirmed that the Australian Government has kindly agreed to continue funding the secretariat of the AFEO RAWS for a 2-year period and that the first meeting of the RAWS Coordination Group is expected to take place in March/April 2011.

Dr Kahn added that this strategy can serve as a model for other OIE regions and stressed the importance of funding support. She also commented about developing a RAWS for Europe, and the need to address the different standards that currently exist in western and eastern European countries. The ad hoc Group noted the focal point training to be held in Ukraine in March 2011, as an opportunity to analyse the feasibility of developing a RAWS in Europe and the potential commitment of the countries to this approach.

Dr Kahn then commented on the animal welfare focal point seminar held in Ethiopia in November 2010. It is not clear that Africa is ready to develop a RAWS; it may be worth considering the development of a strategy at a sub-regional level, for example in the South African Development Community, with support from the relevant Regional Economic Community. Dr Varas said that during the OIE animal welfare focal point seminar in Lebanon in November 2010, it was agreed to prepare a document for the implementation of a RAWS in the Middle East Region to be submitted to the OIE Members at the 79th General Session. She also mentioned that RAWS development in the Americas is ongoing and that a Coordination Group has been created.

3. **Review of Code Commission and Member’s comments on Chapter 7.8: Use of Animals in Research and Education**

The *ad hoc* Group discussed and responded to comments provided by 3 Members, including the European Union, Chinese Taipei and the Republic of Korea and modified the text that had been reviewed by the Code Commission at its September 2010 meeting.

The Group also noted that the AWWG had made no specific comments and had generally supported the text.

The Group discussed the deletion of the wording “Euthanasia” from Chapter 7.8. and its inclusion in the Code Glossary. Dr Kahn clarified definitions are normally included in the Glossary if they are used in more than one Code chapter. The definition used in the Glossary was taken from the definition in Chapter 7.7 ‘Stray Dog Population Control’, i.e. *Euthanasia*: means the act of inducing death in a humane manner. An extract from the report of the Terrestrial Code Commission is presented in Appendix V.

Chapter 7.8, including proposed text changes by the *ad hoc* Group, is at Appendix VI.

4. **Development of draft strategic direction for consideration by the Terrestrial Animal Health Standards Commission**

The *ad hoc* Group confirmed that the three priority areas for future OIE work remained as follows:

- **Veterinary training in Laboratory Animal Medicine**

Concerning Veterinary Training in Laboratory Animal Medicine, Dr Kahn mentioned the First OIE Global Conference on Veterinary Legislation held on 2-9 December 2010 in Djerba. One of the key points addressed during the conference related to Veterinary Education. Dr Kahn indicated that the recommendations focused on how to improve the competencies of veterinarians in delivering the OIE mandate and on the need for global harmonisation and evaluation of the veterinary curriculum.

Dr Kahn added that the *ad hoc* Group on Veterinary Education was also holding its second meeting this week and it was agreed that the two *ad hoc* Groups should liaise on issues relating to veterinary education. She also mentioned the Second World Conference on Veterinary Education, to be held on 13-14 May 2011 in Lyon, where the work of the *ad hoc* Group on Veterinary Education would be presented, before being submitted to for consideration of OIE Members at the 79th General Session.
Dr Bayne reported on actions taken subsequent to the development of the original Issues and Options paper regarding a potential role for the OIE in addressing international variability in training for veterinarians specializing in laboratory animal medicine. She noted that 2010 had offered a unique opportunity to meet with colleagues from around the world at three key meetings that were serendipitously scheduled in 2010, specifically:

- The June 2010 meeting of the Federation of Laboratory Animal Science Associations in Helsinki, Finland;
- The September 2010 meeting of the Association for Laboratory Animal Science in Atlanta, Georgia, United States; and
- The November 2010 meeting of the Asian Federation of Laboratory Animal Science Associations in Taipei, Taiwan.

Dr Bayne confirmed that a total of 106 individuals representing 27 countries participated in the three meetings, and that there was a strong consensus among the meeting participants that harmonizing the skill level and training of laboratory animal veterinarians, at the global level, was both timely and important. She explained that several themes emerged from the three focus group discussions. After discussion of the *ad hoc* Group, a document listing and identifying keys factors for Training Veterinarians in Laboratory Animal Medicine was drafted (Appendix VII).

Dr Bayne stated that one specific recommendation that came out of the focus groups was that a repository of resources in a variety of languages should be developed and possibly placed on the OIE server.

Dr Bayne then led the group through the summary notes from the focus groups, elaborating on the context of the remarks with assistance from other *ad hoc* Group Members who attended one or more of the meetings, i.e. Drs. Demers, Kurosawa, and Souilem. She referred to the various supporting meeting documents related to veterinary training and qualifications in laboratory animal medicine and noted that these would serve as a good resource for this subject, but that other related information should also be forwarded by the *ad hoc* Group members. This review prompted additional constructive input into framing a planned article for the Journal of the Institute for Laboratory Animal Research (ILAR) and the proposed development of an OIE standard. An outline for the article was discussed and writing assignments were agreed (Appendix VIII). A timeline for the draft article and for proposed submission to the ILAR Journal was established, with the World Veterinary Association Congress, October 2011, as the target publication date. This congress marks the culmination of World Veterinary Year 2011.

Dr Bayne reminded members that input from the International Association of Colleges of Laboratory Animal Medicine (IACLAM) and the American Association of Veterinary Medical Colleges (AAVMC) would be sought in the review of the article for the ILAR Journal. The paper would provide a summary of the input from the three international focus groups and would recommend the development of international standards for training and qualification of veterinarians in laboratory animal medicine. She also mentioned that IACLAM partners in this activity would bring the expertise of the laboratory animal veterinary community. Publication of an article in the ILAR Journal provides the opportunity for disseminating the information obtained from the focus groups and provides a platform on which to build the recommendation for the development of international standards by the OIE. The AAVMC’s interests lie in veterinary training and curricula.

Dr Bayne noted that the OIE’s strategic initiative on veterinary education initiated at the October 2009 global conference, fits well with this proposed new work in standards development and is highly relevant to the content of the Second World Conference on Veterinary Education.
There was consensus among the *ad hoc* Group members that an exchange of views with the *ad hoc* Group on Veterinary Education would be mutually beneficial given the synergies of the two Groups’ mandates.

The *ad hoc* Group acknowledged Dr Bayne’s considerable commitment and hard work and thanked her for attending these three meetings and for the feedback. It was agreed that Dr Bayne would finalise the Issues and Options Paper on this subject to reflect the outcome of the discussion.

- **Air transport of laboratory animals: IATA discussion paper and updates**

Dr Bayvel briefly summarised the documents provided for the meeting on this topic, including the OIE/International Air Transport Association (IATA) Discussion Paper available on the OIE website at [http://www.oie.int/eng/bien_etre/ENG_IATA%20paper_2009.pdf](http://www.oie.int/eng/bien_etre/ENG_IATA%20paper_2009.pdf) and Dr Varas’ report on the IATA meeting held in Kuala Lumpur in October 2010. The OIE/IATA discussion paper which explains that, due to the decisions of many commercial airlines to cease carrying animals (especially dogs, cats and non-human primates), that are intended for use in scientific studies, it is increasingly difficult for institutes in developed countries to obtain these animals, which are needed for studies in some important areas of medical and veterinary research. In addition, there is a risk that the transport of laboratory animals may increasingly be undertaken by airlines that are less aware of OIE standards and IATA Regulations.

Dr Varas noted that few of the cargo airlines that attended the recent meeting in Kuala Lumpur were still transporting laboratory animals, and that these are basically limited to carrying rats and mice. This is based on commercial decisions of airlines, taking into account public opinion and the influence of lobby groups opposed to the use of animals. Dr Demers proposed that the *ad hoc* Group develop guiding principles on air transport of animals used in research for inclusion in Chapter 7.8. Dr Kahn reminded the Group that the OIE has a formal agreement with IATA and that the text of Chapter 7.4 ‘Air Transport’ is modified as required to reflect updates to the IATA Live Animals Regulations ([www.iata.org](http://www.iata.org)).

It was agreed that the Group would develop a new Article 7.8.10 on Transport between Institutions ([Appendix IX](#)), to be proposed to the Code Commission at its meeting in September 2011.

Dr Varas and Dr Kahn recommended that the Group also consider the Code recommendations on veterinary certification for international transport of animals, as the current Chapter 5.10. probably does not address the specific needs of animals used in research. The development of new text on air transport of animals should be undertaken in coordination with the IATA. It was proposed that the OIE invite Dr William White, currently serving as an expert advisor to IATA, to attend a meeting with the *ad hoc* Group, with the objective of providing input to the draft Code text and drafting a model Health Certificate that would specifically address the needs of international transportation of animals used in research and education, and to consider what other measures could be taken to support companies that are prepared to transport research animals and are looking for guidance on appropriate health and welfare standards.

- **Regulatory Testing and the adoption of alternatives to animal use: Liaison with VICH/ICH**

Dr Kahn mentioned that the OIE is working in collaboration with the US Food and Drug Administration (FDA), and that this could provide an opportunity for the development of recommendations on alternatives to reduce the use of animals in regulatory testing. She added that the International Federation for Animal Health (IFAH) and the FDA, at the Conference on Veterinary Legislation in Djerba urged the OIE to encourage and support the acceptance by developing countries of regulatory approvals provided by appropriate authorities (such as the European Medicines Agency (EMA) and FDA) as a means to improve efficiency in the appropriate approval of new drugs. This approach could also help to reduce the use of animals in regulatory testing.

As recorded in the report of the second meeting of the *ad hoc* Group, the organisation known as VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products), formed under the auspices of the OIE, is an important international organisation. The *ad hoc* group intends to further develop its relationship with VICH, particularly in relation to the strategy for reducing the use of animals in regulatory testing and their replacement, where possible, with scientifically validated non-animal tests.
Following discussion about the strategic approach involving VICH/ICH, it was agreed that this project should initially focus on the adoption of alternatives for those regulatory tests within the remit of VICH. This would include some relatively severe tests, for example, testing batches of veterinary vaccines and other biological products.

The Group discussed the fact that far more animals are used in the regulatory testing of human drugs. The International Conference on Harmonisation (ICH) covers safety testing of products intended for human use. While the Group considered that it was too ambitious to develop a work programme with ICH at this time, this should be addressed in future. It was agreed that the two Europe-based Group members (Dr Joubert and Dr MacArthur Clark) would initially lead efforts to strengthen coordination with VICH and to develop a strategic approach, in liaison with Dr Varas at OIE Headquarters. It was also agreed that Dr Bayvel would finalise the revised position paper on this subject to reflect the outcomes of this meeting.

5. Other Business

- **Feedback from the Second Global Conference of OIE Reference Laboratories and Collaborating Centres**

  It was indicated that all the presentations and recommendations of that conference are available online on the OIE website. Dr Bayvel mentioned that there are 35 OIE Collaborating Centres, and listed the three dealing with Animal Welfare (Italy, New Zealand-Australia, and Chile-Uruguay). Dr Bayvel commented on the applications from Mexico and Sweden and their status. He also commented on a potential new application from Edinburgh and Bristol, in the United Kingdom.

  Dr Varas mentioned that the OIE will launch its new portal in early 2011, and that, during the joint meeting between the CCs and the AWWG meeting in June 2010, it was proposed to facilitate communication between CCs through this new portal, making their annual reports available online.

  Dr Bayvel referred to the concept of twinning, supported by the World Fund, and mentioned the ongoing twinning interest between Malaysia, India and Bangladesh with the NZ-AUS CC.

  Dr Kurosawa mentioned that CCs should be encouraged to work with animals for research and education. Dr Bayvel added that in the case of the NZ-AUS CC it is planned to do so, with expertise existing at both Massey and the University of Queensland.

  The ad hoc Group noted that the third Global Conference of OIE Reference Laboratories and Collaborating Centres will be held in 2014.

- **Directive 2010/63/EU on the protection of animals used for scientific purposes**

  Dr MacArthur Clark noted that the new Directive had been approved by all parties and entered into force on 10 November 2010. This means that all Member States must have implemented it into their domestic legislation by 10 November 2012, with a view to applying the new legislation from 1 January 2013. Key aims were to harmonise rules across Member States, to raise standards of animal welfare, and to promote alternatives (the 3Rs). It was generally agreed that all policy objectives had been achieved although the application in each Member State would not be identical.

  Examples of harmonization included that each Member State would have a system of project authorization, as well an inspectorate to monitor compliance. Each establishment would be required to specify a number of responsible individuals including a designated veterinarian. There was some disappointment that the veterinarian was not an obligatory member of the Animal Welfare Body, but it was felt that most would nevertheless strongly influence the activities of that Body in each establishment. All procedures would be classified according to predicted severity, and reporting would include a retrospective review of actual severity.
Dr Joubert agreed with this summary and mentioned that a number of Member States were struggling with how best to implement project authorization. Dr Bayne mentioned that a number of Member States had expressed an interest in the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) system of accreditation as a possible means of delivering inspection.

- **Eighth World Congress on Alternatives and Animal Use in the Life Sciences (WC8)**

  Dr Demers confirmed that Canada will be hosting the Eighth World Congress on Alternatives and Animal Use in the Life Sciences in Montreal in August 2011 ([www.wc8.ccac.ca](http://www.wc8.ccac.ca)). He mentioned he would be chairing a session on ethical review.

Dr Kurosawa proposed a satellite prior meeting of the *ad hoc* Group but it was decided that this would not be feasible. It was agreed to liaise with the 2013 conference organisers, with a view to OIE involvement in the conference programme.

- **Australian College of Veterinary Scientists**

  Dr Bayvel and Dr MacArthur Clark had been invited to examine the first Fellowship candidates for the Australian College of Veterinary Scientists Animal Welfare Chapter. They had prepared two written papers (three hours each) and then attended “Science Week” for the day of practical and oral exams on the Gold Coast in Queensland. The Fellowship standard had been set at that for Diplomas of other Colleges such as the Royal College in the UK. Two candidates had presented and both had passed. This now means that Australia and New Zealand has Fellowship level graduates in this subject able to conduct future exams in this topic.

- **International Conference on Veterinary and Animal Ethics**

  Dr MacArthur Clark has been invited to participate in the first international conference on Veterinary and Animal Ethics due to be held in London in September (12th to 14th) 2011. A detailed programme should be available shortly on the website ([www.icvae.co.uk](http://www.icvae.co.uk)).

- **International Organization for Standardization (ISO)**

  Dr Kurosawa advised that, in contrast to ICH and VICH, which mainly discuss medicinal drugs, the ISO focuses on medical devices. The ISO is discussing the International Standard (IS) for testing medical devices under the ISO Technical Committee (TC) 194: Biocompatibility testing of medical devices. ISO has decided to set an IS for therapeutic use of live human cells and is going to extend its work to embryonic stem (ES) cells and Induced Pluripotent Stem (IPS) cells through TC150, which is responsible for the horizontal standard for medical devices. TC194 references the OIE regarding the safety of animal products utilized for medical devices in relation specifically to Transmissible spongiform encephalopathy (TSE) agents. TC194 created a subcommittee to address this issue and made ISO 22442 to clarify the safety of animal products for medical devices in terms of prions. The geographical location of source animal safety relied on the OIE BSE risk status of the cattle population of a country, zone or compartment. Any further discussion of the therapeutic use of cells using bovine and calf serum for cell cultures should be made in terms of BSE risk. ISO TC194 (Biological Evaluation of Medical Devices) has a working group (WG3) in which animal welfare requirements are discussed. ISO standard 10993, part two, refers to the 3Rs.

  The *ad hoc* Group decided that the OIE should collaborate with the ISO on the issue of regulatory testing and the adoption of alternatives to animal use.

- **Brazil Conference : Feedback from Dr Rivera**

  Dr Rivera provided feedback from the First International Trans Disciplinary Congress on Fauna Protection held recently in Brazil. The recommendations from this successful Congress will be discussed separately with Dr Vallat, with a view to future OIE involvement, including subsequent conferences involving the Brazilian veterinary and legal professions.
Annex 36 (contd)

- **American Veterinary Medical Association (AMVA) update**

  Dr Bayne briefed the group on the status of the American College of Animal Welfare (ACAW), a proposed board certification specialty group under the auspices of the American Veterinary Medical Association (AMVA). ACAW filed its petition for recognition last winter and has undergone a one year comment period. Those comments were addressed by the ACAW Organizing Committee, and the information has been forwarded to the AVMA’s American Board of Veterinary Specialties—the body within the AVMA that reviews board specialty applications. The ACAW application packet will be reviewed in February 2011, and it is hoped that approval of Provisional Status of the College will be granted at the April 2011 meeting of the AVMA Executive Board. Of further note, the AVMA recently modified the oath taken by every graduating veterinary student to include reference to animal welfare.

- **Institute for Laboratory Animal Research (ILAR) update**

  Both Dr Bayne and Dr MacArthur Clark are members of ILAR Council. Dr MacArthur Clark reported on the development of the International Primate Plan (IPP) for which ILAR was currently seeking financial support. The EU Commission had provided funding through the EUPRIM-Net II programme which would cover the costs of European participation as well as hosting a workshop in Europe. It was hoped that similar funding would come forward from South East Asia (probably China) and the remainder of the funding be derived from National Institute of Health (NIH) in the USA as well as from the pharmaceutical industry. It was hoped to commence the development of the IPP during 2011 with a consensus report produced by a committee with international membership in 2013. It was agreed that the IPP was an important international initiative and the Group should monitor its development.

  Dr Bayne updated the group on the status of the 8th edition of the Guide for the Care and Use of Laboratory Animals (National Research Council). The revised version is in press at the National Academies and has been published in December 2010. In its review of the pre-publication version, AAALAC International’s Council on Accreditation identified 121 items for attention. AAALAC intends to publish several new documents (Position Statements and Frequently Asked Questions) to clarify its position on the new Guide. Standards included were largely based upon performance (as opposed to engineering standards) and this approach had been welcomed by the community at large.

- **Council For International Organizations of Medical Sciences (CIOMS) Guiding Principles**

  Dr Demers reported on recent activities in relation to the ICLAS revision of the 1985 CIOMS Guiding Principles for Biomedical Research Involving Animals.

  Following the Fourth ICLAS meeting on Harmonization held in Indianapolis, USA, in November 2008, the revision process has continued through the production and dissemination of documents via email including the production of a Chart comparing documents (Statements, Guidance, and Principles regarding the humane care and use of animals in research produced by other international and national organisations). Then, several drafts of revised principles were produced.

  These drafts were discussed during several Scientific meetings held in 2009-2010 in Thailand (TALAS), USA (PRIM&R), Finland (FELASA), Poland (PAS), Taiwan (AFLAS), India (LASA), etc.

  The Fifth ICLAS Meeting on Harmonization of Guidelines held in Helsinki, Finland (FELASA) on June 14, 2010, was used to refine the last draft version of the CIOMS Guiding Principles. The final draft document was completed on November 24th, 2010.
The next few months (until May 2011) will be used for a large consultation with the national and international organisations, scientific societies and interested parties (NIH). The Issues to consider are:

- Do the revised Guidelines provide a foundation for the future?
- Review of the content – what’s missing?
- Are they achievable and culturally sensitive for developing countries?
- Do they facilitate science while enhancing animal welfare?

The ICLAS ad hoc group, which includes Dr Bayne, will be meeting in 2011 to complete the work.

The publication of the final document is expected for 2011-2012.

6. Emerging/Strategic Issues

- The following topics were identified as priorities in relation to welfare of animals used in research and education:
  - Biotechnology research
  - Globalization of research
  - Veterinary legislation
  - The OIE Global Fund
  - The OIE PVS Tool

7. Review and finalise report of meeting

The ad hoc Group agreed on the work needed to complete the draft text for Article 7.8.10 and the discussion papers on veterinary training and animal use in regulatory testing.

8. Programme for further work after this meeting

The ad hoc Group developed a proposed future work programme

9. Next Meeting

Proposal: 5-7 July 2011 with second option: 19 to 21 July 2011.
4th MEETING OF THE OIE AD HOC GROUP ON LABORATORY ANIMALS WELFARE

Paris, 14–16 December 2010

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Annex 36 (contd)

Appendix I (contd)

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4th MEETING OF THE OIE AD HOC GROUP ON LABORATORY ANIMALS WELFARE

Paris, 14−16 December 2010

Adopted Agenda

Welcome and introduction – Dr Sarah Kahn

1. Comments from Chair of AHG on the Report of the Third Meeting of the OIE ad hoc Group on Laboratory Animal Welfare

2. Feedback from Chair of AHG on the report of the Ninth meeting of the OIE Animal Welfare Working Group

3. Review of Code Commission and Member’s comments on the Chapter 7.8: Use of Animals in Research and Education

4. Development of draft text strategic direction for consideration by the Terrestrial Animal Health Standards Commission
   a) Veterinary Training in Laboratory Animal Medicine
   b) Air transport of laboratory animals: IATA, Discussion paper and update
   c) Regulatory Testing and the adoption of alternatives to animal use: Liaison with VICH/ICH

5. Other Business
   a) Feedback from the Second Global Conference of OIE Reference Laboratories and Collaborating Centres
   b) EC Directive Update
   c) Eighth World Congress on Alternatives and Animal Use in the Life Sciences

6. Emerging/Strategic Issues

7. Review and finalise report of meeting

8. Programme for further work after this meeting
GLOSSARY

3Rs Replacement, Reduction, and Refinement
AAALAC Association for Assessment and Accreditation of Laboratory Animal Care International
AAVMC American Association of Veterinary Medical Colleges
ACAW American College of Animal Welfare
AFEO Asia, Far East and Oceania
AVMA American Veterinary Medical Association
AWWG Animal Welfare Working Group
BSE Bovine spongiform encephalopathy
CCs OIE Collaborating Centres
CIOMS Council For International Organizations Of Medical Sciences
EC European Commission
ECLAM European College of Laboratory Animal Medicine
EMA European Medicines Agency
FDA Food and Drug Administration
IACLAM International Association of Colleges of Laboratory Animal Medicine
IATA International Air Transport Association
ICH International Conference on Harmonisation of Technical Requirement for Registration of Pharmaceuticals for Human Use
ICLAM International Committee for Insurance Medicine
ICLAS International Council for Laboratory Animal Science
IFAH International Federation for Animal Health
ILAR Institute for Laboratory Animal Research
INRA Institute Nationale de la Recherche Agronomique
IPP International Primate Plan
ISO International Organization for Standardization
PETA People for the Ethical Treatment of Animals
RAWS Regional Animal Welfare Strategy
VICH International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products
When ‘welfare codes’ were first developed in the 1970s and 1980s, they tended to contain truisms such as ‘Animals should have adequate space’ and ‘Noise levels should not be excessive’. Although such statements can be useful to identify important variables in the course of providing more specific advice, they do not provide any implementable information or any means of determining whether a given practice or facility is in compliance. In contrast, an OIE animal welfare standard should contain recommendations that can be implemented, and criteria that can be used to tell whether a given practice or facility is in compliance with the standard.

Outcome-based or animal-based criteria should be used where possible because they are generally related most directly to animal welfare, and because they can be applied to a wide range of production systems. Such criteria can be qualitative (all animals should be able to lie down at the same time without lying on top of each other) or quantitative (no more than 1% of animals should be dead on arrival).

In some cases, input-based or resource-based criteria may be possible, for example if welfare is likely to be reduced by a certain factor in a wide range of systems. Again these can be qualitative (no animal should be hoisted while conscious) or quantitative (ammonia level in the air should not exceed 25 ppm).

In other cases, ‘conditional’ criteria can be used. These generally specify what actions should be taken under certain conditions. These can include both qualitative and quantitative elements, as in: (1) If more than 2% of birds arrive at the slaughter plant with broken wings, catching crews should be re-trained to catch birds in ways that are less likely to cause injuries. (2) In months where hot weather is expected, stocking density should be reduced so that birds have enough space to perform wing-stretching unimpeded.

For certain variables, it is possible to identify ‘critical levels’ beyond which welfare is expected to be affected. Such levels are normally determined by scientific research. For example, welfare in many species is noticeably affected if ammonia levels in the air exceed 25 ppm.

For other variables (percent lame, percent dead during transport) there are no critical levels but it may be possible to set or recommend ‘performance targets’. In the case of performance targets, an ad hoc committee may be able to agree that a certain level of performance should be achieved broadly, for example, that no more than 1% of animals should fall while being moved in a slaughter facility. In other cases, there may be so much variation between breeds or locations that a standard merely identifies variables that should be used to assess performance, and calls for national or breed-specific targets to be set. In such cases it is helpful to provide examples of performance targets from other standards that are broadly applicable under different conditions.

June 25, 2010

Dr David Fraser
EXTRACT FROM THE REPORT OF THE TERRESTRIAL ANIMAL HEALTH CODE COMMISSION

The Code Commission received comments from Chinese Taipei and the EU.

The Code Commission noted Members’ comments calling for modification of terms such as ‘committee’, ‘local committee’ and ‘ethics committee’ in Chapter 7.8. The Commission noted that the goal of this chapter is to identify an overall framework for correct use of animals, and not to specify the detailed structure to be used. For this reason, the chapter provides for flexibility in selecting elements within the framework. The Commission did not see value in trying to achieve more specificity by qualifying ‘committee’ or other terms used in this chapter.

The Code Commission proposed to delete the definition of ‘euthanasia’ from Article 7.8.1. and include it in the Glossary.

The Code Commission modified the text of point 5 Article 7.8.7 to clarify the distinction between genetically altered and cloned animals.
Preamble: The purpose of this chapter is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live animals in research and education. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live animals in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and animals and emphasise the importance of the Three Rs (see Article 7.8.3.). Most scientists and members of the public agree that the animals should only be used when necessary; ethically justified (thereby avoiding unnecessary duplication of animal-based research); and when no other alternative methods, not using live animals, are available; that the minimum number of animals should be used to achieve the scientific or educational goals; and that such use of animals should cause as little pain and/or distress as possible. In addition, animal suffering is often recognised separately from pain and distress and should be considered alongside any lasting harm which is expected to be caused to animals.

The OIE emphasises the need for humane treatment of animals and that good quality science depends upon good animal welfare. It is the responsibility of all involved in the use of animals to ensure that they give due regard to these recommendations. In keeping with the overall approach to animal welfare detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the animal.

The OIE recognises the significant role of veterinarians in animal-based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of animals has an ethical responsibility for the animals’ welfare. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum welfare for the animals used.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events and interventions should be recorded to aid decision making and promote good science and welfare. A summary of these records may be gathered on a national basis and be published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

Article 7.8.1.

Definitions

**Biocontainment:** means the system and procedures designed to prevent the accidental release of biological material including allergens.

**Bioexclusion:** means the prevention of the unintentional transfer of adventitious organisms with subsequent infection of animals, resulting in adverse effects on their health or suitability for research.
Annex 36 (contd)

Appendix VI (contd)

**Biosecurity:** means a continuous process of risk assessment and risk management designed to minimise or eliminate microbiological infection with adventitious organisms that can cause clinical disease in the infected *animals* or humans, or make *animals* unsuitable for biomedical research.

**Cloned animal:** means a genetic copy of another living or dead *animal* produced by somatic cell nuclear transfer or other reproductive technology.

**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.

**Endangered species:** means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

**Environmental enrichment:** means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive *animal’s* environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

**Ethical review:** means consideration of the validity and justification for using *animals* including: an assessment and weighing of the potential harms for *animals* and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

**Euthanasia:** means the act of inducing death using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to the *animal*.

**Harm-benefit analysis:** means the process of weighing the likely adverse effects (harms) to the *animals* against the benefits likely to accrue as a result of the proposed project.

**Humane endpoint:** means the point in time at which an experimental *animal’s* pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal*.

**Operant conditioning:** means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal* can be modified (e.g. increased or decreased in frequency or intensity).

**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.

**Project proposal (sometimes called protocol):** means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work; characterises the use of the *animals*; and includes ethical considerations.

**Suffering:** means an unpleasant, undesired state of being, which is the outcome of the impact on an *animal* of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good *welfare*. 
Proposed text by the ad hoc Group

Suffering: means an unpleasant, undesired state of being which is the outcome of the impact on an animal of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare.

Article 7.8.2.

Scope

This chapter applies to animals as defined in the Terrestrial Code (excluding bees) bred, supplied and/or used in research (including testing) and higher education. Animals to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the animal in implementing these standards.

Article 7.8.3.

The Three Rs

The internationally accepted tenet, the ‘Three Rs’, comprises the following alternatives:

1. replacement refers to the use of methods utilizing cells, tissues or organs of animals (relative replacement), as well as those that do not require the use of animals to achieve the scientific aims (absolute replacement);

2. reduction refers to the use of methods that enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals;

3. refinement refers to the use of methods that prevent, alleviate or minimise pain, suffering, distress or lasting harm and/or enhance welfare for the animals used. Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the animal and include, for example, housing and transportation as well as procedures and euthanasia.

Article 7.8.4.

The oversight framework

The role of a Competent Authority is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance, which may be assessed at the institutional, regional and/or national level.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and welfare. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve animal welfare officers, regional, national or local committees or bodies. An institution may utilise a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee, Animal Welfare Body or Animal Care Committee) to deliver some, or all, of this oversight framework. It is important that the local committee report to senior management within the institution, to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.
Annex 36 (contd)

Appendix VI (contd)

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given on how to ensure impartiality and independence from all those serving on the committees. In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

a) one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;

b) one veterinarian, with the necessary expertise to work with research animals, whose specific role is to provide advice on the care, use and welfare of such animals;

c) one public member to represent general community interests who is independent of the science and care of the animals and is not involved in the use of animals in research, where appropriate.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the welfare of animals used. Other participants, especially in relation to ethical review, may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve student representation.

Oversight responsibilities include three key elements:

1. **Project proposal review**

   The purpose of the project proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

   Project proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work. The proposal should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

   a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or welfare, the environment, or the advancement of biological knowledge;
b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;

c) the experimental design, including justification for choice of species, source and number of animals, including any proposed reuse;

d) the experimental procedures;

e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;

f) the methods to avoid or minimise pain, discomfort, distress, suffering or lasting impairment of physical or physiological function, including the use of anaesthesia and/or analgesia and other means to limit discomfort such as warmth, soft bedding and assisted feeding;

g) application of humane endpoints and the final disposition of animals, including methods of euthanasia;

h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;

i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis; the benefits should be maximised and the harms, in terms of pain and distress, should be minimized;

j) an indication of any special health and safety risks; and

k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, staff trained and found competent to perform the procedures described in the proposed project).

The oversight body has a critical responsibility in determining the acceptability of project proposals, taking account of the animal welfare implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live animals.

Following approval of a project proposal, consideration should be given to implementing an independent (of those managing the projects) oversight method to ensure that animal activities conform with those described in the approved project proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body, which may be the local committee, animal welfare officer, compliance/quality assurance officer or government inspector.
Annex 36 (contd)

Appendix VI (contd)

2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

a) the animals and their records, including cage labels and other methods of animal identification;
b) husbandry practices;
c) maintenance, cleanliness and security of the facility;
d) type and condition of caging and other equipment;
e) environmental conditions of the animals at the cage and room level;
f) procedure areas such as surgery; necropsy and animal research laboratories;
g) support areas such as washing equipment; animal feed, bedding and drug storage locations;
h) occupational health and safety concerns.

Principles of risk management should be followed when determining the frequency and nature of inspections.

3. Ethical evaluation

The ethical evaluation reflects the policies and practices of the institution in complying with regulations and relevant guidance. It should include consideration of the functioning of the local committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of animals; and occupational health and safety. The programme should be reviewed regularly. A requirement for the components of such a programme should be included in relevant regulations to empower the Competent Authority to take appropriate action to ensure compliance.

Article 7.8.5.

Assurance of training and competency

An essential component of the animal care and use programme is the assurance that the personnel working with the animals are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. Scientific staff

Researchers using animals have a direct ethical and legal responsibility for all matters relating to the welfare of the animals in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory animal veterinarian is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research (e.g. surgery, anaesthesia, sampling and administration, etc.).
2. **Veterinarians**

   It is important that veterinarians working in an animal research environment have veterinary medical knowledge and experience in the species used, including the normal behaviour of the species, and they should understand research methodology. Relevant approvals issued by the veterinary statutory body and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3. **Animal care staff**

   Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. **Students**

   Students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of live animals and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving live animals, they should receive appropriate supervision in the use of animals until such time that they have demonstrated competency in the related procedure(s).

5. **Members of the local oversight committee or others involved with oversight**

   Continuing education about the use of animals in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious diseases which may infect research animals and thus compromise research results, as well as possible zoonoses. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards.

**Article 7.8.6.**

**Provision of veterinary care**

Adequate veterinary care includes responsibility for promoting an animal’s health and welfare before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the animal. The veterinarian should have authority and responsibility for making judgements concerning animal welfare. Veterinary advice and care should be available at all times.

1. **Clinical responsibilities**

   Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. Disease surveillance is a major responsibility of the veterinarian and should include routine monitoring of colony animals for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical diseases. The veterinarian should have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources, following diagnosis of an animal disease or injury. Where possible, the veterinarian should discuss the situation with the scientist to determine a course of action consistent with experimental goals. Controlled drugs prescribed by the veterinary staff should be managed in accordance with applicable regulations.
2. Post-mortem examinations

In the case of unexpected *diseases* or *deaths*, the *veterinarian* should provide advice based on post-mortem examination results. As part of health monitoring, a planned programme of post-mortem examinations may be considered.

3. Veterinary medical records

Veterinary medical records, including post-mortem records, are considered to be a key element of a programme of adequate veterinary care for *animals* used in research and education. Application of performance standards within the veterinary medical record programme allows the *veterinarian* to effectively employ professional judgment, ensuring that the *animals* receive the highest level of care available.

4. Advice on zoonotic risks and notifiable diseases

The use of some species of *animals* poses a significant risk of the transmission of zoonotic disease (e.g. some nonhuman primates). The *veterinarian* should be consulted to identify sources of *animals* that minimise these risks and to advice on measures that may be taken in the animal facility to minimize the risk of transmission (e.g. personal protective equipment, appropriate *disinfection* procedures, air pressure differentials in animal holding rooms, etc.). *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care

A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian*. A *veterinarian*’s inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia

Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of euthanasia.

7. Advice on humane endpoints

Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* has the authority to ensure euthanasia or other measures are carried out as required to relieve pain and distress unless the project proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study’s objectives. In consultation with the veterinarian, humane endpoints should be described in the project proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, death (other than euthanasia) as a planned endpoint is considered ethically unacceptable.
Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement

Animals should be acquired legally. It is preferable that animals are purchased from recognised sources producing or securing high quality animals. Purpose bred animals should be used whenever these are available and animals that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm animals, non traditional breeds and species, and animals captured in the wild, non purpose bred animals are often used to achieve specific study goals. The use of wild caught nonhuman primates is generally discouraged.

Proposed text by the ad hoc Group

Animals should be acquired legally. It is preferable that animals are purchased from recognised sources producing or securing high quality animals. The use of wild caught nonhuman primates is generally discouraged.

Purpose bred animals should be used whenever these are available and animals that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm animals, non traditional breeds and species, and animals captured in the wild, non purpose bred animals are often used to achieve specific study goals. The use of wild caught nonhuman primates is generally discouraged.

2. Documentation

Relevant documentation related to the source of the animals, such as health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the animals.

3. Animal health status

The health status of animals can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. Animals should have appropriate health profiles for their intended use. The health status of animals should be known before initiating research.

4. Genetically defined animals

A known genetic profile of the animals used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined animals are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which should be validated by periodic genetic monitoring. Detailed and accurate documentation of the colony breeding records should be maintained.
Annex 36 (contd)

Appendix VI (contd)

5. Genetically altered (also genetically modified or genetically engineered) or cloned animals (also genetically modified animal and genetically engineered animal).

A genetically altered or cloned animal is one that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an animal(s), where they have inherited the modification. If genetically altered or cloned animals are used, such use should be conducted in accordance with relevant regulatory guidance. With such animals, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and welfare needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised animals.

6. Animals captured in the wild

If wild animals are to be used, the capture technique should be humane and should give due regard to human and animal health, welfare and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the project proposal.

7. Endangered species

Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the animals as well as exclusion of contaminants. The amount of time animals spend on a journey should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the animals and that relevant documentation accompanies animals during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. Risks to biosecurity

In order to minimise the risk of contamination of animals with unwanted infectious microorganisms or parasites that may compromise the health of animals or make them unsuitable for use in research, the microbiological status of the animals should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.
Physical facility and environmental conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the animals to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. Animals should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the animals and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of welfare concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. **Ventilation**
   
   The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an animal's primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of animals involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. **Temperature and humidity**
   
   Environmental temperature is a physical factor which has a profound effect on the welfare of animals. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be appropriately limited to avoid repeated demands on the animals' metabolic and behavioural processes to compensate for large changes in the thermal environment as well as to promote reproducible and valid scientific data. Relative humidity may also be controlled where appropriate for the species.

3. **Lighting**
   
   Light can affect the physiology, morphology and behaviour of various animals. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the welfare of the animals while facilitating good husbandry practices, adequate inspection of animals and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. **Noise**
   
   Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy animals, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the welfare of quieter animals, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.
Husbandry

Good husbandry practices enhance the health and welfare of the animals used and contribute to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the animal, and should minimise stress to the animal. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the animals’ welfare.

1. Transportation

Transportation is a typically stressful experience. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of animals should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social animals should be transported in established pairs or groups and maintained in these on arrival.

2. Acclimatisation

Newly received animals should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the animals. Facilities should be available to isolate animals showing signs of ill health.

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the animals are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese animals, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social animals should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the animals.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the animals and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the animals or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each animal to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.
6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and animal welfare. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the animals clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading infection between animals through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. Animals may be identified individually or by group. Where it is desirable to individually identify animals, this should be done by a reliable and the least painful method.

10. Handling

Staff dealing with animals should have a caring and respectful attitude towards the animals and be competent in handling and restraint. Familiarising animals to handling during routine husbandry and procedures reduces stress both to animals and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the animals, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with wild animals. Consideration should be given to setting up habituation and training programmes suitable for the animals, the procedures and length of projects.

_______________
1. Characterizing (defining) the Laboratory Animal Veterinarian (LAV)

2. This should be post-graduate training (i.e., to occur after completion of general veterinary training)

3. Distance learning, mentor programs will likely play a key role to reach the diversity of target countries

4. Ladder approach to the skills and knowledge *

5. Assessing competency

6. Resource issues (people, funding, and educational materials)

7. Translation strategy and accessibility of information

8. Ensuring veterinary training and skills matches researchers’ needs so that veterinary participation is considered as a ‘value added’ by the scientist

9. Continuing professional development (CPD)

10. Regulatory authority appreciation of the need for specialised training for laboratory animal veterinarians

11. Partnership approach, between veterinarian and technician

12. Role within a team

* The veterinarian should be skilled in diagnostics. Optimally, take the ACLAM Role Delineation Document (RDD) as a model for describing the necessary skills (for non-country-specific topics). (Dr W. White)

Knowledge of the moral and ethical use of laboratory animals (e.g., the 3Rs); knowledge of the regulations; basic surgical skills; research methodology; recognize clinical signs.

Training in protocol review, literature searches to assist the investigator in identifying the appropriate model, endpoints

Important for LAV to be familiar with the regulations in his/her own country and/or territory.

Impact of facility environmental factors on health and welfare of animals, to include biosecurity; effects of non-experimental variables.

Preventive medicine

Role of veterinarian in research team: brings to the team knowledge of and experience in working with: the regulatory framework of the country, as well as pharmacology, basic sciences and basic pathology.
ILAR JOURNAL ARTICLE ASSIGNMENT

1) Introduction: Dr Bayne and Dr MacArthur Clark
   a. Zurlo article
   b. Convening of focus groups

2) Core knowledge and practical skills: Dr Demers, Dr Ouajdi, Dr Bayne, Dr Kurosawa

3) Delivery of Training: Dr Demers, Dr Bayne and Dr Pat Turner (regional conferences, mentors, distance learning)

4) Ladder approach: Dr Bayne, Dr Demers, Dr Rivera

5) Assessing competency: Dr Demers and Pat Turner

6) Accessibility and translation: Dr Rivera, Dr Kurosawa and Dr Demers

7) Recommendations
   a. Team approach: J Dr Mac Arthur Clark and Dr Joubert
   b. Conflict of interest: Dr Bayne and Dr Mac Arthur Clark
   c. Standards development: Dr Bayvel
   d. CPD: Dr Bayvel

8) Conclusions
   a. WVY: Dr Bayvel
   b. OIE: Dr Bayvel
Transportation

Transportation is a typically stressful experience for animals. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. In addition, animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the animals as well as exclusion of contaminants. The amount of time animals spend on a journey should be kept to a minimum. Consignments of animals should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social animals should be transported in established pairs or groups and maintained in these on arrival.

1. An ethical review of the planned transport should occur during the broader review of the proposed use of the animals. (cross-ref to 7.8)
   a) The source and transport of animals should be justified based on a scientific rationale or to obtain an animal of defined genetic or health status (e.g., a specialized colony located at a different institution, animals from a commercial breeder), with alternative sources considered.
   b) The method, and route and duration of transport should be addressed with reference to the impact on the health and welfare of the animal.
   c) The potential for delays in transportation should be anticipated and avoided through the development of a complete and well constructed journey plan.

2. The documentation required to accomplish the transport should be based on the OIE Model Veterinary Certificate for Movement of Live Animals (chapter 5.10) to facilitate the safe and efficient movement of the animals.
   a) There should be assurance that complete, relevant and legible documentation accompanies animals during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.
   b) Newer technologies, such as electronic certificates that minimize errors in paperwork, and the potential consequent impediments to transport, should be implemented.

3. The journey plan and the monitoring of the transport, should always be under the general oversight of a veterinarian knowledgeable and experienced in the biology and needs of the particular species to ensure animal welfare is preserved throughout the journey.
   a) The transportation of research animals should be managed so that the journey time is the shortest possible and most comfortable for the animal to minimize stress to the animal. Where journeys of some distance are involved, this is generally best achieved through air transport, preferably by direct routes where possible.
   b) Some animals (e.g., genetically altered animals) may have special requirements that should be addressed by the veterinarian in the journey plan.
   c) Issues of biosecurity and biosafety should always be addressed in the journey plan. (Get input from Bill White)
Annex 36 (contd)

Appendix IX

4. In accordance with the relevant OIE standards and regulations (e.g., IATA), an appropriate environment (e.g., container design and construction, temperature, food, and water) must be provided to the animal at the point of departure, throughout transport, and at the point of arrival.

5. Personnel handling animals at the point of departure, throughout transport, and at the point of arrival, should be trained in the species-specific requirements of the animals, in good handling practices to facilitate the loading and unloading of animals, and in the husbandry and environmental requirements of animals being transported.
DISCUSSION PAPER

Animal Use in Regulatory Testing

A strategic approach to encouraging international adoption of scientifically validated non-animal alternatives

Purpose

The purpose of this discussion paper is to assist the OIE Laboratory Animal Welfare ad hoc Group in formulating a possible strategic approach to encouraging and facilitating (at an international level) the replacement of live animal use in regulatory testing, where scientifically-validated, non-animal tests exist.

This paper is a revised version of an earlier paper, of 26 July 2009, discussed at LAWAHG 3 and reflects both discussion at that meeting and subsequent discussions involving ad hoc group members. The paper also takes note of recent developments in the subject area, including the outcome of General Session 78.

Background

Laboratory animals are used for regulatory testing to assess the safety, efficacy and/or potential adverse health effects of new chemicals and products such as vaccines, medicines, food additives, pesticides and industrial chemicals. These regulatory tests are required by law in most countries, and companies performing these tests have to comply with the regulatory protocols.

At the May 2010 General Session of the World Assembly of Delegates, OIE members adopted for inclusion in the Terrestrial Animal Health Code, as Chapter 7.8, “The use of animals in Research and Education”. This text is considered to underpin Guiding Principles relevant to the use of animals in regulatory testing detailed in Appendix 1. Likewise, it is considered that relevant OIE definitions are included in existing OIE documents, with the exception of those included in Appendix 2.

The original discussion paper “Issues and options regarding a future international role for the OIE in laboratory animal welfare” identified “facilitating the regulatory acceptance and adoption of internationally-validated, non-animal test methods” as a possible priority area for OIE focus.

As for laboratory animal welfare in general, the unique benefit of OIE involvement was seen to be the scientific and policy credibility provided by an internationally recognised inter-governmental body dedicated to animal health and welfare issues and representing 176 members.

In this same discussion paper, the important role played by VICH and its relationship with the OIE was highlighted. The factors which influenced the establishment of VICH in 1996, under the auspices of the OIE, were emphasised i.e.

- The drive to reduce the number of animals used in regulatory testing by eliminating the need for duplication of tests in each VICH region.
- The International drive to harmonise regulatory standards and minimise their impact on trade.
Annex 36 (contd)

Discussion

- Considerable research investment has been made in non-animal test methods over the last two decades, by both the private and public sectors, with a number of significant achievements.
- Validation bodies have been established in both Europe (ECVAM) and North America and the “European Partnership on Alternative Approaches to Animal Testing” is an important component of the EU animal welfare action plan.
- Individual Governments (eg. Canada in 2001), NGOs (RSPCA and UK 3Rs Centre) have taken a particular interest in this policy area, from both a scientific and regulatory perspective, and the subject continues to be an important programme item at World Congresses on Alternatives and Animal Use in the Life Sciences.
- Regulatory acceptance, however, continues to be perceived to be hampered by a conservative regulatory approach, with liability and litigation risks considered to be influencing attitudes of regulatory bodies and individual decision matters.
- A number of regulatory bodies have, however, taken a leadership position and confirmed formal policies promoting the use of validated non-animal tests.
- For transnational companies supplying a significant number of international markets, it is important that non-animal tests are acceptable in all markets, if changes to testing requirements are to be introduced.
- Selected relevant developments, since LAWAHG 3, include progress with EC acceptance of non-animal regulatory tests for shellfish biotoxin testing and the proposed EC establishment of a Reference Laboratory, at European level, to continue the work so far carried out by ECVAM.

The OIE LAWAHG has held valuable initial discussions with VICH on this issue but, to date, has had no contact with the human health equivalent, ICH.

Recommendations

The key decision for the OIE is whether it wishes to take an inter-governmental leadership position in encouraging regulatory acceptance of scientifically-validated, non-animal alternatives utilising its unique relationship with 176 Governments and the VICH.

It is proposed that the preferred strategic approach is to work through the existing relationship with VICH and to look at establishing a similar relationship with ICH depending on progress made with VICH.

It is recommended that:

i) The OIE continues dialogue with VICH to identify opportunities for both organisations to encourage international regulatory acceptance of scientifically-validated, non-animal alternative test requirements in relation to veterinary product testing.

ii) Depending on progress made with VICH, OIE initiates dialogue with ICH to identify opportunities for both organisations to encourage international regulatory acceptance of scientifically-validated, non-animal alternative test requirements in relation to medical product testing.

iii) If there is support for the strategic approach proposed in i) and ii) a LAWAHG sub committee meet with VICH to formally advance this dialogue and identify specific opportunities and agree appropriate short and medium term actions and initiatives.

iv) On completion of a draft action plan as outlined in iii), that this be discussed with selected regulatory authorities, private sector commercial organisations and animal welfare NGOs focused on the use of animals in regulatory testing, prior to finalisation.

v) The final agreed action plan be submitted to the OIE Council for endorsement and consideration of resourcing implications.
### Selected Background Publications

<table>
<thead>
<tr>
<th>Title</th>
<th>Author</th>
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<tbody>
<tr>
<td>Proceedings of the 6th World Congress on Alternatives &amp; Animal Use in the Life Sciences, 2008</td>
<td>Japanese Society for Alternatives to Animal Experiments (JSAAE)</td>
</tr>
<tr>
<td>Working in partnership to advance the 3Rs in toxicity testing - Toxicology, 2010, 267, 1-3, 14-19, Elsevier Ireland Ltd, Ireland</td>
<td>Holmes, A.M.; Creton, S.; Chapman, K.</td>
</tr>
</tbody>
</table>
Annex 36 (contd)

Appendix 1

Guiding Principles

1. Laboratories or companies performing regulatory testing have to follow rigid international protocols.

2. Every laboratory or company should have an animal care and use committee. It will play a key role in implementing the humane endpoints, best practices and public accountability.

3. Tests should only be accepted by the regulatory bodies if they are performed by laboratories that have full implementation of Good laboratory Animal Science Principles and Good Laboratory Practices.

4. The animals selected for a procedure should be of an appropriate species and quality required by the protocols and obtained from a known source.

5. The living conditions of animals should be appropriate for their species and contribute to their health and comfort.

6. Investigators and personnel performing the tests should be properly trained and experienced in the proper care, handling and use of the species being maintained. Provisions should be taken for their in service training, including the proper and humane care of laboratory animals.

7. Adequate veterinary care should be provided as indicated.

8. Proper use of animals, including the avoidance or minimisation of discomfort, distress and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

9. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia or anesthesia. Surgical or other painful procedures should not be performed on unanesthetised animals paralysed by chemical agents.

10. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

11. Mutual acceptance of test data can significantly reduce animal test requirements, and facilitate timely and ethical regulatory decisions.

12. If there is a need for deviations from the protocol these should be soundly justified to the pertinent authorities.
Appendix 2

Terms and Definitions

1. Animal test – any use of an animal for scientific purposes which may cause it pain, suffering, distress or lasting harm.

   a. Note 1: the definition of an animal test excludes acts of recognised veterinary practice applied for the benefit of an animal or the group of animals of which it is part; recognised husbandry practices to manage or conserve the animal or the group of which it is part; marking by methods which cause no more than momentary pain or distress; and humane killing.

   b. Note 2: The prevention of pain, suffering, distress or lasting harm by the effective use of anaesthesia or analgesia or other methods of rendering the animal insentient (eg. decerebration) does not place animal tests outside the scope of this definition. The administration of anaesthetics, analgesics or other methods of rendering the animal insentient are considered to constitute an integral part of the animal test.

2. Procedural training (acclimatisation) – training and acclimatising animals to the interventions to be performed during an animal test, with a view to minimising stress to the animal when animal tests are conducted.

3. Purpose-bred animal – any animal purpose-bred for use in animal tests or for other experimental or scientific purposes.

4. Test animal – Any animal used in in vivo animal tests, or used to provide tissue for ex vivo or in vitro tests.

5. Validation – process by which the reliability and relevance of a test method is established for a particular purpose.
The meeting of the OIE ad hoc Group on Veterinary Education (ad hoc Group) was held at the OIE Headquarters in Paris, France from 15 to 17 September 2010. A list of the members of the ad hoc Group may be found at Annex I and the adopted agenda for the meeting at Annex II.

1. Meeting with Dr Vallat, Director General

Dr DeHaven opened the meeting with a particular welcome to Dr Vallat, who joined the ad hoc Group for a discussion on the objectives of the OIE’s work in the domain of veterinary education. Dr Vallat thanked the members of the Group for their ongoing work on this important topic. He emphasised the fact that high quality veterinary education is an essential need for high quality veterinary services and that the topic of veterinary education falls within the scope of the OIE global initiative for strengthening Veterinary Services, ‘the PVS Pathway for efficient veterinary services’. He reminded Group members that the term ‘veterinary services’, as defined by the OIE, covers all veterinarians, whether working in the public or private sector, while the term ‘veterinary authority’ covers veterinarians working in governmental services.

Dr Vallat explained that it is important to share the concepts elaborated by this Group with OIE Member Countries and to give Members the tools to help them to put the concepts into practice. Dr Thiermann mentioned that it will be important to develop an appropriate communication strategy to raise awareness of and create support for the OIE’s recommendations. In particular, the OIE needed to reach out to veterinary Deans, who are independent of Delegates and not closely engaged with the OIE. De DeHaven noted that there were some concerns from Deans in developed countries about the OIE recommending quality standards, as there are well established mechanisms via accreditation of veterinary education establishments that meet the objective of quality assurance. He noted that situating the work on veterinary education within the global PVS initiative was a good way to address these concerns.

Dr Vallat noted that it has been estimated that up to 80% of the OIE’s 177 Member countries lack an appropriate infrastructure for veterinary education. Many countries are obliged to use veterinarians trained outside and have little to no capacity to assure the quality of these veterinarians with respect to their education. The OIE is working to provide standards and tools to enable all countries to apply a standardised approach to the quality of veterinary education. Continuing education is also an essential tool to maintain or improve the competency of veterinarians.

Dr Thiermann noted that veterinary education establishments would continue to be responsible for deciding how to deliver veterinary education, with hopefully appropriate reference to the OIE recommendations.
Annex 37 (contd)

Dr Vallat commented that the Veterinary Statutory Body (VSB) is the key organisation contributing to assure the quality of veterinarians within a country; hence the focus of OIE on encouraging Members to ensure that they have a VSB, including by providing legislation setting up an independent VSB with the powers to regulate the veterinary profession and, as appropriate, veterinary para-professions.

Dr Vallat noted that the OIE has established a ‘pyramid’ for assuring the quality of veterinary services, as follows:

Dr Vallat explained that the OIE PVS Pathway is not a mechanism for auditing or accreditation of veterinary schools. This activity is handled by other organisations, including for example the EAEVE in Europe and the AVMA Council on Education in Canada and the USA and it is not the mandate of the OIE to accredit veterinary schools. Rather, OIE Members that are developing countries and countries with in-transition economies have asked the OIE to provide guidance on the minimum competencies that veterinary education establishments (VEE’s) should aim to attain, as guidance in developing and refining the veterinary curriculum. Dr Vallat advised that he saw the development of minimum ‘day 1’ competencies as an important first step. Consideration should be given to the future status of these recommendations in terms of OIE standards and recommendations.

Dr Vallat noted that the Terrestrial Code, specifically Article 3.2.14., contains references to veterinary education but that there are not, for the moment, recommendations on minimum quality requirements for veterinary education. The OIE PVS Tool also contains specific references to initial (and ongoing) training of veterinarians, but the basis for the evaluation of competency is quantitative i.e. the critical competencies Nos. I-1 and I-2 respectively refer to the number of veterinarians and the fact that they hold a recognised veterinary qualification and relevant experience. Qualitative aspects relating to education (both initial and ongoing) are not currently addressed in detail in the OIE PVS Tool. Dr Vallat advised that the recommendations of this Group on ‘day 1’ minimum competencies and other topics could in the future serve as a key reference for OIE PVS assessors in determining the competence of national veterinary services with respect to the quality of veterinary education.

Dr Vallat commented on the next steps for the ad hoc Group as follows: the report will be presented to the Terrestrial Code Commission when it meets on 1–10 February 2011. The Code Commission is expected to propose some additional text in Code Chapter 3.2., to provide appropriate cross reference to the OIE Recommendations on Minimum Competencies for Day 1 Veterinary Graduates.

With agreement of the Code Commission, the document on minimum competencies could be placed on the OIE internet site, within the menu dealing with the PVS Pathway.

Any proposed amendments to the Terrestrial Code will be managed in accordance with the OIE standard setting procedures, i.e. by consensual decision of the World Assembly of Delegates. The next opportunity for modification of the Terrestrial Code is at the OIE General Assembly in May 2011.
Dr Jorna mentioned that it is important for the OIE to consider the role of companion animal veterinarians and the fact that most (up to 80% in the USA) veterinary graduates follow a career in companion animal practice. Dr Bedard added that by paying more attention to careers in Veterinary Services in the undergraduate curriculum, more graduate veterinarians may become interested in pursuing a career in the public sector.

Dr Bedard presented the Veterinary Services-related work of the World Bank in Europe and Central Asia regions (see Annex III), including a current WB project in Azerbaijan. Dr Bedard highlighted the value of twinning as an approach to improve the capacities of veterinary education establishments and the possibility of the OIE gaining donor support, including from WG, for such proposals.

2. Discussion on the 2nd OIE Global Conference on Veterinary Education

Dr Stéphane Martinot, Dean VetAgro Sup, joined the Group for a discussion on the proposed arrangements for the 2nd Global Conference on Veterinary Education. Dr Martinot noted that 2011 would mark the 250th world anniversary of the veterinary profession and of veterinary education. As part of the celebration of World Veterinary Year 2011, a 2nd Global Conference on Veterinary Education will take place on 13 - 14 May 2011 (after the General Assembly of the European Association of Establishments for Veterinary Education, EAEVE) at the campus of VetAgro Sup, Lyon. The OIE’s work on veterinary education will be presented, including presentations by several members of the Group and a round table, chaired by Dr Vallat, on the future needs of veterinary education worldwide.

The Group discussed the proposed programme with Dr Martinot and made several suggestions for speakers and topics to be addressed at the meeting. It was agreed that this conference would provide a good opportunity to raise awareness of the OIE’s work on veterinary education and, in particular, to build linkages with the veterinary education community.

3. Addressing OIE Member comments

The OIE received comments from 7 Members, i.e. Argentina, Australia, Canada, Chile, Japan, New Zealand and Norway. In addition Dr DeHaven provided comments from the American Veterinary Medical Association. The Group dedicated considerable time to addressing these comments and finalised the document on Minimum competencies of ‘Day 1’ veterinary graduates (see Annex IV).

The Group noted that the definition of veterinary services in the introduction was not aligned with the Terrestrial Code definition and modified this text accordingly.

One Member asked for clarification on the recommendations of the OIE in regard to competency of ‘Day 1’ graduates on communication. Members of the Group identified two important elements in relation to communication. The veterinarian is well placed to play an advocacy role, i.e. to improve the awareness of the general public about the important role and responsibilities of the Veterinary Services in animal health and public health. Secondly, communication skills are an important competency for veterinarians who deliver the activities defined under the OIE’s definition of the veterinary domain. The Group considered that it was important to ensure that basic education gives the ‘Day 1’ graduate the tools he/she needs to be an effective communicator. As a minimum, ‘day 1’ graduates should have excellent interpersonal skills, as covered in point 3.5.2. For communication in the context of the administration of veterinary services, the words ‘public awareness and advocacy’, in parentheses, were added to point 3.6.3.

In response to comments of Members, the Group was of the opinion that the addition of more detailed recommendations (for example required hours, numbers of teachers) was not desirable.

The Group deleted the word ‘average’, which had been used, for example, as follows: ‘this competency includes the average entry-level veterinarian’ as the word ‘average’ was considered to be superfluous in the contexts of the OIE recommendations.
Noting that the competencies pertain to the mandate of the OIE, the Group divided the competencies into three categories, all being part of the core curriculum i.e: 1) general competencies, 2) specific competencies and 3) introduction to advanced competencies. The Group decided not to provide any details on the general competencies that do not relate directly to the OIE mandate as other organisations are responsible for this work.

An OIE Member proposed to modify the title of the document by referring to ‘veterinarians’ rather than ‘veterinary graduates’, to reflect the fact that the defined competencies were directed to veterinarians working in the public sector. The Group disagreed with this recommendation, as the competencies were relevant to all ‘Day 1’ graduates. The Group made some changes in the document to clarify this fact. For example, the title of the paragraph about advanced competencies was changed into ‘Introduction to advanced competencies’, to reflect the fact that ‘day 1’ graduates should have an appreciation of these competencies but were not expected to have specific expertise.

The definition of skills was modified to avoid excluding veterinarians with handicaps.

The comments of several OIE Members revealed a level of confusion about the scope of the Group’s work and the intention of proposing three categories of competencies. The Group changed the description of these categories in order to clarify that all categories were considered to be relevant to the education of veterinary students and included in the core curriculum, regardless of their eventual career choices.

An OIE Member proposed to replace paragraph 1. ‘General competencies’ with ‘General Veterinary Competencies’. The Group disagreed with this suggestion because the report covers veterinary education and the general competencies are, in fact, veterinary competencies.

Two OIE Members commented on the animal welfare – related recommendations, arguing that the wording used was not appropriate for all countries. The Group modified the text of the report accordingly.

The Group decided to move the content of paragraph 2.8. ‘Inspection and certification procedures’ to section 3. ‘Introduction to advanced competencies’ because it relates directly to public sector work whether performed by a veterinarian in the public or private sector. However, a paragraph 2.8 was kept to take into account the necessary competency on general animal health certification.

The Group agreed that an understanding of ethical issues, in particular those underlying the Codes of Ethical Practice that apply in many countries, should be included as a basic competency. The words ‘and ethics’ were therefore added to the title of item 2.9 i.e. ‘Veterinary legislation and ethics’.

On Sections 2.7–2.9., the Group addressed a question about the intended scope of the quoted disease programmes by adding the following text:

‘It is understood that these disease prevention and control programmes will be unique to each country or region, compliant with applicable OIE standards as appropriate, and that entry level veterinarians need to be familiar with these programmes.’

The meaning of the reference to ‘research’ in point 3.4 was discussed, in particular whether this recommendation is appropriate as a ‘Day 1’ competency. It was agreed that the recommendation called for the ‘Day 1’ veterinarian to have general awareness of the relevance of research, not to have competence in the conduct of research and that, on this basis, the text did not need modification.

The Group discussed whether the recommendation under administration and management (Point 3.6.), ‘general awareness and appreciation of at least one language other than the official language of the country’, was reasonable to expect for a ‘Day 1’ veterinary graduate. The Group noted that there was undoubtedly a need for all veterinary graduates to appreciate the international dimension of veterinary medicine. The ability to access peer reviewed scientific publications was greatly influenced by the capacity of graduates to read and understand one of the major languages of publication of scientific journals. Furthermore, the OIE standards are published in English, French and Spanish, with unofficial and/or partial translations available in some other languages. In conclusion, the Group decided not to modify this text.
In response to Members’ comments, the Group agreed that the word ‘notions’ (point 3.6.6.) was too vague and replaced it with ‘principles’.

In response to a Member comment, the Group reviewed the text on communications in the report of the OIE ad hoc Group on Communications to ensure that the definitions and recommendations of this Group had been taken into account. The Group agreed that the intent was to address the broader context of communication, beyond interpersonal skills, including public awareness, media management, dissemination of technical information and advocacy especially in relation to decision-makers.

Noting that success in the practice of veterinary medicine depends on effective communication skills, the Group included new text in the Recommendations for Day 1 graduates in a new point 2.10.

The Group clarified and simplified the text on veterinary health certificates in point 2.8. The Group also made some minor text modifications to improve the clarity of the text.

4. Ongoing work

The Group continued to work on defining competencies and topics, delivery methods and sources relevant to veterinary education, in the three following areas:

1. Critical skills needed by senior level veterinarians in the Veterinary Authority
2. Continuing education topics for private veterinarians conducting work for the Veterinary Authority
3. Delivery methods and sources of continuing veterinary education.

Three working documents were produced and will be the subject of further discussion between members and finalization at the next Group meeting.

5. Discussion on the potential future role of the OIE in accreditation

In the report of the previous meeting the Chairman recalled that the Group had stated that veterinary schools that could not meet basic competencies should be closed. The Group agreed with an OIE Member’s comment that the intent of the OIE recommendations is to improve the quality of veterinary education globally. It is not the task of the OIE to accredit universities or to make recommendations that veterinary education establishments should be closed down. Applying the quality requirements when hiring veterinarians should result in improvement of the VEE curriculum (i.e. market mechanisms). This is a process that will occur gradually, particularly in developing countries.

The Group had a detailed discussion on the potential future role of the OIE in relation to the accreditation of veterinary education establishments. Noting that veterinary Deans in developed countries have expressed concerns about the OIE’s role in this area, it was agreed that if the OIE undertook assessments on this topic, this would be done, as for all OIE missions, in response to voluntary requests from Members and in conjunction with the PVS Pathway.

Dr Peralta pointed to the usefulness of OIE standards on veterinary education as a benchmark for VEEs in developing countries. He agreed that market mechanisms would play an important role in bringing about the alignment of veterinary education quality with OIE standards.

Dr LeGall commented that the World Bank was interested in the OIE’s work on standards for veterinary education. Noting that Deans in many developing countries may be intimidated by the daunting task of meeting internationals standards for veterinary education, Dr LeGall considered that the OIE standards could be a useful and relevant benchmark when considering requests from developing countries.
Annex 37 (contd)

Dr Kahn made the observation that the OIE’s work programme on veterinary education falls within the PVS Pathway and that assessments of VEEs and/or the quality of veterinary education could be undertaken in the context of countries following the PVS Pathway. Dr Thiermann noted that if the OIE decided to undertake assessments of VEEs, it would follow a similar approach as that taken to other specific elements of the PVS Pathway, i.e. the recruitment of experts and conduct of seminars to ensure that all participants had the necessary skills and expertise to undertake missions.

6. Dates for next meeting

It was agreed that the next meeting would take place in early July 2011. Members agreed to inform the OIE International Trade Department of their availability.
MEETING OF THE OIE AD HOC GROUP ON VETERINARY EDUCATION
Paris, 15–17 December 2010

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Annex 37 (contd)

Annex I (contd)

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MEETING OF THE OIE AD HOC GROUP ON VETERINARY EDUCATION

Paris, 15–17 December 2010

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Adopted Agenda

1. Welcome, adoption of the agenda, and introductory remarks
2. Meeting with the OIE Director General
3. Discussion on the 2nd OIE Global Conference on Veterinary Education
4. Addressing OIE member comments on the draft Minimum competencies of ‘Day 1’ veterinary graduates
5. Ongoing work
6. Discussion on the potential future role of the OIE in accreditation
7. Dates for next meeting
Livestock and animal health in ECA

Livestock make a significant contribution to GDP in the ECA region from the extensive grazing systems in Central Asia to the more intensive production systems and the concentrated animal feeding systems. Livestock are an integral part of the agricultural systems and rural livelihood but the traditional animal raising approaches are evolving to more market oriented production and accompanying challenges. Livestock raising households are also facing challenges of animal disease and food safety risks that compromise market access, regional and international trade. More recently, the risk of zoonotic diseases has been increasing in rural communities and urban centers and the economic impact locally and nationally is becoming a concern.

These challenges are being addressed in ECA through innovative interventions that are being integrated into existing operations and as stand-alone projects. The recognition of the role of livestock is being promoted through investments that are linked to and dependent upon livestock as the main risk factor and best opportunity for poverty alleviation, market access, public health and environmental sustainability. These include (i) food safety, for which livestock pose the most significant risk, (ii) climate change including biogas and carbon finance associated with grassland rehabilitation, (iii) the One Health agenda in close partnerships with the human health colleagues and building on the avian influenza projects, (iv) traditional approaches to livestock production for more efficient production and sustainable livelihood, and (v) livestock as an important means to mitigate food security risks and the financial crisis. Fundamental to all of these interventions are specific activities related to the reform of veterinary services in close cooperation with the OIE and other international agencies and including formal education, in-service training and professional development for veterinarians and animal health workers.

The WB has financed more than 50 Avian Influenza Projects worldwide of which 13 are in the ECA region and animal health constitutes important components of many other projects. The implementation of the OIE’s Performance of Veterinary Services (PVS), Gap Analysis and has been actively promoted and has served as the basis for the development of strategic plans for the reform of veterinary services and design and preparation of new projects that include veterinary reform as important components. The focus of such projects’ development objectives includes food safety and agri-food modernization (Turkey EU pre-accession), agricultural competitiveness (Armenia, Georgia), agri-food value-chain development (Azerbaijan), pasture rehabilitation and livestock development (Kyrgyzstan) and regional One Health Project for Central Asia (Kazakhstan, Uzbekistan, Tajikistan, Kyrgyzstan). The World Bank (WB) is currently working with the OIE to complete the Strategic Plans in these countries as the basis for planned new investments and the upgrading of veterinary faculties is considered as an important intervention under these projects. The World Bank has worked with other donors to develop a veterinary faculty self-evaluation tool and this would be used along with the PVS results to inform the activities related to faculty upgrading. In addition to the WB and OIE activities, support for veterinary services upgrading in the region is being financed by a number of donors and international agencies including the EU, Swiss Development Cooperation, the Netherlands, EU, IFAD, USAID, US DTRA/DOD, Canada and others.

An example: Ganja Agricultural University Veterinary Faculty, Azerbaijan

In Azerbaijan, for example, the veterinary faculty has been pro-active in applying the self-evaluation tool with international technical assistance and has prepared the strategic plan for development of the faculty. The design of the evaluation tool and preparation of the plan was supported with technical assistance from the WB, USDA and US DTRA. The completed plan was promoted within the Government of Azerbaijan and has provided advocacy and justification for Government investments of more than US$10 million in facilities and infrastructure for the veterinary faculty at GAU. The World Bank financed project and other donors have additionally provided essential supplementary teaching materials and resources based on the guidance under the strategic plan.
Annex III (contd)

A field laboratory has been replicated in the veterinary school for hands-on, applied teaching purposes through the WB-financed Avian Influenza Project (AIP). The AIP has established a computer centre for teaching purposes but this has also been used to demonstrate the national animal disease information system, AzVet. The AzVet system development has also been financed under the AIP and the computer facilities at the GAU have been utilized for in-service training for field staff and district veterinarians to set up the national e-networks to the AzVet centre in Baku. The AIP is also financing exchanges between the GAU faculty and counterpart faculty in Turkey to align curriculum and share other resources in support of a more regional approach.

The concurrent WB-financed Agriculture Development and Competitiveness Project II (ADCP II) is supporting the establishment of private veterinarians throughout Azerbaijan and has financed the establishment of a Private Veterinary Unit at the faculty to demonstrate the opportunities to students and to provide experiential ambulatory farm services for training students. This has been complemented with the provision of international technical assistance with experienced veterinary practitioners from the Netherlands and elsewhere. The ADCP II has also financed a pilot brucellosis control program in several districts and, as a matter of practice, has involved faculty and students (with stipends) to be involved in the baseline surveys, vaccination programs, data collection and analysis. This program is now being scaled up country-wide under a new ADCP III project which will become operational in 2011. The new project will continue to address the key priorities in the faculty strategic plan to the extent that it addresses project objectives and operational needs.

The GAU vet faculty is in the process of revising and upgrading its curriculum and discussions are ongoing in terms of the most appropriate standards and approaches to develop a competency-based curriculum that will address the national disease control needs and farmers’ demands for services. The World Bank is promoting twinning arrangements with faculties in the EU and US to develop long term partnerships and MOUs for student and faculty exchanges, sandwich graduate programs, joint R&D projects with grants from international agencies, curriculum development, etc.

III The WB-ECA Regional Approach to Veterinary Education

The approach to reform and upgrading of veterinary education in ECA has been previously outlined in presentations to the OIE. As a fundamental principle, the WB is promoting the application of the self-evaluation tool as part of the national veterinary service strategic plan development in cooperation with the OIE. The national plans are expected to include faculty upgrading as a sub-set of the national plans.

In addition, the Bank is promoting long-term twinning programs with faculties in the EU, Australia, New Zealand and the US and commitments through substantive MOUs or agreements. The sustainability of short term project interventions is contingent upon these kinds of established institutional relationships and the continued faculty upgrading and research programs independent of the time limited project interventions.

The future of veterinary medicine to provide the essential services for farmers and their animals in the region is contingent upon young people seeing opportunities and a reasonable livelihood within the profession. In Kyrgyzstan, for example, a donor-financed (WB/IFAD/SDC/EU) pasture management project has been supporting the implementation of animal health programs with initial vaccination fee-for-service to private veterinarians which is being transferred to farmers. This is part of one component that is promoting the establishment of 800 private veterinarians throughout Kyrgyzstan. Income for private veterinarians is created through ongoing fee-for-service from farmers and Government contracts for vaccination, blood testing, etc. This approach has provided young people with a demonstration of the potential for a reasonable income from the profession and has stimulated intake in the veterinary faculty. Last year 30% of the new students were from the project areas. Faculty upgrading should be integrated with innovative approaches for promoting the image of the profession and impact of services within communities. More importantly, the employment and livelihood opportunities would be presented to youth in a practical way that would create interest in becoming part of a reputable profession with a future.
In this context curriculum development would be market driven for the immediate needs of the country, the farmers, the industry and in a way that provides sustainable employment through demand-driven fee-based services.

The ECA region of the WB has been working closely with the South Asia region to develop an international multi-lingual epidemiology training program for veterinarians and doctors that is being delivered through a combination of e-learning and in-service residential programs. This program is funded under the EU Global Avian Influenza Trust Funds and is now operational in SA. It is expected to be operational in ECA in 2011.

IV Development of institutional twinning for veterinary education – an outline

The objective of such a program would be to establish sustainable veterinary training institutions capable of developing veterinarians and animal health workers to meet the “needs” of food animal producers in developing countries and focusing on three primary competencies:

1. Field based ambulatory vets and animal health workers for which farmers and herders are prepared to pay for basic services and some fee-for-service govt functions.

2. Government veterinarians capable of fulfilling regulatory and disease surveillance functions – active and passive surveillance, animal movement control, meat inspection and other public goods.

3. Lab diagnosticians – simple lab tests

Methodology:

- Undertake OIE PVS, Gap and Strategic Plan exercise to include faculty evaluation and development of strategic plan including competency-based curriculum
- Develop regional centres in selected countries that could serve to train trainers in other countries in region.
- Promote twinning between developed, transitional and developing country faculties under MOUs officially endorsed for:
  - Training of trainers – faculty
  - Sandwich MSc and PhD for faculty: coursework in developed country but field research work and defense in home country
  - Joint applied research projects based on solving in-country problems and
  - Student exchanges
  - Faculty on sabbatical assignments to twinned institutions to develop curriculum and research. Overseas assignment tenure credited.
  - Digitize and translate curriculum
  - Language training, translation, interpretation, glossaries, reference books and materials.
  - Focus on competencies and basic skills development – clinical practice, pathology, epidemiology.
  - Applied ICT
  - “Teaching” facility development including: (i) physical facilities, (ii) “field” labs, (iii) farm/animals for practice, (iv) ambulatory farm service, (v) clinics, (vi) research.
Annex 37 (contd)

Annex III (contd)

Funding and participating institutions/organizations

- Integrated into ongoing or planned investment and donor projects

- Seed money – required for TA, selection, feasibility and needs assessments through OIE PVS and existing donor projects.

- Developed country vet colleges reimbursable salary costs only excluding benefits

- Developed colleges seek endowments and long term scholarships funding

- Bilateral donor partnership programs (eg TEMPUS)

- OIE endorsement as part of international programs

- Donor projects design principles: FAO, UNDP, WHO, VWB, WB, Gates, Google new initiatives in public health, IDRC (applied research), USAID CRSP (research), Winrock, etc.

- Cooperative research funding proposals

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MINIMUM COMPETENCIES EXPECTED OF DAY 1 VETERINARY GRADUATES TO ASSURE DELIVERY OF HIGH-QUALITY NATIONAL VETERINARY SERVICES

Introduction

The assurance of global public health is not limited to the expertise of human medical professionals, but requires the knowledge and skill set of veterinarians. Specifically, veterinarians in every nation are responsible for the delivery of National Veterinary Services (NVS) - that is, services provided under the legislative framework and the auspices of the governmental authority of a given country to implement animal health to assure the health and wellbeing of animals, people and ecosystems. The term “Veterinary Services” refers to the OIE Terrestrial Animal Health Code (Terrestrial Code) definition, which includes both public and private components of the veterinary profession involved in the promotion of animal and public health as well as animal welfare.

National Veterinary Services should be able to meet standards adopted by each country, but should also be able to comply with appropriate international standards and recommendations, particularly those in the OIE’s Terrestrial Code. In delivering National Veterinary Services, veterinarians serve as an integral partner in the One Health effort—a collaboration of multiple disciplines working locally, nationally, and globally, to address critical challenges and attain optimal health for people, domestic animals, wildlife, and the environment (www.onehealthcommission.org).

Although only some veterinarians will focus their careers on the delivery of National Veterinary Services, all veterinarians, regardless of professional area of practice after graduation, are responsible for promoting animal health, animal welfare and veterinary public health, act frequently as sub-contractors for National Veterinary Services and in many instances opt for career changes into National Veterinary Services. As such, veterinary education is a cornerstone to assure that the average veterinary graduate not only has received a level of education and training provided that ensures sound overall day-one competencies, as well as the required skills, knowledge, aptitudes, and attitudes (competencies) to understand and be able to perform entry-level national veterinary service tasks that relate to the security and promotion of animal and public health. In addition, basic education that includes instruction in the minimum competencies will establish a basis on which those veterinarians seeking national veterinary service careers can build expertise through on-the-job training and quality postgraduate continuing education.

Taking into account the vast societal, economic, and political differences among OIE member countries, including the different existing VEE accreditation schemes, the following list of competencies are those that the OIE ad hoc Group on Veterinary Education believe necessary for the veterinary graduate to be adequately prepared to participate in entry-level national veterinary services.

Competencies as used by the ad hoc Group include:

- Skills: psychomotor abilities, both manual and physical, ability to perform specific tasks

- Knowledge: cognitive abilities, meaning mental skills

- Attitude: affective abilities, meaning feelings and emotions; and

- Aptitude: a student’s natural ability, talent, or capacity for learning.
While the ad hoc Group outlined minimum competencies relevant to the delivery of National Veterinary Services, no attempt was made to dictate in which specific course or during which educational year each competency should be taught. Indeed, it may be that many of the following competencies cross course boundaries and can be integrated across the curriculum in multiple courses. Nor did the ad hoc Group suggest how many credit hours of educational contact were required to teach each competency, as this might vary depending on the needs and resources of each country. What was unanimously agreed upon, though, is that education in the following minimum competencies during the course of each veterinary school’s curriculum will prepare the average entry level (new graduate) veterinarian to promote global veterinary public health and provide an excellent base for advanced training and education for those veterinarians wishing to pursue a career in both public and private components of National Veterinary Services. It is important to note that Veteranay education includes not only school education but also postgraduate continuing education and on-the-job training. The authorities should bear in mind the importance of the lifelong learning to ensure the various competencies of veterinary graduates such as protecting animal and public health.

Day 1 Competencies Relevant to the Delivery of National Veterinary Services

The OIE’s ad hoc Group on Veterinary Education grouped the following minimum competencies to be part of the core curriculum relating to national veterinary services into three categories.

1. General competencies

   are those that are part of every veterinary school’s core curriculum. Basic veterinary and clinical veterinary sciences Because these competencies are essential fundamental to more than just the national veterinary services, but the ad hoc Group only listed them here without further definition because it did not consider it was part of its remit. Animal production, food hygiene and safety are more precisely defined since they are more relevant to the national Veterinary Services.

2. Specific competencies are those essential even more directly relate to critical competences found in the OIE Terrestrial Code, for all veterinary students to be taught during the course of the professional curriculum. Thus each competency is defined with the definitions based largely on those competencies found in the OIE Terrestrial Code, and Learning objectives for the average entry-level veterinarian are also provided for each specific competency identified.

3. Introduction to Advanced competencies are those that should be instructed to veterinary students during the course of the professional curriculum. However, expertise in these competencies, while essential to those veterinarians whose career is limited to national veterinary services, is better obtained through quality postgraduate continuing education and on-the-job training. The ad hoc Group included introduction to these advanced competencies here, with the understanding that the primary learning objective for each centres on the average entry-level veterinarian being able to have a general awareness of and appreciation for each competency, with the ability to know where to find up-to-date credible information should deeper knowledge be needed or desired.

1. General competencies

   1.1. Basic veterinary sciences

   1.2. Clinical veterinary sciences

   1.3. Animal production including:

   1.3.1. Animal identification and traceability;

   1.3.2. Herd health management and economics of animal production.
1.4. Food hygiene and safety including:

1.4.1. on farm food safety practices;
1.4.2. traceability;
1.4.3. drug and chemical use and residue testing programs;
1.4.4. slaughter inspection: this includes ante mortem, post mortem, humane slaughter and hygienic dressing;
1.4.5. integration between animal health controls and veterinary public health: the role of veterinarians in conjunction with physicians, public health practitioners, and risk analysts to ensure healthy, hazard-free food both nationally and internationally from animal production on the farm to traceability of animal movement, sanitation at food processing plants, proper storage of processed animal products, in-home food storage and preparation safety, and health and cleanliness of all humans involved in the food chain from farm to fork.

1.5. Commitment to lifelong learning

2. Specific competencies

2.1. Zoonoses (including food borne diseases)

Zoonoses are diseases or infections that are naturally transmissible from animals or their products to humans or from humans to animals. Many food borne pathogens are zoonotic and most emerging human pathogens have an animal (livestock or wildlife) origin. As such, zoonoses have major implications on human health and trade in animals and animal products.

Specific learning objectives for this competency include the average entry-level veterinarian being able to:

2.1.1. identify the clinical signs, clinical course, transmission potential, and pathogen associated with common zoonotic and food borne diseases, to include including those on the OIE list of notifiable diseases;
2.1.2. directly use or explain the use of current diagnostic and therapeutic tools for common zoonotic and relevant food borne diseases;
2.1.3. understand the implications of common zoonotic and relevant food borne diseases on human health (e.g., how does the disease spread from animals to humans) and know where to find up-to-date and information regarding these implications;
2.1.4. understand regulatory implications (e.g., which national services veterinarian must be contacted if a zoonotic pathogen is identified) of common zoonotic and food borne diseases and pathogens and know where to find up-to-date information regarding these implications.

2.2. Transboundary animal diseases

Transboundary animal diseases (TADs) are those epizootic diseases that are highly contagious or transmissible and have the potential to spread very rapidly irrespective of national borders. Transboundary animal disease agents may or may not be zoonotic, but regardless of zoonotic potential, the highly contagious nature of these diseases invariably impacts global economy, global trade and global public health. Examples of transboundary diseases include highly pathogenic avian influenza, rinderpest, classical swine fever and foot and mouth disease.
Specific learning objectives for this competency include the average entry-level veterinarian being able to:

2.2.1. identify the clinical signs, clinical course, transmission potential (including vectors), and pathogen associated with important transboundary diseases and pathogens, to include those on the OIE list of notifiable diseases;

2.2.2. describe the current global distribution of important transboundary diseases and/or know where to find up-to-date distribution information;

2.2.3. directly use or explain the management of samples and use of current diagnostic tools for confirmation and therapeutic tools to prevent and combat important transboundary diseases and pathogens;

2.2.4. understand regulatory implications (eg, which national services veterinarian must be contacted if a epizootic pathogen is identified or suspected) of important transboundary diseases and pathogens and know where to find up-to-date information regarding these implications.

2.3. Emerging and re-emerging diseases

An emerging disease is a new infection resulting from the evolution or change of an existing pathogenic agent, a known infection spreading to a new geographic area or population, or a previously unrecognized pathogenic agent or disease diagnosed for the first time. A ‘re-emerging disease’ is a resurgence in a defined time period and location, of a disease considered to have been eradicated or controlled in the past. Both emerging and re-emerging diseases have significant impacts on animal (naive populations) and/or public health.

Specific learning objectives for this competency include the average entry-level veterinarian being able to:

2.3.1. define “emerging disease” and provide contemporary examples;

2.3.2. define “re-emerging disease” and provide contemporary examples;

2.3.3. understand the reasons/hypotheses to explain the emergence/re-emergence of diseases;

2.3.4. know where to find up-to-date information regarding emerging and re-emerging diseases.

2.4. Regulation of animal welfare

Animal welfare means how an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter (when relevant), management, nutrition, humane handling, and humane slaughter/killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

Specific learning objectives of this competency include the average entry-level veterinarian being able to:

2.4.1. define animal welfare and the related responsibilities of owners, handlers, veterinarians;

2.4.2. identify major signs of bad welfare;
2.4.3. know where to find up-to-date information regarding local, national and international animal welfare regulations/standards in order to describe contemporary humane care for:

2.4.3.1. slaughtering and killing techniques for major livestock species (e.g., cattle, sheep, swine, poultry);

2.4.3.2. animal-handling techniques for the aforementioned major livestock species at all levels and for all systems of production (e.g., farm, feedlot, sale barn, slaughter house);

2.4.3.3. housing for the aforementioned major livestock species at all levels and for all systems of production (e.g., farm, feedlot, sale barn, slaughter house);

2.4.3.4. transport of the major livestock species.

2.5. Veterinary products, drugs and biologicals

‘Veterinary products, drugs and biologicals’ means drugs, insecticides/acaricides, vaccines, and biological products used or presented as suitable for use to prevent, treat, control, or eradicate animal pests or diseases; or to be given to animals to establish a veterinary diagnosis; or to restore, correct or modify organic functions in an animal or group of animals.

Specific learning objectives for this competency include the average entry-level veterinarian being able to:

2.5.1. use common veterinary products, drugs and biologicals in the appropriate manner and administered to the appropriate species;

2.5.2. explain and/or utilize the concept of drug withdrawal time as a means to prevent drug residues in products of animal origin meant for human consumption, and know how to find up-to-date information regarding specific withdrawal times;

2.5.3. explain common mechanisms leading to development of antimicrobial resistance in common pathogens;

2.5.4. know where to find and how to interpret up-to-date information regarding the link between use of antimicrobials in food animals and development of antimicrobial resistance by pathogens of human importance;

2.5.5. understand and describe local, regional, national, and international regulations authorizing the registration, distribution and use of common drugs in food animals;

2.5.6. know the appropriate use of drugs and biologicals to ensure the safety of the food chain and a proper environment (e.g., residues, waste).

2.6. Epidemiology

Epidemiology is the study of factors affecting the health and illness of populations, and serves as the foundation and logic of interventions made in the interest of veterinary public health and preventive medicine.

Specific learning objectives for this competency include the average entry-level veterinarian being able to:
Annex 37 (contd)

Annex IV (contd)

2.6.1. know and understand the general principles of descriptive epidemiology;

2.6.2. trace the source and spread of a disease, to include the ability to:

2.6.2.1. access and use appropriate information sources;

2.6.2.2. understand and participate appropriately to an epidemiological inquiry in case of occurrence of a reportable disease;

2.6.2.3. monitor and conduct initial surveillance of diseases, to include communication of epidemiological information to other public health practitioners;

2.6.2.4. directly perform and/or explain the use of common and current diagnostic tests and procedures, to include proper collection, handling, and transport of appropriate specimens/samples.

2.7. Disease prevention and control programs

Disease prevention and control programs are those programs, most often approved and managed or supervised by the veterinary authority of a country, established for the purpose of controlling a vector, pathogen or disease by specific control or preventive measures, to include movement controls, vaccination and treatment. It is understood these disease prevention and control programmes will be specific to each country or region, compliant with applicable OIE standards, as appropriate and that entry level veterinarians need to be familiar with these programmes.

Specific learning objectives for this competency include the average entry-level veterinarian being able to:

2.7.1. describe established programs for the prevention and/or control of common zoonotic or contagious diseases or emerging/re-emerging diseases, to include the relevant veterinary authority oversight;

2.7.2. understand and implement contingency plans to control transboundary diseases, to include methods to:

2.7.2.1. control movement of animals, animal products, equipment, and people;

2.7.2.2. quarantine infected and at-risk premises/areas;

2.7.2.3. humanely kill affected animals;

2.7.2.4. dispose of infected carcasses in an appropriate manner;

2.7.2.5. disinfect or destroy contaminated materials;

2.7.3. understand and participate to regular or emergency vaccination campaigns, as well as in regular test-and-cull/treat programmes;

2.7.4. explain the concept of “early detection system,” which is defined as a system, under the control of the veterinary services, for the timely detection and identification of an incursion or emergence of diseases/infections in a country, zone or compartment;

2.7.5. know which diseases of animals (including companion animals) require compulsory notification by the veterinarian to the prescribed national authority in order to mitigate disease transmission;
2.7.6. know where to find up-to-date and reliable information regarding specific disease, prevention and control measures, including rapid response mechanisms.

2.8. General certification procedures

Veterinarians are responsible to certify the health status of an animal or herd in private practice or as an element of official certification.

Inspection means examination and evaluation of animals and animal products by an authorized veterinarian prior to completing a certificate to document the health or sanitary status, respectively. Certification means an official document, completed by an authorized veterinarian, for purposes of verifying the health or sanitary status of animals and animal products, respectively, most often prior to transport. For example, as defined in the OIE Terrestrial Code, an international veterinary certificate describes the animal health and/or public health requirements that are fulfilled by the exported animal commodity.

Specific learning objectives for this competency include the average entry-level veterinarian being able to:

2.8.1. examine and monitor an animal or a group of animals with a view to certifying freedom from specified diseases or conditions according to established procedures; directly inspect, identify, and document, or explain such processes used to assess the health or risks of animals and animal products for the purpose of transport / export;

2.8.2. draft health certificates and handle these documents according to the rules; directly conduct or explain the process of ante and post mortem risk-based inspection of animals and animal products;

2.8.3. directly certify or explain the process leading to certification of commodity quality and wholesomeness as it relates to sanitary matters for export;

2.8.4. explain common import control mechanisms (e.g., border controls) and certification processes related to assurance of the health of animals, the public, and the ecosystem in the importing country.

2.9. Veterinary legislation and ethics

Veterinary legislation is an essential element of the national infrastructure that enables veterinary authorities to carry out their key functions, including surveillance, early detection and control of animal diseases and zoonoses, animal production food safety and certification of animals and animal products for export. VEE’s should teach ethics and value issues to promote high standards of conduct and maintain the integrity of the profession.

Specific learning objectives for this competency include the average entry-level veterinarian:

2.9.1. having a working knowledge of the fundamentals of national legislation in general, and of specific rules and regulations governing the veterinary profession at the local, provincial, national, and regional level, particularly in relation to delivery of national veterinary services;

2.9.2. knowing where to find up-to-date and credible information regarding veterinary legislation and the rules and regulations governing the veterinary profession in his/her own state, province, region and/or country.
Annex IV (contd)

2.9.3. understand and apply high standards of veterinary medical ethics in carrying out day-to-day duties.

2.10. Communication skills

Effective communication skills are as important to success in veterinary medicine as are technical skills. In general, communication entails the exchange of information between various individual, institutional and public audiences for purposes of informing, guiding and motivating action. The application of the science and technique of communication involves modulating messages according to situations, objectives and target audiences.

Specific learning objectives for this competency include the entry-level veterinarian being able to:

2.10.1. communicate technical information in a way that the public can understand

2.10.2. communicate effectively with fellow health professionals to exchange scientific and technical information and practical experience.

3. Introduction to advanced competencies

3.1. Organization of veterinary services

Veterinary services means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the Terrestrial Code and the OIE Aquatic Animal Health Code in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. An objective in the delivery of national veterinary services is to bring a country, territory, or region in line with international standards in terms of legislation, structure, organization, resources, capacities, and the role of the private sector and paraprofessionals.

Veterinary services means the implementation by governmental and non-governmental organizations of animal health and welfare measures and other standards and recommendations, such as those in the OIE Terrestrial Code, related primarily to the trade/movement of animals and animal products throughout a given country, territory, or region. The delivery of national veterinary services brings a country, territory, or region in line with international standards in terms of legislation, structure, organization, resources, capacities, and the role of the private sector and paraprofessionals.

The primary learning objectives for this competency include the average entry-level veterinarian having a general awareness of and appreciation for:

3.1.1. the delivery of national veterinary services as a global public good;

3.1.2. how veterinary services are organized within his/her own country/region (e.g., central and local levels, epidemiological networks);

3.1.3. the function and authority of the national veterinary service within his/her own country/region;

3.1.4. how his/her country’s national veterinary service agencies interact with veterinary services in other countries and international partners;

3.1.5. the relationship between private and public sector veterinarians in delivery of national veterinary services within his/her own country;
3.1.6. the essential need to evaluate the quality of veterinary services and the fundamental principles to ensure the quality of veterinary service activities (e.g., professional judgment, independence, impartiality, integrity, objectivity, procedures and standards, communication, and human and financial resources);

3.1.7. where to find up-to-date and reliable information should deeper knowledge be needed or desired.

Secondary learning objectives include the average entry-level veterinarian understanding, in addition to the definition of veterinary services outlined above, the following definitions:

3.1.8. Veterinary authority: The governmental authority of a country, territory, or region that comprises veterinarians, other professionals, and paraprofessionals and with the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification, international standards and recommendations such as those in the OIE Terrestrial Code, and other relevant legislation related to animal and public health and animal welfare. The veterinary authority typically accredits or approves private-sector organizations, veterinarians, and veterinary paraprofessionals to deliver veterinary service functions.

3.1.9. Veterinary statutory body means: an autonomous authority, typically at the national level, that regulates veterinarians and veterinary para-professionals.

3.2. Inspection and certification procedures

Inspection means examination and evaluation of animals and animal products by an authorized veterinarian prior to completing a certificate to document the health or sanitary status, respectively. Certification means an official document, completed by an authorized veterinarian, for purposes of verifying the health or sanitary status of animals and animal products, respectively, most often prior to transport.

Primary learning objectives for this competency include the entry-level veterinarian having general awareness of and appreciation for:

3.2.1. such processes used to assess the sanitary status of animals and animal products for the purpose of transport / export;

3.2.2. the process of ante and post mortem risk-based inspection of animals, and of the inspection of animal products;

3.3. Application of risk analysis

Risk means—the likelihood of the occurrence and likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health. The process of risk analysis involves hazard identification, risk assessment, risk management, and risk communication. The importation of animals and animal products involves a degree of disease risk to the importing country. Risk analysis as applied to importation provides the importing country with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material using, particularly as a basis, relevant existing OIE standards.

Primary learning objectives for this competency include the average entry-level veterinarian having a general awareness of and appreciation for:
Annex 37 (contd)

Annex IV (contd)

3.3.1. how risk analysis can be applied to assessment of animal disease related risks and residues of veterinary drugs, including importation of animals and animal products and other related veterinary services activities;

3.3.2. how risk analysis can be used to ensure veterinary services adequately protect animal and human health;

3.3.3. where to find up-to-date credible information should deeper knowledge be needed or desired (e.g. the OIE Handbook on Import Risk Analysis).

Secondary learning objectives include the average entry-level veterinarian understanding, in addition to the definitions of risk and risk analysis outlined above, the following definitions:

3.3.4. hazard identification: the process of identifying pathogenic agents which could potentially be introduced in the commodity that could potentially be introduced in a commodity (e.g., food of animal origin);

3.3.5. risk assessment: evaluation of the likelihood and the biological and economic consequences of entry, establishment, and spread of a hazard within a territory;

3.3.6. risk management: the process of identifying, selecting, and implementing measures that can be applied to reduce the level of risk;

3.3.7. risk communication: the interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk; risk-related factors; and risk perceptions among risk assessors, risk managers, risk communicators, the general public, and other interested parties (e.g., stakeholders).

3.4. Research

Research means the seeking for and gathering and analyzing of data, information, and facts to extract new meaning or develop unique solutions to problems or cases for the advancement of knowledge.

The primary learning objective for this competency is for the average entry-level veterinarian:

3.4.1. to have a general awareness of and appreciation for how both basic and applied research are essential to advance veterinary knowledge in the areas relevant to delivery of national veterinary services (e.g., zoonoses, transboundary diseases, (re-)emerging diseases, epidemiology, animal welfare, veterinary drugs and biologicals) so that future generations are better equipped to assure the health of animals, the public, and the ecosystem.

3.5. International trade framework

The framework on which regulations governing safe international trade in animals and animal products relies on the interaction and cooperation among several organizations as well as on the latest scientific advances so as to improve animal health world-wide and to promote and preserve the safety of the international trade in animals and animal products.

Primary learning objectives for this competency include the average entry-level veterinarian having have a general awareness of and appreciation for:

3.5.2. the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (i.e., SPS Agreement);
3.5.2 the role and responsibilities of the WTO standard setting organizations such as the OIE and the Codex Alimentarius Commission (CAC) in developing science-based contemporary regulations governing international trade in animals and animal products;

3.5.3 contemporary international regulations, such as the following, that govern the safe trade of animals and animal products, including understanding whether veterinary legislation in his/her region is in line with international standards and guidelines, such as particularly those of established by the OIE and the CAC;

Secondary learning objective include the entry-level veterinarian:

3.5.4 understanding the potential implications of transboundary diseases, including zoonoses, on international trade, e.g., does presence of a disease in one country potentially impede international trade of the affected animal species and its products, and knowing where to find up-to-date information regarding these implications, the process leading to certification of commodity quality and wholesomeness as it relates to sanitary matters for export;

3.5.5 understanding import control mechanisms and certification processes related to protection of the health of animals, the public, and the ecosystem in the importing country.

3.6. Administration and management

In the broadest sense, administration consists of the performance or management of business or organizational operations and, thus, the making or implementing of major decisions, whereas management is the act of getting people together to accomplish desired goals and objectives. Administration can also be defined as the universal process of organizing people and resources efficiently so as to direct activities toward common goals and objectives, with management comprising planning, organizing, staffing, leading or directing, and controlling an organization or effort for the purpose of accomplishing a goal.

Primary learning objectives for this competency include the average entry-level veterinarian having general awareness and appreciation of:

3.6.1. best practices in administration and management as those relate to delivery of quality national veterinary services;

3.6.2. the importance of excellent interpersonal communication skills in the delivery of quality national veterinary services, to include self-knowledge and knowledge of others;

3.6.3. the understanding importance of effective communication (public awareness and advocacy), as a critical discipline in the administration of veterinary services;
Annex 37 (contd)

Annex IV (contd)

3.6.4. where to find up-to-date credible information should deeper knowledge be needed or desired;

3.6.5. at least one language other than the official language of the country.

Secondary learning objectives include the average entry-level veterinarian understanding:

3.6.6. __notions principles__ of the categorisation of disease related risks as regards their socio/economic impacts and the impacts of their control measures, as well as prioritisation of actions according to these categories and the situation of a territory, country, region.

__________________________
# FUTURE WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

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<thead>
<tr>
<th>Topic</th>
<th>Action</th>
<th>How to be managed</th>
<th>Status (February 2011)</th>
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<tbody>
<tr>
<td><strong>Restructuring of the Terrestrial Code</strong></td>
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</table>
| | | TAHSC & ITD | 1. Ongoing  
2. Proposed for adoption 2011  
3. Ongoing |
| **Harmonisation of Terrestrial and Aquatic Codes** | | | |
| 1. Work with AAHSC towards harmonisation, as appropriate, of the Codes | TAHSC & SCAD & AHG | Revised CH for MC  
New text drafted by AHG |
| 2. Chapters / references of non listed disease | | | |
| 3. CH rename by disease agents | SCAD | Propose CH |
| **Listed disease** | | | |
| Criteria for listing | | | |
| Decision on listing ‘on hold’ (new CH) | TAHSC & SCAD | Propose CH |
| New CH (pending new info on diagnostics) | SCAD | Propose CH |
| **Evaluation of VS and OIE PVS pathway** | | | |
| Inclusion of legislation aspect | TAHSC & ITD | Modified new CH for MC |
| Inclusion of reference to education | TAHSC & ITD | Text proposed for MC/adoption 2011 |
| **AI, ND, CSF** | | | |
| Modify for consistency | SCAD | Revised CH for MC/adoption 2011 |
| Official recognition CSF | SCAD/AHG | Pending production of draft + Q |
| **AHS** | | | |
| Official recognition | SCAD & TAHSC | Revised CH & Q for MC 2011 |
| **FMD** | | | |
| Official recognition of official programme | SCAD & TAHSC | Revised CH & Q for MC/adoption 2011 |
| **RP** | | | |
| Global freedom era | SCAD & TAHSC & AHG | Revised CH to be proposed for MC in Sept 2011 |
| **Other Terrestrial Code texts in need of revision** | | | |
| Pet food CH | New AHG & TAHSC | Modified new CH for MC in Sept 2011 |
| Update CH on Brucellosis | SCAD; | AHG in July 2011 under SCAD |
| Update CH on Rabies | SCAD & TAHSC & AHG | Revised CH for MC in Sept 2011 |
| Update CH on Bee diseases | New AHG/SCAD & TAHSC | Revised CH for MC in Sept 2011 |
| Update CH on PPR | SCAD | AHG under SCAD |
| CH on EHD | SCAD | AHG in March 2011 |
| Update CH on scrapie | TAHSC & SCAD | Revised CH for adoption 2011 |
| Update CH on SVD | SCAD & TAHSC | Revised CH back to SCAD/AHG |
| Update CH on ASF (inactivation + SURV) | SCAD | To be prioritised |
| CH on Paratuberculosis | BSC (diagnostic test) & STD (guidance document) | On hold pending further development in diagnostics |
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Note: MC; Member comments, CH: chapter, Q: questionnaire, SURV: surveillance, ITD: International Trade Department, S&T Dept: Scientific & Technical Department
## ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

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A: decided for adoption at 79th GS, C: For Member comments, E: under expert consultation (ad hoc Group/SCAD/BSC etc.), D: deferred at Sep 2011 meeting, I: For Member information.
Annex 38 (contd)

List of abbreviations

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<th>Description</th>
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</thead>
<tbody>
<tr>
<td>AAHSC</td>
<td>Aquatic Animal Health Standards Commission</td>
</tr>
<tr>
<td>AHS</td>
<td>African horse sickness</td>
</tr>
<tr>
<td>APFSWG</td>
<td>Animal Production Food Safety Working Group</td>
</tr>
<tr>
<td>AWWG</td>
<td>Animal Welfare Working Group</td>
</tr>
<tr>
<td>EHD</td>
<td>Epizootic haemorrhagic disease</td>
</tr>
<tr>
<td>FMD</td>
<td>Foot and mouth disease</td>
</tr>
<tr>
<td>LAW</td>
<td>Laboratory Animal Welfare</td>
</tr>
<tr>
<td>PPR</td>
<td>Peste des petits ruminants</td>
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<tr>
<td>PRRS</td>
<td>Porcine reproductive and respiratory syndrome</td>
</tr>
<tr>
<td>SCAD</td>
<td>Scientific Commission for Animal Diseases</td>
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<tr>
<td>TAHSC</td>
<td>Terrestrial Animal Health Standards Commission</td>
</tr>
<tr>
<td>VE</td>
<td>Veterinary Education</td>
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