Annex XXXVIII

INTERNATIONAL TRADE: RIGHTS AND OBLIGATIONS OF OIE MEMBERS

Introduction

This document is a guide to the rights and obligations of OIE Members with regard to international trade and trade disputes.

In part one, the OIE explains its informal mediation procedure for resolving trade disputes between Members. The OIE informal mediation procedure is different and independent from the World Trade Organization (WTO) procedures for resolving trade disputes. The WTO provides formal and informal approaches to solve trade disputes arising in relation to its Agreements. The OIE's informal procedure provides for OIE Members, on a voluntary basis, to seek to resolve their differences by using an approach that is based on science and on the OIE's standards for safe international trade in animals and animal products.

The revised OIE informal mediation procedure may be found in Annex A.

In part two the OIE presents the rights and the obligations of Members with reference to the conduct of international trade. Members should base their import measures on the OIE standards. This approach provides for safe trade, the avoidance of unjustified trade barriers and a strong presumption of compliance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). The relevant OIE standards are contained in the OIE *Terrestrial Animal Health Code* and *Aquatic Animal Health Code*, for terrestrial animals and aquatic animals respectively, and in the respective publications on *Diagnostic Tests and Vaccines*. Members should refer to these normative publications when making decisions on the management of risks associated with international trade in animals and animal products.

This paper primarily references terrestrial animals and the *Terrestrial Code*. However, Members should follow the same principles in regard to trade in aquatic animals and their products, based on the standards set out in the *Aquatic Code*.

Part 1 - Dispute mediation procedure

1.1. Introduction

Mediation is an informal procedure for resolving disagreements whereby a third party (a mediator) meets with parties to help them to resolve disagreements. The task of the mediator is to gain an understanding of the positions of the parties and to give advice and propose solutions to the disagreement. The mediator must be neutral and independent of the parties to the dispute. The use of this mechanism can help to minimise disagreements and promote effective trading relationships.

1.2. The WTO Framework

The WTO framework provides both formal and informal dispute settlement procedures.

WTO Members can raise SPS-related trade concerns with regard to other Members for discussion at meetings of the SPS Committee. This often concerns a situation where an importing country is thought not to have complied with a relevant international standard or not to have based an import measure on scientific evidence or, as appropriate, a risk assessment. Raising concerns in the SPS Committee often triggers bilateral discussions and may be helpful in resolving a specific trade problem. However, if this step proves insufficient to resolve the matter, the parties may jointly request Good Offices by the Chair of the SPS Committee. By resorting to this pathway, WTO Members may arrive at a mutually agreed solution to their SPS-related trade problems and avoid initiating a formal dispute under the WTO Dispute Settlement Mechanism.

The WTO Dispute Settlement Mechanism covers, *inter alia*, matters relating to the application of SPS measures subject to the disciplines of the SPS Agreement. This mechanism is based on the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), which is conducted under the auspices of the WTO Dispute Settlement Body (DSB). Every WTO Member is represented with equal decision-making status in the DSB.

The WTO Dispute Settlement Mechanism is comprised of two main phases, a panel examination and, if requested, an Appellate Body review. The process begins with a compulsory preliminary stage, wherein the parties to the dispute must participate in a consultation process to address the form and content of the disagreement and to try to find a mutually agreed solution. A minimum of 60 days is available for this formal bilateral process. After 60 days, a WTO Member can request that a panel be established by the DSB to examine both factual matters and issues relating to legal interpretation. The members of the panel are usually three well-qualified experts acting in their own capacities and who are normally chosen in consultation with the countries in dispute The report issued by the Panel can be appealed by one or both parties, in which case it will be reviewed by the Appellate Body. The Appellate Body limits its review to issues of law and legal interpretation. The Panel report, or the Appellate Body report in case of appeal, is submitted for adoption by the entire WTO membership through the DSB. The DSB will adopt the final report unless there is a consensus among all WTO Members to reject , a procedure known as a negative consensus. At any time during the process, the parties may resort to the Good Offices of the WTO Director-General, conciliation or arbitration to try to solve the dispute.

The WTO Dispute Settlement Mechanism is vital for enforcing the trade rules and therefore for ensuring that trade flows smoothly. The DSB oversees the implementation of the legal rulings. In the (rare) cases of non-compliance with a DSB decision, a WTO Member may be allowed to impose commercial sanctions against the violating member. This mechanism underscores the rule of law, and it makes the trading system more secure and predictable. One recognized downside to this mechanism are the costs incurred to the parties in a dispute, since they normally require extensive involvement of well-qualified lawyers, specialized in trade law, as well as individuals with the necessary technical/scientific expertise, to defend a Member's position.

To date, thanks to its worldwide experts' network, the OIE has provided technical assistance and information on scientific matters to panels in every dispute taken to the WTO involving animal health issues.

1.3. The OIE Framework

The OIE has established a voluntary, science based approach to support resolving differences between Members. The OIE procedure does not aim to find fault. Rather, the goal is to find a mutually agreed compromise that will allow trade to be established (or re-established), preferably on the basis of compliance with OIE standards. The OIE mechanism is technically based and cost effective. However, any solution proposed is not legally binding on OIE Members.

The **OIE** mediation mechanism has been the subject of discussion within the SPS Committee (see SPS Committee paper G/SPS/GEN/437) and the 4th OIE Strategic Plan 2006-2010 calls for further development of this mechanism.

The OIE mechanism for mediation comprises the following steps.

Initiation of the procedure

The OIE publishes scientific and technical standards with which Members should comply. When a Member considers that a trading partner has not complied with these provisions, or that its import policies are not based on science or, as appropriate, a risk analysis, the OIE can be asked to conduct an informal mediation process. This must be requested by both parties to the disagreement. OIE mediation cannot be initiated on a unilateral basis. In response to a request from parties to a disagreement, the OIE Director General designates one or more experts to conduct the mediation.

By initiating the OIE mechanism, Members create an environment conducive to friendly bilateral discussions, with the objective of finding a basis for compromise. The OIE contribution is to help identify approaches to resolve differences in Members' interpretation of the scientific issues and in the application of OIE standards.

A cooperative process

The consent of both parties is fundamental to the OIE mediation procedure. The process is voluntary and reports of all discussions remain entirely confidential unless both parties agree to release them.

The OIE only begins the process once all parties have given their consent in writing.

The designation of experts likewise requires the consent of both parties.

Confidentiality is maintained throughout the process.

The proposed means of resolving the disagreement are not binding on the parties, unless both have previously agreed to be bound by the adopted solution. The outcome of the mediation may only be divulged with the consent of all parties.

The OIE mediation process may be terminated at any time, based on a written notification from one of the parties.

The designation of experts

Following initiation of the OIE mediation procedure, the Director General of the OIE recommends a number of experts, usually from OIE Reference Laboratories or Collaborating Centres. The parties to the disagreement then mutually agree on the list of experts.

The experts must be neutral, independent and impartial. It is desirable that they are not of the same nationality as the parties to the disagreement and it is preferable to designate an odd number of experts to aid in reaching a majority recommendation.

The designated experts endeavour to find a consensus solution based on scientific considerations and relevant OIE standards. To assist them in their task, the experts may ask the parties for additional information or data and/or ask for data to be clarified.

Conduct of the mediation procedure

To achieve a successful outcome, the parties must cooperate and act in good faith.

To commence, each party explains its position, the facts that have led to the dispute and the consequences of it. In collaboration with the parties, the experts identify the scope of the discussions and draw up terms of reference and a work programme. A timetable and a schedule of meetings and their agendas are developed. These documents must be endorsed by both parties before discussions on the case can begin.

The parties may nominate additional experts to help them present their case.

The experts may hold joint or separate meetings with the parties.

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Developing a consensus

The OIE mediation mechanism provides a basis for a technically sound compromise acceptable to both parties. The parties, with the help of the designated experts, focus on the scientific and technical reasons for their differences rather than on legal aspects (which may be subjective, depending on the viewpoint and legal/administrative systems of each party). The search for a compromise is facilitated by referring to the OIE standards, which also provide the 'legal' context for the mechanism.

If, at the end of the mediation procedure, it has not been possible to find a mutually agreed solution parties may still benefit from the work undertaken. Participation in the process can help to reduce the differences between the parties and normally gives each party a better understanding of the other's positions and concerns. The results of the mediation process can trigger subsequent discussions, which may assist in resolving the difference.

Conclusion of the mediation procedure

The experts draft a report on the OIE mediation procedure, detailing the discussions and recommendations and the status of the disagreement between parties at the end of the process.

The report is drafted in one of the three official languages of the OIE. Part one of the report summarises the scientific and technical aspects of the discussion while Part two presents the findings and recommendations of the experts. Any dissenting views are explained in the report.

The report is handled in a totally confidential manner.

The draft report is provided to the OIE Director General, who transmits it to the parties. The report is not legally binding (unless this had been confirmed by the parties at the outset). The parties decide how they will address the recommendations in the report.

Confidentiality

All discussions, including the final report, are confidential unless the parties decide otherwise.

All those associated with the procedure, including the parties, their representatives and the experts, must respect confidentiality. However, the findings may be cited in a formal WTO dispute case if one of the parties decides to do so.

Administrative procedures

At the first meeting, the parties and the OIE agree upon the administrative procedures for the dispute mediation, including:

- the language(s) for the mediation; opting for more than one language means that interpreters and translators may be needed;
- where the mediation procedure will take place; this is normally but not essentially at the OIE headquarters in Paris;
- the cost of the process. Article 5.3.8. of the *Terrestrial Code* (2008) states that the parties shall agree to meet all expenses incurred by the OIE during the procedure. In accordance with established OIE procedures, the experts assisting the mediation will not receive an honorarium. They will however be compensated for the cost of their intervention (travel and per diem) by the OIE. The parties must pay a fixed fee in order to defray the costs assumed by the OIE. This fee will increase in 2009 to 8000 euros.

Part 2 - The rights and obligations of OIE Members

2.1. Introduction

The adoption, in 1995, of the WTO SPS Agreement provided the legal framework for international trade that applies to WTO Members today. In the Preamble to the SPS Agreement it is stated "that it is desirable to further the use of harmonized sanitary (…) measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including (…) the International Office of Epizootics". The SPS Agreement further refers to and recognises the OIE standards in its Article 3 on Harmonization, and in Annex A, paragraph 3(b). Thus, the SPS Agreement recognizes the OIE as the relevant standard-setting body for SPS measures relating to animal health and zoonoses.

The relevant recommendations are contained in particular in the OIE *Terrestrial Code* and *Aquatic Code*, for terrestrial animals and aquatic animals respectively, and in the OIE *Manuals of Diagnostic Tests and Vaccines*.

The WTO recognises that each Member has the sovereign right to set its appropriate level of protection when applying sanitary measures for international trade as long as they comply with the provisions established in the SPS Agreement. In the OIE context, the term "sanitary measure" means "a measure, such as those described in various Chapters of the *Terrestrial Code*, destined to protect animal or human health or life within the territory of the OIE Member from risks arising from the entry, establishment or spread of a hazard".[1] .

OIE Members who are WTO Members may comply with their obligations under the SPS Agreement either by basing their measures on relevant OIE international standards, or by carrying out a scientific risk analysis as outlined in Section 2 of the *Terrestrial Code* (2008).

The standards and recommendations contained in the *Code* are designed to facilitate and promote international trade. The OIE *Code* is a reference document for use by veterinary authorities, those responsible for making decisions on the import and export of animals and their products, and all those involved in international trade.[2] The application by Members of the OIE standards is the best means of avoiding disagreement and other problems in international trade.

2.2. The procedure for developing OIE standards and recommendations

The aim of the *Code* is, *inter alia*, to ensure the sanitary safety of international trade in terrestrial animals and their products by detailing science based health measures to be used by the veterinary authorities of the importing and exporting countries to avoid the transfer of agents pathogenic for animals or humans, while avoiding unjustified sanitary barriers.[3]

The *Terrestrial Code* is prepared by the Terrestrial Animal Health Standards Commission and the *Aquatic Code* is produced by the Aquatic Animal Health Standards Commission. These Specialist Commissions work closely with other relevant international organisations and non-governmental organisations, and with the National Delegates of OIE Members. Members of the Commission are elected by the General Assembly of national Delegates of OIE Members. Draft standards and recommendations are circulated to Delegates at least twice for comment before being proposed for adoption by the OIE International Committee, comprising all National Delegates. The transparent and democratic procedures followed by the OIE provide a basis for consensus and support implementation of the standards by OIE Members.

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1 http://www.oie.int/eng/normes/mcode/en_glossaire.htm#sous-chapitre-2

2 http://www.oie.int/eng/normes/en_mcode.htm

3 http://www.oie.int/eng/normes/en_mcode.htm

2.3. Obligations of importing countries

Importing countries should consider the exporting country's sanitary status, as relevant to the animals or animal products that are to be traded. Relevant data are contained in the WAHID database, which is accessible on the OIE Web site[4]. WAHID contains much useful information, including in the six monthly reports describing the status of each country with regard to OIE-listed diseases and in other useful information provided by Members. It is useful for Members to compare the sanitary situation between the importing country and the exporting country, based on data in the most recent six monthly reports.

As established in the WTO SPS Agreement, an importing country has the right to choose its appropriate level of protection for animal health, plant protection and food safety matters.

As stated in the *Code*, import conditions must take account of the animal health situation of both the importing country and the exporting country, as relevant to the animals/animal products to be traded.

The importing country should not impose measures in relation to diseases or pathogens that are not listed by the OIE, unless the disease or pathogen has been identified as presenting a significant risk on the basis of an import risk analysis conducted according to Section 2 of the *Terrestrial Code* [5] (2008).

The importing country should not impose sanitary measures for diseases or pathogens that occur in the importing country and are not the subject of official controls. Where official controls are implemented, the measures applied to imported animals/animal products should not be more restrictive than those applied nationally to similar animals/animal products under the official control programme.

Importing countries should publish a list of their border posts for imported animals and animal products. This helps to promote international trade since it provides information that helps exporting countries to make arrangements for importation to take place effectively and efficiently.

2.4. Obligations of exporting countries

Exporting countries should provide the following sanitary information, as listed in Article 5.1.3. of the *Terrestrial Code* (2008)[6], at the request of the importing country:

- the animal health situation and the national animal health information systems;
- the occurrence of notifiable diseases;
- the ability to apply measures to control and prevent the relevant OIE-listed diseases[7];
- the structure of the Veterinary Services and the authority which they exercise;
- technical information, particularly on biological tests and vaccines applied in all or part of the national territory.

4 http://www.oie.int/wahid-prod/public.php?page=home

5 http://www.oie.int/eng/normes/mcode/en_titre_1.2.htm

6 http://www.oie.int/eng/normes/mcode/en_chapitre_1.5.1.htm

7 List of transmissible diseases approved by the OIE International Committee and listed in Chapter 1.2. of the *Code*.

For trade in animals and some animal products, it is usual for an official veterinarian (or a private veterinarian holding an appropriate official delegation) to inspect the consignment prior to export. The veterinarian issues a veterinary health certificate[8] according to the arrangements agreed between the Veterinary Authorities of the exporting and importing country, preferably using the models published in the OIE *Code*.

At the request of the importing country, the exporting country should supply information on the exported animals or animal products, including:

- the estimated date of entry of the consignment into the territory of the importing country;
- the animal species involved;
- the quantity;
- the means of transport;
- the border post in the importing country where the consignment will arrive.

Veterinary Authorities of exporting countries should[9]:

- have official procedures for authorisation of certifying veterinarians;
- ensure that relevant instructions and training are provided to certifying veterinarians;
- monitor the activities of certifying veterinarians to verify their integrity and impartiality.

Exchange of this information helps to assure safe international trade.

2.5. The use of the OIE PVS Tool as a mechanism to support safe international trade

The performance of Veterinary Services (VS) is an important element assuring safe international trade. Not only must the VS be capable of promptly and efficiently detecting and managing OIE listed diseases, including those that present food safety and other public health risks, they must also provide effective sanitary guarantees via the veterinary health certificate. The maintenance of confidence between trading partners relies on consistent performance in these, and other, aspects.

The quality of VS is addressed in Section 3 of the *Terrestrial Code* (2008).

With this in mind, the OIE has developed a Tool for Evaluation of the Performance of the Veterinary Services (the PVS Tool). The legal basis for the PVS Tool is found in Chapters 3.1. and 3.2. of the *Terrestrial Code*.

The OIE PVS Tool may be used to evaluate the quality of VS, to assess their compliance with OIE international standards on quality and, if needed, to establish priorities for investment and strengthening of their infrastructure [10].

OIE Members have strongly supported the PVS evaluation procedure and this mechanism has been very successful at global level to date.

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8 http://www.oie.int/eng/normes/mcode/en_chapitre_1.5.1.htm and http://www.oie.int/eng/normes/mcode/en_chapitre_1.5.2.htm

9 http://www.oie.int/eng/normes/mcode/en_chapitre_1.5.1.htm

10 http://www.oie.int/eng/oie/organisation/EN_OIE%20PVS%20Tool_2008.pdf

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2.6. The use of equivalence as a mechanism to facilitate safe trade

The concept of "equivalence" as applied to sanitary measures refers to the acceptance by an importing country that the measure(s) proposed by an exporting country achieves the appropriate level of protection required by the importing country, even though the measures may be different to those applied by the importing country.[11]

Equivalence is referred to in Article 4 of the SPS Agreement[12]. The OIE has issued relevant standards, which Members should take into account when making decisions on trade measures. The OIE standards on equivalence may be found in Chapter 5.3. of the *Terrestrial Code* (2008).

The OIE informal mediation process may be used to help resolve a difference between Members regarding the use of the equivalence principle.

2.7. The use of zoning and compartmentalisation as mechanisms to facilitate safe trade

In view of the difficulty for a country in maintaining disease free status for the whole of its territory, the OIE has developed the concepts of zoning and compartmentalisation to help manage diseases and facilitate safe trade. Zoning and compartmentalization enable Members to define, within the national territory, animal subpopulations with a different health status. Relevant standards and guidance may be found in Chapters 4.3. and 4.4. of the *Terrestrial Code* (2008). The OIE has also provided guidance on the practical application of compartmentalization to avian influenza and Newcastle Disease in a checklist, which may be found on the OIE internet site[13].

For an importing country to recognise the existence of a zone or compartment in an exporting country as the basis for trade in animals or animal products, the exporting country should be able to demonstrate that it has complied with the relevant OIE standards. Detailed documentation should be provided by the exporting country for discussion between the Veterinary Authorities. As previously mentioned, the findings of an OIE PVS Evaluation should also be taken into account.

This concept is also recognized in the Article 6 of the SPS Agreement, and the SPS Committee has adopted Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of SPS Measures (Regionalization) (see SPS Committee paper G/SPS/48).

2.8. Risk analysis

"Risk analysis" means the process consisting of hazard identification, risk assessment, risk management and risk communication. "Risk" means the likelihood of the occurrence, and the likely magnitude of the biological and economic consequences of an adverse event to animal or human health in the importing country during a specified time period.[14]

The WTO SPS Agreement obliges Members to base their import measures on relevant international standards (of the OIE, in the case of animal health and zoonotic diseases) or a scientific risk analysis carried out according to relevant international standards.

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11 http://www.oie.int/eng/normes/mcode/en_glossaire.htm#sous-chapitre-2

12 Equivalence is referred in Article 4 of the SPS Agreement. In addition, the SPS Committee has adopted a Decision on the Implementation of Article 4 of the Agreement on the Application of SPS Measures (Equivalence) (see SPS Committee paper G/SPS/19/Rev.2).

13 http://www.oie.int/eng/info_ev/Other%20Files/En_final_Compartmentalisation_AI_ND_10_05_2007.pdf

14 http://www.oie.int/eng/normes/mcode/en_glossaire.htm#sous-chapitre-2

The OIE provides guidance on the conduct of an import risk analysis in Section 2 of the *Terrestrial Code* (2008) and more detailed guidance is provided in the two volumes of the OIE *Handbook on Import Risk Analysis for Animals and Animal Products*.

In the situation where relevant international standards have not been developed and/or an importing country considers that it requires a higher level of protection than that provided by the international standard, the importing country should carry out an import risk analysis. This should take into account the results of an evaluation of the Veterinary Services of the exporting country, if one has been conducted. In some cases, the application of zoning and compartmentalisation must also be addressed.

2.9. Conclusions

By adopting the OIE standards as the basis for their sanitary measures, OIE Members obtain guarantees for safe international trade in animals and animal products. In the case where there is no relevant international standard or where Members require a higher level of sanitary safety, science based risk analysis following OIE standards should be undertaken. The use of concepts such as equivalence, zoning and compartmentalization, according to OIE standards, can help to facilitate safe international trade.

In the event where OIE standards are not respected and differences arise, Members should first consider using the OIE informal mediation mechanism.

Confidence in the quality of veterinary services is the cornerstone of international trade. Good governance, ensuring transparency in disease reporting, efficiency in disease management and reliability in veterinary certification, is key to provide the necessary assurances to trading partners.

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Annex A - The OIE informal mediation procedure

1. When a Member considers that another Member is not applying relevant OIE standards or has adopted import measures that are not based on an import risk analysis according to OIE standards, the Member may send a written request to the OIE for mediation. The request should outline the grounds for requesting the mediation process. The OIE then forwards the request to the Member in question.

2. On receipt of the request, the Member in question should provide a written reply within a period of 20 days, stating whether or not it agrees to mediation.

   - Silence on the part of one of the parties is not taken to indicate agreement. The entire mediation process depends on the consent of the parties. Furthermore, if the Member in question does not reply within the given time limit, the OIE will take this as a refusal to engage in mediation.

   - If both parties agree to mediation, the OIE will initiate the process.

3. The mediation process takes place within a period of 90 days, with a single extension available at the request of both parties. The procedure begins once the Director General of the OIE confirms that the OIE will undertake the mediation.

4. The Parties select one or more experts (desirably an odd number), selected from a list provided by the Director General. The experts should be impartial and independent of the parties and, preferably, not be of the same nationality as the parties. The experts may request the provision by the parties of any information they deem to be relevant to the mediation.

5. At the first meeting the parties agree administrative arrangements for the mediation, including the venue for meetings, the language(s) to be used and the conditions to be established for meeting the cost of the mediation by the OIE. Needs for interpretation and/or translation should be agreed and the timeframes for the mediation procedure established. The mediator nominated by the Director General of the OIE should remind the parties that the findings of the mediation will not be published and the conclusions will not be binding without prior agreement of both parties unless they decide a different option. The position of both parties on these two points should be confirmed at this stage.

   The parties explain their respective positions and provide relevant documentation to the mediator. Subsequently, the parties and the mediator draft the terms of reference and a work programme, including the framework for the mediator's involvement and the main issues to be dealt with during the mediation process.

   If they wish, the parties may terminate the mediation process at any time. To do so, they should notify the other party in writing and send a copy to the Director General.

6. Bilateral consultations between the parties take place in accordance with the agreed work programme and the undertaking on confidentiality. Unless the parties agree to the contrary, both the discussion and the final report will remain confidential.

7. The mediator drafts a report on the mediation in one of the three OIE official languages. This report is in two parts: part one summarises the technical issues discussed and part two presents the mediator's findings and recommendations to the parties.

- A preliminary draft report will be sent to the parties for comment. Parties should provide their comments within 60 days of receiving the preliminary draft report. The mediator will then produce a final draft report, taking account of comments provided by the parties. If a party provides no comments, the mediator may assume that the party is in agreement with the preliminary draft report.

- The final draft report is sent to the Director General, who then transmits it to the parties. This step will be completed within one month after the mediator receives comment from the parties (or one month after expiry of the 60 day period for comment, if no comment is received).

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Annex XXXVIII (contd)

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Annex XXXIX

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November 2008

REPORT OF THE EIGHTH MEETING OF THE

OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 4-6 November 2008

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The OIE Working Group on Animal Production Food Safety (hereinafter referred to as the Working Group) met for the eighth time at the OIE Headquarters on 4 to 6 November 2008.

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

Dr Kahn, Head of the International Trade Department, welcomed the members of the Working Group on behalf of Dr Vallat, OIE Director General. Dr Kahn emphasized the importance of the animal production food safety work programme of the OIE. Dr Kahn indicated that while it is clear that the OIE's role in food safety is largely focused on the farm production step of the continuum, there are areas where both OIE and Codex were involved (such as antimicrobial resistance and biotechnology). In those cross over areas it is important that OIE and Codex and its parent bodies continue to co-ordinated their activities and work to ensure that there are no contradictions between OIE and Codex standards and that cross references are used where appropriate. She encouraged members to consider the strategic issues for the future work programme, as well as the ongoing standard setting work on the agenda for this meeting.

Dr Kahn thanked members and especially the chairman for their ongoing support of the OIE.

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

1.1. OIE

The Working Group was informed that the OIE had proposed to the WHO to add a new article to the existing OIE/WHO Agreement, to provide for the possibility of OIE and Codex developing joint standards as appropriate to the subject under consideration and the mandates of the two organisations. This matter had been discussed between the Directors General of the OIE and WHO and several letters have been exchanged. The proposed text to be added to the OIE/WHO Agreement already exists in the OIE/FAO Agreement.

The Working Group noted that the OIE Fifth Strategic Plan (2011-2015) was under development.

Refer to agenda item 2 below for additional information.

1.2. FAO

Dr Domenech introduced Dr de Balogh as the leader of FAO's Veterinary Public Health work programme within the AGAH Service, which addresses food safety issues associated with animal production at the farm level in close collaboration with the Codex Secretariat and the Nutrition and Consumer Protection Division of FAO. Dr Domenech advised that Dr Traoré, a veterinarian and former director of African Union Bureau for Animal Resources (AU-IBAR) had been appointed as the new Assistant Director General of FAO's Agriculture and Consumer Protection Department.

Dr Domenech elaborated on the ongoing FAO reform process and its possible implications for Animal Production and Health Division. The FAO Chief Veterinary Officer (CVO) position would remain. At present within the Animal Production and Health Division, the Animal Health Service includes the Emergency Prevention System (EMPRES) and the Veterinary Public Health (VHP) activities. In addition the CVO of FAO is also Head of the Emergency Centre for Transboundary Diseases (ECTAD) and the Crisis Management Centre (CMC), integrating the technical and operational components of FAO and addressing highly pathogenic avian influenza and other transboundary animal diseases. In future it is expected that the Animal Health Service will become an Animal Health Programme, which will still include EMPRES and VPH groups and will follow a global multidisciplinary approach. The recently established CMC - Food Chain will integrate the animal health, plant health and food safety aspects of emergency responses.

Dr de Balogh introduced herself and presented the activities developed since her appointment in October 2007. Much work had been done to establish links with other related programmes within FAO (Nutrition and Consumer Protection Division, Codex, Forestry and Fisheries Departments), with other international organizations (OIE, WHO, UNICEF, World Bank) and the private sector (SSAFE, IDF). The recruitment of an animal health officer working on food safety issues is being finalised. Two consultants (Eric Cardinale (CIRAD) and Gilles Salvat (AFSA)) have assisted in defining the Veterinary Public Health/Food Safety (VPH/FS) programme within the Animal Health Service through the definition of priority areas and activities in pilot countries. A meeting with OIE and WHO in planned for 2009 to define further the FAO VPH/FS work in coordination and cooperation with other programmes. So far a number of virtual networks on VPH/FS have been established at global and regional level for exchange of relevant information and as a platform for discussions.

Dr de Balogh has coordinated the development of the FAO/OIE/World Bank biosecurity documents for HPAI that were presented at New Delhi and Sharm-El-Sheik meetings as well as national and regional desktop-simulation exercises for HPAI to strengthen coordination, cooperation and communication between the different sectors (animal and human health, wildlife, emergency, police, border control) This approach could also be further developed for other zoonotic diseases. Dr de Balogh also participated in the joint FAO/WHO Expert meeting on Animal Feed Impact on Food Safety (October 2007) as resource person and member of the secretariat of the FAO/WHO/OIE Expert meeting on Critically Important Antimicrobials (November 2007).

Dr Domenech further elaborated on the Good Farming Practice Guide that resulted from a FAO/OIE working group and FAO is developing specific aspects to address good farming practices for different animal species, animal products and production systems in developing countries. He further expressed the importance of FAO to collaborate in the organisation of the Traceability and Animal Identification Conference scheduled for March 2009 in Buenos Aires, as has been recommended by the Working Group last year. FAO has close links to the International Center for Agricultural Research in the Dry Areas (ICARDA) and develops activities (e.g. workshops) in the field of animal identification in developing countries.

Dr Domenech further mentioned the One World – One Health strategy that was elaborated jointly by FAO, OIE, WHO, UNICEF, UNSIC and the World Bank and the FAO/OIE HPAI global strategy to prevent and control HPAI that were both presented in Sharm El Sheik at the Sixth International Ministerial Conference on Avian and Pandemic Influenza (24-26 October, 2008) to set the scene to address avian influenza and beyond. The next steps will aim to secure ownership by countries and a more defined operationalisation, including funding options. Dr Domenech emphasized the adoption of the food chain approach and the need for interagency collaboration for addressing emerging diseases at the animal-human interface.

Some relevant FAO weblinks are provided in Annex C.

1.3. Codex

Dr Kazuaki Miyagishima provided an update on the work of Codex. Detailed information is provided in Annex D.

1.4. WHO

Dr Schlundt provided an update on the work of WHO. Further information is provided in Annex E and information on melamine toxicity is available from the WHO website at http://www.who.int/foodsafety/fs_management/Melamine.pdf

Regarding the OIE's proposal to amend the OIE/WHO Agreement, Dr Schlundt indicated that the OIE should receive a final response from WHO shortly.

2. **OIE *Terrestrial Animal Health Code***

Dr Thiermann, President of the Terrestrial Animal Health Standards Commission (Terrestrial Code Commission), outlined the discussions of the Terrestrial Code Commission at its October 2008 meeting. He indicated that the points of main importance to the Working Group include the division into two volumes of the *Terrestrial Code*; the report of the *ad hoc* Group on Trade in Animal Products ('commodities'); finalised texts on animal feed; control of salmonella species in broilers and egg-producing chickens, veterinary certificates and animal identification. Dr Thiermann also drew the attention of members to the next meeting of the *ad hoc* Group on Salmonellosis, which would address OIE Members comments on the previously circulated text on biosecurity in poultry establishments.

Dr Kahn provided some additional information on current work of the International Trade Department. Key issues of interest to the Working Group include the OIE initiative on Veterinary Legislation (missions being undertaken at the request of Members, with linkage to the ongoing work on Evaluation of Performance of Veterinary Services (OIE PVS)) and the production of a revised edition of the OIE Handbook on Import Risk Analysis, which will be undertaken by an *ad hoc* Group to be convened in 2009. The Working Group expressed interest in these new areas of work and members undertook to review and comment on the text of the revised Handbook on Import Risk Analysis.

Dr Kahn reported on the work of the OIE *ad hoc* Group on Trade in Animal Products (commodities). The report of the first meeting of this Group will be released shortly, as an annex to the report of the October 2008 meeting of the Code Commission. This Group is looking primarily at animal diseases. The *ad hoc* Group recommended that the OIE undertake the following actions:

a) Publications to communicate the OIE's commitment to animal origin commodity trade;

b) Seek funds for research to support safe commodity trade;

c) Feedback on Members' expectations on OIE standards in regard to commodity trade;

d) The adoption in the *Terrestrial Code* of additional standards to facilitate commodity trade;

e) Promotion of and technical support for commodity trade;

f) Strengthening veterinary services to underpin commodity trade;

g) Addressing antigenic variation within serotypes of FMD-SAT viruses in terms of vaccine and diagnostic tools improvement to help African countries to apply acceptable risk mitigation measures ensuring safety of commodity trade.

In light of the availability of funding from the UK government for targeted research into some animal diseases, the OIE is developing project proposals to establish the infectivity of pork for CSF and of matured, pH tested boneless beef for FMD, to ascertain if these commodities can be safely traded regardless of the disease status of the exporting country/zone.

The Working Group supported this work and requested that it be kept informed of ongoing work, specifically any potential changes to the *Terrestrial Code* chapters on food safety related zoonotic diseases.

The Working Group stressed the importance of a product based approach and the need to ensure that this does not act to the detriment of disease control programmes, especially in developing countries. To avoid this, it was recommended that the OIE should continue to promote strengthening of the Veterinary Services through the OIE PVS Tool including follow-up activities.

Although developing countries' Veterinary Services face many challenges, it is important that their role in inspection, certification and accreditation procedures is respected and priority given to strengthening them. In particular, approaches that are based on transferring the mandate of official Veterinary Services to the private sector and bypassing proper management and control of animal health and production and veterinary certification should not be supported.

Dr Domenech further suggested that the OIE *ad hoc* Group on Trade in Animal Products should be pro-active in producing new proposals for commodity and processing standards and in conducting socioeconomic analysis of proposed approaches. The costs and benefits of taking a commodity based approach should be compared to other approaches and options.

There is a clear need for reliable data and good scientific research to define how to promote commodity trade without risking the transmission of pathogens to animals and consumers

Dr Domenech raised the need for OIE to include the socio-economic dimension in its standard setting process (for example to assess the cost-benefit of implementing specific standards and guidelines). The OIE could draw upon its partnership with FAO as this organisation has considerable expertise in multidisciplinary and multi-sector global approaches including socio-economics and long term interventions addressing the causes of disease emergence and can provide the developing country perspective.

3. OIE- FAO Guide to Good Farming Practices

The Working Group noted that the text for the Guide to Good Farming Practices has been finalised and will be published as a booklet in English, French and Spanish. The FAO is preparing the text for a publication which is due for release in late 2008. The text was published in a recent edition of the OIE Bulletin (No. 2008-3).

The Working Group noted that this text had been reviewed at its first meeting and that they were pleased to see that this work had been completed and noted that the Guide meets their expectations and will be useful to Members.

The Working Group discussed the possibility of conducting further work, for example the production of a Guide to Good Practices in specific sectors. Dr Domenech noted that FAO has already produced several sector specific Guides to Good Practice. He reported that FAO will continue to work on the elaboration of guides especially for developing countries and consider different production systems (e.g. commercial/village level), specific products (meat/milk/eggs) and animal species (ruminants/pigs/poultry).

The Working Group concluded that it was not a high priority for the OIE to develop additional Guides at this time, preferring to await feedback from Members.

4. Animal Identification and Traceability

Dr Atagi of the International Trade Department joined the meeting for this item.

The Working Group noted that *Terrestrial Code* Chapter 4.2. Design and Implementation of Identification Systems to achieve Animal Traceability, on which members had provided comment, was adopted at the 76th General Session in May 2008. No specific further work is planned for the *ad hoc* Group that developed Chapter 4.2. but new issues may arise at the OIE International Conference (see below).

Dr Kahn reported on progress in the organisation of the OIE International Conference on Animal Identification and Traceability, drawing attention of members to the changed dates for the conference, now to be held 23-25 March 2009, in Buenos Aires. The preliminary draft programme is now available on the OIE website (in English, translation in progress) and the OIE is in the process of drawing up a list of speakers.

Dr Miyagishima noted that Codex wishes to maintain high visibility at this important event. Dr Domenech requested that the recommendations from the 2007 meeting of the Working Group be taken into account and that FAO's ongoing work on animal identification in developing countries be considered. It was agreed that there is scope for the OIE to collaborate with FAO in the organisation of the Conference on Animal Identification and Traceability.

The EU has provided a significant financial contribution to support this conference and considers identification and traceability of animals and animal products to be very important. The EC has organised training seminars for countries exporting animal products to the EU. The next such seminar will take place in November 2008 and Dr Atagi will represent the OIE at the seminar.

The Working Group discussed with Dr Vallat their proposal that the OIE collaborate with FAO in the organisation of the International Conference on Animal Identification and Traceability to be held in Buenos Aires 23-25 March 2009. Dr Vallat indicated that he supported this approach and that he sees the role of FAO in this context as supporting developing countries to apply the OIE international standards. With this in mind, Dr Vallat indicated that he has encouraged FAO to become involved in the conference, including via the provision of financial support to developing countries to participate.

The Working Group agreed to revisit the need for any additional standard setting work on animal identification and traceability at its next meeting, in light of discussions at the conference.

5. Revision of OIE Model Veterinary Certificates

The Working Group noted that *Terrestrial Code* Chapter 5.10. Model Veterinary Certificates for International Trade in Live Animals, Hatching Eggs and Products of Animal Origin, on which members had commented previously, had been adopted at the 76th General Session in May 2008.

Dr Miyagishima reported that the Codex proposed draft Generic Model Health Certificate will be discussed at the next meeting of Codex Committee on Food Import and Export Inspection and Certification Systems in November 2008. He indicated that Codex had worked to ensure consistency with work of the OIE and the United Nations Centre for Trade Facilitation and Electronic Business when developing the Certificate.

6. Terrestrial Animal Feed

The Working Group noted that the Terrestrial Code Commission had reviewed Member comments on the draft *Terrestrial Code c*hapter on the control of hazards of animal health and public health importance in animal feed. The Terrestrial Code Commission accepted the recommendations made by the Working Group at their November 2007 meeting. The revised draft will be sent out to Members as part of the Terrestrial Code Commission's October 2008 report and the text will be proposed for adoption at the 77th OIE General Session in May 2009.

The Working Group noted that the 32nd Session of the Codex Alimentarius Commission in June 2009 will make a decision on possible new work in relation to animal feed.

Dr Domenech reported that FAO and WHO organised a joint FAO/WHO Expert meeting on the Impact of Animal Feed on Food Safety (October 2007).

Dr Thiermann reported that the OIE will develop recommendations on feed for animals that are not used for food production (i.e. pets) in 2009. The Working Group supported this new area of work and requested that members be kept informed of developments and be invited to review text in regard to relevant food safety issues. In doing so it noted the potential risk that controls over the use of raw materials and other ingredients in pet food may fail, that food intended for human consumption may be contaminated by ingredients/materials intended for pet food and that there are situations where humans consume food intended for pets.

7. Aquatic Animal Feed

Dr Kahn reported that the Aquatic Animal Health Standards Commission (AAHSC), at its October 2008 meeting, had finalised a text on aquatic animal feed. This text addresses aquatic animal health risks but not food safety issues.

The AAHSC also recommended that the OIE consider extending its mandate to address the food safety implications of aquatic animals and aquatic animal products. Topics that may need to be addressed include identification and traceability, biotechnology and antimicrobial resistance but the first priority for the OIE will be the development of advice on the food safety implications of feed for aquatic animals. The OIE plans to convene an *ad hoc* Group to develop this text. This *ad hoc* Group will report to the Working Group and texts will then be submitted to the AAHSC for possible inclusion in the Aquatic Animal Health Code. The expansion of the AAHSC mandate will be considered by the International Committee in May 2009.

The Working Group noted this positive development and agreed to review draft text prepared by the *ad hoc* Group. Dr Miyagishima indicated that the Codex Secretariat would be willing to participate in the *ad hoc* Group to ensure consistency with the existing work in Codex.

8. Salmonellosis

The Working Group noted that the Terrestrial Code Commission at its October 2008 meeting had reviewed Member comments on a draft *Terrestrial Code* chapter on the detection, control and prevention of Salmonella spp. in poultry and would issue the revised text for Member comments with a view to possible adoption in May 2009.

The Working Group recommended that the Terrestrial Code Commission consider the inclusion of the following text in this chapter, Article X.X. 5., as a new point after the current point 6:

> 'While *Salmonella* in general contaminates poultry flocks through a number of (environmental) sources, *Salmonella* Enteritidis is characterised by its ovarian transmission pattern. Some countries have succeeded in and others have targets for eradicating (or significantly reducing) *Salmonella* Enteritidis from egg-producing flocks through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent flocks through breeder flocks to layer flocks.'

The Working Group noted that the Terrestrial Code Commission had received extensive comments from Members on the revision of Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production and that these comments had been forwarded to the *ad hoc* Group on Salmonellosis for review at its February 2009 meeting. The Working Group undertook to review a further text once this is available.

The Working Group requested to be kept informed of progress on work in the above areas. It also recommended that the OIE continue to collaborate with Codex Committee on Food Hygiene, particularly in regard to the work on food safety aspects of salmonellosis and campylobacteriosis. The Working Group's attention was drawn to document CX/FH 08/40/6 "Proposed Draft Guidelines for Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat at Step 3", which was due to be discussed at the Fortieth Session of the Codex Committee on Food Hygiene, to be held in Guatemala City on 1-5 December 2008.

Dr Domenech reported that FAO, OIE and the World Bank developed a report on biosecurity for poultry which was presented at the Sixth International Ministerial Conference on Avian and Pandemic Influenza (http://www.imcapi2008.gov.eg/). This work will be followed up to test different options for the implementation of biosecurity in developing countries under different conditions. The feasibility/acceptability of different options and their cost-effectiveness will be investigated with the aim of elaborating specific guidelines on what can be implemented in developing countries under various production systems and in compliance with OIE norms.

9. Antimicrobial resistance

Dr Erlacher-Vindel and Dr Diaz, of the Scientific Department, joined the Working Group for this item. Dr Erlacher-Vindel reported on the work done by the OIE over the last 5 years on the issue of antimicrobial resistance. In 2003, three chapters were developed for the *Terrestrial Code* (Chapter 6.5. Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes; Chapter 6.6. Monitoring of the Quantities of Antimicrobials used in Animal Husbandry, and Chapter 6.7. Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine). In 2004, an additional chapter was developed for the *Terrestrial Code* (Chapter 6.8. Risk Assessment for Antimicrobial Resistance arising from the Use of Antimicrobials in Animals). In 2005, Chapter 6.7. was revised in light of Codex recommendations. In 2006/2007, a list of antimicrobials of veterinary importance was developed. The relevant principles were adopted by the OIE International Committee at the 74th General Session in May 2006 and the list was unanimously adopted in its current form by the International Committee at the 75th General Session in May 2007.

Dr Erlacher-Vindel also reported on OIE work aimed at helping countries to implement effective legislation to ensure quality of veterinary medicinal products. In this context, the first OIE Regional Conference on Veterinary Medicinal Products was held in Africa in 2008 with the aim to support harmonisation and improvement of registration, distribution and quality control of these products. The next OIE Regional Conference on Veterinary Medicinal Products is planned to take place in the Middle East in late 2009.

Dr Diaz provided an update on the 2nd Session of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (Seoul, Republic of Korea, 20-24 October 2008), where the OIE was invited to participate as an observer. At this meeting the Task Force agreed to consolidate three Codex documents (on Risk Assessment, Risk Profiles and Risk Management Guidance to Contain Foodborne Antimicrobial Resistant Microorganisms) into a single document entitled "Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance" and to send the document to Codex Steps 2 for redrafting by an electronic working group led by the USA. This working group will prepare a revised document by the end of May 2009 on the basis of the comments received by the end of February 2009 from Members and Observers. The revised version will then be circulated for comment at Step 3 and will be further considered at the third session of the Task Force, to be held in Seoul, Republic of Korea in November 2009.

The Working Group encouraged the OIE to continue to engage closely with Codex, FAO, WHO and VICH on the important topic of antimicrobial resistance.

Dr Domenech reported that the FAO/WHO/OIE Expert meeting on Critically Important Antimicrobials took place in November 2007.

10. Biotechnology

Dr Erlacher-Vindel and Dr Diaz, of the Scientific Department, joined the Working Group for this item. Dr Slorach, who attended the 26-29 November 2007 meeting of the *ad hoc* Group on Biotechnology, provided a summary of the OIE's proposed approach to biotechnology issues. In future the *ad hoc* Group on Biotechnology will be divided into two separate groups: one focused on vaccinology and the other on molecular diagnostic tests. The priority issues for the *ad hoc* Group on vaccinology, which meets for the first time in November 2008, will be the use of biotechnology derived vaccines on animals. The OIE will first consider the animal health implications then the food safety implications of the use of this technology.

Dr Erlacher-Vindel explained that the OIE would examine the animal health implications of biotechnology derived vaccines (including DNA vaccines) using its established *ad hoc* Group procedure. Dr Schlundt raised concerns about the process that the OIE intends to follow, urging that a tripartite (FAO/OIE/WHO) expert group be convened to address the food safety implications of the use of recombinant DNA vaccines.

The Working Group noted that broad scientific expertise would be needed to address possible food safety implications of biotechnology derived vaccines, including both vaccine experts and experts in human health. This work could be done via the established OIE *ad hoc* Group process or via another process, such as a tripartite OIE/FAO/WHO expert meeting. Regardless of which approach is taken, the key consideration is that appropriately qualified experts be involved in this procedure and the Working Group recommended that FAO, OIE and WHO all be involved in nominating appropriate experts for this work.

Dr Domenech reported that the FAO/AGN and WHO will organise an expert meeting on Nanotechnology in Food and Agriculture, to be held in Rome in early 2009.

The Working Group recommended that insofar as food safety issues related to the use of nanotechnology in animal vaccines are concerned, the OIE and the Working Group should be involved.

11. Application for OIE Collaborating Centre for Animal Feed Safety and Analysis

The Working Group noted the application of a Japanese institute for recognition as an OIE Collaborating Centre for Animal Feed Safety and Analysis and asked the OIE International Trade Department to forward the application according to the OIE's established procedures.

12. World Bank Study - Livestock and Slaughter Waste Management

Dr Kahn briefly summarised the discussions held at the June 2008 meeting on the World Bank project on Livestock and Slaughter Waste Management. The World Bank may wish to conduct some further work on the environmental impacts of livestock and slaughter effluent in collaboration with the OIE and FAO. Dr Domenech commented that the FAO's LEAD programme has collected extensive information on the issue of livestock production/ processing waste in developing countries. FAO would be interested to collaborate in this work, should it proceed.

Dr Domenech proposed that the OIE and the World Bank liaise with FAO and take into account the work done under the LEAD programme.

13. Other business

No other business was raised.

14. Work Programme for 2009

The Working Group considered that to a considerable degree it had achieved many of the goals established at its first meeting and that the time had come to re-examine the Working Group's mandate and *modus operandi* with a view to ensuring its ongoing relevance. It agreed that this should be a major item of discussion at its next meeting. As a special case, the Working Group requested the Director General prepare a discussion paper on identifying the priority pathogens for standard setting activities in the animal production food safety area.

Dr Vallat joined the Working Group to discuss the work carried out at the meeting. Dr Slorach provided an overview of the Working Group's deliberations with a focus on the recommendation for a review of the Working Group's terms of reference and *modus operandi*. Dr Vallat supported this recommendation. The Working Group members agreed to develop the terms of reference and *modus operandi* prior to the next meeting via email and teleconference discussions.

The timing of release of the Working Group report was also discussed. Dr Vallat agreed with the Working Group's proposal to release the report shortly after it has been approved by the Terrestrial Code Commission. This would allow for focal points in Member countries and territories, especially those responsible for veterinary public health, to receive the report in a more timely manner. This change will take effect immediately, i.e. the report of this meeting will be placed on the OIE internet site once it has been discussed and approved by the Terrestrial Code Commission, whose next meeting will take place on March 2009.

The Work programme for 2008/09 is presented at Annex F

15 Next meeting

3-5th November 2009

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Annexes/…

MEETING OF THE OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 4-6 November 2008

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Annex XXXIX (contd)

Annex A (contd)

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Annex B

MEETING OF THE OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 4-6 November 2008

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Adopted Agenda

Welcome from the OIE Director General
Adoption of the Agenda

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

OIE

FAO

Codex

WHO

2. ***OIE Terrestrial Animal Health Code***

New Structure

New Veterinary Public Health section: future work

Work of the OIE on trade in animal products (commodities).

3. Guide to Good Farming Practices

Update on status of publication

Future work

4. Animal Identification and Traceability

New *Terrestrial Code* Chapter 4.1 Design and implementation of identification systems to achieve animal traceability

OIE International Conference on Animal Identification and Traceability, Buenos Aires

5. Revision of OIE Model Veterinary Certificates

Revised *Terrestrial Code* Chapter 5.10. Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

6. Terrestrial Animal Feed

Draft *Terrestrial Code* Chapter X.X. The control of hazards of animal health and public health importance in animal feed - Terrestrial Code Commission amendments

Annex XXXIX (contd)

Annex B (contd)

7. Aquatic Animal Feed

Future work

8. **Salmonellosis**

Draft Chapter X.X.X. The detection, control and prevention of *Salmonella* spp. in poultry – Review Member comments and Terrestrial Code Commission amendments

Draft Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production including member comments

Future work

9. Antimicrobial resistance

10. Biotechnology

Report of the *ad hoc* Group meeting

Future Work

11. **Application for OIE Collaborating Centre for Animal Feed Safety and Analysis**

12. World Bank Study - Livestock and Slaughter Waste Management

13. Other business

14. Work Programme for 2009

15. Next meeting

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Relevant FAO Web links:

1. FAO/WHO Expert meeting on Animal Feed Impact on Food Safety (October 2007): ftp://ftp.fao.org/docrep/fao/010/a1507e/a1507e00.pdf
2. FAO/WHO/OIE Expert meeting on Critically Important Antimicrobials (November 2007): http://www.fao.org/ag/againfo/resources/en/pubs_vph.html
3. FAO/OIE/WB Biosecurity for HPAI: issues and options: ftp://ftp.fao.org/docrep/fao/011/i0359e/i0359e00.pdf
4. FAO/OIE/WB Biosecurity advocacy document: http://www.fao.org/docs/eims/upload//249466/aj132e00.pdf
5. FAO/OIE/WHO/UNICEF/WB One World One Health http://www.fao.org/avianflu/documents/OWOH_14Oct08.pdf

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Annex D

CODEX WORK RELEVANT TO OIE APFSWG SINCE ITS LAST MEETING

(October 2007 – October 2008)

A. 31st Session of the Codex Alimentarius Commission (30 June - 4 July 2008)[15]

In accordance with the "Guidelines for Cooperation between the Codex Alimentarius Commission and International Intergovernmental Organizations in the Elaboration of Standards and Related Texts" and its decision at the 28th Session, the Commission was informed of the OIE activities relevant to Codex work[16]. In replying to the statement of Dr Vallat, Director-General of OIE, delegations pointed out that strengthened collaboration with OIE was important to ensure that the risk-based approach be applied in the pre-harvest sector of the food chain, especially in addressing the control of microorganisms in animal products, currently undertaken by the Committee on Food Hygiene. It was also pointed out that this strengthened collaboration would minimize potential overlaps in the work of the two organizations, would prevent the setting of contradictory standards, and was consistent with Goal 4 and Activity 4.4 of the Codex Strategic Plan 2008-2013. The Commission concluded its discussion by noting that collaboration with the OIE had considerably enhanced over the years and needed to continue to be strengthened, in particular in the area of control of microorganisms in animal products (ALINORM 08/31/REP paras 190-195).

The 31st Session of Commission adopted 35 new or revised Codex standards or related texts, several amendments to the Procedural Manual and a number of new work proposals.

i) Texts adopted

Texts adopted, relevant to the OIE, include:

- Live and Raw Bivalve Molluscs and relevant Definitions for inclusion in the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) [17]
- Standard for Raw and Live Bivalve Molluscs (CODEX STAN 292-2008)
- Model Export Certificate for Milk and Milk Products (CAC/GL 67-2008)[18]
- Maximum Residues Limits (MRLs) for Veterinary Drugs (colistin and erythromycin) (CAC/MRL 2)[19]
- Annex II on the Guidance on Microbiological Risk Management Metrics to the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007)[20]
- Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003)[21]

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[15] Report of the 31st Session of the Codex Alimentarius Commission is available on Codex website : http://www.codexalimentarius.net/download/report/698/al31REPe.pdf
[16] CAC/31 INF/4 "OIE Contribution to the 31st Session of the Codex Alimentarius Commission"
[17] http://www.codexalimentarius.net/download/standards/10273/CXP_052e.pdf
[18] http://www.codexalimentarius.net/download/standards/11027/cxg_067e.pdf
[19] http://www.codexalimentarius.net/download/standards/45/MRL2_e.pdf
[20] http://www.codexalimentarius.net/download/standards/10741/cxg_063e.pdf
[21] http://www.codexalimentarius.net/download/standards/10047/CXG_053e.pdf

- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (CAC/GL 68-2008)
- Revised Recommended International Code of Practice for the Processing and Handling of Quick Frozen Foods (CAC/RCP 8-1976)[22]

ii) New work

New work items approved by the 31st Session of the Commission, relevant to the OIE, include:

Codex Intergovernmental Task Force on Antimicrobial Resistance:

- Science-based Risk Assessment Guidance Regarding Food-borne Antimicrobial Resistant Microorganisms (job number N01-2008);
- Risk Management Guidance to Contain Food-borne Antimicrobial Resistant Microorganisms (job number N02-2008); and
- Guidance on Creating Risk Profiles for Antimicrobial Resistant Food-borne Microorganisms for Setting Risk Assessment and Management Priorities (job number N03-2008).

Codex Committee on Food Hygiene:

- Code of Hygienic Practice for *Vibrio* Species in Seafood (job number N05-2008).

Codex Committee on Food Import and Export Inspection and Certification Systems:

- Principles and Guidelines for the Conduct of Foreign on-Site Audits and Inspections (job number N07-2008); and
- Annex to the *Guidelines for Design, Production, Issuance and Use of Generic Official* Certificates (CAC/GL 38-2001): Generic Model Health Certificate (job number N08-2008).

iii) Officers of the Codex Alimentarius Commission

The Commission elected Ms Karen HULEBAK (USA) as the new Chairperson and Mr Sanjay DAVE (India), Mr Ben MANYINDO (Uganda), and Mr Knud ØSTERGAARD (Denmark) as vice-Chairpersons.

B. Codex Committee on Fish and Fishery Products

The Committee on Fish and Fishery Products continues to work on the development of the Code of Practice for Fish and Fishery Products, which integrates the revision of all existing Codes of Practice applying to fish and fishery products and several new sections. The revision was intended to reflect a risk-based approach and to integrate the application of the HACCP system, while ensuring consistency of food hygiene provisions with the General Principles of Food Hygiene and other relevant Codex texts. All existing codes have been integrated into a single Code, which covers both food safety and quality provisions. The general sections and many sections corresponding to previous codes have been finalised and adopted by the Commission between 2003 and 2008. The Code of Practice includes a Section on Aquaculture in which reference is made to the OIE International Aquatic Animal Health Code. The sections remaining to be finalised are the Draft Sections on Lobsters and Crabs, and the Proposed Draft Section on Smoked Fish.

[22] http://www.codexalimentarius.net/download/standards/285/CXP_008e.pdf

The two texts adopted by the 31st Session of the Commission i.e. Standard for Live and Raw Bivalve Molluscs; and Code of Practice for Fish and Fishery Products (Live and Raw Bivalve Molluscs) provide guidance on microbiological contamination, biotoxins, control measures and methodology and is based on scientific advice provided by FAO/WHO. Further scientific advice is being sought from FAO/WHO on the estimation of risk mitigation for *Salmonella* in bivalve molluscs when different sampling plans and microbiological criteria are used, for future review of the criteria and sampling plans for *Salmonella* in the Standard for Live and Raw Bivalve Molluscs.

The next 30th session of the Committee will be held on 28 September - 2 October 2009 in Morocco.

C. Codex Task Force on Foods Derived from Biotechnology

The 7th Session of the Task Force (24-28 September 2007) completed, among others, its work on the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, which was adopted by the 31st Session of the Commission.

The Task Force welcomed the recommendations from the 2007 FAO/WHO Expert Consultation on the Safety of Foods Derived from Recombinant-DNA Animals, especially those addressed to FAO, WHO and OIE, which, among others, called for a joint FAO/WHO/OIE expert group to consider the animal health and food safety issues raised by recombinant-DNA vaccines. The Task Force noted that these agencies would further discuss priorities and concrete modalities for conducting joint activities, including issues on food safety assessment of recombinant-DNA vaccines.

The Task Force was later informed by the Representative of the OIE that as a follow-up to the FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA animals, the OIE would convene an expert meeting, jointly with FAO and WHO, probably in 2008, to consider the issues related to the animals with non-heritable recombinant-DNA constructs including recombinant-DNA vaccines.

The Task Force, having completed its work (one year ahead its schedule) was dissolved by the 31st Session of the Commission (ALINORM 08/31/REP para. 214).

D. Codex Committee on Food Import and Export Inspection and Certification Systems

The 16th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (29-30 November 2007), completed its work on Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003. The Appendix, adopted by the 31st session of the Commission, provides guidance to assist exporting and importing countries in undertaking an equivalence determination of sanitary measure and clarifies certain aspect of the Guidelines.

The Committee also forwarded to the 31st Session of the Commission for approval two project documents for new work on the development of: i) Guidelines for the Conduct of Foreign Audit Team Inspections; and ii) Generic Model Health Certificate as an Annex to the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001). It further agreed to revise the discussion papers on the Need for Guidance for National Food Inspection Systems and Guidance on Traceability/ Product Tracing for consideration at its next session.

A report on OIE activities relevant to the work of the Committee will be included in document CX/FICS 08/17/3.

E. Codex Task Force on Antimicrobial Resistance

The Task Force was established by the 29th Session of the Commission (2006) in order to develop science based guidance, taking full account of Codex risk analysis principles and the work and standards of other relevant international Organizations, such as FAO, WHO and OIE. The intent of this guidance is to assess the risks to human health associated with the presence in food and feed including aquaculture and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes and to develop appropriate risk management advice based on that assessment to reduce such risk.

The 2nd Session of the Task Force (Seoul, Republic of Korea, 20-24 October 2008), will start working on the elaboration of three texts (listed below) on the basis of the reports of three working groups and comments from Codex members and observers.

i) Science-based Risk Assessment Guidance Regarding Foodborne Antimicrobial Resistant Microorganisms;

ii) Risk Management Guidance to Contain Food-borne Antimicrobial Resistant Microorganisms; and

iii) Guidance on Creating Risk Profiles for Antimicrobial Resistant Food-borne Microorganisms for Setting Risk Assessment and Management Priorities.

The Task Force will also be updated on recent work done and/or being done by FAO, WHO and OIE on antimicrobial resistance (CX/AMR 08/2/3).

F. Codex Committee on Food Hygiene

The 40th Session of the CCFH (Guatemala 1-5 December 2008) will consider at Step 4 the following texts:

i) Commodity-Specific Annexes to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003); and

ii) Code of Hygienic Practice for *Vibrio* Species in Seafood.

The proposed draft Code of Hygienic Practice for Fresh Fruits and Vegetables is being prepared by a working group led by the United States of America.

The proposed draft Code of Hygienic Practice for *Vibrio* Species in Seafood, elaborated by a working group led by Japan, has already been circulated for government comments. This Code covers seafood, including finfish and shellfish that are marketed in a live, raw, undercooked and cooked state. The target microbiological hazards of this Code are pathogenic *V. parahaemolyticus*, *V. vulnificus* and choleragenic *V. cholerae.* This Code is intended for seafood and is applicable throughout the food chain, from primary production through consumption. Based on the results of FAO/WHO risk assessment, as well as other available risk assessments and epidemiological evaluations, this Code will focus on control measures that can be used, where appropriate, to minimise and/or prevent the contamination and/or the growth of pathogenic *Vibrio* spp. in seafood. This Code highlights the key control measures that influence the frequency and extent of contamination with pathogenic *Vibrio* spp. and thus the risk of foodborne diseases caused by these pathogens. In many instances, these control measures are articulated in a general manner in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) as part of the general strategy for the control of foodborne pathogens in all foods. In providing this Code, it is assumed that these *General Principles of Food Hygiene* are being implemented. The proposed draft Code is available from: ftp://ftp.fao.org/codex/ccfh40/fh4003ae.pdf

The OIE will present a document (CX/FH 08/40/3-Add.1) to the Committee describing its activities relevant to the work of the CCFH.

G. Codex Committee on Milk and Milk Products

The 8th Session of the Committee (4-8 February 2008) completed, among others, its work on the Model Export Certificate for Milk and Milk Products, adopted by the 31st Session of the Commission.

The 9th Session of the Committee (New Zealand, February 2010) will continue its discussion on drinks based on fermented milk and on processed cheese. It is expected that, after this session, the Committee will be adjourned *sine die*.

H. Codex Committee on Residues of Veterinary Drugs in Foods

The 31st Session of the Commission decided to return the new work proposal on the elaboration of Risk Management Recommendations for Veterinary Drugs without ADI and/or MRLs due to Specific Health Concern, proposed by the 17th session of the Codex Committee on Residues of Veterinary Drugs in Foods, back to the Committee for further consideration (ALINORM 08/31/REP para. 93). The Commission took this decision in noting a proposal from the Delegation of United States of America to revise the project document to broaden the scope of new work on risk management decisions to also include substances for which no ADI/MRL were set because the information needed to evaluate human health concerns was lacking.

In addition the Commission, after an extensive discussion, agreed to hold the MRLs for ractopamine at Step 8 for further discussion at its 32nd Session. It requested Members to submit relevant information on the availability of scientific data to the 18th Session of the Committee on Residues of Veterinary Drugs in Foods (May 2009) thus allowing for a decision by the Committee regarding the inclusion of ractopamine in the priority list of substances for re-evaluation by JECFA. The Commission further agreed that at its 32nd Session, it would decide on the adoption of the MRLs for ractopamine based on the report of the 18th Session of the Committee on Residues of Veterinary Drugs in Foods (ALINORM 08/31/REP para. 58).

The 18th Session of the Committee will be held in Brazil on 11-15 May 2009. The Committee will consider: the recommendations of the 70th Meeting of JECFA (October 2008); report of OIE activities including VICH; Draft Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals; and the reports of the electronic working groups on: (i) Methods of Analysis for Residues of Veterinary Drugs in Foods; (ii) Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation; and (iii) Risk Management Topics and Options. The Committee will also consider the proposal to revise the project document to broaden the scope of new work on risk management decisions to also include substances for which no ADI/MRL were set because the information needed to evaluate human health concerns was lacking.

I. Codex Task Force on Animal Feeding

The 31st Session of the Commission discussed new work on animal feeding and agreed to postpone decision of possible new work on animal feeding until its 32nd Session. In order to facilitate discussion and decision at its 32nd Session, the Commission agreed to establish an electronic working group, hosted by Denmark and co-chaired by Mexico, to prepare: (i) proposal for the scope and terms of reference of future work on animal feeding. In doing so the working group should take into consideration the conclusions and recommendations of the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety; and (ii) a proposal as to suitable mechanisms for Codex to carry out this work, including, but not limited to, the establishment of an *Ad hoc* Intergovernmental Task Force (ALINORM 08/31/REP paras 177-178).

J. Other Future Meetings

Codex Alimentarius Commission, 32nd Session, Rome (Italy) 29 June – 4 July 2009

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Annex E

RECENT WHO INITIATIVES/ACTIVITIES ON FOOD SAFETY

Department of Food safety, Zoonoses and Foodborne Diseases (FOS)

Foodborne disease burden estimations

Foodborne diseases threaten international public health security and economic development. As trade, travel and migration increase, so does the spread of dangerous pathogens and contaminants in food across borders. Diarrhoeal diseases alone - a considerable proportion of which is foodborne - kill 1.9 million children globally every year, but the true full burden of foodborne diseases is clearly larger and results from a variety of diseases arising from both microbiological and chemical contamination. The heaviest share of the human as well as animal burden occurs in poor countries and jeopardizes international development efforts, including the achievement of the Millennium Development Goals (particularly those relating to poverty and child mortality).

The full extent of the burden and cost of unsafe food, however, is currently unknown. Although several initiatives are under way in the area of enteric diseases, no consistent global information has ever been assembled to describe the full spectrum of foodborne diseases.

WHO therefore launched the Initiative to Estimate the Global Burden of Foodborne Diseases from all major causes (of microbiological, parasitic and chemical origin) which operates through the *Foodborne Disease Burden Epidemiology Reference Group (FERG)*. The FERG - which is a multi-sectoral and multi-disciplinary group - took up its work in November 2007. In addition to eminent international academics, the FERG includes UN sister organizations (FAO, OIE, UNEP, IARC, among others) and operates through Task Forces working in the area of enteric, parasitic and chemical foodborne diseases. One Task Force is dedicated to assisting countries to conduct national burden of disease studies to complete the burden picture.

While FERG is focusing on the human burden of foodborne diseases, it will be using and describing the animal burden data particularly in parasitic diseases of livestock origin. The FERG will provide the very first global burden of foodborne diseases assessment using traditional epidemiology as well as summary measures of population health (DALYs) by 2011.This report will form the much-needed basis for the evaluation of prevention, control and intervention efforts in foodborne diseases at country level.

Antimicrobial resistance

Joint WHO, FAO and OIE activities on non-human use of antimicrobials and antimicrobial resistance continue. The second session of the Codex Task Force on Antimicrobial Resistance took place 20-24 October 2008 in Seoul, Korea. Good progress was achieved, with the main outstanding issue still remaining the a definition of relevant management options

FOS will establish a WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR). This multidisciplinary group of experts (medical doctors, veterinarians, food safety specialists) will provide guidance to WHO on a framework that promotes surveillance integrating antimicrobial resistance data from enteric/zoonotic bacteria isolated from animal, food and human sources. In addition to selected experts representatives from FAO and OIE are invited to take part in AGISAR's activities.

The Global Alliance for Patient Safety has established acoalition of WHO internal and external partners to address antimicrobial resistance, as the topic of its third Global Patient Safety Challenge. An international working group consisting of experts in various areas (surveillance, drug regulation, animal husbandry, research and development of new drugs, vaccines, infection control) will develop guidance for addressing the driving forces of antimicrobial resistance. The launch of the third Global Patient Safety challenge is scheduled in 2010.

Annex XXXIX (contd)

Annex E (contd)

Training and education in food safety - Global Salm-Surv

Food safety is the assurance that food will not cause harm to the consumer when it is prepared and/or eaten. The provision of this assurance covers an incredibly complex area of work and responsibilities. It involves multiple sectors of government, including Ministries of Health, Agriculture and Trade, and requires the involvement of multiple professional disciplines and a broad array of stakeholders.

An effective food safety system, national and international, requires the sharing of information and expertise in order to face the global nature of modern food safety issues. An increasingly important role for food safety systems is the delivery of information, education and advice to stakeholders across the farm-to-consumption continuum.

WHO Global Salm-Surv is a global capacity-building network of institutions and individuals working in veterinary, food and public health disciplines committed to enhancing capacity of countries to detect, respond and prevent foodborne and other enteric infectious diseases. WHO Global Salm-Surv promotes integrated, laboratory-based surveillance and fosters inter-sectoral collaboration among human health, veterinary, and food-related disciplines, through international training courses, workshops, projects and external quality assurance.

To date, WHO Global Salm-Surv has conducted 55 international training courses in Chinese, English, French, Portuguese, Spanish, and Russian for more than 1000 microbiologists and epidemiologists from over 120 countries around the world.

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Annex F

WORK PROGRAMME FOR 2008/09

The Working Group discussed issues that had been identified at its previous meeting and that still needed to be addressed at some stage. The following issues for 2008/2009 were agreed:

1. Horizontal issues

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

      – Animal Identification and Traceability Conference 2009 – issues arising

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

   c) Good farming practices – await the reaction to the publication of the *Guide to Farming Practices*, developments in CAC (CCRVDF and possible new work on animal feed), and FAO (guidelines in specific farming production systems in developing countries with a focus on biosecurity matters).

   d) Draft *Terrestrial Code* Chapter X.X. The control of hazards of animal health and public health importance in animal feed - addressing the food safety issues and complementing the existing Codex international standards – underway through the Terrestrial Code Commission.

      Follow developments within this area including FAO work.

   e) Petfood - be kept informed of developments within this area and review text for any relevant food safety issues.

   f) Food safety implications of aquatic animal feed – review text produced by an OIE *ad hoc* Group, taking into account relevant FAO work (Fisheries Department).

   g) Biotechnology – animals and animal products derived from biotechnological interventions – review text on potential food safety implications of biotechnology vaccines when this work is undertaken.

   h) Revision of OIE Handbook on Import Risk Analysis – review draft text.

2. Disease-specific OIE texts

   a) Chapters of the OIE *Terrestrial Animal Health Code* on brucellosis. A further *ad hoc* Group meeting is to be held in 2009.

   b) Foodborne zoonoses

      – salmonellosis in poultry – ongoing development of *Terrestrial Code* chapters covering eggs and broilers.

      – campylobacteriosis in broilers – taking into account progress in Codex

      – OIE develop a discussion paper on identifying the priority pathogens for standard setting activities in the animal production food safety area (including E.coli O157:H7, parasites such as *Taenia solium*, *Trichinella spiralis*, and parasites in fish).

Annex XXXIX (contd)

Annex F (contd)

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

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

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

Annex XL

Original: English
February 2009

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON SALMONELLOSIS

Paris, 3-5 February 2009

The OIE *ad hoc* Group on Salmonellosis (hereinafter referred to as the *ad hoc* Group) met at the OIE Headquarters from 3 to 5 February 2009.

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

On behalf of the Director General of the OIE, Dr Sarah Kahn, Head of the OIE International Trade Department, welcomed the group. Dr Kahn noted that many countries are interested in the work of the *ad hoc* Group and a very large number of Members have submitted comments. She emphasised the significance of the work of the *ad hoc* Group in relation to food safety and the importance of coordinating this work with that of other international organisations, notably the Codex Alimentarius Commission (CAC). She advised that the results of the *ad hoc* Group's work will be considered by the OIE Terrestrial Animal Health Standards Commission (hereinafter referred to as the Code Commission) at its meeting in the first week of March 2009, when the review of the draft chapter on salmonellosis chapter will be one of the Code Commission's priorities. Dr Kahn noted the large number of comments for the *ad hoc* Group to consider and indicated that the review of comments on Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production should only be done if time allows. Dr Kahn noted that one expert, Dr Daranai Viboolpong from Thailand, had been unable to attend but would be invited to provide comments on the text immediately after the meeting.

In regard to possible future work priorities, Dr Kahn reported that, on the recommendation of the Animal Production Food Safety Working Group (APFSWG), the OIE will prepare a discussion paper on the priority pathogens for standard setting activities in the animal production food safety area. Members of this *ad hoc* Group will be consulted in the development of this paper.

Dr Ignacio Sánchez Esteban then took over as Chair of the meeting, welcomed members of the *ad hoc* Group and noted the high workload for the meeting given the large number of Members' comments that had been received.

Dr Vallat joined the *ad hoc* Group on the third day of the meeting and thanked the members for their ongoing support of the work of the OIE. Dr Vallat noted this was an important topic for the OIE and that OIE Members, in commenting on the draft chapter, had raised animal health, trade and public health issues. Dr Vallat appreciated Dr Esteban's recommendation that a further meeting would be needed to complete the review of Members' comments on Chapter 6.3. due to the large volume and complexity of Members' comments received. Dr Vallat reported that OIE work on salmonella and other zoonotic pathogens had been discussed at the Tripartite meeting (OIE/World Health Organisation/UN Food and Agriculture Organization) held at the OIE on 3-4 February 2009. Discussions at the tripartite meeting had touched upon the respective roles of the OIE and the CAC for the on farm and subsequent stages of the food production chain and the need for close collaboration in standard setting, as well as the possibility in future of establishing common OIE/Codex standards. The objective of the OIE is to be the leader in setting standards for on farm prevention and control methods.

1. Update on OIE / Codex activities

OIE activities. Dr Gillian Mylrea, Chargée de Mission in the OIE International Trade Department, provided an update on relevant work of the Code Commission meetings held in March and October 2008 and the APFSWG meeting held in November 2008.

The Code Commission at its October 2008 meeting reviewed some of the Members' comments received on the draft Chapter on the Detection, Control and Prevention of *Salmonella* in Poultry (circulated with the March 2008 report) and amended the chapter and distributed it for a second round of Member's comment (circulated with the October 2008 report). As some comments were of a highly technical nature the Code Commission forwarded these to the *ad hoc* Group for consideration and also requested that the *ad hoc* Group review any Members' comments received in January 2009 on the amended draft chapter that had been circulated at the end of 2008.

At the October 2008 meeting of the Code Commission, time did not allow for the review of Members' comments received on the draft Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production. Therefore, these comments were forwarded to the *ad hoc* Group for review.

The APFSWG met in November 2008 and reviewed the draft chapter on the Detection, Control and Prevention of *Salmonella* in Poultry and proposed some amendments to the text. The APFSWG undertook to review any further text and requested to be kept informed of progress on work on *Salmonella*. It also recommended that the OIE continue to collaborate with the Codex Committee on Food Hygiene, particularly in regard to the Codex work on food safety aspects of salmonellosis and campylobacteriosis.

Codex activities. The OIE was represented at the 40th session of the Codex Committee on Food Hygiene (in Guatemala, December 2008) by Dr Luis Barcos, Regional Representative for the Americas. The proposed Codex draft guidelines for the control of *Campylobacter* and *Salmonella* spp. in chicken meat were prepared by a working group led by New Zealand and Sweden. At this meeting, the delegation of Brazil, supported by several other delegations, highlighted the importance of the work of the OIE on the control of *Salmonella* in primary production, and the importance of harmonization between the work of Codex and of OIE in this domain. The next meeting of the Codex working group will be held in late 2009 in Brazil.

2. Item 2. Draft Guidelines on the Detection, Control and Prevention of *Salmonella* in Poultry

The *ad hoc* Group reviewed the reports of the Code Commission and the APFSWG. Comments were received from Argentina, Australia, Canada, Chile, Chinese Taipei, CIRSA (the Inter-American Committee on Avian Health), the European Union, Guatemala, Japan, Mexico, New Zealand, OIRSA (the Regional International Organization for Plant Protection and Animal Health. Member Countries: México, Belize, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panamá, Dominican Republic), South Africa and the United States of America. The *ad hoc* Group appreciated the depth and quality of Members' comments and reviewed these comments and amended the text accordingly (refer to Annex III).

The *ad hoc* Group considered that the use of the word poultry, as in the revised draft chapter, was appropriate to the scope of the chapter, as the recommendations are relevant to all species of poultry and to most sectors. It was agreed that the recommendation for more work to be done in relation to certain species and sectors (see report of *ad hoc* Group meeting 4-7 February 2008 included in the March 2008 report of the Code Commission) was not entirely warranted and that with the review of the text, the recommendations were in fact generally applicable to the common domestically raised poultry. In view of Members' comments calling for the adoption of harmonised definitions in the *Terrestrial Code*, the *ad hoc* Group agreed that the definition for poultry that appears in Chapter 10.4 Avian Influenza and 10.13 Newcastle Disease of the *Terrestrial Code* was appropriate to the draft chapter on salmonellosis. The *ad hoc* Group also recommended that the Code Commission consider including this definition in the Glossary of the *Terrestrial Code*.

The *ad hoc* Group considered comments from several Members as to whether to limit the text to address only *S.* Typhimurium and/or *S.* Enteritidis or whether to include all *Salmonella* serotypes. The *ad hoc* Group recommended that the chapter include all *Salmonella* serotypes because *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries. The *ad hoc* Group noted that references to *Salmonella* in the text are inclusive of S.E and S.T. and introduced this clarification into the text

The *ad hoc* Group recommended the deletion of the proposed definition for 'non-typhoid' *Salmonella* as this referred to *Salmonella* infections in humans (*S.* Typhi and *S.* Paratyphi). The *ad hoc* Group recommended against the use of the term 'non-typhoid' in the chapter as it is unnecessary and confusing.

Several Members submitted extensive comments of a general nature. These were thoroughly considered by the *ad hoc* Group and, where appropriate, specific amendments were made in the text of the draft chapter. The *ad hoc* Group encountered difficulties where Members submitted comments and proposed text changes without providing a rationale for such amendments. Also, in some cases, Members made recommendations that were contradictory.

Several Members submitted proposed amendments that related to the draft Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production. The *ad hoc* Group recommended that an additional reference to Chapter 6.3. be included in Article X.X.5.

The *ad hoc* Group considered comments from several Members on definitions and recommended amendments to some definitions for clarification and the deletion of some that were redundant.

The *ad hoc* Group considered comments from several Members regarding sample sizes and details of sampling methods (Article X.X.4.). Opposing views were expressed by Members as to whether to specify the number, amount and frequency of sampling. The *ad hoc* Group decided that it was more appropriate to simplify the text and make it less prescriptive and that detailed methodology should be placed in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereinafter referred to as the *Terrestrial Manual*).

The *ad hoc* Group recommended that the applicable chapter in the *Terrestrial Manual* be updated to include details on sampling methodology for *Salmonella* prevention and control.

The *ad hoc* Group considered comments from several Members regarding the scope and clarity of Articles X.X.5. and X.X.6. The *ad hoc* Group recommended rewording the titles of the two articles to more accurately reflect their contents.

The *ad hoc* Group noted that several Members made proposals that were country specific. The *ad hoc* Group believed that the Chapter should be relevant to all OIE Members and should contain recommendations for minimum standards that were broadly applicable by OIE Members.

The *ad hoc* Group noted that all the points in Article X.X.7. were covered elsewhere in the chapter and therefore recommended that this Article be deleted.

The amended text is also provided as clean text in Annex IV.

3. Item 3. Draft Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production

Unfortunately the *ad hoc* Group did not have time to review Members' comments but made a preliminary evaluation to assess the scope of work needed to address them.

The *ad hoc* Group noted a large number of Members' comments related to Articles 6.3.6. and 6.3.7. The *ad hoc* Group reviewed these comments and recommended deleting details on the use of disinfectants in these articles. The reasons for this decision were as follows: i) products available are constantly changing as new products are being developed and therefore to mention any specific products will make the document incomplete and outdated over time; ii) some products that had been used historically are now considered to be dangerous (e.g. formaldehyde, a carcinogen) and potential problems with other products are being investigated; iii) preferences in the choice of disinfectants varies between countries and there is a danger of this chapter becoming too prescriptive and inappropriate for some Members.

Therefore, the *ad hoc* Group recommended that these articles only include general hygiene principles and that, if Members sought more detailed information, consideration be given to including such information in the *Terrestrial Manual*.

The *ad hoc* Group requested that the Terrestrial Code Commission consider these recommendations.

4. Item 4. New work

The *ad hoc* Group recommended that proposed new work on the prevention and control of *Salmonella* in eggs and live birds in markets be included in the future review of Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production, as recommendations would be applicable to other pathogens, in addition to *Salmonella*.

The *ad hoc* Group noted that their suggestions for new work (Item 4.2.) had been addressed in the amended chapter on Prevention, Detection and Control of *Salmonella* in Poultry, with the exception of livestock species.

Members of the *ad hoc* Group undertook to contribute, if possible, to the OIE discussion paper on the priority pathogens for standard setting activities in the animal production food safety area.

.../Annexes

MEETING OF THE OIE *AD HOC* GROUP ON SALMONELLOSIS

Paris, 3-5 February 2009

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Annex II

MEETING OF THE OIE *AD HOC* GROUP ON SALMONELLOSIS

Paris, 3-5 February 2009

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Adopted Agenda

Welcome from the Director General

Adoption of the Agenda

1. Update on OIE / Codex activities

1.1. Terrestrial Animal Health Standards Commission (TAHSC) - March and October 2008 meetings.

1.2. Animal Production Food Safety Working Group (APFSWG) - November 2008 meeting.

1.3. Codex Alimentarius - CX/FH 08/40/6 Proposed Draft Guidelines for Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat at Step 3.

2. Detection, Control and Prevention of Non-Typhoid Salmonella spp. in Poultry (new chapter)

Consider comments made by OIE Members, TAHSC and APFSWG. Revise the draft chapter.

3. Hygiene and Biosecurity Procedures in Poultry Production (Chapter 6.3.)

3.1. Review this chapter's content and format in light of OIE Members' comments.

3.2. In particular, review Articles 6.3.6. (Sanitation of hatching eggs and hatchery equipment) and 6.3.7. (Fumigation procedures at the hatchery).

4. New Work – proposals to be discussed

4.1. Prevention and control of Salmonellosis in markets (eggs and live birds) – TAHSC proposal, March 2008 meeting.

4.2. The Salmonellosis *ad hoc* Group (2008 meeting) recommended consideration of the following issues: *Salmonella* in livestock species, meat of spent hens, meat of other avian species (turkeys, ducks, ratites), and duck eggs for human consumption.

5. Any other business

Annex XL (contd)

Annex III

CHAPTER X.X.

~~GUIDELINES ON~~ ~~THE~~ PREVENTION, DETECTION AND~~,~~ CONTROL ~~AND PREVENTION~~ OF ~~NON-TYPHOID~~ *SALMONELLA* ~~SPP.~~ IN POULTRY ~~POULTRY~~ ~~CHICKENS~~

Article X.X.1.

Introduction

~~The aim of the *Code* is to assist Members in the management and control of significant animal diseases, including diseases with zoonotic potential, and in developing animal health measures applicable to trade in terrestrial animals and their products.~~ ~~These guidelines~~ This Chapter provides recommendations on the prevention, detection~~,~~ and control ~~and prevention~~ of ~~*non-typhoid*~~ *Salmonella* ~~spp.~~ in *poultry*. ~~poultry~~ ~~chickens (*Gallus gallus domesticus*) used for the production of *meat* and eggs for human consumption~~.

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

Salmonellosis is one of the most common foodborne bacterial *diseases* in the world. ~~It is estimated that over 90%~~ The great majority of *Salmonella infections* in humans are foodborne with *Salmonella* Enteritidis ~~Phage Type 4 (PT4)~~ and *Salmonella* Typhimurium ~~serotypes~~ accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably~~e~~ between localities, districts, regions and countries~~.~~ and therefore, *surveillance* and identification of the prevalent *Salmonella* serotypes in humans and *poultry* should be carried out in order to develop a control programme for the area.

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

~~In the development and implementation of programmes to achieve control of *S.* Enteritidis PT4 and *S.* Typhimurium, an improvement in *flock* status for other *Salmonella* serotypes can be expected.~~

Article X.X.2.

Purpose and scope

~~These guidelines~~ This Chapter deals with methods for on farm prevention, detection~~,~~ and control ~~and prevention~~ of *Salmonella* ~~spp.~~ in *poultry* ~~poultry~~ ~~chickens~~, and ~~. These guidelines~~ complements the Codex Alimentarius Code of Hygiene Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 Revision 2007). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in reducing ~~minimizing~~ the presence of foodborne pathogens in ~~producing~~ eggs and *meat* ~~that are safe to eat~~.

Annex XL (contd)

Annex III (contd)

All hHygiene and biosecurity procedures to be implemented in *poultry* poultry chicken *flocks* and hatcheries are described in Chapter 6.3. on Hygiene and Biosecurity Procedures in Poultry Production.

The scope covers breeding flocks, chickens and other domesticated birds used for the production of eggs and *meat* for human consumption. The recommendations presented in these guidelines this Chapter are relevant to the control of all *non typhoid* *Salmonella* spp. with special attention to *S.* Enteritidis PT4 and *S.* Typhimurium serotypes, as these are common *Salmonella* serotypes problems in many countries. It should be noted that the definition of the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Ssalmonella*osis.

Article X.X.3.

Definitions (for this chapter only)

Breeders

means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing day-old chicks.

Broilers

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

Broken/leaker egg

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

Competitive exclusion

means the administration of defined or undefined bacterial flora to *poultry* to poultry to to or the administration of substrates which allow for the proliferation of beneficial bacteria and which prevent gut colonisation by enteropathogens, including *non typhoid* *Salmonella*.

Cracked egg

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

Culling

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

Dirty egg

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

Layers or laying flock

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

Non typhoid Salmonella

means those serotypes of *Salmonella enterica* for which the reservoir hosts are domestic and wild animals, as opposed to the serotypes *S.* Typhi and *S.* Paratyphi which cause typhoid fever in humans, which are the reservoir host.

Peak of lay

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

~~*Poultry*~~

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

Poultry

means all domesticated birds, including backyard poultry, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

~~*Pullet flock*~~

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

Article X.X.4.

Surveillance of *poultry* ~~poultry~~ ~~chicken~~ flocks for *Salmonella* ~~spp~~ ~~serotype~~

Where justified by *risk assessment*, *surveillance* should be carried out ~~performed~~ to identify infected *flocks* in order to take measures that will reduce the prevalence in *poultry* ~~poultry~~ ~~chickens~~ and the risk of transmission of *Salmonella* ~~spp.~~ ~~serotypes~~ to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broilers ~~s~~ *flocks* and higher specificity in *breeders* and *layer~~s~~* *flocks*. In the framework of regulatory programmes for the control of ~~*Salmonella* spp.~~ *Salmonella* in *poultry* and salmonellosis in humans, confirmatory testing may be required ~~appropriate~~ to ensure that decisions are soundly based.

~~Results of from *surveillance* may lead to the implementation of will allow control measures to be implemented to reduce the risk of transmission of *Salmonella* spp. serotypes to humans:~~

~~a) In breeders, control measures may be taken implemented to will minimise prevent the transmission of *Salmonella* spp. serotypes to the next generation.~~

~~b) In *layer flocks* control measures will reduce or eliminate *Salmonella* spp. contamination of eggs for human consumption with *Salmonella* serotypes.~~

~~c) In *broilers*, this control measures, such as logistic *slaughter* and channelling, may will permit measures to be taken implemented at *slaughter* and or further down the food chain (logistic slaughter and channelling).~~

Sampling

1. Available methods for sampling

   Drag swabs: sampling is done by dragging swabs throughout ~~around~~ the *poultry* building ~~to collect samples of 10-25 g and to include faeces, and moist and dry litter~~.

Annex XL (contd)

Annex III (contd)

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

Faecal samples: multiple ~~samples of~~ fresh faecal~~es~~/caecal samples collected from different areas in the *poultry* building.

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

Hatchery samples: throughout the hatchery, including the inner liner of the incubators.

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

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

Refer to the *Terrestrial Manual*.

~~Recommendation is five pairs of boot swabs or 10 drag swabs. These swabs may be pooled into no less than two samples with each pool containing 10-25 g of material.~~

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

~~**Table I**~~

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

3. Laboratory methods

Refer to the *Terrestrial Manual*.

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

Time~~,~~ and frequency ~~and type~~ of sampl~~e~~ing for each *poultry* type ~~poultry~~ ~~category~~ are listed below~~:~~ ~~are based on *risk assessment* and production methods~~:

a) *Breeders* and hatcheries

i) *Breeder ~~pullet~~ flock*s before lay

- Before ~~At~~ the end of the first week of life~~.~~ when the status of the breeding farm and the hatchery is not known or does not comply with this Chapter.
- Within the four weeks before being moved to another house, or before going into production if the animals will remain in the same house for the production period.
- One or more times during the growing period if there is a *culling* policy in place. The frequency would be determined on commercial considerations.

ii) *Breeder~~ing~~ flocks* in lay

- At least at monthly intervals during the laying period.
- Additional testing ~~The minimal frequency~~ should ~~would~~ be determined by the *Veterinary Services*.

iii) Hatcheries

- Testing ~~in~~ hatcheries may complement~~s~~ on farm testing.
- The minimal frequency should ~~would~~ be determined by the *Veterinary Services*.

b) Poultry ~~Poultry~~ ~~Chickens~~ for the production of eggs for human consumption

i) *Flocks* grown to be *layers* ~~*Layer pullet flocks*~~

- Before ~~At~~ the end of the first week of life when the status of the breeding farm and the hatchery is not known or does not comply with ~~these guidelines~~ this Chapter.
- Within the four weeks before being moved to another house, or before going into production if the animals will remain in the same house for the production period.
- One or more times during the growing period if there is a *culling* policy in place. The frequency would be determined on commercial considerations.

ii) *Layer ~~or laying~~ flocks*

- At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).

Annex XL (contd)

Annex III (contd)

- One or more times if there is a *culling* policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should ~~would~~ be determined by the *Veterinary Services*.

c) Poultry for the production of *meat*~~Broilers~~

i) *Flocks* should be sampled at least once. ~~On farms where there is a long period (2 weeks or more) between thinning and final depopulation further testing should be considered.~~

ii) Where sampling occurs on farms and where there is a long period (2 weeks or more) between thinning and final depopulation further testing should be considered.

iii) Where sampling occurs on farms, ~~F~~*flocks* should be sampled as late as possible before the first birds are transported to the *slaughterhouse*. Where this is done to allow for the implementation of control measures during processing, ~~However,~~ this must be done at a time that ensures the results are available before slaughter.

Whether sampling occurs on the farm or at the processing plant, there should be an integrated system in place which allows for investigation of the source of positive flocks.

d) Empty building testing

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

~~ii)~~ As appropriate, s~~S~~ampling of equipment and surfaces as well as boot swabs or drag swabs of the empty building after depopulation, cleaning and *disinfection*.

Results from *surveillance* may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of *Salmonella* to humans:

a) In *breeders*, control measures may be implemented to reduce the transmission of *Salmonella* to the next generation, especially for trans-ovarian transmitted serotypes such as *S.* Enteriditis.

b) In *layer flocks* control measures will reduce and may eliminate contamination of eggs with *Salmonella*.

c) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article X.X.5.

Prevention and Control measures

Salmonella prevention and control ~~can~~ may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective *Salmonella* control.

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

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

1. Day old chicks used to stock a *poultry* house should be obtained from breeding *flocks* and hatcheries that are ~~certified as~~ free from at least *S.* Enteritidis ~~PT4~~ and *S.* Typhimurium and have been monitored according to ~~these guidelines~~ this Chapter.

2. *Layer* ~~or~~ ~~and *laying flocks*~~ ~~or~~ and *breeder flocks* should be stocked from ~~*pullet* *flocks*~~ that are ~~certified as~~ free from at least *S.* Enteritidis ~~PT4~~ and *S.* Typhimurium and have been monitored according to ~~these guidelines~~ this Chapter.

3. Feed ~~may be~~ contamination ~~contaminated~~ with *Salmonella* is known to be a source of *infection* for *poultry* ~~poultry chickens~~. Therefore, it is recommended to monitor the *Salmonella* status of *poultry* ~~poultry~~ ~~chicken~~ feed, and if found positive to take corrective measures. The use of ~~pelletised~~ heat treated feeds or feeds subjected to other bacteriostatic or bactericidal treatment (e.g. organic acids) is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

4. *Competitive exclusion* ~~can~~ may be used in day old chicks to reduce colonisation by *Salmonella* ~~spp~~ ~~serotypes~~.

   When used, *competitive exclusion* should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

5. ~~As far as *vaccination* is concerned, many v~~Vaccines are used against *Salmonella infections* caused by different ~~serovars~~ serotypes in various *poultry* ~~poultry~~ ~~chicken~~ species, including single or combined vaccines ~~against *S.* Enteritidis and *S.* Typhimurium~~. Vaccines produced according to the *Terrestrial Manual* should be used.

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

   Vaccination can be used as part of an overall *Salmonella* control programme. ~~Vaccination should never be used as the sole~~ control ~~measure.~~ It is recommended that vaccination not be used as the sole control measure.

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

Annex XL (contd)

Annex III (contd)

Vaccination against the *Salmonella* serotypes known to be significant should be considered when moving day-old chicks to a previously contaminated shed so as to minimisze the risk of the birds contracting *Salmonella infection* ~~with *S.* Enteritidis and *S.* Typhimurium~~.

When used, vaccinesation should be administered ~~performed~~ according to the instructions provided by the manufacturer and in accordance with the ~~instructions~~ standards and recommendations of the *Veterinary Services*.

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

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

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

7. *S.* Enteritidis is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *Salmonella* Enteritidis from egg-producing flocks through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent *flocks* through *breeder flocks* to *layer flocks*.

~~7.~~ 8. As far as the veterinary involvement is concerned, the responsible veterinarian should monitor the results of *surveillance* testing for *Salmonella* ~~spp~~. This information should be available to the veterinarian before marketing if a veterinary certificate for *flock Salmonella* status is required ~~prior to~~ ~~in order to certify the flock for~~ ~~the *flock* for *slaughter*~~. When required by the *Competent Authority*, ~~This~~ the veterinarian or other authorised person should notify the ~~*Veterinary*~~ *Competent Authority* if the presence of *Salmonella* ~~spp.~~ of the relevant serotypes is confirmed.

Article X.X.6.

Prevention of *Salmonella* spread from infected flocks

If a *flock* is found infected with ~~*non-typhoid*~~ specific *Salmonella* ~~spp.,~~ serotypes of concern, the following actions should be taken in addition to general measures detailed in ~~the~~ Chapter 6.3. ~~on~~ Hygiene and Biosecurity Procedures in Poultry Production:

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

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

3. Litter should not be reused. Poultry ~~Poultry~~ ~~Chicken~~ litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the ~~spread of infections with~~ direct or indirect exposure of humans, livestock and wildlife to ~~with~~ *Salmonella* ~~spp.~~ Particular care needs to be taken in regard to *poultry* ~~poultry~~ ~~chicken~~ litter/faeces used to fertilise plants intended for human consumption. If litter is not removed then it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.

4. Particular care should be taken in cleaning and *disinfection* of the *poultry* house and equipment.

~~4~~5. Before restocking the facility, a bacteriological examination should be carried out as detailed in ~~these guidelines~~ this Chapter and the *Terrestrial Manual*.

~~Article X.X.7.~~

~~**Special considerations for broiler flocks**~~

~~1. The grow-out phase of broiler production is short and therefore it is important to emphasize the *Salmonella* status of the source *flock*.~~

~~2. Broilers are susceptible to colonisation with *non-typhoid Salmonella* spp. because of high level exposure they are young and are grown at the high stocking rates at which they are kept and because they are immunologically naive.~~

~~3. To reduce *Salmonella* spp. contamination in the abattoir it is helpful to reduce the amount of feed in the bird's gut at the time of *slaughter*. Feed transits the gut in about four hours; therefore, it is recommended to withdraw feed to the birds at an appropriate period before *slaughter* (8-10 hours).~~

~~4. Slaughter processing should be conducted in accordance with Chapter 6.2.~~

– Text deleted

CHAPTER X.X.

PREVENTION, DETECTION AND CONTROL OF *SALMONELLA* IN POULTRY

Article X.X.1.

Introduction

This Chapter provides recommendations on the prevention, detection and control of *Salmonella* in *poultry*.

Salmonellosis is one of the most common foodborne bacterial *diseases* in the world. The great majority of *Salmonella infections* in humans are foodborne with *Salmonella* Enteritidis and *Salmonella* Typhimurium accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries and therefore, *surveillance* and identification of the prevalent *Salmonella* serotypes in humans and *poultry* should be carried out in order to develop a control programme for the area.

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

Article X.X.2.

Purpose and scope

This Chapter deals with methods for on farm prevention, detection and control of *Salmonella* in *poultry*, and complements the Codex Alimentarius Code of Hygiene Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976 Revision 2007). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in reducing the presence of foodborne pathogens in eggs and *meat*.

Hygiene and biosecurity procedures to be implemented in *poultry flocks* and hatcheries are described in Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production.

The recommendations presented in this Chapter are relevant to the control of all *Salmonella* with special attention to *S*. Enteritidis and *S*. Typhimurium, as these are common *Salmonella* serotypes in many countries. It should be noted that the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Salmonella*.

Article X.X.3.

Definitions (for this chapter only)

Breeders

means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing day-old chicks.

Annex XL (contd)

Annex IV (contd)

Competitive exclusion

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

Culling

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

Layers

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

Poultry

means all domesticated birds, including backyard poultry, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

Article X.X.4.

Surveillance of *poultry* flocks for *Salmonella*

Where justified by *risk assessment*, *surveillance* should be carried out to identify infected *flocks* in order to take measures that will reduce the prevalence in *poultry* and the risk of transmission of *Salmonella* to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broiler *flocks* and higher specificity in *breeders* and *layer flocks*. In the framework of regulatory programmes for the control of *Salmonella* in *poultry* and salmonellosis in humans, confirmatory testing may be required to ensure that decisions are soundly based.

Sampling

1. Available methods for sampling

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

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

Faecal samples: multiple fresh faecal/caecal samples collected from different areas in the *poultry* building.

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

Hatchery samples: throughout the hatchery, including the inner liner of the incubators.

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

2. Sample size

Refer to the *Terrestrial Manual*.

3. Laboratory methods

Refer to the *Terrestrial Manual*.

4. Time and frequency of testing

Time and frequency of sampling for each *poultry* type are listed below:

a) *Breeders* and hatcheries

i) *Breeder flocks* before lay

- Before the end of the first week of life when the status of the breeding farm and the hatchery is not known or does not comply with this Chapter.
- Within the four weeks before being moved to another house, or before going into production if the animals will remain in the same house for the production period.
- One or more times during the growing period if there is a *culling* policy in place. The frequency would be determined on commercial considerations.

ii) *Breeder flocks* in lay

- At least at monthly intervals during the laying period.
- Additional testing should be determined by the *Veterinary Services*.

iii) Hatcheries

- Testing hatcheries may complement on farm testing.
- The minimal frequency should be determined by the *Veterinary Services*.

b) Poultry for the production of eggs for human consumption

i) *Flocks* grown to be *layers*

- Before the end of the first week of life when the status of the breeding farm and the hatchery is not known or does not comply with this Chapter.
- Within the four weeks before being moved to another house, or before going into production if the animals will remain in the same house for the production period.

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

ii) *Layer flocks*

- At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).

- One or more times if there is a *culling* policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should be determined by the *Veterinary Services*.

c) Poultry for the production of *meat*

i) *Flocks* should be sampled at least once.

ii) Where sampling occurs on farms and where there is a long period (2 weeks or more) between thinning and final depopulation further testing should be considered.

iii) Where sampling occurs on farms, *flocks* should be sampled as late as possible before the first birds are transported to the slaughter house. Where this is done to allow for the implementation of control measures during processing, this must be done at a time that ensures the results are available before slaughter.

Whether sampling occurs on the farm or at the processing plant, there should be an integrated system in place which allows for investigation of the source of positive flocks.

d) Empty building testing

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

As appropriate, sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty building after depopulation, cleaning and *disinfection*.

Results from *surveillance* may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of *Salmonella* to humans:

a) In *breeders*, control measures may be implemented to reduce the transmission of *Salmonella* to the next generation, especially for trans-ovarian transmitted serotypes such as *S*. Enteriditis.

b) In *layer flocks* control measures will reduce and may eliminate contamination of eggs with *Salmonella*.

c) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article X.X.5.

Prevention and Control measures

Salmonella prevention and control be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective *Salmonella* control.

Additional prevention and control measures include: vaccination, *competitive exclusion*, *flock culling*, organic acids and product diversion to processing.

Antimicrobials should not be used to control *infection* with *Salmonella* in *poultry* because the effectiveness of the treatment is limited, may mask the infection at sampling, has the potential to produce residues in *meat* and eggs and can contribute to the development of antimicrobial resistance. Antimicrobials may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella.* In special circumstances antimicrobials may be used to salvage animals with high genetic value.

1. Day old chicks used to stock a *poultry* house should be obtained from breeding *flocks* and hatcheries that are free from at least *S*. Enteritidis and *S*. Typhimurium and have been monitored according to this Chapter.

2. *Layer* and *breeder flocks* should be stocked from *flocks* that are free from at least *S*. Enteritidis and *S*. Typhimurium and have been monitored according to this Chapter.

3. Feed contamination with *Salmonella* is known to be a source of *infection* for *poultry*. Therefore, it is recommended to monitor the *Salmonella* status of *poultry* feed, and if found positive to take corrective measures. The use of heat treated feeds or feeds subjected to other bacteriostatic or bactericidal treatment (e.g. organic acids) is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

4. *Competitive exclusion* may be used in day old chicks to reduce colonisation by *Salmonella.*

   When used, *competitive exclusion* should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services.*

5. Vaccines are used against *Salmonella infections* caused by different serotypes in various *poultry* species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

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

Vaccination can be used as part of an overall *Salmonella* control programme. It is recommended that vaccination not be used as the sole control measure.

When the status of the breeding farm and the hatchery from which the *flock* originates is not known or does not comply with this Chapter, vaccination of *flocks*, starting with day-old chicks, against the *Salmonella* serotypes known to be significant should be considered.

Vaccination against the *Salmonella* serotypes known to be significant should be considered when moving day-old chicks to a previously contaminated shed so as to minimise the risk of the birds contracting *Salmonella infection*.

When used, vaccines should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

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

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

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

7. *S.* Enteritidis is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *Salmonella* Enteritidis from egg-producing flocks through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent *flocks* through *breeder flocks* to *layer flocks*.

8. As far as the veterinary involvement is concerned, the responsible veterinarian should monitor the results of *surveillance* testing for *Salmonella*. This information should be available to the veterinarian before marketing if a veterinary certificate for *flock Salmonella* status is required. When required by the *Competent Authority*, the veterinarian or other authorised person should notify the *Competent Authority* if the presence of *Salmonella* of the relevant serotype is confirmed.

Article X.X.6.

Prevention of *Salmonella* spread from infected flocks

If a *flock* is found infected with specific *Salmonella* serotypes of concern, the following actions should be taken in addition to general measures detailed in Chapter 6.3. Hygiene and Biosecurity Procedures in Poultry Production:

1. According to the epidemiological situation, investigations should be carried out to determine the origin of the *infection*.

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

3. Litter should not be reused. Poultry litter/faeces and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and wildlife to *Salmonella.* Particular care needs to be taken in regard to *poultry* litter/faeces used to fertilise plants intended for human consumption. If litter is not removed then it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.

4. Particular care should be taken in cleaning and *disinfection* of the *poultry* house and equipment.

5. Before restocking the facility, a bacteriological examination should be carried out as detailed in this Chapter and the *Terrestrial Manual.*

Annex XLI

Original: English
December 2008

REPORT OF THE SECOND MEETING OF THE OIE *AD HOC* GROUP ON LABORATORY ANIMAL WELFARE

Paris, 8-10 December 2008

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The OIE *ad hoc* Group on Laboratory Animal Welfare (hereinafter referred to as the *ad hoc* Group) met at the OIE Headquarters from 8 to 10 December 2008.

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

Agenda Item 1

On behalf of Dr Vallat, Director General of the OIE, the President of the Terrestrial Animal Health Standards Commission, Dr Alex Thiermann, welcomed all members and thanked them for continuing to work with the OIE on this important topic and highlighted the experience of the Members of the Group in this field which have allowed it to develop a first draft set of recommendations in the laboratory animal welfare field. Dr Thiermann also explained to the Group the OIE procedure for adoption of standards and expressed the willingness of the OIE to have a draft text to send for Members comments after the Terrestrial Animal Health Standards Commission (the Code Commission) meeting in March 2009.

An extract from the report of the seventh meeting of the AWWG is presented in Appendix III.

Agenda Item 2

Dr Bayvel opened the discussion with some comments on the first Report of the ad hoc Group. He noted that the role of the International Cooperation and Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) programme continues to be seen as important in the international coordination of moves to replace animals in regulatory testing, where and when validated non animal tests are available. This role specifically refers to harmonising regulatory requirements within the VICH regions to minimise the use of laboratory animals and cost of product development.

After the successful initial meeting with Dr Patrick Dehaumont on behalf of VICH and Drs Kahn, Stuardo and Bayvel in December 2007, it was agreed that a formal follow up letter will be drafted to be sent to VICH by Dr Vallat. This letter will canvass opportunities and initiatives for the OIE and VICH to cooperate closely in this important area. Consideration will be given to a similar approach to ICH. An opportunity was also seen to include this important area in the programme for the Seventh World Congress on Alternatives and Animal Use in the Life Sciences, to be held in Rome in August, 2009. An approach to the Conference organisers will be made by Dr MacArthur Clark

Annex XLI (contd)

Dr Demers provided an update on his recent activities in relation to the ICLAS revision of the 1985 CIOMS Guiding Principles for Biomedical Research Involving Animals.

Following his participation in the Council for International Organizations of Medical Sciences (CIOMS) Executive Committee meeting and in the 74th CIOMS General Assembly, held in Geneva in December 2007, ICLAS submitted in February 2008, a formal proposal to the CIOMS Executive Committee members to revise the CIOMS Guidelines. In April 2008, the ICLAS proposal was accepted. The revision process was initiated during the fourth meeting of the ICLAS Working Group on Harmonization of Guidelines, held in November 2008 before the AALAS meeting in Indianapolis, USA. In January 2009, a joint CIOMS-ICLAS *ad hoc* committee (6-8 members maximum) with international expertise will be convened. ICLAS will be using its annual participation in different scientific meetings to discuss this topic with several Scientific Organizations to assure an open and wide revision process.

A first face to face meeting will be held in 2009, in Geneva. ICLAS has already identified some sponsorship from American institutions. ICLAS will be also seeking sponsorship from European and international scientific organizations. The process of reviewing CIOMS guidelines normally takes 2-3 years.

Agenda Item 3

The *ad hoc* Group discussed the working documents and identified some additional inputs, as follows:

Dr MacArthur Clark and Dr Joubert summarized the situation regarding the proposed revision of the Directive 86/609/EEC, which was published on 5th November 2008. The declared objectives are to improve the welfare of research animals throughout the European Union. They exp lained that this proposition will go through a co-decision process involving the European Parliament and the European Council leading to its adoption.

The proposed Directive aims to promote and develop alternative approaches (National reference laboratory, sharing of data, etc.). Additionally, there are a number of proposals causing significant concern including those relating to the use of primates, and the limited time before all primates used in the EU must be F2 purpose bred.

Dr MacArthur Clark informed that, during 2008, IACLAM has carried out a demographic survey through its member colleges – the American, European, Japanese and Korean Colleges of Laboratory Animal Medicine. Of the total 1,007 Diplomates registered as College members, 847 (84%) are active in the field and 441 of those (52%) responded to the survey questionnaire. This included Diplomates from all four Colleges who were active in 23 different countries. Over 30 areas of active sub-specialism were identified, as well as an overwhelming willingness of Diplomates to be consulted in their specialist areas.

A review of employment showed that only 25% of Diplomates were primarily employed in industry, the remainder being employed in academia (at 49%, the largest sector), Government service (12%), Non-profit sector roles (6%), independent consulting (5%), with the remaining 3% in other categories.

The analysis also showed a significant number of respondents (59%) planning to work at least ten more years in the field. Also that the majority of Diplomates (70%) possess qualifications in addition to those in veterinary and laboratory animal medicine. Primarily these were Masters (42%) and Doctoral (29%) degrees, with a small number of MBAs (1.3%), legal and medical qualifications (both less than 1%).

It was also discussed in the meeting that the problem of airlines refusing to carry laboratory animals was increasing. This was largely due to pressure from animal rights activists. For most airlines, the volume of cargo traffic accounts for less than 10% of total revenue, the remainder being largely passenger generated revenue. The size of the animal cargo business is only a small proportion of total cargo and is, thus, insufficient to encourage airline management to resist animal rights pressure. The damaging effect on research, especially in relation to transport of primates from their breeding colonies to their country of intended use, is very significant. In addition, some sea freight companies, and those responsible for handling and importation through airports and docks, were also being targeted and now refusing to handle laboratory animal shipments.

The problem of international transportation was a key topic at the ILAR Conference in Washington DC in September 2008. The group agreed that the problems were sufficiently important to merit OIE taking a position. The group would prepare a strategic proposal in consultation with others such as Dr William White of Charles River USA. Dr Bayne agreed to contact him.

Dr. Bayne provided a status report on actions being taken to update the Guide for the Care and Use of Laboratory Animals (NRC 1996). The goal of the update is to reflect new scientific information related to the issues already covered in the Guide, and to add discussion and guidance on new topics of laboratory animal care and use related to state-of-the-art animal research programmes. The committee will review the scientific literature published since the release of the 1996 Guide and determine whether the information in the Guide concurs with current scientific evidence. The committee will also review the literature pertaining to new technologies in the field of laboratory animal care and use and determine where new guidance is necessary to ensure the best scientific outcomes and optimal animal welfare. It is estimated that the project will take 2 years. Thus far, the committee has held three open forums for public comment and has had their first meeting. Written comments will be accepted until end of January 2009. The fourteen member committee includes two Canadians and two Europeans.

Agenda Item 4

The *ad hoc* Group reviewed the draft text: '**OIE Guidelines on Research Animal Welfare**' to be presented for consideration by the Code Commission at its March 2009 meeting. The AHG agreed to change the title of the proposed standard to: **The Use of Animals in Research, Testing or Teaching".**

The draft text, including proposed definitions, is at Appendix V.

Agenda Item 5

The *ad hoc* Group also confirmed the following three priority areas for future OIE attention:

- **Veterinary Training in Laboratory Animal Medicine**
- **Laboratory Animal Transport**
- **Regulatory Testing and the adoption of alternatives**

Strategies to follow in regard to these priority areas should be developed by the *ad hoc* Group for consideration by the Code Commission. The *ad hoc* Group will also address the other issues identified in its Terms of Reference, as part of its future work programme.

Agenda Item 6

The *ad hoc* Group discussed and agreed on further work needed to complete the meeting report (see Appendix VI).

Agenda Item 7

The *ad hoc* Group developed a proposed future work programme (see Appendix VI).

Annex XLI (contd)

Next Meeting

It is proposed that a third meeting take place from 4-6 August 2009.

Meeting with the Director General

Dr Vallat participated in the *ad hoc* Group meeting on the morning of Wednesday 10 December.

Dr Bayvel welcomed Dr Vallat and sumarised the work conducted by the AHG on the previous two days of the meeting. Dr Bayvel congratulated Dr Vallat for his Penn/Vet award received this year, and also mentioned some important events such as the successful second OIE Global Animal Welfare Conference and the completion of the OIE Technical Series publication on animal pain and pain management.

Dr Vallat thanked the members of the AHG and apologized for not being at the first day of the meeting because of other commitments. Dr Vallat emphasised the importance of the work conducted by this AHG not only because of the animal welfare implications but also for the future of animal and public health research.

Dr Vallat also noted that the future standards in this field could be an important starting point for OIE Members without any laboratory animal welfare legislation. He also invited the AHG Members to promote the discussion of the proposed standards on their regions to receive as much comment as possible.

Finally, Dr Vallat noted that one of the important issues to work on for this AHG should be the transport of laboratory animals, which involved significant political and commercial issues. It is necessary to develop and adopt internationally accepted standards with all the involved parties on this important and crucial activity. . This work could also involve important collaboration with IATA with which the OIE now has an official cooperation agreement.

The Members of the AHG thanked the OIE for the opportunity to work with the OIE in this important field of animal welfare and updated Dr Vallat on the work of the ISO TC 194, the ICLAS – CIOMS joint work and the IACLAM study to be published next year.

.../Appendices

Annex XLI (contd)

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON LABORATORY ANIMAL WELFARE
Paris, 8–10 December 2008

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Appendix I (contd)

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2nd MEETING OF THE OIE AD HOC GROUP ON LABORATORY ANIMAL WELFARE

Paris, 8-10 December 2008

Adopted Agenda

1. Welcome and introduction – Dr Alejandro Thiermann
2. Comments from Chair of AHG on the Report of the First Meeting of the OIE ad hoc Group on Laboratory Animal Welfare
3. Discussion of working documents and other relevant documents provided by the ad hoc Group Members
    a) Directive 86/609 EC Revision
    b) Guidelines on the Use of Wild Birds in Research
4. Review of OIE Members' comments on the Draft annex; OIE Guidelines on Research Animal Welfare
5. Discussion on the future work of the AHG:
    a) Veterinary Training in Laboratory Animal Medicine
    b) Air transport of laboratory animals
    c) Regulatory Testing and the adoption of alternatives to animal use
6. Other Business
    a) RSPCA doc.
7. Review and finalise report of meeting
8. Programme for further work after this meeting

Annex XLI (contd)

Appendix III

Original: English
June 2008

EXTRACT FROM THE REPORT OF THE SEVENTH MEETING OF THE OIE WORKING GROUP ON ANIMAL WELFARE

5. Report of the *ad hoc* Group on Laboratory Animal Welfare

5.1. First draft report

Dr Bayvel summarised the findings of the *ad hoc* Group, noting that their work was based on the terms of reference presented in the "issues and options" paper.

Dr Gavinelli commented that this is a sensitive topic in the EU and that it is important for the OIE to produce clear and positive communication regarding this new set of guidelines. The OIE guidelines should in particular become a useful tool in this area for less developed countries where there is little support for introducing welfare standards.

Dr Bayvel confirmed that and it was seen as more useful for developing countries to use the term Animal Care and Use Committees as opposed to Animal Ethic Committees. There was some debate about whether a statistician should be included in committees. This had been debated in the *ad hoc* Group but was not seen as feasible for all countries.

Dr Beaumond suggested that there should still be consistency in the animal welfare guidelines regardless of whether animals were used in livestock production or in laboratory situations.

5.2. Next steps

The AWWG commended the report of the *ad hoc* Group and will review the report of the second meeting of this *ad hoc* Group, with the intention of securing a prompt finalisation of the work.

Annex XLI (contd)

Appendix IV

TERMS OF REFERENCE

OIE *AD-HOC* GROUP ON LABORATORY ANIMAL WELFARE

1. To review and provide specific advice on recommendations in Issues and Options paper

2. To advise on Guiding Principles for the OIE in the development of standards on laboratory animal welfare and to make recommendations on future priorities and strategies

3. To advise strategies for supporting OIE Members

4. To make recommendations on how the OIE can strengthen linkages with key international stakeholders in the field of laboratory animal science

CHAPTER 7.X.

USE OF ANIMALS IN RESEARCH, TESTING OR TEACHING

Preamble

The purpose of this Chapter is to provide standards for OIE Members to follow when formulating regulatory requirements for the use of live animals in research, testing or teaching[23]. It is the responsibility of all scientists using animals to ensure that they give due regard to these standards in designing and implementing their research protocols.

The OIE recognises the vital role played by the use of live animals in research. The OIE Guiding Principles state that such use makes a major contribution to the wellbeing of people and animals and emphasise the importance of the Three Rs of Russell and Burch (1959). Most scientists and members of the public agree that the use of animals in science should cause as little pain and/or distress to animals as possible, and those animals should only be used when necessary. The OIE also recognises the need for humane treatment of sentient animals and that good quality science depends upon good animal welfare. In keeping with the overall approach to animal welfare, as detailed in the Guiding Principles, the OIE emphasises the importance of standards based on outcomes for the animal.

A system of animal research 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 these standards 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 central role of veterinarians in animal-based research. Given their unique training and skills, they are an essential member of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of animals has an ethical responsibility for the animals' welfare. The approach also ensures that animal use in science leads to high quality scientific outcomes and optimum welfare for the animals used.

Article 7.X.X.

Definitions

Animal Care and Use Committee (ACUC)

means a committee responsible for overseeing the care and use of animals within an institution, including ethical considerations. It is also sometimes called Animal Care Committee, Animal Ethics Committee, Ethical Review Committee or Institutional Animal Care and Use Committee.

[23] Wherever the term "research" is used, it means "research, testing or teaching".

Annex XLI (contd)

Annex V (contd)

Project Proposal

or protocol, means a written description of a study or experiment,, programme of work, or other activities that includes the goals, characterises the use of the animals, and includes ethical considerations. The purpose of the *Project Proposal* is to enable assessment of the quality and integrity of the study, work or activity.

Operant (Instrumental) conditioning

means the association that an animal makes between a particular response (such as pressing a bar) and a particular reinforcement (for example, a food reward). 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).

Biological safety or biosafety

means the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards.

Biological containment or biocontainment

means the system and procedures designed to prevent the accidental release of biological material. The objective of biocontainment is to confine biohazards and to reduce the potential exposure of the laboratory worker, animals on other studies, persons outside of the laboratory, and the environment to potentially infectious agents.

Bioexclusion

means the prevention of the unintentional transfer of pathogenic organisms and subsequent infection of animals by human, vermin or other means.

Humane endpoint

means the point at which an experimental animal's pain and/or distress is terminated, minimized or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure or humanely killing the animal.

Genetically altered animal (GA animal)

means an animal that has had a random or targeted change in its nuclear or mitochondrial DNA achieved through a deliberate human technological intervention.

Harm-benefit analysis

means the process of weighing the likely adverse effects (harms) on the animals against the benefits likely to accrue as a result of the proposed project. The analysis should require more than just establishing that the benefit is likely to exceed the harms. The benefits should be maximised and the harms, in terms of animal use and suffering, should be minimised.

The Three Rs

means the internationally accepted philosophy of Russell and Burch (1959) for the use of animals in research. The Three Rs comprise:

- **replacement** which refers to methods which do not require the use of animals to achieve the scientific aims;
- **reduction** which refers to methods that enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals;
- **refinement** which refers to methods that prevent, alleviate or minimise known and potential pain, distress, discomfort or lasting harm and/or enhance animal welfare for the animals used; or which replace higher animals with those of lower neurophysiological sensitivity which have less capacity to experience pain, distress, discomfort or lasting harm.

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 species-typical behaviours and reduce the expression of aberrant behaviours, as well as provide cognitive stimulation.

Article 7.X.X.

Scope

These standards apply to animals as defined in the Terrestrial Animal Health Code (the *Terrestrial Code*) (excluding bees) bred, supplied and/or used in research, testing or teaching. Animals to be 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.

Article 7.X.X.

The Oversight Framework

The role of *Competent Authorities* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of approval (such as licensing or registering of institutions, scientists, and/or projects) and compliance may be assessed at the institutional, regional and/or national level.

The framework for compliance should comprise three key elements:

1. Project Proposal Review,
2. Facility Inspections; and
3. Animal Care and Use Programme (ACUP) Review.

Different systems of oversight may involve animal welfare officers, regional/local committees, or national bodies. One common system is for each institution using live animals for research to have an Animal Care and Use Committee (ACUC) that is responsible, at the institutional level, for ensuring compliance with applicable requirements regarding the use of live animals as well as cells, tissues and organs derived from live animals. It is important that an ACUC should report to a senior individual within the institution to ensure the committee has an appropriate level of authority and support. An ACUC should undertake periodic review of its own policies, procedures and performance.

In providing this oversight, the following expertise should be included, as a minimum:

- one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;

- 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 the animals.

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 may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted.

It may be appropriate to involve representatives of the community (general public) or, in teaching institutions, a student representative. This increases public confidence in the oversight process.

1. Project Proposal Review

Project Proposals should be reviewed and approved prior to commencement of the research and should include a description of the following elements:

a) the scientific aims;

b) the experimental design, including statistics where appropriate;

c) the experimental procedures;

d) methods of handling and restraint and consideration of alternatives such as animal training and operant conditioning;

e) the application of the Three Rs;

f) the methods to avoid or minimise pain, discomfort, distress or lasting impairment of physical or physiologic function,, including the use of anaesthesia and/or analgesia;

g) application of humane endpoints and the final disposition of animals, including methods of euthanasia;

h) consideration of the husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;

i) consideration of the relevance of the experiment to human or anima health or the advancement of biologic knowledge;

j) an assessment for any occupational health and safety risks; and

k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, qualified staff).

The provision of a non-technical (lay) summary may enhance understanding of the 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 oversight method to ensure that animal activities conform with those described in the approved project proposal.

2. Facility inspection

There should be regular inspections of the facilities. These inspections should include the following elements:

- the animals and their records, including cage labels;
- husbandry practices
- maintenance and cleanliness and security of the facility;
- type and condition of caging and other equipment;
- environmental conditions;
- occupational health and safety concerns.

Principles of risk-management should be followed when determining the frequency and nature of inspections.

3. Animal Care and Use Programme (ACUP) Review

Critical elements of the Animal Care and Use Programme (ACUP) should be included in relevant regulations to empower the government authority to take appropriate action to ensure compliance. The ACUP should be reviewed regularly to include the following:

- training and competency of all staff;
- the programme of veterinary care;
- husbandry and operational conditions;
- sourcing and final disposition of animals; and
- occupational health and safety programme;

Annex XLI (contd)

Annex V (contd)

A requirement for keeping records on animal use, as appropriate to the institution, project proposal and species, should be included. It may be appropriate to maintain such records on a regional or national basis and to provide some degree of public access without compromising personnel or animal safety, or releasing proprietary information.

Article 7.X.X.

Assurance of Training and Competency

An essential component of the ACUP is the assurance that the personnel working with the animals are appropriately trained and qualified to work with the species used and the procedures to be performed. A system (institutional, regional or national) to assure competency should be in place. Continuing professional and paraprofessional education opportunities should be made available to relevant staff.

a) Scientists. 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, institutional policies and ethical considerations. The laboratory animal veterinarian is often a resource for this and other training. Competency in performance of procedures related to the scientist's research (e.g., surgery, anaesthesia, sampling and administration, etc.) should be verified.

b) Veterinarians. It is important that veterinarians working in an animal research environment have veterinary medical knowledge and experience in the species used and they should understand research methodology. Relevant approvals issued by the *Veterinary statutory body* and appropriate national schemes (where these exist) should be adopted as the reference for veterinary training.

c) Animal Care Staff. Animal care staff should receive training that is consistent with the scope of their work responsibilities and their competency in the performance of these tasks should be verified.

d) Students. Wherever possible, students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc). Wherever it is necessary for students to participate in classroom or research activities involving animals, they should receive appropriate supervision in the use of animals until such time that they have demonstrated competency in the related procedure(s).

Article 7.X.X.

Provision of Veterinary Care

Adequate veterinary care includes responsibility for promoting and monitoring an animal's welfare before, during and after research. Veterinary care includes attention to the physical and behavioural status of the animal. The veterinarian must have the authority and responsibility for making judgements concerning animal welfare.

a) 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 must 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. The veterinarian has the responsibility to ensure that controlled drugs prescribed by the veterinary staff are managed in accordance with applicable regulations.

b) Veterinary Medical Records. Medical records are considered to be a key element of a programme of adequate veterinary care for animals used in research, teaching, and testing. Application of performance standards within the medical record program allows the veterinarian to effectively employ professional judgment, ensuring that the animal receives the highest level of care available.

c) Advice on zoonotic risks and notifiable diseases. The use of some species of 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 minimize these risks and to advise on measures that may be taken in the animal facility to minimize the risk of transmission (e.g., personal protective equipment, air pressure differentials in animal holding rooms, etc.). Animals brought into the institution may carry diseases that require notification to government officials. It is important that the veterinarian be aware of, and complies with these requirements.

d) 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 monitoring, and providing recommendations concerning, preoperative procedures, aseptic surgical techniques, the qualifications of institutional staff to perform surgery and the provision of postoperative care.

e) Advice on analgesia and anaesthesia. Adequate veterinary care includes providing guidance to animal users and monitoring animal use to ensure that appropriate methods of handling and restraint are being used as well as the proper use of anaesthetics, analgesics, tranquilizers, and methods of euthanasia for all species.

f) Advice on humane endpoints and euthanasia. Endpoints are established for both experimental and humane reasons. An experimental endpoint is chosen to mark the planned end of an experimental manipulation and associated data gathering. In experiments with unrelieved or unanticipated pain/or distress, humane endpoints are criteria that indicate or predict pain, distress, or death and are used as signals to end a study early to avoid or terminate pain and/or distress. Ideal endpoints are those that can be used to end a study before the onset of pain and/or distress without jeopardizing the study's objectives. However, in most cases, humane endpoints are developed and used to reduce the severity and duration of pain and/or distress.

The veterinarian and the ACUC where applicable, have a key role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the veterinarian have the responsibility and authority to ensure euthanasia is 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.

Article 7.X.X.

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 dedicated to, or assigned 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.

Article 7.X.X.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

a) 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 scientifically justified or the only available source. The use of non purpose bred animals, including farm animals, non-traditional breeds and species, and animals captured in the wild, is sometimes necessary to achieve study goals.

b) Documentation. Relevant documentation related to the source of the animals, including health and other certification, breeding records, genetic status and animal identification, should accompany the animals.

c) 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.

d) 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 must be validated by periodic genetic monitoring, typically using biochemical or immunological markers. Detailed and accurate documentation of the colony breeding records must be maintained

e) Genetically altered animals. If genetically altered animals are used, such use should be conducted in accordance with relevant regulatory guidance. Consideration should be given to addressing special husbandry and welfare needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic information, and individual identification, and be communicated by the animal provider to the recipient.

f) Animals captured in the wild. If wild animals are to be used, the capture technique should be humane and give due regard to human and animal health and safety. Endangered species should only be used in exceptional circumstances where there is strong scientific justification which cannot be achieved with any other species.

g) 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 relevant documentation accompanies animals during transport to avoid unnecessary delays during the *journey* from the sender to the receiving institution.

h) Biosecurity risks. To reduce biosecurity risks related to animals, the pathogen status of animals should be confirmed and appropriate biocontainment and bioexclusion measures should be practised. Biosecurity risks to animals arising from exposure to humans should also be addressed.

Article 7.X.X.

Husbandry

High standards of care and accommodation enhance the health and welfare of the animals used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant, published national or international animal care, accommodation and husbandry guidelines.

a) 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 animal transportation, the species involved, place of origin, and the intended use of the animals.

b) Normal Behaviour. The housing environment and husbandry practices should take into consideration the normal behaviour of the species and age of the animal and minimise stress to the animal.

Annex XLI (contd)

Annex V (contd)

c) Enrichment. Animals should be housed with a goal of maximising species-specific behaviours and minimising stress-induced behaviours. One way to achieve this is to enrich the structural and social environment of the research animals and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the animals or people, nor significantly interfere with the scientific goals.

Article 7.X.X.

Occupational Health and Safety

Institutional occupational health and safety programmes should be developed and implemented to protect personnel from workplace hazards. National or state legislation requires employers to provide a safe working environment for staff. In addition to national or state legislative requirements, particular precautions need to be in place for those involved in the care and use of animals. These measures should extend to animal users, animal care staff, students, and others who may be exposed to animals or animal by products.

Occupational health and safety training for animal related risks should be provided as part of the assurance of training and competency for personnel. Specific training may be required for particular species, and for specific procedures/studies involving animals.

a) Infectious diseases. To protect personnel, all infectious diseases or potentially infectious diseases within the institution, including zoonoses, should be identified.

i) Biological Hazards

Hazards can arise from pathogens that are endemic to the particular animals as well as from pathogens (bacteria, viruses, parasites, fungi, prions) that have been brought into an institution for research purposes. National or state regulations or guidelines for working with biological hazards (biohazards) must be followed. These should include requirements for biocontainment, laboratory design, personal hygiene and safety. Any biozardous materials should be labelled as such. Necropsy of animals with highly infectious agents should be carried out in certified biological safety cabinets. Animals, animal waste and carcasses should be disposed of appropriately, depending on the pathogenicity of the organisms to which they have been exposed. Material contaminated with highly infectious agents should be decontaminated before disposal.

ii) Zoonoses

The institutional veterinarian(s) should be able to provide input to the occupational health and safety program concerning any zoonoses (infections that are secondarily transmitted from animals to humans) that might be contracted from the species used by the institution. He/she should also be able to provide advice on the measures needed to protect those involved with the animals. These may include personal protective equipment, vaccination, special restrictions for vulnerable employees (e.g., pregnant women). In general, the closer phylogenetically a species is to humans, the greater the likelihood of zoonoses.

Particular precautions should be taken when working with non-human primates

b) Allergies

Individuals exposed to laboratory animals run a risk of developing allergies. Protective measures should be in place for personnel who may be exposed to animal allergens. These should include:

Environmental control and air handling systems to control air flow and contain allergens in the areas where the animals are housed and/or used;

Personal protective equipment such as masks, gloves and clothing dedicated to animal rooms;

Equipment such as filtered bedding disposal units and ventilated hoods for carrying out procedures;

Use of filtered transfer cages when transporting animals.

c) Physical injuries

Injuries that can be incurred as a result of handling animals include: bites, scratches, or being kicked, stepped on or crushed by larger species. These injuries can be minimized by ensuring that all personnel are: competent to handle the animals; aware of the particular hazards associated with each species; familiar with the hazards of the experiment; are provided with a proper working area and protective clothing; and have access to and use the appropriate restraining equipment or drugs. A mechanism should be in place to deal with animal inflicted injury, including referral for further medical treatment. Cuts, bites, scratches or needle punctures acquired while working with non-human primates require particular attention and should be reported to the medical authority designated by the institution.

Other physical injuries can occur as a result of working in a laboratory animal facility (e.g. burns, injuries from lifting animals or heavy equipment, repetitive strain injuries). These should be minimized through the implementation of an occupational health and safety programme, which examines the workplace hazards and ensures that adequate safeguards are in place for personnel.

d) Chemical injuries

There are potentially hazardous materials involved in most animal-based studies. These include drugs; cleaning agents and chemical compounds used for research studies. All hazardous substances must be labelled appropriately. The relevant national or state authority should provide licences to veterinarians or scientists requiring access to drugs for animal based studies. Licence holders are thereby responsible and liable for the use of substances purchased by them. Drugs must be handled, stored and used according to the requirements of national or state legislation.

Material Safety Data Sheets should be made available to personnel who are likely to come into contact with hazardous materials. Personnel should also be trained to use hazardous materials safely.

e) Radiation

Where radioactive materials are to be used, the national authority responsible for nuclear safety should be informed. National authorities should require personnel to obtain a licence and should impose restrictions on the use of radioisotopes. A radiation safety officer should be designated within the institution to be responsible for radioactive material use and disposal. Strict measures should be in place to limit and contain radioactive contamination, including appropriate signage and limiting access to rooms containing radioactive material. Strict measures should also be in place to protect personnel working with radioactive animals, and staff in the vicinity, from exposure to the animals, animal wastes and carcasses.

Annex XLI (contd)

Annex V (contd)

Article 7.X.X.

Post Approval Monitoring

The institution should ensure that a culture of compliance exists within the animal care and use programme. Key to that compliance is assuring that studies are conducted in accordance with the written description in the project proposals that has been approved by the oversight body (animal care and use committee, government agency, etc.). The focus of post approval monitoring is to determine what happens to the animals after approval of the work has been granted and the study is underway. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry procedures; observations made by the veterinary medical staff during their rounds; or by inspections by an animal care and use committee, animal welfare officer, compliance/quality assurance officer or government inspector

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Annex XLI (contd)

Appendix VI

PLAN TO COMPLETE THE SECOND REPORT OF THE *AD HOC* GROUP ON LABORATORY ANIMAL WELFARE

(December 2008 -February 2009)

Topic	Deadline	Who	Specific Actions
1. Draft report	09/01/09	Central Bureau	To revise draft report
2. Draft report	16/01/09	*ad hoc* Group Members	Members to return the draft report with comments
3. Final report	28/01/09	Central Bureau	OIE to send final report to *ad hoc* Group Members
4. Final report	03/02/09	*ad hoc* Group Members	
5. Final report	10/02/09	Central Bureau	To circulate final report to the AWWG for comment
6. Final report	03/03/09	Central Bureau	To include final report on the Code Commission agenda

Annex XLI (contd)

Appendix VII

AD HOC GROUP ON LABORATORY ANIMALS WELFARE WORK PROGRAMME

General issue	Priorities of *Ad hoc* Group	Implementation /Responsibility	Status
Ad hoc Group report	To finalise the ad hoc Group report	*ad hoc* Group Members	
Ad hoc Group report	To finalise the proposed strategic priorities	*ad hoc* Group Members	
Ad hoc Group report	To complete the work on items identified in the Terms of Reference including the recommendations in the Issues and Options Discussion Paper	*ad hoc* Group Members and Central Bureau	