Annex XXXVII

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December 2009

REPORT OF THE MEETING OF THE

OIE *AD HOC* GROUP ON EVALUATION OF VETERINARY SERVICES

Paris, 11 December 2009

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The OIE *ad hoc* Group on Evaluation of Veterinary Services met at the OIE Headquarters in Paris on 11 December 2009.

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

1. Agenda item 1: Welcome and briefing – Director General

Dr Kahn introduced the objectives of the meeting. Based on the advice of experienced evaluators during the preceding two-day PVS Feedback workshop, some competencies and indicators in OIE PVS Tool with Provisional Indicators (the *PVS Tool*) should be fine tuned. The OIE has undertaken to produce a fifth edition of the *PVS Tool* in 2010 and the *ad hoc* Group is asked to undertake this process of revision.

The status of the indicators remains provisional, reflecting the fact that these are modified over time based on experience with PVS evaluations. The OIE has received 100 requests for PVS evaluations from Members and has conducted 91 evaluations to date. The *PVS Tool* appears to be well accepted, based on the uptake of the PVS procedures and the support of major donors. Some competencies are used all the time and are highly relevant; some less so.

Dr Kahn reminded members of the Group that the legal base for the *PVS Tool* is the *Terrestrial Animal Health Code* (the *Code*) and that new competencies should only be included in the *PVS Tool* where there are relevant standards in the *Code*.

Dr Vallat joined the meeting for a short discussion on the Group's conclusions. He indicated that, based on the PVS Feedback workshop, the most important areas for inclusion of new text or review of existing text in the *PVS Tool* are animal welfare, aquatic animals and management of veterinary services (VS).

Dr Schneider presented the recommendations of the *ad hoc* Group to Dr Vallat as outlined below.

In the short time available for this meeting, the members of the *ad hoc* Group were able to discuss and agree on the work that should be done (as outlined below) and to agree on the text for new competencies on animal welfare and VS management, but not to undertake a full revision of the *PVS Tool*. The focus of the one-day meeting was on the competencies and there was a small amount of discussion on indicators.

It was agreed that the OIE would follow up this discussion by preparing a revised 5th edition of the *PVS Tool* and that the *ad hoc* Group would review by electronic exchange the revised text, which should eventually be provided to the Terrestrial Animal Health Standards Commission for information.

2. Agenda item 2: Recommendations relevant to OIE PVS Experts

The *ad hoc* Group recommended that newly accredited OIE PVS evaluators, having undergone no dedicated training and only having attended the December 2009 OIE PVS Feedback Session, should participate in at least 2 to 3 missions under guidance of an experienced (senior) Team Leader before deployment as Team Leader is considered. In addition, the attention of Team Leaders should be drawn to the requirement [under Section 6.3 of the Standing Rules on OIE PVS No. NS/2009_8] to inform the OIE in the event of team members failing to meet the OIE requirements for rigour and professionalism in the conduct of a PVS evaluation.

The *ad hoc* Group encouraged the OIE to investigate a performance assessment procedure for all OIE PVS Evaluators, in order to safeguard the credibility and general acceptance of the *PVS Tool* and its Evaluation Reports.

In addition, the *ad hoc* Group recommended that further training be provided to PVS certified experts, both in the form of refresher training for experienced evaluators and as training for new experts, particularly for new evaluators that have the knowledge and experience to conduct evaluations of aquatic animal health services.

3. Agenda item 3: Recommendations on new competencies

The *ad hoc* Group endorsed a new draft competency on animal welfare be included in Chapter II Technical Authority and Capability. Animal welfare is (or should be) under the technical authority and capability of VS. However, it was agreed that the evaluation of VS against this competency should be considered judiciously because issues relating directly to food security and human health are normally the highest priorities for developing countries and the primary target for support by donors in the context of investment in VS.

It was agreed to draft a new competency on VS management, including human and financial resource management, to be included in Chapter I. While some aspects relevant to VS management, e.g. coordination (I-6) and funding (I-8), are already addressed, there was general agreement that VS management should be covered in a specific competency. This should be drafted in clear and plain terminology that appropriately reflects the needs of developing countries, taking care to avoid the jargon favoured by some management consultants.

4. Agenda item 4: Recommendations on the Evaluation of Aquatic Animal Health Services

It was agreed that the evaluation of aquatic animal health services is best addressed by developing a modified *PVS Tool* for use in the evaluation of such services. Drs Schneider and Bar-Yaacov drafted a text, based on the recent pilot evaluation of an OIE Member. The International Trade Department will circulate this text to members of the *ad hoc* Group for comment.

Dr Bar-Yaacov recommended that the OIE PVS (Aquatic) Tool be maintained as an electronic document and provided (paper and electronic file) to experts when undertaking missions for the OIE.

5. Agenda item 5: Discussion and recommendations on existing competencies

a) I-4 Technical independence

A possible need to modify this competency was discussed at length. Several experts made the point that scientific advice may be subjected to legitimate non-scientific considerations in the process of developing government policy and that this should not be considered as a gap on the part of VS. However, the text of the competency was not modified because the *ad hoc* Group considered that the wording 'in a manner contrary to the provisions of the OIE (and of the WTO SPS Agreement where applicable)' adequately covered this consideration.

b) I-5 Stability of structures and sustainability of policies

Some experts considered that this competency places too much emphasis on stability in the organisational structure of the VS and that the need for flexibility and modernisation should be covered more explicitly.

c) I-6 Coordination capability of the sectors and institutions of the Veterinary Services

A new sub point should be added under this competency, dealing with the capability of the VS to coordinate with other Ministries and organisations within government.

Coordination with veterinary associations, private veterinarians and farmers should also be dealt with, in a separate sub point.

d) Competencies relating to financial resources [1 – 8 Funding; 1 – 9 Contingency and compensatory funding; and 1 – 10 Capability to invest and develop]

It was agreed that the basic core operations of VS are disease surveillance and rapid response. The capabilities for financial management and budgeting should be addressed in more detail, preferably as part of a new competency dealing with VS Management. In addition to VS funding through national sources, the availability of donor contributions should be addressed as these can be an important source of resources to the VS in some developing countries. It was noted that in many cases and countries VS do not have a mandate for 'investment and development'; the absence of this capacity should not be treated as a significant gap.

e) II-1 Veterinary laboratory diagnosis

The *ad hoc* Group discussed the best way to approach this competency. Should VS be classified at a higher level based on the presence of a veterinary diagnostic laboratory in the national territory? Bearing in mind that small countries with limited numbers of livestock do not need to have their own laboratory, it was agreed that the decision on classification should be based on common sense and experience. If a country is dependant on a laboratory in another country, experts agreed that the arrangements for access to the laboratory (including any relevant official agreements) should be included in the evaluation.

f) II-4 Quarantine and border security

The Group discussed that this competence could be divided into two separate elements.

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g) II-8 Veterinary public health and food safety

The importance of abattoir inspection for disease control and surveillance should be clarified, as this activity is not limited to food safety. The addition of a specific competency in relation to VS controls in slaughtering and processing facilities should be considered. Coordination with other government officials in relation to slaughter and processing facilities should also be addressed.

It was agreed that VS competence in relation to veterinary public health should address not only food borne disease but all zoonoses and should consider disease issues arising at the interface of the human population with domestic and wild animal populations. The OIE is engaged with key international partners in 'One World, One Health' and, depending on developments through 2010, will further consider the implications of this important initiative for the role and competencies of VS.

h) II-9 Veterinary medicines and veterinary biologicals

The chain of command and procedures for the approval and prudent use of veterinary products, in accordance with the *Code* recommendations, should be included in the *PVS Tool*. This competency (or a sub competency) should address the arrangements for the registration of veterinary medical products and control of usage, including import, export, manufacture and GMP, labelling, sale, prescription – only medicines, over the counter medicines, off-label use and the requirements for withdrawal.

i) III-2 Consultation with stakeholders

The veterinary professional associations are important stakeholders and references to them should be included in this competency.

j) IV-6 Traceability

Noting the relevance of traceability for disease surveillance and control, and other purposes, the *ad hoc* Group considered that this competence could be moved to Chapter 2 (Technical Authority and Capability). Furthermore, identification and traceability are distinct functions and may be best dealt with as separate points or sub-points under this competency.

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MEETING OF THE OIE *AD HOC* GROUP ON EVALUATION OF VETERINARY SERVICES

Paris, 11 December 2009

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Annex II

MEETING OF THE OIE *AD HOC* GROUP ON EVALUATION OF VETERINARY SERVICES

Paris, 11 December 2009

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Agenda

1. Welcome and briefing – Director General
2. Recommendations relevant to OIE PVS Experts
3. Recommendations on new competencies
4. Recommendations on the Evaluation of Aquatic Animal Health Services
5. Discussion and recommendations on existing competencies

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Annex III

1. CHAPTER I – HUMAN, PHYSICAL AND FINANCIAL RESOURCES

Institutional and financial sustainability as evidenced by the level of professional/technical physical and financial resources available.

Critical competencies:

Section I-1	Professional and technical staffing of the Veterinary Services
Section I-2	Competencies of veterinarians and veterinary para-professionals
Section I-3	Continuing education
Section I-4	Technical independence
Section I-5	Stability of structures and sustainability of policies
Section I-6	Coordination capability of the Veterinary Services
Section I-7	Physical resources
Section I-8	Operational funding
Section I-9	Emergency funding
Section I-10	Capital investment
Section I-11	Management of resources and operations

Terrestrial Code References:

Points 1-6, 8 and 13 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity / General organisation / Procedures and standards / Human and financial resources.

Article 3.2.2. on Scope.

Points 1 and 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Point 2 of Article 3.2.4. on Evaluation criteria for quality system: “Where the Veterinary Services undergoing evaluation… than on the resource and infrastructural components of the services”.

Article 3.2.5. on Evaluation criteria for human resources.

Points 1-3 of Article 3.2.6. on Evaluation criteria for material resources: Financial / Administrative / Technical.

Points 3 and Sub-point d) of Point 4 of Article 3.2.10. on Performance assessment and audit programmes: Compliance / In-Service training and development programme for staff.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-5 and 9 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Financial management information / Administration details / Laboratory services / Performance assessment and audit programmes.

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Annex III (contd)

I-1 Professional and technical staffing of the Veterinary Services The appropriate staffing of the VS to allow for veterinary and technical functions to be undertaken efficiently and effectively. **A. Veterinary and other professionals (university qualification)**	**Levels of advancement**
	1. The majority of veterinary and other professional positions are not occupied by appropriately qualified personnel.
	2. The majority of veterinary and other professional positions are occupied by appropriately qualified personnel at central and state / provincial levels.
	3. The majority of veterinary and other professional positions are occupied by appropriately qualified personnel at local (field) levels.
	4. There is a systematic approach to defining job descriptions and formal appointment procedures for veterinarians and other professionals.
	5. There are effective management procedures for performance assessment of veterinarians and other professionals.

Terrestrial Code reference(s):

Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.

Points 6 and 13 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.

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Annex III (contd)

B. Veterinary para-professionals and other technical personnel	**Levels of advancement**
	1. The majority of technical positions are not occupied by personnel holding technical qualifications.
	2. The majority of technical positions at central and state / provincial levels are occupied by personnel holding technical qualifications.
	3. The majority of technical positions at local (field) levels are occupied by personnel holding technical qualifications.
	4. The majority of technical positions are effectively supervised on a regular basis.
	5. There are effective management procedures for formal appointment and performance assessment of *veterinary para-professionals.*

Terrestrial Code reference(s):

Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.

Points 6 and 13 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.

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I-2 Competencies of veterinarians and veterinary para-professionals	**Levels of advancement**
The capability of the VS to efficiently carry out their veterinary and technical functions; measured by the qualifications of their personnel in veterinary and technical positions[1].	1. The veterinarians' practices, knowledge and attitudes are of a variable standard that usually allow for elementary clinical and administrative activities of the VS.
A. Professional competencies of veterinarians	2. The veterinarians' practices, knowledge and attitudes are of a uniform standard that usually allow for accurate and appropriate clinical and administrative activities of the VS.
	3. The veterinarians' practices, knowledge and attitudes usually allow undertaking all professional/technical activities of the VS (e.g. epidemiological surveillance, early warning, public health, etc.).
	4. The veterinarians' practices, knowledge and attitudes usually allow undertaking specialized activities as may be needed by the VS.
	5. The veterinarians' practices, knowledge and attitudes are subject to regular updating, or international harmonisation, or evaluation.

Terrestrial Code reference(s):

Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.

Points 6 and 13 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.

[1] Not all professional positions require an academic degree. Nonetheless, the proportion of academic degrees serves as an indicator of professional excellence within the VS.

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Annex III (contd)

B. Competencies of veterinary para-professionals	**Levels of advancement**
	1. The majority of *veterinary para-professionals* have no formal entry-level training.
	2. The training of *veterinary para-professionals* is of a very variable standard and allows the development of only limited animal health competencies.
	3. The training of *veterinary para-professionals* is of a uniform standard that allows the development of only basic animal health competencies.
	4. The training of *veterinary para-professionals* is of a uniform standard that allows the development of some specialist animal health competencies (e.g. meat inspection).
	5. The training of *veterinary para-professionals* is of a uniform standard and is subject to regular evaluation and/or updating.

Terrestrial Code reference(s):

Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.

Points 6 and 13 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.

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Annex III (contd)

I-3 Continuing education (CE) [2] The capability of the VS to maintain and improve the competence of their personnel in terms of relevant information and understanding; measured in terms of the implementation of a relevant training programme.	**Levels of advancement**
	1. The VS have no access to continuing veterinary, professional or technical CE.
	2. The VS have access to CE (internal and/or external programmes) on an irregular basis but it does not take into account needs, or new information or understanding.
	3. The VS have access to CE that is reviewed annually and updated as necessary, but it is implemented only for some categories of the relevant personnel.
	4. The VS have access to CE that is reviewed annually and updated as necessary, and it is implemented for all categories of the relevant personnel.
	5. The VS have up-to-date CE that is implemented for all relevant personnel and is submitted to periodic evaluation of effectiveness.

Terrestrial Code reference(s):

Points 1, 6 and 13 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / General organization / Human and financial resources.

Article 3.2.5. on Evaluation criteria for human resources.

Sub-point d) of Point 4 of Article 3.2.10. on Veterinary Services administration: In-Service training and development programme for staff.

Point 9 of Article 3.2.14. on Performance assessment and audit programmes.

[2] Continuing education includes Continuous Professional Development (CPD) for veterinary, professional and technical personnel.

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Annex III (contd)

I-4 Technical independence	**Levels of advancement**
The capability of the VS to carry out their duties with autonomy and free from commercial, financial, hierarchical and political influences that may affect technical decisions in a manner contrary to the provisions of the OIE (and of the WTO SPS Agreement where applicable).	1. The technical decisions made by the VS are generally not based on scientific considerations.
	2. The technical decisions take into account the scientific evidence, but are routinely modified to conform to non-scientific considerations.
	3. The technical decisions are based on scientific evidence but are subject to review and possible modification based on non-scientific considerations.
	4. The technical decisions are based only on scientific evidence and are not changed to meet non-scientific considerations.
	5. The technical decisions are made and implemented in full accordance with the country's OIE obligations (and with the country's WTO SPS Agreement obligations where applicable).

Terrestrial Code reference(s):

Point 2 of Article 3.1.2. on Fundamental principles of quality: Independence.

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Annex III (contd)

I-5 Stability of structures and sustainability of policies	**Levels of advancement**
The capability of the VS structure and/or leadership to implement and sustain policies over time.	1. Substantial changes to the organisational structure and/or leadership of the public sector of the VS frequently occur (e.g. annually) resulting in lack of sustainability of policies.
	2. The organisational structure and/or leadership of the public sector of the VS is substantially changed each time there is a change in the political leadership and this has negative effects on sustainability of policies.
	3. Significant changes to the organisational structure and/or leadership of the public sector of the VS occur rarely, but this stability does not have a positive impact on the sustainability of policies.
	4. Some changes occur in the organisational structure and/or leadership of the public sector of the VS following a change in the political leadership, but these have little or no negative effect on sustainability of policies.
	5. The organisational structure and leadership of the public sector of the VS are generally stable. Modifications are based on an evaluation process, with positive effect on the sustainability of policies.

Terrestrial Code reference(s):

Point 1 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.
Point 9 of Article 3.2.14. on Performance assessment and audit programmes.

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Annex III (contd)

I-6 Coordination capability of the Veterinary Services	**Levels of advancement**
A. Internal coordination (chain of command) The capability of the VS to coordinate its resources and activities (public and private sectors) with a clear chain of command, from the central level (the Chief Veterinary Officer), to the field level of the VS in order to implement all national activities relevant for OIE *Codes* (i.e. surveillance, disease control and eradication, food safety and early detection and rapid response programs).	1. There is no formal internal coordination and the chain of command is not clear.
	2. There are internal coordination mechanisms for some activities but the chain of command is not clear.
	3. There are internal coordination mechanisms and a clear and effective chain of command for some activities.
	4. There are internal coordination mechanisms and a clear and effective chain of command at the national level for most activities.
	5. There are internal coordination mechanisms and a clear and effective chain of command for all activities and these are periodically reviewed/audited and updated.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and Standards.
Article 3.2.2. on Scope.
Points 1 and 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

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Annex III (contd)

B. External coordination	**Levels of advancement**
The capability of the VS to coordinate its resources and activities (public and private sectors) at all levels with other relevant authorities as appropriate, in order to implement all national activities relevant for OIE Codes (i.e. surveillance, disease control and eradication, food safety and early detection and rapid response programs). Relevant authorities include other ministries and competent authorities, national agencies and decentralised institutions.	1. There is no external coordination.
	2. There are informal external coordination mechanisms for some activities, but the procedures are not clear and/or external coordination occurs irregularly.
	3. There are formal external coordination mechanisms with clearly described procedures or agreements for some activities and/or sectors.
	4. There are formal external coordination mechanisms with clearly described procedures or agreements at the national level for most activities, and these are uniformly implemented throughout the country.
	5. There are national external coordination mechanisms for all activities and these are periodically reviewed and updated.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and Standards.
Article 3.2.2. on Scope.
Points 1 and 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.
Point 4 of Article 3.2.10 on Performance assessment and audit programmes.

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I-7 Physical resources	**Levels of advancement**
The access of the VS to relevant physical resources including buildings, transport telecommunications, cold chain, and other relevant equipment (e.g. computers).	1. The VS have no or unsuitable physical resources at almost all levels and maintenance of existing infrastructure is poor or non-existent.
	2. The VS have suitable physical resources at the national (central) level and at some regional levels, and maintenance and replacement of obsolete items occurs only occasionally.
	3. The VS have suitable physical resources at national, regional and some local levels and maintenance and replacement of obsolete items occurs only occasionally.
	4. The VS have suitable physical resources at all levels and these are regularly maintained.
	5. The VS have suitable physical resources at all levels (national, sub-national and local levels) and these are regularly maintained and updated as more advanced and sophisticated items become available.

Terrestrial Code reference(s):

Point 2 of Article 3.2.4. on Evaluation criteria for quality system: “Where the Veterinary Services undergoing evaluation… than on the resource and infrastructural components of the services”.

Points 2 and 3 of Article 3.2.6. on Evaluation criteria for material resources: Administrative / Technical.

Point 3 of Article 3.2.10. on Performance assessment and audit programmes: Compliance.

Point 4 of- Article 3.2.14. on Administrative details.

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I-8 Operational Funding	**Levels of advancement**
The ability of the VS to access financial resources adequate for their continued operations, independent of political pressure.	1. Funding for the VS is neither stable nor clearly defined but depends on resources allocated irregularly.
	2. Funding for the VS is clearly defined and regular, but is inadequate for their required base operations (i.e. disease surveillance, early detection and rapid response and veterinary public health).
	3. Funding for the VS is clearly defined and regular, and is adequate for their base operations, but there is no provision for new or expanded operations.
	4. Funding for new or expanded operations is on a case-by-case basis, not always based on risk analysis and/or cost benefit analysis.
	5. Funding for all aspects of VS activities is adequate; all funding is provided under full transparency and allows for full technical independence, based on risk analysis and/or cost benefit analysis.

Terrestrial Code reference(s):

Point 13 of Article 3.1.2. on Fundamental principles of quality: Human and financial resources.
Point 1 of Article 3.2.6. on Evaluation criteria for material resources: Financial.
Point 3 of Article 3.2.14. on Financial management information.

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I-9 Emergency funding	**Levels of advancement**
The capability of the VS to access extraordinary financial resources in order to respond to emergency situations or emerging issues; measured by the ease of which contingency and compensatory funding (i.e. arrangements for compensation of producers in emergency situations) can be made available when required.	1. No contingency and compensatory funding arrangements exist and there is no provision for emergency financial resources.
	2. Contingency and compensatory funding arrangements with limited resources have been established, but these are inadequate for expected emergency situations (including emerging issues).
	3. Contingency and compensatory funding arrangements with limited resources have been established; additional resources for emergencies may be approved but approval is through a political process.
	4. Contingency and compensatory funding arrangements with adequate resources have been established, but in an emergency situation, their operation must be agreed through a non-political process on a case-by-case basis.
	5. Contingency and compensatory funding arrangements with adequate resources have been established and their rules of operation documented and agreed with stakeholders.

Terrestrial Code reference(s):

Point 13 of Article 3.1.2. on Fundamental principles of quality: Human and financial resources.
Point 1 of Article 3.2.6. on Evaluation criteria for material resources: Financial.
Point 3 of Article 3.2.14. on Financial management information.

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Annex III (contd)

I-10 Capital investment The capability of the VS to access funding for basic and additional investments (material and non material) that lead to a sustained improvement in the VS operational infrastructure.	**Levels of advancement**
	1. There is no capability to establish, maintain or improve the operational infrastructure of the VS.
	2. The VS occasionally develops proposals and secures funding for the establishment, maintenance or improvement of operational infrastructure but this is normally through extraordinary allocations.
	3. The VS regularly secures funding for maintenance and improvements of operational infrastructure, through allocations from the national budget or from other sources, but there are constraints on the use of these allocations.
	4. The VS routinely secures adequate funding for the necessary maintenance and improvement in operational infrastructure.
	5. The VS systematically secures adequate funding for the necessary improvements in operational infrastructure, including with participation from stakeholders as required.

Terrestrial Code reference(s):

Point 13 of Article 3.1.2. on Fundamental principles of quality: Human and financial resources.
Point 1 of Article 3.2.6. on Evaluation criteria for material resources: Financial.
Point 3 of Article 3.2.14. on Financial management information.

Annex XXXVII (contd)

Annex III (contd)

I-11 Management of resources and operations	**Levels of advancement**
The capability of the VS to document and manage their resources and operations in order to analyze, plan and improve both efficiency and effectiveness.	1. The VS have some records or documented procedures, but these do not provide for adequate management of resources and operations.
	2. The VS routinely use records and/or documented procedures in the management of resources and some operations, but these do not provide for adequate management, analysis, control or planning.
	3. The VS have comprehensive records, documentation and management systems and they regularly use records and documented procedures in the management of resources and operations, providing for the control of effectiveness and the conduct of analysis and planning.
	4. The VS have adequate management skills, including the capacity to analyse and improve efficiency and effectiveness.
	5. The VS have fully effective management systems, which are regularly audited and permit a proactive continuous improvement of efficiency and effectiveness.

Terrestrial Code reference(s):

Points 6, 10 and 13 of Article 3.1.2. on Fundamental principles of quality: General organisation / Documentation / Human and financial resources.

Point 4 of Article 3.2.1. on General considerations.

Point 1 of Article 3.2.2. on Scope.

Article 3.2.6. on Evaluation criteria for material resources.

Article 3.2.10. on Performance assessment and audit programmes.

CHAPTER II - TECHNICAL AUTHORITY AND CAPABILITY

The authority and capability of the VS to develop and apply sanitary measures and science-based procedures supporting those measures.

Critical competencies:

Section II-1 Veterinary laboratory diagnosis
Section II-2 Laboratory quality assurance
Section II-3 Risk analysis
Section II-4 Quarantine and border security
Section II-5 Epidemiological surveillance
Section II-6 Early detection and emergency response
Section II-7 Disease prevention, control and eradication
Section II-8 Food safety
Section II-9 Veterinary medicines and biologicals
Section II-10 Residue testing
Section II-11 Emerging issues
Section II-12 Technical innovation
Section II-13 Identification and traceability
Section II-14 Animal welfare

Terrestrial Code References:

Chapter 2.1. on Import risk analysis.

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General Organisation / Procedures and standards.

Point 1 of Article 3.2.4. on Evaluation criteria for quality systems.

Point 3 of Article 3.2.6. on Evaluation criteria for material resources: Technical.

Points 1 and 2 of Article 3.2.7. on Functional capabilities and legislative support: Animal health and veterinary public health / Export/Import inspection.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Points 1-5 of Article 3.2.9. on Veterinary public health controls: Food hygiene / Zoonoses / Chemical residue testing programmes / Veterinary medicines/ Integration between animal health controls and veterinary public health.

Sub-point f) of Point 4 of Article 3.2.10. on Veterinary Services administration: Formal linkages with sources of independent scientific expertise.

Points 2 and 5-7 of Article 3.2.14. on National information on human resources / Laboratory services / Functional capabilities and legislative support / Animal health and veterinary public health controls.

Chapter 4.1. on General principles on identification and traceability of live animals.

Chapter 4.2. on Design and implementation of identification systems to achieve animal traceability.

Chapter 6.2. on Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

Chapters 6.7. to 6.11. on Antimicrobial resistance.

Chapter 7.1. Introduction to the recommendations for animal welfare.

Chapter 7.2. Transport of animals by sea.

Chapter 7.3. Transport of animals by land.

Chapter 7.4. Transport of animals by air.

Chapter 7.5. Slaughter of animals.

Chapter 7.6. Killing of animals for disease control purposes.

Annex XXXVII (contd)

Annex III (contd)

II-1 Veterinary laboratory diagnosis	**Levels of advancement**
The authority and capability of the VS to identify and record pathogenic agents, including those relevant for public health, that can adversely affect animals and animal products.	1. Disease diagnosis is almost always conducted by clinical means only, with laboratory diagnostic capability being generally unavailable.
	2. For major zoonoses and diseases of national economic importance, the VS have access to and use a laboratory to obtain a correct diagnosis.
	3. For other zoonoses and diseases present in the country, the VS have access to and use a *laboratory* to obtain a correct diagnosis.
	4. For diseases of zoonotic or economic importance not present in the country, but known to exist in the region and/ or that could enter the country, the VS have access to and use a *laboratory* to obtain a correct diagnosis.
	5. In the case of new and *emerging diseases* in the region or world, the VS have access to and use a network of national or international reference laboratories (e.g. an OIE Reference Laboratory) to obtain a correct diagnosis.

Terrestrial Code reference(s):

Point 8 of Article 3.1.2. on Fundamental principles of quality: Procedures and standards.
Point 3 of Article 3.2.6. on Evaluation criteria for material resources: Technical.
Point 5 of Article 3.2.14. on Laboratory services.

Annex XXXVII (contd)

Annex III (contd)

II-2 Laboratory quality assurance	**Levels of advancement**
The quality of laboratories (that conduct diagnostic testing or analysis for chemical residues, antimicrobial residues, toxins, or tests for, biological efficacy, etc.) as measured by the use of formal QA systems and participation in relevant proficiency testing programmes.	1. No laboratories used by the public sector VS are using formal QA systems.
	2. Some laboratories used by the public sector VS are using formal QA systems.
	3. All laboratories used by the public sector VS are using formal QA systems.
	4. All the laboratories used by the public sector VS and most or all private laboratories are using formal QA systems.
	5. All the laboratories used by the public sector VS and most or all private laboratories are using formal QA programmes that meet OIE, ISO 17025, or equivalent QA standard guidelines.

Terrestrial Code reference(s):

Point 8 of Article 3.1.2. on Fundamental principles of quality: Procedures and standards.
Point 1 of Article 3.2.4. on Evaluation criteria for quality systems.
Point 3 of Article 3.2.6. on Evaluation criteria for material resources: Technical.
Point 5 of Article 3.2.14. on Laboratory services.

Annex XXXVII (contd)

Annex III (contd)

II-3 Risk analysis	**Levels of advancement**
The authority and capability of the VS to base its risk management decisions on a scientific assessment of the risks.	1. Risk management decisions are not usually supported by scientific risk assessment.
	2. The VS compile and maintain data but do not have the capability to systematically assess risks. Some risk management decisions are based on scientific risk assessment.
	3. The VS can systematically compile and maintain relevant data and carry out risk assessment. Scientific principles and evidence, including risk assessment, generally provide the basis for risk management decisions.
	4. The VS systematically conduct risk assessments in compliance with relevant OIE standards, and base their risk management decisions on the outcomes of these risk assessments.
	5. The VS are consistent in basing sanitary decisions on *risk analysis*, and in communicating their procedures and outcomes internationally, meeting all their OIE obligations (including WTO SPS Agreement obligations where applicable).

Terrestrial Code reference(s):

Chapter 2.1. on Import risk analysis.

Annex XXXVII (contd)

Annex III (contd)

II-4 Quarantine and border security	**Levels of advancement**
The authority and capability of the VS to prevent the entry and spread of diseases and other hazards of animals and animal products.	1. The VS cannot apply any type of quarantine or border security procedures for animals or animal products with their neighbouring countries or trading partners.
	2. The VS can establish and apply quarantine and border security procedures; however, these are generally based neither on international standards nor on a *risk analysis*.
	3. The VS can establish and apply quarantine and border security procedures based on international standards, but the procedures do not systematically address illegal activities[3] relating to the import of animals and animal products.
	4. The VS can establish and apply quarantine and border security procedures which systematically address legal pathways and illegal activities.
	5. The VS work with their neighbouring countries and trading partners to establish, apply and audit quarantine and border security procedures which systematically address all risks identified.

Terrestrial Code reference(s):

Point 8 of Article 3.1.2. on Fundamental principles of quality: Procedures and standards.

Point 2 of Article 3.2.7. on Functional capabilities and legislative support: Export/Import inspection.

Points 6 and 7 of Article 3.2.14. on Functional capabilities and legislative support and Animal health and veterinary public health controls.

[3] Illegal activities include attempts to gain entry for animals or animal products other than through legal entry points and/or using certification and/or other procedures not meeting the country's requirements.

Annex XXXVII (contd)

Annex III (contd)

II-5 Epidemiological surveillance	**Levels of advancement**
The authority and capability of the VS to determine, verify and report on the sanitary status of the animal populations under their mandate.	1. The VS have no passive surveillance programme.
	2. The VS conduct passive surveillance for some relevant diseases and have the capacity to produce national reports on some diseases.
A. Passive epidemiological surveillance	3. The VS conduct passive surveillance in compliance with OIE standards for some relevant diseases at the national level through appropriate networks in the field, whereby samples from suspect cases are collected and sent for laboratory diagnosis with evidence of correct results obtained. The VS have a basic national disease reporting system.
	4. The VS conduct passive surveillance and report at the national level in compliance with OIE standards for most relevant diseases. Appropriate field networks are established for the collection of samples and submission for laboratory diagnosis of suspect cases with evidence of correct results obtained. Stakeholders are aware of and comply with their obligation to report the suspicion and occurrence of notifiable diseases to the VS.
	5. The VS regularly report to stakeholders and the international community (where applicable) on the findings of passive surveillance programmes.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Sub-points a) i), ii) and iii) of Point 7 of Article 3.2.14. on Animal health: Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services* / Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services* / Description and relevant data of current official control programmes including:… or eradication programmes for specific diseases.

Annex XXXVII (contd)

Annex III (contd)

B. Active epidemiological surveillance	**Levels of advancement**
	1. The VS have no active surveillance programme.
	2. The VS conduct active surveillance for some relevant diseases (of economic and zoonotic importance) but apply it only in a part of susceptible populations and/or do not update it regularly.
	3. The VS conduct active surveillance in compliance with scientific principles and OIE standards for some relevant diseases and apply it to all susceptible populations but do not update it regularly.
	4. The VS conduct active surveillance in compliance with scientific principles and OIE standards for some relevant diseases, apply it to all susceptible populations, update it regularly and report the results systematically.
	5. The VS conduct active surveillance for most or all relevant diseases and apply it to all susceptible populations. The surveillance programmes are evaluated and meet the country's OIE obligations.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Sub-points a) i), ii) and iii) of Point 7 of Article 3.2.14. on Animal health: Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services* / Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services* / Description and relevant data of current official control programmes including:… or eradication programmes for specific diseases.

Annex XXXVII (contd)

Annex III (contd)

II-6 Early detection and emergency response	**Levels of advancement**
The authority and capability of the VS to detect and respond rapidly to a sanitary emergency (such as a significant disease outbreak or food safety emergency).	1. The VS have no field network or established procedure to determine whether a sanitary emergency exists or the authority to declare such an emergency and respond appropriately.
	2. The VS have a field network and an established procedure to determine whether or not a sanitary emergency exists, but lack the necessary legal and financial support to respond appropriately.
	3. The VS have the legal framework and financial support to respond rapidly to sanitary emergencies, but the response is not coordinated through a chain of command.
	4. The VS have an established procedure to make timely decisions on whether or not a sanitary emergency exists. The VS have the legal framework and financial support to respond rapidly to sanitary emergencies through a chain of command. They have national contingency plans for some exotic diseases.
	5. The VS have national contingency plans for all diseases of concern through coordinated actions with all stakeholders through a chain of command.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Sub-point a) of Point 7 of Article 3.2.14. on Animal health and veterinary public health controls: Animal health.

Annex XXXVII (contd)

Annex III (contd)

II-7 Disease prevention, control and eradication	**Levels of advancement**
The authority and capability of the VS to actively perform actions to prevent, control or eradicate OIE listed diseases and/or to demonstrate that the country or a zone are free of relevant diseases.	1. The VS have no authority or capability to prevent, control or eradicate animal diseases.
	2. The VS implement prevention, control and eradication programmes for some diseases and/or in some areas with little or no scientific evaluation of their efficacy and efficiency.
	3. The VS implement prevention, control and eradication programmes for some diseases and/or in some areas with scientific evaluation of their efficacy and efficiency.
	4. The VS implement prevention, control and eradication programmes for all relevant diseases but with scientific evaluation of their efficacy and efficiency of some programmes.
	5. The VS implement prevention, control and eradication programmes for all relevant diseases with scientific evaluation of their efficacy and efficiency consistent with relevant OIE international standards.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.

Sub-point a) of Point 7 of Article 3.2.14. on Animal health and veterinary public health controls: Animal health.

II-8 Food safety	**Levels of advancement**
A. Ante- and post-mortem Inspection at abattoirs and associated premises (e.g. meat boning, cutting establishments and rendering plants) The authority and capability of the VS to implement and manage the inspection of animals destined for slaughter at abattoirs and associated premises, including for assuring meat hygiene and for the collection of information relevant to livestock diseases and zoonoses. This competency also covers coordination with other authorities where there is shared responsibility for the functions.	1. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are generally not undertaken in conformity with international standards.
	2. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are undertaken in conformity with international standards only at export premises.
	3. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are undertaken in conformity with international standards for export premises and for major abattoirs producing meat for distribution throughout the national market.
	4. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are undertaken in conformity with international standards for export premises and for all abattoirs producing meat for distribution in the national and local markets.
	5. Ante- and post-mortem inspection and collection of disease information (and coordination, as required) are undertaken in conformity with international standards at all premises (including family and on farm slaughtering) and are subject to periodic audit of effectiveness.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1-5 of Article 3.2.9. on Veterinary public health controls: Food hygiene / Zoonoses / Chemical residue testing programmes / Veterinary medicines/ Integration between animal health controls and veterinary public health.

Points 2, 6 and 7 of Article 3.2.14. on National information on human resources / Functional capabilities and legislative support / Animal health and veterinary public health controls.

Chapter 6.2. on Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

Annex XXXVII (contd)

Annex III (contd)

B. Inspection of collection, processing and distribution of products of animal origin The authority and capability of the VS to implement, manage and coordinate food safety measures on collection, processing and distribution of products of animals, including programmes for the prevention of specific food-borne zoonoses and general food safety programmes. This competency also covers coordination with other authorities where there is shared responsibility for the functions.	**Levels of advancement**
	1. Implementation, management and coordination (as appropriate) are generally not undertaken in conformity with international standards.
	2. Implementation, management and coordination (as appropriate) are generally undertaken in conformity with international standards only for export purposes.
	3. Implementation, management and coordination (as appropriate) are generally undertaken in conformity with international standards only for export purposes and for products that are distributed throughout the national market.
	4. Implementation, management and coordination (as appropriate) are generally undertaken in conformity with international standards for export purposes and for products that are distributed throughout the national and local markets.
	5. Implementation, management and coordination (as appropriate) are undertaken in full conformity with international standards for products at all levels of distribution (including on farm-processing and farm gate sale).

[Note: This critical competency primarily refers to inspection of processed animal products and raw products other than meat (e.g. milk, honey, etc.). It may in some countries be undertaken by an agency other than the VS.]

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1-5 of Article 3.2.9. on Veterinary public health controls: Food hygiene / Zoonoses / Chemical residue testing programmes / Veterinary medicines/ Integration between animal health controls and veterinary public health.

Points 2, 6 and 7 of Article 3.2.14. on National information on human resources / Functional capabilities and legislative support / Animal health and veterinary public health controls.

Chapter 6.2. on Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

Annex XXXVII (contd)

Annex III (contd)

II-9 Veterinary medicines and biologicals	**Levels of advancement**
The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals, i.e. the authorisation, registration, import, production, labelling, distribution, sale and use of these products.	1. The VS cannot regulate veterinary medicines and veterinary biologicals.
	2. The VS have some capability to exercise administrative control over veterinary medicines and veterinary biologicals.
	3. The VS exercise effective administrative control and implement quality standards for most aspects of the regulation of veterinary medicines and veterinary biologicals.
	4. The VS exercise comprehensive and effective regulatory control of veterinary medicines and veterinary biologicals.
	5. In addition to complete regulatory control, the VS systematically monitor for adverse reactions (pharmacovigilance) and take appropriate corrective steps. The control systems are subjected to periodic audit of effectiveness.

Terrestrial Code reference(s):

Point 8 of Article 3.1.2. on Fundamental principles of quality: Procedures and standards.

Points 3 and 4 of Article 3.2.9. on Veterinary public health controls: Chemical residue testing programmes / Veterinary medicines.

Sub-point a) ii) of Point 6 of Article 3.2.14. on Animal health and veterinary public health: “Assessment of ability of Veterinary Services to enforce legislation”.

Chapters 6.7. to 6.11. on Antimicrobial resistance.

Annex XXXVII (contd)

Annex III (contd)

II-10 Residue testing	**Levels of advancement**
The capability of the VS to undertake residue testing programmes for veterinary medicines (e.g. antimicrobials and hormones), chemicals, pesticides, radionuclides, metals, etc.	1. No residue testing programme for animal products exists in the country.
	2. Some residue testing programme is performed but only for selected animal products for export.
	3. A comprehensive residue testing programme is performed for all animal products for export and some for domestic use.
	4. A comprehensive residue testing programme is performed for all animal products for export and/or internal consumption.
	5. The residue testing programme is subject to routine quality assurance and regular ev aluation.

[Note: This critical competency may in some countries be undertaken by an agency or agencies other than the VS.]

Terrestrial Code reference(s):

Points 3 and 4 of Article 3.2.9. on Veterinary public health controls: Chemical residue testing programmes / Veterinary medicines.

Sub-points b) iii) and iv) of Point 7 of Article 3.2.14. on Veterinary public health: Chemical residue testing programmes / Veterinary medicines.

Chapters 6.7. to 6.11. on Antimicrobial resistance.

Annex XXXVII (contd)

Annex III (contd)

II-11 Emerging issues	**Levels of advancement**
The authority and capability of the VS to identify in advance, and take appropriate action in response to likely emerging issues under their mandate relating to the sanitary status of the country, public health, the environment, or trade in animals and animal products.	1. The VS do not have procedures to identify in advance likely emerging issues.
	2. The VS monitor and review developments at national and international levels relating to emerging issues.
	3. The VS assess the risks, costs and/or opportunities of the identified emerging issues, including preparation of appropriate national preparedness plans. The VS have some collaboration with other agencies (e.g. human health, wildlife and environment) and with stakeholders on emerging issues.
	4. The VS implement, in coordination with stakeholders, prevention or control actions due to an adverse emerging issue, or beneficial actions from a positive emerging issue. The VS have well-developed formal collaboration with other agencies (e.g. human health, wildlife and environment) and with stakeholders on emerging issues.
	5. The VS coordinate actions with neighbouring countries and trading partners to respond to emerging issues, including audits of each other's ability to detect and address emerging issues in their early stages.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General Organisation / Procedures and standards.
Point 1 of Article 3.2.7. on Functional capabilities and legislative support: Animal health and veterinary public health.

Annex XXXVII (contd)

Annex III (contd)

II-12 Technical innovation[4]	**Levels of advancement**
The capability of the VS to keep up-to-date with the latest scientific advances and to comply with the standards of the OIE (and Codex Alimentarius Commission where applicable).	1. The VS have only informal access to technical innovations, through personal contacts and external sources.
	2. The VS maintain a database of technical innovations and international standards, through subscriptions to scientific journals and electronic media.
	3. The VS have a specific programme to actively identify relevant technical innovations and international standards.
	4. The VS incorporate technical innovations and international standards into selected policies and procedures, in collaboration with stakeholders.
	5. The VS systematically implement relevant technical innovations and international standards.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General Organisation / Procedures and standards.

Point 3 of Article 3.2.8. on Animal health controls: National animal disease reporting systems.

Sub-point f) of Point 4 of Article 3.2.10. on Veterinary Services administration: Formal linkages with sources of independent scientific expertise.

Points 6 and 7 of Article 3.2.14. on Functional capabilities and legislative support / Animal health and veterinary public health controls.

[4] Technical innovation includes new disease control methods, new types of vaccines and diagnostic tests, food safety technologies, and connections to electronic networks on disease information and food emergencies.

Annex XXXVII (contd)

Annex III (contd)

II-13 Identification and traceability	**Levels of advancement**
A. Animal identification and movement control The authority and capability of the VS, normally in coordination with stakeholders, to identify animals under their mandate and trace their history, location and distribution for the purpose of animal disease control, food safety, or trade or any other legal requirements under the VS/OIE mandate.	1. The VS do not have the authority or the capability to identify animals or control their movements.
	2. The VS can identify some animals and control some movements, using traditional methods and/or actions designed and implemented to deal with a specific problem (e.g. to prevent robbery).
	3. The VS implement procedures for animal identification and movement control for specific animal sub-populations as required for disease control, in accordance with relevant international standards.
	4. The VS implement all relevant animal identification and movement control procedures, in accordance with relevant international standards.
	5. The VS carry out periodic audits of the effectiveness of their identification and movement control systems.

Terrestrial Code reference(s):

Chapter 4.1. on General principles on identification and traceability of live animals.
Chapter 4.2. on Design and implementation of identification systems to achieve animal traceability.

Annex XXXVII (contd)

Annex III (contd)

B. Identification and traceability of products of animal origin.	**Levels of advancement**
The authority and capability of the VS, normally in coordination with stakeholders, to identify and trace products of animal origin for the purpose of food safety, animal health or trade.	1. The VS do not have the authority or the capability to identify or trace products of animal origin.
	2. The VS can identify and trace some products of animal origin to deal with a specific problem (e.g. products originating from farms affected by a disease outbreak).
	3. The VS have implemented procedures to identify and trace some products of animal origin for food safety, animal health and trade purposes, in accordance with relevant international standards.
	4. The VS have implemented national programmes enabling them the identification and tracing of all products of animal origin, in accordance with relevant international standards.
	5. The VS periodically audit the effectiveness of their identification and traceability procedures.

Terrestrial Code reference(s):

Chapter 4.1. on General principles on identification and traceability of live animals.
Chapter 4.2. on Design and implementation of identification systems to achieve animal traceability.

II-14 Animal welfare	**Levels of advancement**	
The authority and capability of the VS to implement the animal welfare standards of the OIE as published in the Terrestrial Code.	1	The standards of the OIE are generally not implemented.
	2.	Some of the standards of the OIE are implemented, e.g. primarily for the export sector.
	3.	All of the standards of the OIE are implemented but this is primarily for the export sector.
	4.	All of the standards of the OIE are implemented, for the export and the domestic sector.
	5.	The standards of the OIE are implemented and implementation is periodically subject to independent external evaluation.

[Note: At this time this competency covers only chapters 7.1. to 7.6. inclusive.]

Terrestrial Code reference(s):

Chapter 7.1. Introduction to the recommendations for animal welfare.
Chapter 7.2. Transport of animals by sea.
Chapter 7.3. Transport of animals by land.
Chapter 7.4. Transport of animals by air.
Chapter 7.5. Slaughter of animals.
Chapter 7.6. Killing of animals for disease control purposes.

CHAPTER III - INTERACTION WITH STAKEHOLDERS

The capability of the VS to collaborate with and involve stakeholders in the implementation of programmes and activities.

Critical competencies:

Section III-1 Communications

Section III-2 Consultation with stakeholders

Section III-3 Official representation

Section III-4 Accreditation / authorisation / delegation

Section III-5 Veterinary Statutory Body

Section III-6 Participation of producers and other stakeholders in joint programmes

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Terrestrial Code References:

Points 6, 8 and 12 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards / Communication.

Point 9 of Article 3.2.1. on General considerations.

Points 2 and 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Sub-point b) of Point 2 of Article 3.2.6. on Administrative resources: Communications.

Article 3.2.11. on Participation on OIE activities.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 4, 7 and Sub-point g) of Point 9 of Article 3.2.14. on Administrative details / Animal health and veterinary public health controls / Sources of independent scientific expertise.

Annex XXXVII (contd)

Annex III (contd)

III-1 Communications	**Levels of advancement**
The capability of the VS to keep stakeholders informed, in a transparent, effective and timely manner, of VS activities and programmes, and of developments in animal health and food safety.	1. The VS have no mechanism in place to inform stakeholders of VS activities and programmes.
	2. The VS have informal communication mechanisms.
	3. The VS maintain an official contact point for communications but it is not always up-to-date in providing information.
	4. The VS contact point for communications provides up-to-date information, accessible via the Internet and other appropriate channels, on activities and programmes.
	5. The VS have a well developed communication plan, and actively and regularly circulate information to stakeholders.

Terrestrial Code reference(s):

Point 12 of Article 3.1.2. on Fundamental principles of quality: Communication.
Sub-point b) of Point 2 of Article 3.2.6. on Administrative resources: Communications.
Point 4 of Article 3.2.14. on Administrative details.

Annex XXXVII (contd)

Annex III (contd)

III-2 Consultation with stakeholders	**Levels of advancement**
The capability of the VS to consult effectively with stakeholders on VS activities and programmes, and on developments in animal health and food safety. .	1. The VS have no mechanisms for consultation with stakeholders.
	2. The VS maintain informal channels of consultation with stakeholders.
	3. The VS maintain a formal consultation mechanism with stakeholders.
	4. The VS regularly hold workshops and meetings with stakeholders.
	5. The VS actively consult with and solicit feedback from stakeholders regarding proposed and current activities and programmes, developments in animal health and food safety, interventions at the OIE (Codex Alimentarius Commission and WTO SPS Committee where applicable), and ways to improve their activities.

Terrestrial Code reference(s):

Point 12 of Article 3.1.2. on Fundamental principles of quality: Communication.

Point 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Point 4 and Sub-point g) of Point 9 of Article 3.2.14. on Administrative details and on Sources of independent scientific expertise.

Annex XXXVII (contd)

Annex III (contd)

III-3 Official representation	**Levels of advancement**
The capability of the VS to regularly and actively participate in, coordinate and provide follow up on relevant meetings of regional and international organisations including the OIE (and Codex Alimentarius Commission and WTO SPS Committee where applicable).	1. The VS do not participate in or follow up on relevant meetings of regional or international organisations.
	2. The VS sporadically participate in relevant meetings and/or make a limited contribution.
	3. The VS actively participate[5] in the majority of relevant meetings.
	4. The VS consult with stakeholders and take into consideration their opinions in providing papers and making interventions in relevant meetings.
	5. The VS consult with stakeholders to ensure that strategic issues are identified, to provide leadership and to ensure coordination among national delegations as part of their participation in relevant meetings.

Terrestrial Code reference(s):

Article 3.2.11. on Participation on OIE activities.
Point 4 of Article 3.2.14. on Administrative details.

[5] *Active participation* refers to preparation in advance of, and contributing during the meetings in question, including exploring common solutions and generating proposals and compromises for possible adoption.

Annex XXXVII (contd)

Annex III (contd)

III-4 Accreditation / authorisation / delegation	**Levels of advancement**
The authority and capability of the public sector of the VS to accredit / authorise / delegate the private sector (e.g. private veterinarians and *laboratories*), to carry out official tasks on its behalf.	1. The public sector of the VS has neither the authority nor the capability to accredit / authorise / delegate the private sector to carry out official tasks.
	2. The public sector of the VS has the authority and capability to accredit / authorise / delegate to the private sector, but there are no current accreditation / authorisation / delegation activities.
	3. The public sector of the VS develops accreditation / authorisation / delegation programmes for certain tasks, but these are not routinely reviewed.
	4. The public sector of the VS develops and implements accreditation / authorisation / delegation programmes, and these are routinely reviewed.
	5. The public sector of the VS carries out audits of its accreditation / authorisation / delegation programmes, in order to maintain the trust of their trading partners and stakeholders.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.
Point 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Annex XXXVII (contd)

Annex III (contd)

III-5 Veterinary Statutory Body (VSB)	**Levels of advancement**
A. VSB authority The VSB is an autonomous authority responsible for the regulation of the *veterinarians* and *veterinary para-professionals*. Its role is defined in the *Terrestrial Code*.	1. There is no legislation establishing a *VSB*.
	2. The *VSB* regulates *veterinarians* only within certain sectors of the veterinary profession and/or does not systematically apply disciplinary measures.
	3. The *VSB* regulates *veterinarians* in all relevant sectors of the veterinary profession and applies disciplinary measures.
	4. The *VSB* regulates functions and competencies of *veterinarians* in all relevant sectors and *veterinary para-professionals* according to needs.
	5. The *VSB* regulates and applies disciplinary measures to *veterinarians* and *veterinary para-professionals* in all sectors throughout the country.

Terrestrial Code reference(s):

Point 9 of Article 3.2.1. on General considerations.
Article 3.2.12. on Evaluation of the veterinary statutory body.

Annex XXXVII (contd)

Annex III (contd)

B. VSB capacity	**Levels of advancement**
The capacity of the VSB to implement its functions and objectives in conformity with OIE standards.	1. The VSB has no capacity to implement its functions and objectives.
	2. The VSB has the functional capacity to implement its main objectives.
	3. The VSB is an independent representative organisation with the functional capacity to implement all of its objectives.
	4. The VSB has a transparent process of decision making and conforms to OIE standards.
	5. The financial and institutional management of the VSB are submitted to external auditing.

Terrestrial Code reference(s):

Point 9 of Article 3.2.1. on General considerations.
Article 3.2.12. on Evaluation of the veterinary statutory body.

Annex XXXVII (contd)

Annex III (contd)

III-6 Participation of producers and other stakeholders in joint programmes	**Levels of advancement**
The capability of the VS and stakeholders to formulate and implement joint programmes in regard to animal health and food safety.	1. Producers and other stakeholders only comply and do not actively participate in programmes.
	2. Producers and other stakeholders are informed of programmes and assist the VS to deliver the programme in the field.
	3. Producers and other stakeholders are trained to participate in programmes and advise of needed improvements, and participate in early detection of diseases.
	4. Representatives of producers and other stakeholders negotiate with the VS on the organisation and delivery of programmes.
	5. Producers and other stakeholders are formally organised to participate in developing programmes in close collaboration with the VS.

Terrestrial Code reference(s):

Point 12 of Article 3.1.2. on Fundamental principles of quality: Communication.
Points 2 and 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.
Point 7 of Article 3.2.14. on Animal health and veterinary public health controls.

CHAPTER IV - ACCESS TO MARKETS

The authority and capability of the VS to provide support in order to access, expand and retain regional and international markets for animals and animal products.

Critical competencies:

Section IV-1 Preparation of legislation and regulations

Section IV-2 Implementation of legislation and regulations and stakeholder compliance

Section IV-3 International harmonisation

Section IV-4 International certification

Section IV-5 Equivalence and other types of sanitary agreements

Section IV-6 Transparency

Section IV-7 Zoning

Section IV-8 Compartmentalisation

Terrestrial Code References:

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1 and 2 of Article 3.2.7. on Functional capabilities and legislative support: Animal health and veterinary public health / Export/import inspection.

Points 1 and 3 of Article 3.2.8. on Animal health controls: Animal health status / National animal disease reporting systems.

Sub-point g) of Point 4 of Article 3.2.10. on Veterinary Services administration: Trade performance history.

Article 3.2.11. on Participation in OIE activities.

Points 6 and 10 of Article 3.2.14. on Functional capabilities and legislative support / Membership of the OIE.

Chapter 4.3. on Zoning and compartmentalisation.

Chapter 4.4. on Application of compartmentalisation.

Chapter 5.1. on General obligations related to certification.

Chapter 5.2. on Certification procedures.

Chapter 5.3. on OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.

Chapters 5.10. to 5.12. on Model international veterinary certificates.

Annex XXXVII (contd)

Annex III (contd)

IV-1 Preparation of legislation and regulations The authority and capability of the VS to actively participate in the preparation of national legislation and regulations in domains that are under their mandate, in order to warranty its quality with respect to principles of legal drafting and legal issues (internal quality) and its accessibility, acceptability, and technical, social and economical applicability (external quality).	**Levels of advancement**
	1. The VS have neither the authority nor the capability to participate in the preparation of national legislation and regulations, which result in legislation that is lacking or is outdated or of poor quality in most fields of VS activity.
	2. The VS have the authority and the capability to participate in the preparation of national legislation and regulations and can largely ensure their internal quality, but the legislation and regulations are often lacking in external quality.
	3. The VS have the authority and the capability to participate in the preparation of national legislation and regulations with adequate internal and external quality in some fields of activity, but lack formal methodology to develop adequate national legislation and regulations regularly in all domains.
	4. The VS have the authority and the capability to participate in the preparation of national legislation and regulations with a relevant formal methodology to ensure adequate internal and external quality, involving stakeholder participation in most fields of activity.
	5. The VS regularly evaluate and update their legislation and regulations to maintain relevance to evolving national and international contexts.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1 and 2 of Article 3.2.7. on Functional capabilities and legislative support: Animal health and veterinary public health / Export/import inspection.

Point 6 of Article 3.2.14. on Functional capabilities and legislative support.

Annex XXXVII (contd)

Annex III (contd)

IV-2 Implementation of legislation and regulations and stakeholder compliance The authority and capability of the VS to ensure that stakeholders are in compliance with legislation and regulations under the VS mandate.	**Levels of advancement**
	1. The VS have no or very limited programmes or activities to ensure stakeholder compliance with relevant regulations.
	2. The VS implement a programme or activities comprising inspection and verification of compliance with regulations and recording instances of non-compliance, but generally cannot or do not take further action in most relevant fields of activity.
	3. Veterinary legislation is generally implemented. As required, the VS have a power to take legal action / to prosecute in instances of non-compliance in most relevant fields of activity.
	4. Veterinary legislation is implemented in all domains of veterinary competence and the VS work with stakeholders to minimise instances of non-compliance.
	5. The compliance programme is regularly subjected to audit by the VS or external agencies.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.

Points 1 and 2 of Article 3.2.7. on Functional capabilities and legislative support: Animal health and veterinary public health / Export/import inspection.

Point 6 of Article 3.2.14. on Functional capabilities and legislative support.

Annex XXXVII (contd)

Annex III (contd)

IV-3 International harmonisation	**Levels of advancement**	
The authority and capability of the VS to be active in the international harmonisation of regulations and *sanitary measures* and to ensure that the national legislation and regulations under their mandate take account of relevant international standards, as appropriate.	1.	National legislation, regulations and *sanitary measures* under the mandate of the VS do not take account of international standards.
	2.	The VS are aware of gaps, inconsistencies or non-conformities in national legislation, regulations and *sanitary measures* as compared to international standards, but do not have the capability or authority to rectify the problems.
	3.	The VS monitor the establishment of new and revised international standards, and periodically review national legislation, regulations and *sanitary measures* with the aim of harmonising them, as appropriate, with international standards, but do not actively comment on the draft standards of relevant intergovernmental organisations.
	4.	The VS are active in reviewing and commenting on the draft standards of relevant intergovernmental organisations.
	5.	The VS actively and regularly participate at the international level in the formulation, negotiation and adoption of international standards [6], and use the standards to harmonise national legislation, regulations and *sanitary measures*.

Terrestrial Code reference(s):

Article 3.2.11. on Participation in OIE activities.
Points 6 and 10 of Article 3.2.14. on Functional capabilities and legislative support and on Membership of the OIE.

[6] A country could be active in international standard setting without actively pursuing national changes. The importance of this element is to promote national change.

Annex XXXVII (contd)

Annex III (contd)

IV-4 International certification[7]	**Levels of advancement**
The authority and capability of the VS to certify animals, animal products, services and processes under their mandate, in accordance with the national legislation and regulations, and international standards.	1. The VS have neither the authority nor the capability to certify animals, animal products, services or processes.
	2. The VS have the authority to certify certain animals, animal products, services and processes, but are not always in compliance with the national legislation and regulations and international standards.
	3. The VS develop and carry out certification programmes for certain animals, animal products, services and processes under their mandate in compliance with international standards.
	4. The VS develop and carry out all relevant certification programmes for any animals, animal products, services and processes under their mandate in compliance with international standards.
	5. The VS carry out audits of their certification programmes, in order to maintain national and international confidence in their system.

Terrestrial Code reference(s):

Points 6 and 8 of Article 3.1.2. on Fundamental principles of quality: General organisation / Procedures and standards.
Point 2 of Article 3.2.7. on Functional capabilities and legislative support: Export/import inspection.
Sub-point b) of Point 6 of Article 3.2.14. on Functional capabilities and legislative support: Export/import inspection.
Chapter 5.2. on Certification procedures.
Chapters 5.10. to 5.12. on Model international veterinary certificates.

[7] Certification procedures should be based on relevant OIE and Codex Alimentarius standards.

Annex XXXVII (contd)

Annex III (contd)

IV-5 Equivalence and other types of sanitary agreements	**Levels of advancement**
The authority and capability of the VS to negotiate, implement and maintain equivalence and other types of sanitary agreements with trading partners.	1. The VS have neither the authority nor the capability to negotiate or approve equivalence or other types of sanitary agreements with other countries.
	2. The VS have the authority to negotiate and approve equivalence and other types of sanitary agreements with trading partners, but no such agreements have been implemented.
	3. The VS have implemented equivalence and other types of sanitary agreements with trading partners on selected animals, animal products and processes.
	4. The VS actively pursue the development, implementation and maintenance of equivalence and other types of sanitary agreements with trading partners on all matters relevant to animals, animal products and processes under their mandate.
	5. The VS actively work with stakeholders and take account of developments in international standards, in pursuing equivalence and other types of sanitary agreements with trading partners.

Terrestrial Code reference(s):

Point 6 of Article 3.1.2. on Fundamental principles of quality: General organisation.

Sub-point g) of Point 4 of Article 3.2.10. on Veterinary Services administration: Trade performance history.

Chapter 5.3. on OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.

Annex XXXVII (contd)

Annex III (contd)

IV-6 Transparency	**Levels of advancement**
The authority and capability of the VS to notify the OIE of their sanitary status and other relevant matters (and to notify the WTO SPS Committee where applicable), in accordance with established procedures.	1. The VS do not notify.
	2. The VS occasionally notify.
	3. The VS notify in compliance with the procedures established by these organisations.
	4. The VS regularly inform stakeholders of changes in their regulations and decisions on the control of relevant diseases and of the country's sanitary status, and of changes in the regulations and sanitary status of other countries.
	5. The VS, in cooperation with their stakeholders, carry out audits of their transparency procedures.

Terrestrial Code reference(s):

Points 1 and 3 of Article 3.2.8. on Animal health controls: Animal health status / National animal disease reporting systems.

Chapter 5.1. on General obligations related to certification.

Annex XXXVII (contd)

Annex III (contd)

IV-7 Zoning	**Levels of advancement**
The authority and capability of the VS to establish and maintain disease free zones, as necessary and in accordance with the criteria established by the OIE (and by the WTO SPS Agreement where applicable).	1. The VS cannot establish disease free zones.
	2. As necessary, the VS can identify animal sub-populations with distinct health status suitable for zoning.
	3. The VS have implemented biosecurity measures that enable it to establish and maintain disease free zones for selected animals and animal products, as necessary.
	4. The VS collaborate with their stakeholders to define responsibilities and execute actions that enable it to establish and maintain disease free zones for selected animals and animal products, as necessary.
	5. The VS can demonstrate the scientific basis for any disease free zones and can gain recognition by trading partners that they meet the criteria established by the OIE (and by the WTO SPS Agreement where applicable).

Terrestrial Code reference(s):

Chapter 4.3. on Zoning and compartmentalisation.

Annex XXXVII (contd)

Annex III (contd)

IV-8 Compartmentalisation	**Levels of advancement**
The authority and capability of the VS to establish and maintain disease free *compartments* as necessary and in accordance with the criteria established by the OIE (and by the WTO SPS Agreement where applicable).	1. The VS cannot establish disease free *compartments*.
	2. As necessary, the VS can identify animal sub-populations with a distinct health status suitable for compartmentalisation.
	3. The VS have implemented biosecurity measures that enable it to establish and maintain disease free *compartments* for selected animals and animal products, as necessary.
	4. The VS collaborate with their stakeholders to define responsibilities and execute actions that enable it to establish and maintain disease free *compartments* for selected animals and animal products, as necessary.
	5. The VS can demonstrate the scientific basis for any disease free *compartments* and can gain recognition by other countries that they meet the criteria established by the OIE (and by the WTO SPS Agreement where applicable).

Terrestrial Code reference(s):

Chapter 4.3. on Zoning and compartmentalisation.
Chapter 4.4. on Application of compartmentalisation.

Annex XXXVIII

Original: English

November 2009

REPORT OF THE NINTH MEETING OF THE OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 3- 5 November 2009

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The OIE Working Group on Animal Production Food Safety (the Working Group) held its ninth meeting at the OIE Headquarters on 3 to 5 November 2009.

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

Dr Bernard Vallat, OIE Director General, met with the Working Group for a brief discussion of OIE priorities and the future program of activity for the Working Group. After welcoming all participants and thanking members for their ongoing support of the OIE, Dr Vallat identified the horizontal issues that will be included in the OIE fifth Strategic Plan (2011-2016). These include: veterinary education policies globally; the contribution of aquaculture and aquatic animal health to food security and its importance for food safety; the effects of climate and environmental change on diseases and animal production; the interface between human and animal ecosystems, including wildlife; good governance in veterinary services; reinforcement of veterinary services' capacities and infrastructure, including veterinary legislation; and more generally the linkages between animal health, food safety and food security.

Dr Vallat informed the Working Group that since its establishment its activities have been tremendously beneficial to the OIE. Perhaps the most significant achievement is to provide a mechanism for sustainable and reliable coordination with the Codex Alimentarius Commission (CAC) with the goal of avoiding overlap, duplication and gaps in standards for the safety of the whole food production continuum. The meeting this week provides a timely opportunity to reflect on what has been achieved and to consider any reorientation of the Working Group that would be appropriate to take account of the changing needs of OIE Members and changes to the mandate of the OIE in the period of the fifth Strategic Plan.

Dr Vallat informed the Working Group on the continuing discussions with WHO on the revision of the current agreement between OIE and WHO and the possibility of WHO taking timely action to remove the present legal obstacle to the joint development of standards with the CAC.

Dr Vallat also informed the Working Group that he personally sees a need for ongoing input of the Working Group in regard to the following strategic priorities:

- One World, One Health;
- Linkage between animal welfare and animal production food safety;
- Education to support efficiently veterinary services involvement in food safety;
- Contribution of aquaculture and aquatic animal health to food security and its importance for food safety;
- Good governance, particularly in regard to veterinary services' contribution to food security;
- Link between animal health and animal production food safety;
- Implications of climate change for animal diseases and animal production food safety;
- Coordination between OIE Delegates and relevant national CAC and SPS focal points.

Dr Vallat commended the Working Group on its undertaking to review future OIE priorities for standard setting in animal production food safety, and confirmed that the discussion paper on priority pathogens, together with the recommendations of the Working Group, would be reviewed by the OIE Terrestrial Animal Health Standards Commission (the Code Commission) before being provided to OIE Members for comment. Dr Vallat reminded the Working Group that it should continue to approach issues from a scientific base, taking into account the different geographic, socio-economic, cultural and religious contexts of OIE Members. It is important to ensure that the OIE's work in setting international trade standards takes full account of the needs of developing countries, which constitute the majority of OIE Members. He informed the Group that it was possible at any time to invite specific *ad hoc* groups at their request if the Group sees any need for additional expertise.

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

1.1. OIE

Dr Sarah Kahn provided an update on the work of OIE. Detailed information is provided in Annex III.

1.2. Codex

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

1.3. FAO

Dr Katinka de Balogh provided an update on the work of FAO. Detailed information is provided in Annex V.

1.4. WHO

Dr Bernadette Abela-Ridder provided an update on the work of WHO. Detailed information is provided in Annex VI.

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

2. Animal Production Food Safety: priority pathogens for standard setting by the OIE

Dr Sarah Kahn introduced Dr Knight-Jones, who had worked as an intern with the OIE International Trade Department in 2009 and had prepared a discussion paper on 'Animal Production Food Safety: priority pathogens for standard setting by the OIE'.

Dr Knight-Jones gave a presentation of his main findings. He explained that data required for prioritisation of pathogens involved in foodborne disease are lacking, particularly for developing countries. Therefore, he based the discussion paper on expert opinion, consultation with colleagues at WHO, and a literature review. Prioritisation for standard setting was based on a pathogen's impact on human health; the potential for on-farm control and a lack of coverage in OIE *Codes*. As the OIE's mandate includes alleviating global poverty, the study focussed on developing and in-transition countries. Salmonella spp. in poultry, *Bacillus anthracis* and BSE were not considered as relevant standards have been or are being developed by the OIE.

The regions considered were Eastern Europe, Asia (excluding the Middle East), the Middle East, Africa and South America. Opinions from one or two experts from each region were obtained using a postal questionnaire.

In presenting his findings, Dr Knight-Jones explained that experts from four of the five regions considered *Salmonella spp*. from sources other than poultry to be a top priority and pathogenic *E.coli* was considered a top priority in three regions. *Brucella spp*. and *Staphylococcus aureus* were also mentioned by three regions. Control of non-poultry Salmonellosis has been achieved by some countries and non-specific on farm measures have helped to control pathogenic *E. coli*. The OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) contains little or no information on appropriate on-farm measures for these disease agents and Dr Knight-Jones recommended that they be prioritised for future standard setting.

Dr Knight-Jones also noted that on-farm control measures for *Brucella spp*. are known to be feasible and effective. In response, Dr Sarah Kahn advised that standards for *Brucella spp*. are currently under review by an OIE *ad hoc* Group and that the OIE International Trade Department would take steps to ensure that the *ad hoc* Group considers issues relevant to food safety.

E. granulosus, the causative agent of hydatidosis, was estimated to have the greatest impact of all foodborne pathogens in Africa; it was also listed for the Middle East and thought to be of importance by both South American experts consulted. Hydatidosis was inconsistently considered as a foodborne disease by experts. *Taenia saginata* was considered important in South America, Africa and by one expert in the Middle East. Although it causes relatively mild clinical signs in infected humans, it has a major impact through production losses in the beef industry and loss of export trade due to trade restrictions.

As the WHO/FAO/OIE have published recommendations on the control of *Echinococcus*, *Trichinella spiralis* and *Taenia solium*[8] there may be less reason to prioritise these pathogens for future OIE standard setting. However, the opinion of OIE Members should be sought on this question.

[8] WHO/FAO/OIE Guidelines for the Surveillance, Prevention and Control of Taeniosis/Cysticercosis, OIE, Paris, 2005 and WHO/OIE, WHO/OIE manual on Echinococcosis in humans and animals: a public health problem of global concern, OIE, 2001.

Dr Sarah Kahn commented that although the process of review had not been exhaustive, the recommendations in the discussion paper would be submitted to OIE Delegates for comment and that this would provide for a global review and validation of the recommendations by OIE Members. It is proposed that the discussion paper, with any modifications proposed by the Working Group or the Code Commission, would be published in the OIE *Scientific and Technical Review* series.

The Working Group noted the conclusions provided by Dr Knight-Jones and provided him with a number of comments. Noting the limitations of the methodology used, the Working Group concurred with the overall findings of the report that Salmonella spp. and pathogenic *E. coli* are the main candidates for prioritisation from a food safety point of view. The paper was not available at this meeting so the members of the Working Group agreed to provide the secretariat with any further comments by the end of November 2009. Some members suggested that, since the priority assigned by experts was based on their personal opinions and perceptions of problems, rather than on scientific data, the list of pathogens identified in the study should be used in the wider consultation of priority pathogens among OIE Members. The Working Group recommended that the final report, taking into account Working Group members' comments, be provided to OIE Members for further consideration of the proposed standard setting priorities.

The Working Group also requested that the Director General ensures ongoing communication between the OIE and WHO with regard to The Foodborne Disease Burden Epidemiology Reference Group (FERG) to assist in the prioritisation of pathogens for future OIE standard setting.

The 'Animal Production Food Safety: priority pathogens for standard setting by the OIE' paper including Working Group members' comments is presented at Annex VII.

3. Review the Working Group's Terms of Reference and *Modus Operandi*

The Working Group reviewed its Terms of reference and *Modus operandi* with a view to ensuring their ongoing relevance.

The Working Group was of the view that it can continue to provide useful advice to the Director General, Specialist Commissions and Working Groups as well as helping promote alignment/collaboration between OIE and CAC, with some minor modifications to these texts.

The Working Group was of the opinion that co-operation between the main technical partners at the governance level was an important element of its work and encouraged between session contact at the governance level between the bodies represented on the Working Group.

The Working Group proposals for the revised Terms of reference and *Modus operandi* are presented at Annex VIII.

4. OIE work on trade in animal products ('commodities')

Dr Sarah Kahn provided an update on the latest meeting of the *ad hoc* Group on Trade in Animal Products ('Commodities') that met in October 2009. The main objective of the meeting was to review the OIE/DfiD report "Qualitative Assessment of the commodity risk factor for spread of foot and mouth disease associated with international trade in deboned beef". The report of the *ad hoc* Group would be submitted to the Code Commission for consideration of appropriate next steps. Although the focus of this meeting was on FMD which is not a food safety issue, Dr Sarah Kahn highlighted the importance of international trade in animal products ('commodities') for OIE Members and noted that recommendations from a previous meeting of the *ad hoc* Group to review *Terrestrial Code* chapters with regard to the status of animal products as safe commodities was ongoing. Work with food safety relevance included the assessment of beef (Rift valley fever and bovine brucellosis); milk and milk products (bovine brucellosis, lactoperoxidase treatment to inactivate animal pathogens, sheep and goat milk). The *ad hoc* Group also recommended that the Code Commission continue working to improve the *Terrestrial Code* presentation and to make it more user-friendly.

5. Salmonellosis

Dr Gillian Mylrea provided an update on OIE work on salmonellosis and noted the active collaboration between the OIE and Codex to harmonise the relevant standards under development by the two organisations. Dr Mylrea reported that an OIE representative had attended the FAO/WHO Expert meeting on Salmonellosis and Campylobacter in May 2009 and the Codex Committee on Food Hygiene Physical Working Group on the proposed draft Guidelines for control of Campylobacter and Salmonella in chicken meat.

Dr Gillian Mylrea noted that the *Terrestrial Code* Chapter 6.5. Prevention, Detection and Control of Salmonella in Poultry was adopted at the OIE 77th General Session May 2009 and included the text provided by the Working Group to the Code Commission.

Dr Gillian Mylrea noted that the *Terrestrial Code* Chapter 6.4. Biosecurity Procedures in Poultry Production had been revised by the *ad hoc* Group on Salmonellosis following consideration of Member comments. The *ad hoc* Group had reduced the amount of detail that was previously in this chapter resulting in text that addressed in a generic manner the fundamental hygiene and biosecurity practices. The chapter has been circulated to Members as part of the October 2009 Report of the Code Commission and the intention is to propose it for adoption in May 2010.

The Working Group noted the excellent collaboration between the OIE and CAC on standards related to salmonellosis in poultry (leading to aligned standards) and recommended that such collaboration be continued with the CAC in standard setting for salmonellosis and campylobacteriosis in poultry.

6. The control of hazards of animal health and public health importance in heat-treated pet food

Dr Sarah Kahn reported that the Code Commission had accepted a proposal from the international pet food industry to develop a text with recommendations for companion animal feed (pet food) for inclusion in the *Terrestrial Code*. The pet food industry worked with several OIE experts, including a member of the Code Commission, and submitted a supporting document and draft text for consideration by the Code Commission. The Code Commission amended this text at its September 2009 meeting and provided it to Members for comment. The supporting document was also provided to Members for information. Once OIE Members have indicated that they are in agreement with this text, appropriate articles will be added to Chapter 6.3. Control of Hazards of Animal Health and Public Health importance in Animal Feed.

The Working Group reviewed the proposed draft text 'The control of hazards of animal and public health importance in heat-treated pet food' and suggested that the Code Commission consider adding references to the Codex Codes (Recommended International Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods (CAC/RCP 23-1979) and Code of Hygienic Practice for Aseptically Packaged and Processed Low Acid Foods (CAC/RCP 40-1993)) in Article 2 (Objectives and scope).

7. *Aquatic* and *Terrestrial Code* chapters on the control of hazards of animal health and public health importance in animal feed

The Working Group reviewed the revised *Aquatic* and *Terrestrial Code* chapters on the control of hazards of animal health and public health importance in animal feed.

The Working Group noted that the definition of *feed additive* used in the *Terrestrial* and *Aquatic Code* chapters differed from the CAC definition and recommended that the two OIE Commissions align definitions as far as possible with CAC definitions.

The Working Group noted that the *Aquatic Code* Chapter 4.5. included more detailed information on certification procedures (Article 4.5.9.) than the equivalent *Terrestrial Code* Chapter 6.3. and recommended that the Code Commission give consideration to expanding the text on certification procedures to harmonise the two chapters.

The Working Group recommended the following amendments to the *Terrestrial Code* Chapter 6.3.:

- Article 6.3.3. definition for *Feed additive* – add the word 'or' before 'of the animal products' and align with Codex definition.

- Article 6.3.4. point 2 amend as shown below:

  2. Regulatory safety standards

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

The Working Group recommended the following amendments/considerations to the *Aquatic Code* Chapter 4.5.:

- Glossary definition for *Feed additive* – align with the *Terrestrial Code* definition and Codex definition, as far as possible.

- Article 4.5.4., point 6. Bioaccumulation, replace the word 'fatty' with 'certain' as accumulation of some heavy metals occurs in other tissues.

- Article 4.5.4., point 14. Cross-contamination – delete duplication of text ('Procedures, such as flushing, sequencing and physical clean-out, should be used to reduce the likelihood of contamination between batches of feed or feed ingredients.')

- The heading 'safe commodities' in Article 4.5.8. 1a) may be misleading as it refers only to microbiological safety and does not take into account chemical or physical hazards (e.g. dioxins and PCBs).

- Article 4.5.8. 1a) line 3, the words 'normal commercial practice' should be replaced by 'Good Manufacturing Practice'.

- That the OIE Aquatic Animal Health Standards Commission (Aquatic Animals Commission) consider the food safety implications of the use of animal manure and human slurry as feed in aquaculture.

- That the Aquatic Animals Commission consider the addition of a reference to the Codex Code of Practice on Fish and Fishery Products (CAC/RCP 52-2003) to Article 4.5.1.

8. Antimicrobial resistance

Dr Kazuaki Miyagishima, Head of the Scientific Department, joined the Working Group for this item. Dr Miyagishima reported that the OIE continues to participate as an observer in the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance and considers that the chapters in the Terrestrial Code on antimicrobial resistance have provided a good basis for the Codex work.

Dr Bruno noted that the report of the 3rd Session of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance held in Republic of Korea, October 2009 was available on the CAC website and that the 4th Session of the Task Force will be held in Republic of Korea in October/November 2010.

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

Dr Sarah Kahn also noted that the OIE World Assembly of Delegates at the 77th OIE General Session in May 2009 had expanded the mandate of the Aquatic Animals Commission to include animal production food safety and animal welfare. As one of its first priorities, the Aquatic Commission is developing a new text addressing the issue of antimicrobial resistance, along similar lines to Chapters 6.7., 6.8., 6.9., 6.10. and 6.11. in the *Terrestrial Code*.

9. Biotechnology

Dr Miyagishima joined the Working Group for this item. Dr Miyagishima reported that the OIE *ad hoc* Group on Biotechnology had been divided into two separate groups: the *ad hoc* Group on Vaccines in Relation to New and Emerging Technologies, focused on vaccinology and the other on molecular diagnostic tests.

The *ad hoc* Group on Vaccines in Relation to New and Emerging Technologies will meet in November 2009 with the main task of reviewing texts in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and updating them where relevant. The *ad hoc* Group will meet again in January 2010 for one day dedicated to consider food safety aspects related to the use of biotechnology derived vaccines in animals. The members of the latter meeting will include experts to be nominated by FAO and WHO, using official procedures, in addition to OIE experts.

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.

10. Private standards for sanitary measures and animal welfare

Dr Sarah Kahn briefed the Working Group on the current OIE work programme on private standards. In August the OIE sent a questionnaire on private standards for animal welfare and for sanitary measures (i.e. animal health, zoonoses and animal production food safety) to Members. Some 64 Members and 6 organisations that have agreements with the OIE have provided replies, which will be reviewed by the *ad hoc* Group on Private Standards at its meeting on 9-10 November 2009.

The *ad hoc* Group has been asked to recommend actions that could be taken by the OIE strategy to help Members to avoid trade problems arising from private standards on sanitary measures and on animal welfare.

Dr Karen Hulebak informed members that the matter had been discussed at the 32nd session of the CAC. Like the OIE, the CAC is engaged with the SPS Committee Working Group that is examining this issue.

The Working Group noted this update and requested that the OIE provide an update on developments in due course.

11. Animal Identification and Traceability Conference 2009

Dr Gillian Mylrea briefed the Working Group on the recommendations from the 'OIE International Conference on Animal Identification and Traceability' held in Buenos Aires, 23-25 March, 2009. The OIE is collecting the remaining papers submitted by speakers to the conference and it is hoped to publish the proceedings by mid 2010. In the meantime, Powerpoint presentations and abstracts may be found on the OIE website (http://www.oie.int/eng/traceability-2009/documents.html).

12. Work Programme for 2010

The Working Group proposed work programme for 2010 is presented at Annex IX.

13. Next meeting

The Working Group plans to hold its next meeting in early November 2010.

Work on key items will be progressed via physical or electronic working groups on an as needed basis.

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…/ Annexes

MEETING OF THE OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 3- 5 November 2009

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Annex XXXVIII (contd)

Annex I (contd)

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Annex XXXVIII (contd)

Annex II

MEETING OF THE OIE ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

Paris, 3- 5 November 2009

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Adopted agenda

Welcome from the OIE Director General

Adoption of the Agenda

Report of the previous Working Group Meeting

1. Update on OIE / Codex / FAO / WHO activities
   - 1.1. OIE
   - 1.2. Codex
   - 1.3. FAO
   - 1.4. WHO
2. Priority pathogens for future standard setting at the OIE
3. Review the Working Group's Terms of Reference and Modus Operandi
4. OIE work on trade in animal products ('commodities')
5. Salmonellosis
6. The control of hazards of animal health and public health importance in heat treated pet food
7. Aquatic and Terrestrial Code chapters on the control of hazards of animal health and public health importance in animal feed
8. Antimicrobial resistance
9. Biotechnology
10. Private standards for sanitary measures and animal welfare
11. Animal Identification and Traceability Conference 2009
12. Work Programme for 2010
13. Next meeting

Annex III

UPDATE ON OIE ACTIVITIES

Following is a brief summary of OIE activities during 2009 relevant to animal production food safety.

Terrestrial Animal Health Standards Commission

At the 77th OIE General Session, May 2009, new *Terrestrial Code* chapters were adopted on:

- The control of hazards of animal health and public health importance in animal feed (Chapter 6.3.);
- Prevention, detection and control of *Salmonella* in poultry (Chapter 6.5.); and
- Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.7.).

The Commission met in September 2009 to address Member comments received after the last meeting in March 2009 and comments received at the 77th General Session, as well as the work done by OIE *ad hoc* Groups (private standards; import risk analysis; salmonellosis; laboratory animal welfare; electronic consultation on poultry welfare; animal welfare and broiler production systems; animal welfare and beef cattle production systems) and the OIE Animal Welfare Working Group.

The Commission examined and revised existing texts, and proposed new texts, on the following subjects relevant to animal production food safety:

- Design and implementation of systems for animal identification and traceability
- The control of hazards of animal health and public health importance in animal feed
- The control of hazards of animal health and public health importance in heat treated pet food
- Biosecurity procedures in poultry production
- Prevention, detection and control of salmonella in poultry
- Introduction to the recommendations for controlling antimicrobial resistance
- Anthrax; West Nile fever; BSE; bovine tuberculosis.

The *ad hoc* Group on Brucellosis will meet on 24-26 November 2009 to review the *Terrestrial Code* chapters on brucellosis.

Meeting of the Aquatic Animal Health Standards Commission (September 2009)

At the 77th General Session 2009, the OIE World Assembly approved the extension of the mandate of the Aquatic Animal Health Standards Commission to deal with food safety issues at production level. The issue of antimicrobial resistance will be the first item to be addressed by the Commission.

Annex XXXVIII (contd)

Annex III (contd)

The Aquatic Animals Commission met in September 2009 to consider OIE Member comments on the *Aquatic Animal Health Code* and discussion at the 77th General Session in May 2009. Key texts that may be proposed for adoption in 2010 include: the safety of commodities derived from aquatic animals; the food safety implications of aquatic animal feed; and welfare of farmed fish during slaughter for human consumption.

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

The *ad hoc* Group met in August 2009 and reviewed the OIE *Handbook on Import Risk Analysis for Animals and Animal Products* (Volumes I and II). Members agreed that Volume I (Introduction and qualitative risk analysis) was basically sound but the contents should be reorganised to facilitate understanding and make this publication more useful as a training tool. Members recommended that Volume II (quantitative risk assessment) remain unchanged. Finalisation of the revised manuscript for Volume I is anticipated by the end of 2009 with publication in early 2010. The publication will be available by downloading, free of charge, from the OIE website and by purchase in hard copy.

OIE Fifth Strategic Plan (2011-2016)

The OIE fifth Strategic Plan was discussed by the OIE Council at its meeting in October 2009 and the revised Plan will be circulated to Delegates with a view to adoption at the 78th OIE General Session in May 2010.

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Annex XXXVIII (contd)

Annex IV

UPDATE ON CODEX ALIMENTARIUS COMMISSION ACTIVITIES

CODEX SESSIONS SINCE THE LAST MEETING OF THE OIE APFSWG (4-6 NOVEMBER 2008)

- The 30th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (Cape Town, South Africa, 3-7 November 2008)
- The 16th Session of the FAO/WHO Coordinating Committee for Asia (Denpasar, Indonesia, 17-21 November 2008)
- The 17th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (Cebu, Philippines, 24-28 November 2008)
- The 40th Session of the Codex Committee on Food Hygiene (Guatemala City, Guatemala, 1-5 December 2008)
- The 5th Session of the FAO/WHO Coordinating Committee for Near East (Tunis, Tunisia, 26-29 January 2009)
- The 21st Session of the Codex Committee on Fats and Oils (Kota Kinabalu, Malaysia, 16-20 February 2009)
- The 18th Session of the FAO/WHO Coordinating Committee for Africa (Accra, Ghana, 24-27 February 2009)
- The 30th Session of the Codex Committee on Methods of Analysis and Sampling (Balatonalmádi, Hungary, 9 - 13 March 2009)
- The 41st Session of the Codex Committee on Food Additives (Shanghai, China, 16-20 March 2009)
- The 3rd Session of the Codex Committee on Contaminants in Foods (Rotterdam, the Netherlands, 23-27 March 2009)
- The 25th Session of the Codex Committee on General Principles (Paris, France, 30 March – 3 April 2009)
- The 41st Session of the Codex Committee on Pesticide Residues (Beijing, China, 20-25 April 2009)
- The 37th Session of the Codex Committee on Food Labelling (Calgary, Canada, 4-8 May 2009)
- The 18th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (Natal, Brazil, 11-15 May 2009)
- The 62nd Session of the Executive Committee of the Codex Alimentarius Commission (Rome, Italy, 23-26 June 2009)
- The 32nd Session of the Codex Alimentarius Commission (Rome, Italy, 29 June – 4 July 2009)
- The 30th Session of the Codex Committee on Fish and Fishery Products (Agadir, Morocco, 28 September – 2 October 2009)
- The Third Session of the *ad hoc* Codex Intergovernmental Task Force on Antimicrobial Resistance (Jeju, Republic of Korea, 12-16 October 2009)

Annex XXXVIII (contd)

Annex IV (contd)

- The 15th Session of the Codex Committee on Fresh Fruits and Vegetables (Mexico City, Mexico, 19-23 October 2009)

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

The 32nd Session of the **Codex Alimentarius Commission**[9]**,** among others:

- adopted 28 new or revised Codex standards or related texts (see **Appendix I**);
- approved a number of new work proposals (see **Appendix II**);
- noted the status of implementation of the Strategic Plan 2008-2013 of the Codex Alimentarius Commission;
- agreed on a number of recommendations intended to improve the participation of developing countries, especially as regards capacity building and the Codex Trust Fund; and
- supported continued cooperation and coordination with international governmental and non-governmental organizations.

Discussion of the 32nd Session of the Commission on future work on animal feeding.

The Commission considered the report of the electronic working group (e-WG) established at its 31st Session, which identified 6 items for future work:

i) Review of existing Codex risk analysis principles as to their applicability to animal feed;

ii) Review of Codex texts on emergency situations and exchange of information on rejected food as to their applicability to animal feed (CAC/GL 25-1997 and CAC/GL 19-1995);

iii) Review of the Codex *Code of Practice for Sources Directed Measures to Reduce Contamination of Food with Chemical* (CAC/RCP 49-2001) as to their applicability to animal feed;

iv) Development of guidelines for governments on the application of risk assessment methodologies to the various types of hazards related to contaminants/residues in feed ingredients;

v) Development of a prioritised list of hazards in feed and feed ingredients for governments; and

vi) Establishment of criteria for the global identification and notification of emergency situations affecting the feed.

The Commission recognised the full support for further Codex work on animal feeding and established an electronic working group, hosted by Denmark and co-chaired by the United States of America, to:

i) Review of existing Codex risk analysis principles as to their applicability to animal feed;

[9] The full report of the meeting is available at: http://www.codexalimentarius.net or at ftp://ftp.fao.org/codex/Alinorm09/al32REPe.pdf.

ii) Review of Codex texts on emergency situation and exchange of information on rejected food as to their applicability to animal feed (CAC/GL 25-1997 and CAC/GL 19-1995);

iii) Review of the Codex *Code of Practice for Sources Directed Measures to Reduce Contamination of Food with Chemical* (CAC/RCP 49-2001) as to their applicability to animal feed; and

iv) Propose suitable mechanisms for addressing the remaining three items.

The report of the working group, to be completed by January 2010, will be considered by the 33rd Session of the Commission (Geneva, Switzerland, 5-9 July 2010).

The 17th Session of the **Codex Committee on Food Import and Export Inspection and Certification Systems** finalised work on the renamed Generic Model Official Certificate (Annex to the *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* - CAC/GL 38-2001) and recommended the Commission to request the Codex Committees on Fish and Fishery Products and on Milk and Milk Products to consider revising the *Model Certificate for Fish and Fishery Products* (CAC/GL 48-2004) and *Model Export Certificate for Milk and Milk Products* (CAC/GL 67-2008) to ensure consistency with the Generic Model Official Certificate. It agreed to forward to the 32nd Session of the Commission a project document for new work on the development of principles and guidelines for National Food Control Systems; and to discontinue consideration of the discussion papers on the development of Guidance on Traceability / Product Tracing and on Guidance on the Prevention of Intentional Contamination of Food.

The 40th Session of the **Codex Committee on Food Hygiene** expressed appreciation to the OIE for their information and contribution to the work of the Committee and noted the need for continued collaboration in areas of mutual interest. The Committee finalised its work on the Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods; agreed to continue working on the Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat and on the Proposed Draft Code of Hygienic Practice for *Vibrio* spp. in Seafood. It further agreed to forward to the 32nd Session of the Commission a project document for new work on the elaboration of a Code of Hygienic Practice for Viruses in Food.

The 25th Session of the **Codex Committee on General Principles** agreed that the Codex Secretariat should approach the OIE secretariat and prepare a discussion paper on the possible development of joint standards between Codex and OIE, addressing all relevant procedural and other issues, as well as implications, for consideration by its next session.

The 18th Session of the **Codex Committee on Residues of Veterinary Drugs in Foods** forwarded to the 32nd Session of the Commission for adoption MRLs for seven veterinary drugs in various animal species/tissue combinations (avilamycin, dexamethasone, melengestrol acetate, monensin, narasin, triclabendazole and tylosin) and the 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. It also agreed to prepare a discussion paper which would review all the factors taken into account in connection with establishing the ADI and the current process of recommending MRLs; and to further consider future work on risk management recommendations for veterinary drugs with no ADI/MRL.

The 30th Session of the **Codex Committee on Fish and Fishery Products** agreed to forward to the Commission for final adoption the Draft Code of Practice for Fish and Fishery Products (Lobsters and Crabs and relevant Definitions); an amendment to the definition of "clean water" in Section 2.1 General Definitions of the *Code of Practice for Fish and Fishery Products*; and the Draft Standard for Sturgeon Caviar. The Committee also agreed to forward to the Commission the Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish and the Proposed Draft Standard for Fish Sauce, for adoption as a draft standard and further consideration at the next session of the Committee.

Annex XXXVIII (contd)

Annex IV (contd)

The Committee further agreed to continue discussion at its next session on i) the Proposed Draft Amendment to Section 3.4.5.1 Water of the *Code of Practice for Fish and Fishery Products*; ii) the Proposed Draft Standard for Quick Frozen Scallop Adductor Muscle Meat; iii) the Proposed Draft Revision for the Inclusion of Additional Species in Standards for Fish and Fishery Products; iv) the Draft List of Methods for the Determination of Biotoxins in the Standard for Raw and Live Bivalve Molluscs; v) the Proposed Draft Code of Practice for Fish and Fishery Products (Other Sections including Smoked Fish); vi) the Proposed Draft Standard for Fresh/Live and Frozen Abalone (*Haliotis* spp.); and vii) the Proposed Draft Amendment to the *Codex Standard for Quick Frozen Fish Sticks* (Nitrogen Factors).

The Third Session of the ***ad hoc*** **Intergovernmental Task Force on Antimicrobial Resistance** forwarded the Proposed Draft Guidelines for the Risk Analysis of Foodborne Antimicrobial Resistance to the Commission for adoption as Draft Guidelines and finalisation at its next session in 2010, as the Task Force should hold its final meeting and complete its work in 2010.

FORTHCOMING CODEX MEETINGS (relevant to the OIE APFSWG)

- The 41st Session of the Codex Committee on Food Hygiene (San Diego, United States of America, 16-20 November 2009)

- The 63rd Session of the Executive Committee of the Codex Alimentarius Commission (Geneva, Switzerland, 8-11 December 2009)

- The 9th Session of the Codex Committee on Milk and Milk Products (Auckland, New Zealand, 1-5 February 2010)

- The 18th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (Surfers Paradise, Australia, 1-5 March 2010)

- The 26th Session of the Codex Committee on General Principles (Paris, France, 12-16 April 2010)

- The 33rd Session of the Codex Alimentarius Commission (Geneva, Switzerland, 5-9 July 2010)

- The 19th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (30 August – 3 September 2010)

The 41st Session of the **Codex Committee on Food Hygiene** will consider the following proposed drafts: Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat; an Annex on Leafy Green Vegetables including Leafy Herbs for inclusion in the Code of Hygienic Practice for Fresh Fruits and Vegetables; a Code of Hygienic Practice for *Vibrio* spp. in Seafood and an Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Molluscan Shellfish; and a Code of Hygienic Practice for Control of Viruses.

The 9th Session of the **Codex Committee on Milk and Milk Products** will consider draft standards on cheese products and the consistency of the *Model Export Certificate for Milk and Milk Products* (CAC/GL 67-2008) with the *Generic Model Official Certificate* (*Annex to the Guidelines for Design, Production, Issuance and Use of Generic Official Certificates*.

The 18th Session of the **Codex Committee on Food Import and Export Inspection and Certification Systems** will consider the following proposed draft: Principles and Guidelines for the Conduct of Foreign On-Site Audits and Inspections; and Principles and Guidelines for National Food Control Systems. International Organizations, including OIE, have been invited to present relevant work to the Committee.

Annex XXXVIII (contd)

Annex IV (contd)

LISTS OF STANDARDS AND RELATED TEXTS ADOPTED BY THE THIRTY-SECOND SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Part 1 – Standards and Related Texts Adopted at Step 8

Standards and Related Texts	Reference	Status
Regional Standard for Gochujang	ALINORM 09/32/15 Appendix II	Adopted with amendment (see Agenda Item 5)
Regional Standard for Ginseng Products	ALINORM 09/32/15 Appendix III	Adopted with amendment (see Agenda Item 5)
Code of Practice for the Reduction of Acrylamide in Foods	ALINORM 09/32/41 Appendix IV	Adopted
Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes	ALINORM 09/32/41 Appendix V	Adopted
Food Additive Provisions of the General Standard for Food Additives (GSFA)	ALINORM 09/32/12 Appendix IV	Adopted (except erythrosine) (see Agenda Item 5)
Amendment to the Standard for Named Vegetable Oil: Inclusion of Rice Bran Oil	ALINORM 09/32/17 Appendix II	Adopted
Guidelines for Settling Disputes on Analytical (Test) Results	ALINORM 09/32/23 Appendix II	Adopted
Guidelines on Analytical Terminology	ALINORM 09/32/23 Appendix III	Adopted
Table of Conditions for Nutrient Contents (Part B: Provisions on Dietary Fibre) to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997):	ALINORM 09/32/26 Appendix II	Adopted
Provisions on Gum Arabic (Gum acacia) (Section D: Advisory List of Food Additives for Special Nutrient Forms) to the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1997)	ALINORM 09/32/26 Appendix III	Adopted (as a carrier) (see Agenda Item 5)
Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses	ALINORM 09/32/26 Appendix IV	Adopted
Standard for Jams, Jellies and Marmalades	ALINORM 09/32/27 Appendix II	Adopted with amendment (see Agenda Item 5)
Codex Standard for Certain Canned Vegetables (General Provisions)	ALINORM 09/32/27 Appendix III	Adopted
Maximum Residue Limits for Pesticides	ALINORM 09/32/24 Appendix II	Adopted
Maximum Residue Limits for Veterinary Drugs	ALINORM 09/32/31 Appendices II	Adopted
Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals	ALINORM 09/32/31 Appendix V	Adopted

Standards and Related Texts	Reference	Status
Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals	ALINORM 09/32/31 Appendix V	Adopted

Part 2 – Standards and Related Texts Adopted at Step 5/8 (with omission of Step 6 and 7)

Standards and Related Texts	Reference	Status
Regional Standard for Fermented Soybean Paste	ALINORM 09/32/15 Appendix IV	Adopted with amendment (see Agenda Item 5)
Revision to the Preamble of the GSCTF	ALINORM 09/32/41 Appendix III	Adopted
Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee	ALINORM 09/32/41 Appendix VI	Adopted
Food Additive Provisions of the General Standard for Food Additives (GSFA)	ALINORM 09/32/12 Appendix IV	Adopted (except erythrosine) (see Agenda Item 5)
Amendments to the International Numbering System for Food Additives	ALINORM 09/32/12 Appendix VII	Adopted
Specifications for the Identity and Purity of Food Additives arising from the 69th JECFA meeting	ALINORM 09/32/12 Appendix VIII	Adopted
Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods (Annex II to the Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods (CAC/GL 61-2007)	ALINORM 09/32/13 Appendix II	Adopted with amendment (see Agenda Item 5)
Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special Medical Purposes for Young Children (Annex II to the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008))	ALINORM 09/32/13 Appendix III	Adopted with amendment (see Agenda Item 5)
Generic Model Official Certificate (Annex to *Guidelines for Design, Production, Issuance and Use of Generic Official Certificate* (CAC/GL 38-2001)	ALINORM 09/32/30 Appendix II	Adopted
Recommendations on the Scientific Basis of Health Claims (Annex to the *Guidelines for Use of Nutrition and Health Claims* - CAC/GL 23-1997)	ALINORM 09/32/26 Appendix V	Adopted

Annex XXXVIII (contd)

Annex IV (contd)

Standards and Related Texts	Reference	Status
Provisions for packing media for certain canned vegetables: Section 3.1.3 (for inclusion in the Standard for Certain Canned Vegetables)	ALINORM 09/32/27 Appendix IV	Adopted
Annexes specific to certain canned vegetables (for inclusion in the Standard for Certain Canned Vegetables)	ALINORM 09/32/27 Appendix V	Adopted
Maximum Residue Limits for Pesticides	ALINORM 09/32/24 Appendix III	Adopted with amendment (see Agenda Item 5)
Maximum Residue Limits for Veterinary Drugs	ALINORM 09/32/31 Appendix III	Adopted

Part 3 - Standards and Related Texts Adopted at Step 5 of the Accelerated Procedure

Standards and Related Texts	Reference	Status
Amendment to the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*: Annex 2 (conditions for use of rotenone)	ALINORM 09/32/22 Appendix V	Adopted

Part 4 – Other Standards and Related Texts Submitted for Adoption

Standards and Related Texts	Reference	Status
Amendments to Paragraph 10, Sample Preparation in the Sampling Plans for Aflatoxin Contamination in Ready-to-Eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios	ALINORM 09/32/41 Appendix II	Adopted
Amendment to the Annex to Table 3 of the GSFA	ALINORM 09/32/12 para. 9	Adopted
Amendment to the Name and Descriptors of Food Categories 01.2.1.1, 15.1 and 15.2 of the GSFA	ALINORM 09/32/12 Appendix IX	Adopted
Amendment to the Standard for Named Vegetable Oils: replacement of the section on contaminants with the standard language in the *Format for Codex Commodity Standards*	ALINORM 09/32/17	Adopted
Additives Provisions in the *Standard for Fat Spreads and Blended Spreads* and other Standards for Fats and Oils	ALINORM 09/32/17 Appendix VII ALINORM 09/32/12 Appendix III	Adopted
Methods of Analysis in Codex Standards at different steps	ALINORM 09/32/23 Appendix IV	Adopted

Annex XXXVIII (contd)

Annex IV (contd)

APPENDIX II

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

Responsible Body	Standard and Related Texts	Reference	Job Code
CCPR	Priority List of Chemicals scheduled for Evaluation and Re-evaluation by JMPR	ALINORM 09/32/24, par. 186-206 and Appendix XI	Ongoing
CCRVDF	Priority List of Veterinary Drugs for Evaluation or Reevaluation by JECFA	ALINORM 09/32/31, para. 138 and Appendix VI	Ongoing
CCPFV	Revision of the *Standards for Canned Bamboo Shoots* (CODEX STAN 241-2003) and *Canned Mushrooms* (CODEX STAN 55-1981) for inclusion as annexes to the Draft Standard for Certain Canned Vegetables	ALINORM 09/32/27, para. 109	N01-2009
CCPFV	Revision of the Standard for Table Olives (CODEX STAN 66-1981)	ALINORM 09/32/27, para. 109	N02-2009
CCPFV	Revision of the Standard for Grated Desiccated Coconut (CODEX STAN 177-1991)	ALINORM 09/32/27, para. 109	N03-2009
CCLAC	Regional Standard for Culantro Coyote	ALINORM 09/32/36, para. 72	N04-2009
CCLAC	Regional Standard for Lucuma	ALINORM 09/32/36, para. 76	N05-2009
CCFICS	Principles and Guidelines for National Food Control Systems	ALINORM 09/32/30, para. 71 and Appendix III	N06-2009
CCFH	Code of Hygienic Practice for Control of Viruses in Food	ALINORM 09/32/13, para. 138 and Appendix V	N07-2009
CCNEA	Regional Standard for Harissa (hot pepper paste)	ALINORM 09/32/40, para. 41	N08-2009
CCNEA	Regional Standard for Halwa Tehenia (halwa shamia)	ALINORM 09/32/40, para. 44	N09-2009
CCCF	Maximum Levels for Fumonisins in Maize and Maize Products and associated Sampling Plans	ALINORM 09/32/41, para. 100 and Appendix VII	N10-2009
CCCF	Code of Practice for the Reduction of Ethyl Carbamate in Stone Fruit Distillates	ALINORM 09/32/41, para. 114 and Appendix VIII	N11-2009
CCCF	Revision of the Code of Practice for the Prevention and Reduction of Aflatoxins in Tree Nuts (CAC/RCP 59-2005): Additional Measures for Brazil Nuts	ALINORM 09/32/41, para. 122 and Appendix IX	N12-2009
CCCF	Maximum Levels for Melamine in Foods and Feed	ALINORM 09/32/41, para. 125 and Appendix X	N13-2009

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Annex V

UPDATE ON FAO ACTIVITIES

FAO, through the Emergency Centre for Transboundary Animal Diseases (ECTAD) projects, is actively involved in the promotion of biosecurity on farm and along marketing chains. Activities over the last 12 months included:

Poultry production

1. Completion of a series of four sub regional workshops on Biosecurity on farm in West and Central Africa (each involving over 50 participants from 5-8 countries). The workshops were conducted in collaboration with DAI (STOP-AI programme) and involved commercial producers, representatives from smallholders cooperatives but also representatives from local authorities involved in the management of markets and representative from vet services.

2. Production of both a manual for trainers and producers in East Africa (Title: Good Practices in Small Scale Poultry Production) and its pictorial version developed more specifically for semiliterate farmers. The implementation of biosecurity measures on-farm are proposed as part of a package to increase productivity and reduce losses in production. The content of the manual has received the approval of technical experts in three different East African countries (workshops) and is now distributed in the region. A revised version with minimal changes on content but extensive revision of the layout is foreseen.

3. Capacity building to improve technical knowledge on biosecurity related issues among commercial producers and within public vet services in Bangladesh and Indonesia. These activities are implemented under the ongoing FAO "Developing and Maintaining Public-Private Partnerships for the Prevention and Control of Highly Pathogenic Avian Influenza H5N1 and other Emerging Infectious Animal Diseases" project (the PPP Project) which aims at strengthening collaboration and communication between the public and private sector in Egypt, Indonesia and Bangladesh

4. Testing of innovative methodologies to promote biosecurity and assessment of rate of adoption of biosecurity measures among small holder poultry producers in Egypt, Nigeria, Indonesia and Bangladesh. These activities are implemented under the "Improved biosecurity and hygiene at production, collection points and live bird markets (LBM), including decontamination" project.

Pig production

FAO has taken the lead in the development of an FAO, OIE, WB document with the title: "Good practices for Biosecurity in the pig sector - Issues and Options in Developing and in transition countries". The preparation of the document is at its final stage. FAO intends to implement a project on Biosecurity in small scale confined and scavenging pig production systems over the next three years.

Abattoir

The Animal Production Service at HQ (AGAP) and the Livestock Group of the FAO Regional Office for the Asia-Pacific (RAPG) are elaborating a technical publication on Abattoir options and designs for small and medium scale abattoirs. This publication will include designs for ruminants, pig and poultry abattoirs. It is planned to make this technical publication available in hard and soft copy through the FAO website. This publication should be available early next year. AGAP is also currently involved in project TCP/MON/3105 in Mongolia on “Improved meat hygiene and commercial meat processing”.

Annex XXXVIII (contd)

Annex V (contd)

Salmonella and Campylobacter related activities

Draft Codex guidelines on the control of Salmonella and Campylobacter are to be discussed in the next session of the CCFH in November 2009. ftp://ftp.fao.org/codex/ccfh41/fh41_04e.pdf

JEMRA has provided the scientific advice required for the preparation of these guidelines and is preparing a webtool to support the implementation of the Guidelines. The prototype of the tool will be presented at the CCFH. It is expected to have the tool finished the first semester of next year. OIE received the draft report of the JEMRA meeting and used for the work they are doing on Salmonella OIE code. OIE representative/and one expert also participated in JEMRA meeting

Animal Feed

1. In the last 10 year FAO has increase its work and commitment to feed safety, this has resulted in two Expert Meetings (reports available online at: http://www.fao.org/ag/againfo/resources/en/pubs_food.html) and a series of publications and capacity building material also available at the same URL;

2. FAO, jointly with the International Feed Industry Federation (IFIF) has produces a Manual of Good Practices for the Feed Industry, which is now in its final production phase and should be printed in November and translated in all FAO's official languages. This manual has the purpose to support the implementation of the Codex Code of Practice for Good Animal feeding and at this scope provides detailed, concrete indications. Depending of funds availability, FAO is also preparing a series of capacity building activities to disseminate the information of the manual;

3. FAO, also jointly with IFIF is now preparing the 3rd Global Feed and Food Congress, which will take place in Mexico in April 2010;

4. FAO is active in increasing the dialogue and collaboration among relevant players and is now organizing the third International Feed Regulators meeting, which will take place in Atlanta, USA, in January 2010 and bring together worldwide regulators and feed industry representatives, exchanging information and positions on their efforts to ensure feed safety;

5. FAO, together with WHO is including feed safety in the INFOSAN documents and activities;

6. FAO's technical services jointly with its Legal office, have and are continuing to provide support to its members in the development and/or upgrading national legislations in support of feed safety;

7. Finally, FAO, with relevant partners is developing a web-based "Gateway to Adequate, Safe and Sustainable Animal Nutrition and Feeding", which will be a to serve as a single access point for a wide range of information and a participatory platform to retrieve and submit information, as well as to engage in commonly developed projects and thematic discussions. It will gather relevant legislation, statistics, scientific and technical papers, publications, codes of practices and standards, projects, information on available funds, but also a directory of professionals, research and educational centres, etc. As for the Gateway on Animal Welfare, OIE could become a partner if interested.

For all the above, the future work of OIE on feed safety should take into account the already existing and planned FAO activities and collaboration actively sought. Of course, the most appropriate way to ensure coordination and relevant collaboration would be the inclusion of FAO in the OIE Animal feeding (or feed safety) working group; it should be clarified that the presence in that group of a colleague for the Codex Secretariat should be intended as representative of CODEX and NOT FAO.

Antimicrobial resistance

Antimicrobial resistance. AGNS and AGAH are awaiting proposals coming from the new joint group on this matter. There would however be a need for additional funds to support any activities on this matter.

Biotechnology

AGP is organising a big Conference on this matter and AGN is responsible of organising a matter on biosecurity/biosafety. in Mexico in 2010 (March?).

Private Standards

FAO is implementing a programme to support the development of procedures focusing on origin-linked specific quality that will contribute to rural development (quality linked to geographical denomination)

http://www.foodquality-origin.org/eng/index.html

http://www.foodquality-origin.org/guide/guide.pdf

The Codex Chair has requested to FAO and WHO to prepare a paper on impact of private standards on food safety in developing countries and organise a respective session on this matter prior to the next CAC July 2010.

Animal Identification and Traceability Conference 2009

Although the WG had advised for FAO to be part of the conference, FAO was not permitted to co-organise the Conference although a FAO contribution of 50.000 USD could be made available

Within FAO, AGAP is chairing a task force (in liaison with ICAR) for developing countries (with representatives from ASIA, LAC, SADC, MENA, EUROPE) to work on Animal identification, traceability and performance recording. The short term goal is capacity building and to develop Guidelines. Two training workshop have been conducted in Eastern Europe and MENA in collaboration with the FAO regional offices. On 2 November a workshop is organised in Gaboronne by FAO jointly with the Livestock Technical Committee of SADC on the same subject. The participation of 50 persons from 14 countries is expected.

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Annex VI

UPDATE ON WHO ACTIVITIES

WHO Activities

Global Foodborne Infections Network - formerly WHO Global Salm-Surv

Though originally focusing on *Salmonella* diagnostics and epidemiology, the WHO Global Salm-Surv (WHO GSS) training programme has evolved into a capacity-building platform that accommodates a variety of foodborne and other enteric pathogens and diseases of importance in the various regions. In order to reflect this broader scope and application, the WHO GSS network has now changed name to: **Global Foodborne Infections Network (GFN)** - "A WHO network building capacity to detect, control and prevent foodborne and other enteric infections from farm to table".

Created in 2000, the network now has over 1,200 members from 158 countries. At the core of GFN nine internationally renowned institutes and surveillance networks that provide guidance and training capacity to member states. GFN has five main programme components: international training courses, a passive *Salmonella* surveillance system, an annual External Quality Assurance System, focused regional and national projects, and reference testing services.

To date, GFN has held over 65 international training courses in Chinese, English, French, Portuguese, Spanish, and Russian for microbiologists and epidemiologists from over 120 countries. More than 80 countries have provided data to the Country Databank on over 1.5 million human isolates and close to 360.000 isolates from non-human sources to help us provide a global overview of the epidemiology of Salmonella. The GFN External Quality Assurance System is one of the world's largest annual proficiency test with more than 150 laboratories participating worldwide.

The strategic direction of GFN aims to assist the International Health Regulations (2005) by building core-capacities for surveillance and response in countries and to enable countries' full participation in response to international food safety and zoonotic emergencies through the International Food Safety Authorities Network (INFOSAN) and the Global Early Warning System for Major Animal Diseases, including Zoonoses (GLEWS).

For more information: www.who.int/salmsurv

WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR)

The WHO AGISAR was instituted in December 2008 to provide guidance to the WHO for the development of a global network to promote and enhance collaboration on harmonization and data sharing among WHO Member countries on integrated surveillance of antimicrobial resistance (AMR) across sectors (animal health, food and human health) .

This includes:

1. Development of harmonized schemes for monitoring AMR in zoonotic enteric bacteria, including appropriate sampling

2. Support capacity building activities via GFN

3. Promote information sharing between veterinary, food and public health sectors

4. Provide expert advice to WHO of containment of AMR

5. Support and advise WHO for selection of sentinel sites and designing pilot projects

Annex XXXVIII (contd)

Annex VI (contd)

6. Support capacity building for antimicrobial use monitoring

OIE and FAO are invited to take part in WHO-AGISAR activities. An OIE representative attended the first AGISAR meeting in June 2009 in Copenhagen, Denmark.

WHO approach to strategically address zoonotic public health risks

As one of the important and timely outcomes of the recent One World One Health™ (OWOH) strategic framework for reducing risks of infectious diseases at the animal–human–ecosystems interface (http://un-influenza.org/files/OWOH_14Oct08.pdf), the World Health Organization (WHO) is in the process of developing a comprehensive approach to strategically address zoonotic public health risks that are complex and multi-factorial and that involve different sectors and partners.

WHO seeks to present to its Member States a strategy for the management of zoonotic public health risks at the human-animal interface as a starting point to develop a more detailed strategic framework and action plan.

Best practice development progress under the GLEWS framework

WHO is taking the lead to assemble a proposal for drafting best practices for risk mitigation of infectious disease at the human-animal interface under the GLEWS framework. This work item was approved by the GLEWS management committee. A thorough landscape analysis to identify whether a need exists to develop guidelines to address mitigation of human risk to infectious diseases at the human-animal interface was performed that concluded that the need exists for cross-cutting guidelines that address not only the farm to table continuum but the animal-human interface.

The process for the creation of these best practices will involve interaction with regional and country partners and diverse experts and stakeholders. The work should focus on:

- Identifying best practices to reduce transmission of zoonotic infections in humans when humans interface with animals, animal products and their shared environments that adopt an international, interdisciplinary, cross-sectoral approach to human disease risk reduction with respect to disease surveillance, monitoring, prevention, and control while keeping in mind environmental considerations;

- Prevention and proactive intervention in the face of a new and emerging infectious disease outbreak that recommend immediate risk mitigation measure in a broader context and at a very practical and generically applicable level so that a larger proportion of the human animal interface continuum interface is covered. Disease specific recommendations that are being developed or already available that address epidemiological aspects of specific diseases will still be necessary;

- Developing the full definition and describing the term "human animal interface".

FAO/WHO Expert Meeting on Salmonella and Campylobacter in chicken meat, 4 – 8 May 2009

Salmonellosis and campylobacteriosis are among the most frequently reported foodborne diseases worldwide. While numerous potential vehicles of transmission exist, commercial chicken meat has been identified as one of the most important food vehicles for these organisms. Currently, the Codex Committee on Food Hygiene (CCFH) is developing the guidelines for the control of *Salmonella* and *Campylobacter* in poultry, and CCFH requested FAO and WHO to provide necessary scientific advice to continue its work. In response to that request, FAO and WHO convened an ad hoc Technical Meeting from 4 to 8 May 2009 in Rome, Italy. At the Technical Meeting, the experts carried out an independent assessment and review of all available latest scientific information on control of *Salmonella* and *Campylobacter* at relevant stages of the broiler supply chain. The final report of this Technical Meeting will be available on our websites soon.

Annex XXXVIII (contd)

Annex VI (contd)

The Foodborne Disease Burden Epidemiology Reference Group (FERG)

From 26-30 October 2009, the WHO hosted the third formal meeting of the Foodborne Disease Burden Epidemiology Reference Group (FERG) in connection with the third international Foodborne Diseases Stakeholder Event in Geneva. For the first time, the FERG reviewed preliminary burden of disease results in the areas of enteric, parasitic and chemical causes of foodborne diseases. Specifically, they discussed interim results of diarrhoeal disease morbidity and mortality in persons older than 5 years, as well as the burden of dog and pork tapeworm and peanut allergens. The results were presented to stakeholders in a one-day event (reported on by PLoS Medicine: http://speakingofmedicine.plos.org/2009/11/02/counting-the-global-burden-of-foodborne-disease/). Stakeholders were invited to a second day of consultation where they discussed in extended workshops how the burden estimates may be used to inform food safety policy. WHO is now preparing the reports which will be publicly available in due course. For more information please contact foodsafety@who.int.

Leptospirosis Burden Epidemiology Reference Group (LERG)

WHO is currently facilitating the assessment of the Global Burden of Human Leptospirosis that will provide reliable evidence-based disease burden estimates to help countries find the most appropriate, most cost-effective measures they can take to reduce leptospirosis risks and make a commitment to invest in improved health security through avoided disease burden. Although not strictly a foodborne disease, FOS is managing this initiative and invites FAO and OIE to participate in the first meeting that will convene on 2-4 December 2009 in order to participate and bring the animal perspective to bear on the outcome of the initiative.

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Annex VII

ANIMAL PRODUCTION FOOD SAFETY: PRIORITY PATHOGENS FOR STANDARD SETTING BY THE OIE

Theo Knight-Jones
(October 2009)

Summary

Many foodborne pathogens cannot be adequately controlled by harvest and post-harvest measures alone; pre-harvest (on farm) measures are also required. One way that the World Organisation for Animal Health (OIE) is addressing this issue is by producing standards and recommendations for the guidance of Member countries in implementing on-farm control measures. In this study, expert opinion and a literature review were used to identify the pathogens that should be prioritised for this process. Prioritisation was based on a pathogen's impact on human health and amenability to control using on-farm measures. Pathogens for which the OIE has developed or is developing standards were not considered in this report. As the OIE mandate includes fighting global poverty this study focussed on developing countries and those with 'in-transition' economies.

The regions considered were Eastern Europe, Asia (excluding the Middle East), the Middle East, Africa and South America. Opinions from one or two experts from each region were obtained using a postal questionnaire. *Salmonella* spp. in poultry were not considered as they have already been covered by the OIE. Experts from four of the five regions considered *Salmonella* from sources other than poultry to be a top priority and pathogenic *E.coli* was considered a top priority in three regions. *Brucella* spp. and *Staphylococcus aureus* were also mentioned by experts from three regions.

Control of salmonellosis in species other than poultry has been achieved in some countries. Hygiene and other general measures employed on farm have helped to control pathogenic *E.coli.* Standards for on-farm control of these two pathogens for food safety purposes are not addressed in any detail in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*). These pathogens should be considered for prioritisation in future standard setting. *Brucella* spp. have a significant effect on human health and on-farm control measures are known to be feasible and effective. These should be addressed in a review of the *Terrestrial Code* chapter on brucellosis.

E. granulosus, the causative agent of hydatidosis, was estimated to have the greatest impact of all foodborne pathogens in Africa; it was also listed for the Middle East and thought to be of importance by both South American experts consulted. Hydatidosis was inconsistently considered as a FBD by experts. *Taenia saginata* was thought to be of importance in South America, Africa and by one expert in the Middle East. This foodborne disease causes relatively mild clinical signs but causes significant production losses in the beef industry. The WHO/FAO/OIE have published recommendations on the control of *Echinococcus, Trichinella spiralis* and *Taenia solium.* However, the opinion of OIE Members should be sought on whether it would be appropriate to develop standards in the *Terrestrial Code*.

Introduction

Foodborne disease (FBD) is of huge global importance. Diarrhoeal diseases, much of which is foodborne, kill an estimated 2.2 million people each year [54]. Although mortality is particularly high in developing countries, FBD also has a massive impact in developed countries. Mead *et al.* [33] estimated that foodborne diseases cause 76 million illnesses, 325,000 hospitalisations, and 5,000 deaths in the United States each year.

Many cases of FBD produce relatively mild clinical signs that still require medical treatment or affect the patient's ability to work. Hence mortality represents the 'tip of the iceberg' as far as the true cost of FBD to society. Estimation of the global burden of FBD is a major initiative currently being undertaken by the World Health Organisation - Foodborne Disease Burden Epidemiology Reference Group (FERG) [48].

Animals play a particularly important role in FBD. They can be a source of pathogens in animal food products and also through faecal contamination of plant derived foods and water [11]. To minimise the risk of FBD, control measures should target both the harvest level and subsequent stages of food production, i.e. 'from farm to fork'. In many situations, on farm control may be more cost-effective [45, 50] and have a greater impact than control measures applied elsewhere [13].

One of the World Organisation for Animal Health (OIE) objectives is to provide a better guarantee of the safety of food of animal origin. The OIE established the Animal Production Food Safety Working Group (APFSWG) in 2002. This Group's role is to work with other relevant organisations, especially the Codex Alimentarius Commission (CAC) and its parent bodies (the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO)), in reducing food-borne risks to human health due to hazards arising from animals [47]. The APFSWG has a programme for the development of animal production food safety standards covering the level of primary production to the first transformation of animal products, with a primary focus on on-farm measures. Many of the relevant pathogens do not normally cause disease in animals.

Some general standards addressing animal production food safety, including specific recommendations on *Salmonella* in poultry are already in the Veterinary Public Health section of the *Terrestrial Code* [38]. Food safety aspects of certain pathogens that also cause animal disease have also been addressed in specific disease chapters, e.g. for bovine tuberculosis.

However, there are many pathogens for which measures at the on-farm level to prevent FBD are not currently covered in the *Terrestrial Code*. For the most part, CAC standards include only general references to primary production at the farm level [10]. Historically the role of veterinarians (and the OIE) has been primarily to control diseases of animals [14]. The focus on the development of international standards for on-farm measures to prevent FBD is fairly recent. By including animal production food safety in its mandate, the OIE has already taken important steps to address any gaps in standards. The necessary action, including coordination with the CAC, is being addressed through the APFSWG.

Aims

The aim of this work was to identify the pathogens (viruses, bacteria, parasites and prions) that should be given priority in future OIE standard setting for animal production food safety. Clearly, developed and developing countries may have different concerns in regard to food safety in foods of animal origin. As more than two-thirds of OIE Members are developing and in-transition countries, and the OIE's mandate includes fighting global poverty, the needs of developing countries were the primary consideration.

This assessment was done in a qualitative, discursive manner with the focus on identifying important pathogens and issues. In the time available, it was not possible to undertake an in-depth assessment of the relative importance of each pathogen. The pathogens identified as most important and their amenability to control using on farm measures are discussed.

Methods

Prioritisation of pathogens was based on the burden of human FBD they cause; the extent to which they are amenable to control at the farm level; their coverage by current OIE (and CAC) standards; and, as appropriate, the significance of the pathogens to international trade and any other concerns of OIE members.

Pathogens causing diseases that are OIE listed, those that are not OIE listed, and pathogens that do not cause disease in animals were considered. Pathogens were not prioritised for consideration by the OIE if control at the farm level is not currently feasible or cannot be achieved in a practical cost-effective manner. Non-infectious disease agents were not considered.

Approach

Expert Opinion

Experts were identified for each of the following regions:

- Eastern Europe
- Asia (excluding the Middle East)
- The Middle East
- Africa
- South America

Opinions from one or two experts for each region were obtained.

Selection of Experts

OIE associates from each region were asked to recommend appropriate experts in FBD. Expert opinions were obtained from two private consultants, four academics, one state veterinary service employee and one OIE employee. All had regional experience in FBD.

Questionnaire

Experts were asked to complete a brief postal questionnaire. The questionnaire asked experts to list the foodborne pathogens with the greatest impact on human health in their region and the most important food source by which people are exposed to each pathogen. Experts were asked to identify at least three pathogens. They were also asked if the pathogens would be amenable to on farm control and to suggest what control measures were appropriate. Finally, experts were asked if there were foodborne pathogens and zoonotic pathogens, other than those already mentioned, that should be a higher priority for future OIE standard setting; this could be due to effects other than impact on human health or the impact of zoonoses that are not foodborne.

Salmonellosis in poultry, anthrax (*Bacillus anthracis*) and bovine spongiform encephalopathy (BSE) were not considered as they either have been or are currently being considered by the OIE in their review of existing standards.

Wider Consultation

A range of other people with knowledge and interest in the area of FBD were contacted (more than 40 individuals), 20 of whom responded. These people represented government agencies, intergovernmental organisations and academic institutions.

Annex XXXVIII (contd)

Annex VII (contd)

The results of this questionnaire were considered in conjunction with relevant literature and work done by other organisations concerned with FBD.

The recommendations of this report will be considered by the APFSWG and the Terrestrial Animal Health Standards Commission and then provided to OIE Members for comment regarding the animal production food safety standard setting priorities for the OIE in future.

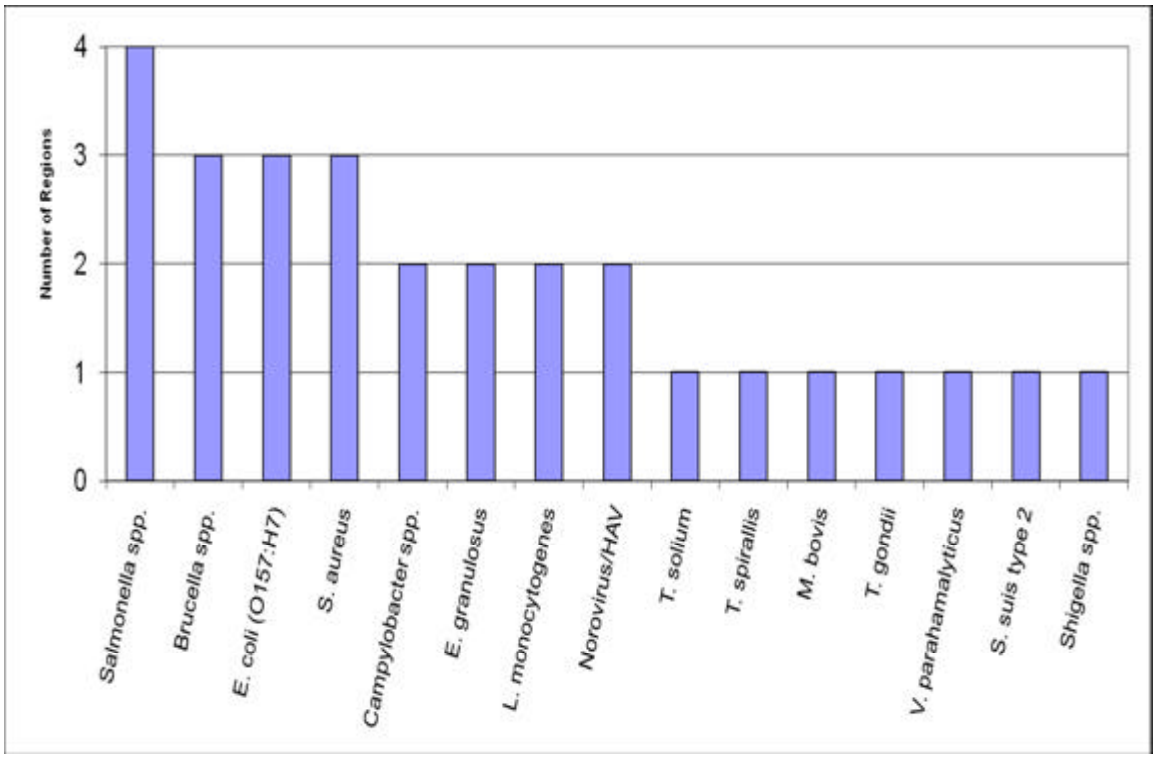
Results

Expert Opinion

The responses from the five regions and the pathogens identified as having the greatest impact on human health are shown in Figure 1 and Table 1.

Note: *Salmonella* spp. represents *Salmonella* spp. from sources other than poultry.

Figure 1: Number of regions that included a foodborne pathogen as a priority due to human health impact, based on expert opinion. (Hepatitis A virus = HAV)



A number of pathogens that were thought by experts to be of priority, although not foodborne, and pathogens that were of priority for reasons not linked to human health were also mentioned and are included in Table 1.

Table 1: Expert opinion on the foodborne pathogens that have the greatest impact on human health.

Note 1: Pathogens that experts consider to be a priority for OIE standard setting, due to reasons other than human health impact or are not foodborne are shown in the lower section of the table.
Note 2: ? indicates uncertain opinion.

REGION	S.AMERICA		AFRICA	ASIA		E. EUROPE	MIDDLE EAST	
EXPERT	Expert A	Expert B	Expert A	Expert A	Expert B	Expert A	Expert A	Expert B
Biggest impact	*Escherichia coli O157:H7*	*E.coli O157:H7*	*E. granulosus*	*Salmonella* spp.	*S. enteriditis & S. typhimurium*	*Salmonella* spp.	*Salmonella* spp.	*E. coli O157:H7*
↓	*Salmonella* spp.	*Salmonella* spp.	*B. mellitensis & B. abortus*	*T. spiralis*	*Vibrio paraharmolyticus*	*Pathogenic E. coli strains*	*Campylobacter* spp.	*S. aureus*
	Listeria. monocytogenes	*L. monocytogenes*		*T. solium*	*Streptococcus suis type 2*	*Viruses*	*B. melitensis*	*Shigella* spp.
	Staphylococcus aureus	*Brucella* spp.		*Mycobacterium bovis*	*Norovirus (HAV?)*	*Toxoplasma gondii*	*E. granulosus*	*Campylobacter jejuni*
Least impact					*S. aureus*	*Campylobacter* spp.		
						L. monocytogenes		

Annex XXXVIII (contd)

Annex VII (contd)

REGION	S.AMERICA		AFRICA	ASIA		E. EUROPE	MIDDLE EAST	
EXPERT	Expert A	Expert B	Expert A	Expert A	Expert B	Expert A	Expert A	Expert B
Other pathogens	***Shown in BLUE if thought to be a lesser priority, RED if greater and BLACK if of equal priority to the foodborne pathogens listed above.***							
	E. granulosus ***Trichinella spiralis*** ***Taenia saginata & T. solium***	***Coxiella burnetti*** ***E. granulosus*** ***T. saginata***	***T. saginata***	***HPAI H5N1*** ***Nipah virus***			***T. saginata*** ***M. bovis*** ***T. gondii***	

Important Sources

The most important food sources of each pathogen were inconsistently provided, but included the following:

- ***Salmonella spp****:* fresh meat from different sources, (pork specified for Asia).
- **Pathogenic *E.coli*** (including O157:H7): beef and other meat.
- ***Listeria monocytogenes****:* fresh meats, ready to eat products and milk products.
- ***Staphlycoocus aureus****:* meat products and dairy products (fermented pork specified for Asia).

- ***Brucella* spp.***:* milk and milk products (products of goats specified for Asia).
- ***Echinococcus granulosus****:* dust inhalation (Africa) and contaminated vegetables (Middle East).

Control Measures

Control measures were identified in varying degrees of detail.

The control measures identified are listed below:

- **General**: sanitary control measures; implementation of Good Agricultural Practices; biosecurity and control of wildlife.
- ***Salmonella* spp.**: on-farm surveillance and hygiene; application of relevant control measures defined by EU legislation.
- ***Trichinella spiralis* and *Taenia solium***: confine livestock; use concrete floors and ensure that feed is obtained from safe sources.
- ***M. bovis* and *Brucella* spp.**: disease surveillance, pasteurization of dairy products; use of vaccination against *Brucella* spp..
- ***B.anthracis:*** vaccination, surveillance; identification of high risk areas.
- ***Echinococcus granulosus:*** Treatment of dogs; meat inspection; destruction of hydatid cysts in meat.
- ***Taenia saginata:*** meat inspection; treatment of carcasses; human hygiene.
- ***E.coli:*** test and cull appears ineffective, preventing *E.coli* growth in wet feeds and sanitation of water troughs may be effective.
- ***Listeria monocytogenes:*** hygiene and sanitation in milk harvesting.
- ***Toxoplasma gondii:*** prevent contamination of feed, water and the environment; prevent consumption of dead pigs and rodents by other animals; serological tests at slaughter; pig confinement systems
- **For aquaculture**: Water quality and non-specified management factors.

Current OIE coverage of FBD pathogens

Standards and/or recommendations for several pathogens that cause FBD are detailed in the *Terrestrial Code* and other publications (Table 2).

Annex XXXVIII (contd)

Annex VII (contd)

Table 2: Current coverage in the *Terrestrial Code* [38] or other OIE published guidelines of farm level control of FBD agents

Pathogen	Coverage	Details in *Code*
Salmonella in poultry	*Terrestrial Code*	Aimed at poultry breeding flocks and hatcheries
Brucella abortus and B.melitensis	*Terrestrial Code* (OIE Listed diseases)	Details on farm disease freedom measures, not specifically public health measures (*ad hoc* group has been scheduled)
Trichinella spiralis	*Terrestrial Code* (OIE Listed disease)	Covers proof of disease freedom and importation of fresh meat (need more consideration of on farm measures)
	FAO/WHO/OIE Guidelines [21]	Prevention of infection in domestic pigs
BSE	*Terrestrial Code* (OIE Listed disease)	Farm level control covered
Mycobacterium bovis	*Terrestrial Code* (OIE Listed disease)	Details on proof of disease freedom but not on recommended farm biosecurity measures
Taenia saginata	*Terrestrial Code* (not an OIE listed disease)	Few details included
Taenia solium	*Terrestrial Code* (OIE Listed disease)	No details included
	FAO/WHO/OIE Guidelines [55]	On-farm control discussed
Echinococcus spp.	*Terrestrial Code* (OIE Listed disease)	Few details included
	WHO/OIE Guidelines [56]	Animal control discussed
Coxiella burnetii	*Terrestrial Code* (OIE Listed disease)	No details included
Bacillus anthracis	*Terrestrial Code* (OIE Listed disease)	Some animal-level measures mentioned but not in detail (currently under review)

Discussion

Justification of methodology

Attempts to openly and objectively prioritise foodborne pathogens for future attention have been undertaken by many organisations [8, 26, 42, 49]. These frequently use a scoring system, whereby each disease is scored on several relevant criteria, the scores then being combined to give an overall semi-quantitative measure of importance.

In this study, several relevant criteria were considered for each pathogen but scoring was not used due to the level of complexity and uncertainty that exists.

Published data on FBD and the control of relevant pathogens are scarce, particularly for most developing countries. The true incidence of FBD is likely to be underestimated in routine disease surveillance data and causative agents may not be definitively identified. Attributing a case to a foodborne source adds another level of uncertainty. Furthermore, the identification of effective and appropriate on farm measures requires evidence that is often lacking.

For the above mentioned reasons, the lack of a need for precise quantitative measures and the request from the APFSWG for the rapid provision of guidance on future standard setting needs, expert opinion was seen as an appropriate and timely way to address this issue. An open questionnaire was used so that experts would be free to highlight issues that may have otherwise been overlooked.

Limitations and biases

The method of selection of experts was non-systematic. The professional background and interest of each expert varies and this influences their opinions. The questionnaire and the accompanying instructions were kept brief to maximize the response rate. This meant that questions could have been interpreted variably. By way of example, an expert may have evaluated “impact on human health” by considering mortality, morbidity, cost to health services or some other measure or combination of measures. The fact that experts from the same region often gave different answers is partly due to this scope for interpretation and partly due to uncertainty as to which pathogens are of relatively greater importance.

A lengthier study with a panel of experts providing each opinion (as used in Delphi studies) was not performed due to lack of time and resources and based on the fact that the most important step in validating the report is requesting input from OIE Members, to ascertain not only factual information but also the considered views of official veterinarians with responsibility for the management of animal health and the prevention of FBD. The approach taken in this study puts greater dependency on the selection of the regional experts and the particular experiences and knowledge of each expert selected [51].

Some pathogens are frequently under-reported and the cases that are reported tend to be the more severe. How this and other complexities were accounted for by experts was not explicitly considered in the questionnaire.

Using a standard measure of impact of disease (e.g. Disability Adjusted Life Years, DALY [4]), as used in the planned output of the FERG is a valid method to assess the impact of a disease but could not be undertaken in the time available for this study.

Another issue relevant to prioritisation is how to assess the relative importance of regions when identifying the pathogen(s) of most significance globally. Population size or number of countries present in the region would be two possible methods. This study does not attempt to deal with such precise comparisons and merely highlights pathogens considered to be significant regional and global importance.

Annex XXXVIII (contd)

Annex VII (contd)

Pathogens prioritised by experts

Non-poultry *Salmonella* spp. were identified by experts as pathogens that should be prioritised for OIE standard setting in the on farm food safety domain for all regions except Africa. Various fresh meats were suggested as the main food source responsible for these *Salmonella* infections. Pathogenic strains of *E.coli* (specifically *E.coli* O157:H7) were thought to be a top FBD priority for South America, the Middle East and Eastern Europe, with meat and beef in particular considered to be the main source. These two pathogens are considered in more detail elsewhere in this report. Support for other pathogens was less consistent. Although three regions mentioned *Brucella* spp. and *S. aureus* as priority pathogens, these pathogens were never mentioned by more than one expert from the same region. This may reflect uncertainty over their relative importance as a cause of FBD compared to other pathogens.

S. aureus of human origin is more important than strains of animal origin in FBD [31]. However, of great concern is the role animals play in the development of antibiotic resistance in pathogens such as methicillin-resistant *S. aureus* (MRSA) [30]. Recommendations for on farm measures to avoid the development of antimicrobial resistance are included in the *Terrestrial Code* [38].

Brucellosis is one of the most widespread zoonoses [53] and causes both human disease as well as reduced productivity in livestock [58]. Methods of controlling *Brucella* spp. are well known and have been successfully applied in many countries. Although *Brucella* spp. are extensively covered by OIE publications [37-38], official recommendations for on farm-control measures are not. FAO has produced guidance on surveillance [41] and FAO and OIE regional activities have addressed this topic [19].

Some pathogens appear to have a marked regional variation in their impact, the most notable examples being in Africa where *Salmonella* spp., *E.coli* and *Staph. aureus* were not mentioned as priority pathogens. This may reflect the lack of detailed studies on FBD in this region.

E. granulosus, the causative agent of hydatidosis, was estimated to have the greatest impact of all foodborne pathogens in Africa; it was also listed for the Middle East and thought to be of importance by both South American experts consulted. Hydatidosis was inconsistently considered as a FBD by experts. Dogs are the usual definitive host of *E. granulosus*, with ungulates such as sheep acting as the intermediate hosts, humans become infected through contact with dogs and food contaminated with parasite eggs [32], dust inhalation is another possible route of transmission [46].

Taenia saginata was thought to be of importance in South America, Africa and by one expert in the Middle East. This FBD causes relatively mild clinical signs [27]. Its major impact is through production losses in the beef industry, condemnation of beef and loss of export trade due to restrictions imposed upon countries that fail to control it [27]. The limited impact of *Taenia saginata* in causing FBD could be a reason for the APFSWG not to consider it of high priority, considering the terms of reference of this report.

As the WHO/FAO/OIE have published recommendations on the control of *Echinococcus*, *Trichinella spiralis* and *Taenia solium* [21, 38, 55-56] there may be less reason to prioritise these pathogens for future OIE standard setting. However, the opinion of OIE Members should be sought on this question.

Non-poultry *Salmonella* spp.

Salmonellosis is possibly the most common FBD in the world [39]. Based on the human isolates reported to the WHO Global Salmonella-Surveillance between 2000-2002, *Salmonella enterica* serovar Enteritidis and *Salmonella enterica* serovar Typhimurium were the most frequently reported isolates for all regions. Ignoring contaminated eggs, contamination of carcasses with animal faeces is considered to be the principle source of human exposure. Contamination of vegetables by animal faeces is another source of infection [39].

Although hen eggs and broiler meat play a major role in human salmonellosis [20], other animals are also of importance. In an international study of 4,093 reported foodborne outbreaks, eggs accounted for 43.4% of *Salmonella* Enteriditis outbreaks and chicken meat 9.9%. The remaining 46.7% of outbreaks were attributed to a range of animal derived and non-animal derived foods [24]. In the same study 18.2% of *Salmonella* Typhimurium outbreaks were attributed to eggs and 10.4% were attributed to chicken meat. Again, the remaining 71.4% of outbreaks was attributed to a range of animal and non-animal derived products. Although noteworthy, the exact relevance of this study is uncertain as outbreaks only represent part of the burden of disease and non-developed countries were poorly represented. This highlights the imperfect knowledge on which assessments of pathogen importance must be made. In a review of invasive non-Typhi *Salmonella* disease in Africa, Morpeth *et al.* stated that non-Typhi *Salmonella* is a leading cause of bloodstream infection, with *Salmonella* Enteriditis and *Salmonella* Typhimurium the most commonly isolated serotypes in sub-Saharan Africa [34]. The appearance of antimicrobial resistance in certain strains of *Salmonella* [45] is an additional concern.

Effective on farm control of *Salmonella* in pigs has been successfully implemented in Denmark [52] and some other countries. The EU has a programme to reduce *Salmonella* contamination of pigs at slaughter with interventions (including on-farm measures) to be implemented by Member States [17]. Feeding, management and hygiene practices have all been used as on farm measures to control *Salmonella*. As no single measure can sufficiently control disease, several measures must be implemented for effective results. Although a Danish style *Salmonella* surveillance and control programme would not be feasible for many countries, some of the control measures that have been successfully used may form an appropriate basis for providing recommendations on on-farm measures.

There is no specific reference to on farm control of *Salmonella* in non-poultry species with respect to food safety in the *Terrestrial Code* [38] or Codex publications.

Pathogenic *E. coli*

E.coli is a common and normally harmless member of the gut micro-flora of most warm-blooded species. However, enteric disease may result if humans are infected with certain pathogenic *E.coli* strains [35].

Of particular concern are certain shiga toxin producing *E.coli* (STEC) also known as verotoxigenic *E.coli*. In wild and domestic animals infection with STEC strains seems fairly common yet it causes little disease [7]. In humans STEC infection is rare but these organisms are known to cause disease with signs including watery diarrhoea, haemorrhagic colitis and haemolytic uraemic syndrome (HUS), particularly in children and the elderly. Most human cases are due to food contaminated with zoonotic STEC of animal origin [18].

Annex XXXVIII (contd)

Annex VII (contd)

Enterohaemorrhagic *E.coli* (EHEC) comprise a subset of STEC serotypes that are commonly associated with bloody diarrhoea and HUS. Although several EHEC serotypes can cause human disease, O157:H7 is the most common [7]. Cattle are the major reservoir for all zoonotic STEC including EHEC O157:H7 [18]. Contaminated foods derived from cattle (particularly ground beef) are the most common source of infection, due to contamination during food preparation. Animal faecal contamination of growing fruit and vegetables is another important source of this pathogen. Various foods are associated with disease outbreaks, including (undercooked) hamburgers, milk, unpasteurised apple cider, sprouts and salad [24, 45].

In 1999 Mead *et al.* estimated that *E.coli* O157:H7 caused more than 60,000 illnesses in the USA annually, 0.5% of all FBD and 2.9% of deaths due to FBD. Greig *et al.* found *E.coli* to be responsible for 9.5% of FDB outbreaks in an international study. Up to 10% of EHEC patients are thought to develop HUS and the case-fatality rate for this is estimated to range from 2% to 7%, although for some outbreaks involving the elderly the figure is as high as 50% [57]. Outbreaks can be very large. One EHEC O157 outbreak in Japan involved approximately 9,000 school children [57]. As well as Europe, Japan and North America, EHEC is an important pathogen in Australia, Chile, Argentina and South Africa [35], although the non-O157 serotypes may be more important than the O157 serotype in these countries. In the developing world, foodborne pathogenic *E.coli* other than EHEC seem to be more important [35].Many cases of disease due to non-EHEC *E.coli*, although foodborne, are due to poor sanitation and are not associated with an animal reservoir [40]. Although zoonotic-STEC are often responsible for disease in developing countries [18], limitations in surveillance make it difficult to know how important they are in FBD [45].

Some countries have adopted a policy of considering raw ground beef 'adulterated' if it contains any *E.coli* O157:H7. This has led to very large recalls of ground beef at enormous cost [9]. This policy setting poses a potential barrier to international trade and is of great concern to beef exporting countries.

Control of pathogenic *E.coli* of animal origin requires the application of measures at all stages of the food chain, including on-farm. On farm measures should be aimed at reducing intestinal colonisation and shedding of the relevant bacteria as well as reducing their persistence in the farm environment [18]. These measures would also reduce human infection due to direct contact with the animals [6].

Vaccination, probiotics and bacteriophages have been investigated as specific measures at reducing EHEC O157:H7 excretion in cattle. The probiotic *Lactobacillus acidophilus* culture appears to be effective and is widely used in the USA. However, the benefits of other specific measures are at present unclear [29, 43]. It was thought by one expert that testing and culling carriers of EHEC O157:H7, although a logical approach [18], may be ineffective; although there is a lack of published data on the matter. It must be remembered that pathogen specific measures may be inefficient as they allow the emergence of other pathogens.

Looking at non-specific measures, manure and slurry management are important. Good management practices including hygiene of troughs and pens, correct silage management and avoiding overcrowding of animals [16]. As faecal contamination of hides is the main source of *E.coli* contamination of meat [28] it is important to ensure that cattle are clean when sent to slaughter.

Control measures for EHEC O157:H7 applied throughout the food chain have had a positive effect in the USA [28]. Although some argue that control of EHEC O157:H7 should focus on harvest and post-harvest [28] for both meat and leafy vegetables, this does not mean that pre-harvest control is unimportant. However, the potential for cross-contamination during transport and processing highlights the need for good post-harvest control in addition to measures applied on farm.

Measures for the control of pathogenic *E.coli* are not provided in the *Terrestrial Code* [38], although the OIE and FAO have produced guidelines on good farming practices [23, 36].

Developed Countries

A significant amount of work has been done on the burden of FBD in developed countries [1-2, 5, 15, 22, 33]. *Campylobacter* spp. and *Salmonella* spp. are often considered to have the biggest impact. However, developing countries have a different view on the relative importance of specific pathogens. Developed countries are generally less concerned about parasitic diseases and other diseases that have been successfully controlled through national programmes, whether the measures are applied on farm (e.g. bovine brucellosis and tuberculosis) or subsequently (e.g. pasteurisation) [44, 53].

Notable pathogens not prioritised by experts

Campylobacter spp. are a major cause of FBD globally [1, 5, 12, 15]. Campylobacteriosis presents as diarrhoea with fever and malaise. Complications may arise, rarely, but very few deaths occur. Poultry meat is regarded as a key source of infection and in 2007 the CAC made the development of guidelines for the control of *Campylobacter* in poultry a priority. These guidelines will include on-farm control measures that will complement the text on hygiene and biosecurity procedures in poultry production developed for inclusion in the *Terrestrial Code* [38]. As this pathogen has been addressed by the CAC and, in a generic manner, by the OIE, there may be little need to prioritise it for the development of OIE standard setting. Perhaps more importantly, there is little evidence for effective on farm control measures for *Campylobacter* spp. Poor biosecurity practices can allow the carriage of the pathogen into farm sheds by wildlife and by humans. Reduction of poultry density by 'thinning' flocks during production has also been found to increase contamination [3]. Restricting access of flies and other insects may also help reduce contamination of flocks [25].

How do OIE standards and guidelines make a positive contribution to public health?

OIE standards and guidelines help to protect public health in two ways. The standards contained in the texts adopted by OIE Members (e.g. the OIE *Codes* and *Manuals*) are legal references for the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS agreement) and should be used by WTO Members to determine the measures applied to animals and animal products moving in international (and regional) trade. These standards can have an impact by defining the on farm measures applied to help minimise any potential food safety risks that could be associated with international trade in live animals and their products. In addition, OIE recommendations can be used by Members to guide the development and implementation of national or regional programmes with the objective of improving animal health and animal production food safety.

It is clear that FBD has an important effect on the poor, even though the specific contribution and relative importance of different pathogens may not be well defined. In the absence of strong veterinary services and good governance, the adoption of official control programmes based on OIE standards may have little effect, for example, where livestock slaughtering and trade in animal products is largely informal and takes place outside any official health or safety framework. In these situations, community level interventions may be more effective than legislation in reducing the impact of FBD in the short term. In the longer term, strengthening of veterinary services and their infrastructure through interventions of international donors working in collaboration with the OIE is a valid approach and an ongoing priority of the OIE.

Conclusions

The data required for prioritisation of pathogens for OIE standard setting in relation to FBD are lacking, particularly for developing countries. The approach of consulting regional experts is a suitable method to provide a snapshot review of the situation but the findings of this review should be validated through further discussion within the OIE and consideration by OIE Members.

Based on the opinion of the experts consulted, non-poultry *Salmonella* spp. and pathogenic *E.coli* (especially *E.coli* O157:H7) should be considered for prioritisation. This was supported by the literature and other factors, including the feasibility of on-farm control and the lack of coverage in current OIE and Codex standards. More is known about effective on-farm control of non-poultry *Salmonella* spp. than *E.coli* O157:H7, which suggests that non-poultry *Salmonella* spp. should be rated as more suitable.

Proven methods for on farm control of *Brucella* spp. exist. However, work is currently under way within the OIE to review the current chapter on brucellosis in the *Terrestrial Code*, so no specific recommendations need be made.

E. granulosus, was estimated to have the greatest impact of all foodborne pathogens in Africa; it was listed for the Middle East and thought to be of importance by both South American experts consulted. However, hydatidosis was inconsistently considered as a foodborne disease by experts. *Taenia saginata* was considered important in South America, Africa and by one expert in the Middle East. It causes relatively mild disease in humans but can have a major impact on the beef industry.

As the WHO/FAO/OIE have published recommendations on the control of Echinococcus, Trichinella spiralis and Taenia solium there may be less reason to prioritise these pathogens for future OIE standard setting. However, the opinion of OIE Members should be sought on this question.

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Annex XXXVIII (contd)

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Annex XXXVIII (contd)

Annex VIII

TERMS OF REFERENCE FOR AND *MODUS OPERANDI* OF THE OIE ~~PERMANENT~~ ANIMAL PRODUCTION FOOD SAFETY WORKING GROUP

TERMS OF REFERENCE

~~1. In accordance with Resolution No. XV of the 70th OIE General Session, t~~The terms of reference for the Animal Production Food Safety Working Group include:

a) consideration of all foodborne hazards arising from animals before slaughter,

b) a primary focus on food safety measures applicable at the farm level,

c) consideration of food safety measures applicable elsewhere, for example during animal transport and harvesting of wild animals for food,

d) work criteria and priorities that take into account global food safety priorities and current work programmes of relevant international organisations, ~~e~~especially the Codex Alimentarius Commission (CAC), FAO and WHO,

e) the taking into account of the food safety standards developed and under development by relevant international organisations, especially the CAC,

f) support for the work of the OIE Specialist Commissions on pre-slaughter animal production food safety,

g) advising the OIE Director General ~~of the OIE~~ on all issues ~~on the implementation of the OIE strategy regarding~~ relating to animal production food safety including but not limited to:

i) establishing *ad hoc* Groups to address specific tasks,

ii) linking at the working level with the CAC, FAO and WHO,

iii) ensuring pre-slaughter animal production food safety is integrated in Specialist Commissions' and *ad hoc* Groups' activities,

iv) providing technical input, as appropriate, into the ~~review~~ work of the Specialist Commissions in relation to~~f~~ OIE relevant food borne disease notification ~~criteria~~ or the official recognition by the OIE of relevant disease status,

v) enhancing communications, information sharing and consultation,

vi) issues relating to good governance including veterinary education.

Annex XXXVIII (contd)

Annex VIII (contd)

MODUS OPERANDI

~~2.~~ Within the~~se~~ above terms of reference, the Working Group sees its role as:

1. providing advice to the OIE Director General on policy and strategic issues relating to the OIE's work on animal production food safety, which has the goal of 'reducing foodborne risks to human health by preventing, eliminating or controlling hazards arising from animals prior to primary processing of animals and animal products'.

   The priorities are:

   ~~i~~a) identifying and addressing gaps, contradictions, areas where harmonisation is necessary and duplications in the work of the OIE and other international/intergovernmental organisations involved in food safety standards (in particular CAC~~odex~~) ~~involved in food safety standards~~,

   ~~ii~~b) strengthening the relationship to other relevant scientific and normative ~~standard setting~~ organisations working in the area of food safety (in particular CAC~~odex~~, FAO and WHO), through enhanced information exchange,

   ~~iii~~c) improving coordination between competent authorities with animal health and food safety responsibilities at the national and regional levels,

   ~~iv~~d) recommending a work programme to address the mandate of the OIE on animal production food safety;

2. ~~b)~~ acting in a steering group capacity, as required by the OIE Director General, regarding the work of OIE expert groups:

   ~~i~~a) advising the Director General on membership, scope and terms of reference for expert groups,

   ~~ii~~b) reviewing texts arising from relevant expert groups for consideration by the relevant Specialist Commissions.

~~3.~~Intended outputs addressed to the Director General and the relevant Specialist Commissions include:

a) ~~discussion papers.~~ policy advice;

b) ~~policy documents~~ discussion papers;

c) reports;

d) comments on draft texts reviewed.

Annex IX

DRAFT WORK PROGRAMME FOR 2010

The Working Group agreed that its work programme for 2010 would include:

1. Horizontal issues

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

   b) Petfood – Working Group to be kept informed of developments relevant to food safety.

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

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

   e) Consideration of the scientific evidence on the relationship between animal welfare and animal production food safety.

   f) Animal production food safety in veterinary education following from the recommendations of the OIE Conference 'Evolving veterinary education for a safer world' held in October 2009.

   g) Policy statement on the importance of animal production food safety for food security.

   h) Food safety issues arising from the ongoing work on the emerging zoonoses at the human animal ecosystem interface ('One World, One Health').

   i) Certification, in particular electronic certification – monitor developments in CAC, IPPC and OIE.

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 November 2009.

   b) Foodborne zoonoses

      – future work on salmonellosis and campylobacteriosis in poultry - taking into account developments in Codex;

      – follow up on the report on priority pathogens for standard setting activities in animal production food safety.

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.

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Annex XXXIX

Original: English
November 2009

AD HOC GROUP ON PRIVATE STANDARDS AND INTERNATIONAL TRADE IN ANIMALS AND ANIMAL PRODUCTS

Paris, 9–10 November 2009

The OIE *ad hoc* Group on Private Standards and International Trade in Animals and Animal Products (hereinafter referred to as the *ad hoc* Group) met at the OIE Headquarters from 9 to 10 November 2009.

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: Welcome and introduction by Dr. Vallat

Dr Bernard Vallat, Director General of the OIE, welcomed all members and thanked them for their agreement to continue working with the OIE on this important topic.

He recalled the history of the topic within the OIE and the ongoing discussions in other international organisations, like the WTO/SPS and the Codex Alimentarius. Especially the diagnostic of the WTO on the legal aspects of international trade and sanitary safety of is of great interest (the practical application of the private and public standards in relation to animal health problems).

The results of the questionnaire (Appendix III) are of great interest despite the fact that de developing countries were not in the majority. The *ad hoc* Group is asked to comment, draw conclusions and develop recommendations based on these results. The information will be shared with WTO/SPS and Codex.

The report of this *ad hoc* Group (together with the report of the questionnaire) will be presented to the Terrestrial Animal Code Commission that will convene in February 2010.

Finally the Dr Vallat stated that the coming years it might be necessary to develop relations with international private standard setting organizations to prevent gaps and promote harmonization and avoid conflicts with OIE standards. Depending on all these developments another meeting of the *ad hoc* Group might be necessary.

Annex XXXIX (contd)

Agenda Item 2: Discussion of the Terms of Reference and comments from Chair of the *ad hoc* Group

The Chair of the *ad hoc* Group, Mr. Scannell (EC), welcomed the members of the meeting also. He commented on the results of the questionnaire stating that the report was accurate and that he was very pleased with it. He was surprised that some developing countries, which should have a clear interest for private standards, did not reply. He observed that only few specific examples of private standards were given by the OIE members. The chair remarked that he didn't see any need to make substantial changes to the report. Finally he listed some suggestions to proceed:

- using the WTO/SPS document "possible actions for the SPS Committee regarding private SPS standards" (Appendix IV),

- urging member countries to monitor private standards and provide a forum where problems can be discussed and

- to discuss the possibility for the OIE to make agreements with global private standard setting organisations.

Dr. Correa Messuti, the President of the OIE, explained that the reason that only few concrete examples were given could be that the exporting industry fear reprisals.

Mr. Scannell clarified that in international trade the most examples of problems with private standards are not in the areas of sanitary safety and animal health, but mainly have environmental, ethical or social aspects.

Dr. Janning, representing the International Poultry Council (IPC), confirms that during the problems with private standards that were brought about during the General Assembly of the IPC mainly concerned official standards (and no private standards).

Dr. Wilkins, representing the World Society for the Protection of Animals (WSPA) and the International Coalition for Animal Welfare (ICFAW), commented that in his view the outcome of the questionnaire reflects that in reality there are no or very few examples of problems of private standards concerning animal welfare. Dr David Bowles, representing the Royal Society for the Prevention of Cruelty to Animals (RSPCA) claimed that some of the problems mentioned the results of the questionnaire may not be concrete problems, but perceived problems.

Dr Musa Fanikiso, consultant and former OIE delegate for Botswana, suggests contacting some of the countries which brought up specific problems and ask for additional information.

The ad hoc Group adopted the proposed TOR (see Appendix V).

Agenda Item 3: Presentation preliminary results questionnaire

Dr. Pelgrim (OIE) presented the results of the questionnaire. The number of OIE members that replied (64) is satisfactory. Some members and industry organizations have replied recently. These replies are not yet included in the report, but will be included in the final version. Dr. Pelgrim explains that this will not have a significant influence on the results of the report.

Agenda Item 4: Discussion of report questionnaire and other working documents

The members of the *ad hoc* Group are pleased with the results. Some minor editorial suggestions and other suggestions were made. For example, Professor Neville Gregory, representing the International Meat Secretariat, suggested including the definition of a private standard in the report. All the suggestions will be taken into account in the final version of the report.

The WTO/SPS document "possible actions for the SPS Committee regarding private SPS standards" was discussed. The members of the *ad hoc* Group could agree with most of the recommendations. Mr. Scannell pointed out that there were neither recommendations to benchmark private standards against international standards to identify where these go beyond the international standards nor to develop complaint mechanisms for those required to comply with private standards.

The ad hoc Group discussed briefly also about the definition of private standards that was developed at the first meeting of the group:

"Private Standard means: commercial requirements developed, owned and implemented by non governmental entities, with which suppliers must comply to have access to specific markets for animals and animal products. They sometimes include sanitary safety and animal welfare issues".

Professor Neville Gregory proposed to narrow this definition and focus it on farm animals instead of on animals in general. However the majority of the *ad hoc* Group considered that the existing definition was right.

Agenda Item 5: Development recommendations

While developing the recommendations a large part of the discussion was focussed on complaint mechanisms. Dr. Wilkins proposed that the OIE should have a role as a mediator in case of problems concerning private standards on sanitary safety and animal welfare. Dr. Kahn, head of the OIE Trade Department disagrees with the idea to develop a specific mediation procedure. The existing ***OIE*** informal ***mediation*** procedure only applies to disputes of OIE members about trade problems concerning the OIE code. However if members want to consult the OIE about problems concerning private standards, of course they are welcome to write to the Director General of the OIE. Mr. Scannell believes that problems should be discussed bilaterally between the concerning governments and private parties.

Dr. Correa Messuti emphasises the need to discuss the problems and possibilities *ad hoc* Group agree.

Before the development of the conclusions and recommendations the members of the *ad hoc* Group agreed on the following considerations:

- It should be recognized that the majority, if not all, of private animal welfare standards have led to an improvement in the welfare of animals produced for food in many countries around the world. These standards are not currently covered by the WTO SPS Agreement.

- On the other hand private sanitary standards generally have not led to an improvement of health or increased safety of food, but may have created an obstacle to trade. These standards are however covered by the WTO SPS Agreement. Therefore the two private standard problems for the OIE sanitary and animal welfare standards should be treated separately.

- It should also be recognized that whatever steps are taken by the OIE, the end result should be to support the continuing improvement of the welfare of farmed animals, including those brought about by private standards.

- Private animal welfare standards should be based as a minimum on OIE standards.

Annex XXXIX (contd)

Conclusions

Building on the responses of members to the OIE questionnaire on private standards for sanitary safety and animal welfare and the suggestions for further action in these responses the ad hoc group concludes as follows:

All parties should adopt a more holistic approach on wider societal concerns (notably climate change, food security, poverty alleviation) in the development of standards and policies on sanitary safety and animal welfare as appropriate to their mandate.

In addition the ad hoc group makes the following specific recommendations:

Recommendations to the OIE

- Reinforce cooperation on sanitary standards with other international standard setting organisations, notably CODEX and IPPC, aimed at a clear and transparent framework for dealing with private standards in WTO/SPS.

- Continued promotion of OIE standards in the areas of sanitary safety and animal welfare especially he respect and implementation of these standards by OIE members and trade interests.

- To improve the communication and capacity building efforts of the OIE in order to strengthen the credibility and the appropriateness of the OIE framework on sanitary safety and animal welfare.

- The accelerated development of OIE standards to ensure that the framework for sanitary safety and animal welfare is up to date and fit for purpose to minimize problems in international trade.

- Creation of links with private standards setting organisations to encourage and promote the use of OIE standards as benchmarks against which private standards would be referenced for international trade in animals and animal products.

- Monitor trends in the evolution of private standards to identify deviations from OIE standards and seek to address problems raised by members arising from any such deviations.

- To explore the possibilities for a forum with global private standards setting organisations aimed at improved cooperation and especially shared efforts towards the facilitation of trade in live animals and animal products (respecting the OIE standards).

Recommendations to OIE members

- To renew and strengthen efforts to fully comply with OIE standards as a sound foundation for the safe international trade of live animals and animal products.

- Work more closely with private standard setting bodies in order to promote the use of official national and international standards as benchmarks against which private standards are referenced for international trade in animals and animal products.

- Create mechanisms to identify private standards which deviate from official standards and create barriers to trade and to bring such deviations to the attention of relevant responsible authorities, the private standard setting bodies concerned and if appropriate the OIE.

- To create mechanisms to identify any evidence that private standards discriminate between OIE members other than on the basis of transparent and science based risk analysis.

- OIE members should target capacity building and technical assistance efforts in developing and in transition countries to improve compliance with international standards as the best means towards participation in international trade in animals and animal products.

Recommendations to private standard setting bodies

- Work towards increased harmonization of private standards, especially with the view to reducing the number of different audit and certification requirements.

- Ensure that official national and international standards serve as benchmarks against which private standards are referenced for international trade in animals and animal products.

- Continue with current efforts to improve the transparency of private standards and the consultation of relevant stakeholders, especially in developing and in transition countries.

- To address the problems identified by OIE members in relation to private standards notably compliance cost, lack of basis in science, lack of transparency, etc.

- Improve links with the official authorities in OIE members to promote improved transparency and cooperation.

Recommendations to NGO's

- Seek that their policies support the implementation and credibility of official international standards.

- Take into account the special needs of developing and in transition countries when promoting or advocating higher standards.

Agenda Item 6: Review and finalise report of meeting

The members of the *ad hoc* Group agree to consider a future meeting in the light of the decisions taken at the meetings of the Terrestrial Animal Code Commission in February 2010 and the General Session in May 2010.

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…/ Appendices

Annex XXIX (contd)

Appendix I

AD HOC GROUP ON PRIVATE STANDARDS AND INTERNATIONAL TRADE IN ANIMALS AND ANIMAL PRODUCTS

Paris, 9–10 November 2009

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Appendix I (contd)

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Appendix II

AD HOC GROUP ON PRIVATE STANDARDS AND INTERNATIONAL TRADE IN ANIMALS AND ANIMAL PRODUCTS

Paris, 9–10 November 2009

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Agenda

1. Welcome and introduction
2. Discussion of the Terms of Reference and comments from Chair of the *ad hoc* Group
3. Presentation results questionnaire
4 Discussion of report questionnaire and other working documents
5. Development recommendations
6. Review and finalise report of meeting

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Annex XXIX (contd)

Appendix III

TERMS OF REFERENCE

AD HOC GROUP ON PRIVATE STANDARDS AND INTERNATIONAL TRADE IN ANIMALS AND ANIMAL PRODUCTS

Paris, 9–10 November 2009

Taking into account:

- Resolution No. XXXII *Implications of private standards in international trade of animals and animal products* (General Session 2008);
- that the OIE International Committee has adopted separate international standards for animal welfare, animal production food safety and animal health;
- that the World Trade Organization, under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), formally recognises the OIE as the organisation responsible for establishing international standards relating to animal diseases, including zoonotic diseases;
- the role of the OIE in facilitating safe international trade in animals and animal products;
- that it is of concern to OIE Members that some private standards for sanitary safety and animal welfare relating to animal products are not consistent with the OIE standards and
- that the OIE has no objection to private standards for animal products that relate to matters other than sanitary safety and animal welfare.

1. **The *ad hoc* Group should propose an OIE strategy to help Members avoid or minimise current or potential negative effects of private standards.**

2. **The *ad hoc* Group should develop a definition of 'private standards' for use by the OIE, taking into account the following considerations:**

Official (OIE) standards are:

- adopted democratically
- based on science and risk analysis
- elaborated with reference to existing standards

Annex XXIX (contd)

Appendix III (contd)

- adopted, published and applied transparently
- non discriminatory
- consistent with the rights and obligations of WTO Members as established under the WTO SPS Agreement.

3. As a basis for its recommendations, the *ad hoc* Group should develop a questionnaire for distribution by the Director General to OIE Members and relevant organisations having an official agreement with the OIE.

The questionnaire should seek:

- information on the negative (and/or positive) effects of private standards in the animal health and public health field to the trading interests of OIE Members;
- information on the negative (and/or positive) effects of private standards in the animal welfare field to the trading interests of OIE Members;

For both animal health and animal welfare, the questionnaire should aim to collect relevant information, including on regional and international trade; costs of compliance with private standards; information on recognition of the standards; identification and/or characterization of businesses that meet private standards; technical or financial assistance received to assist compliance with private standards and benefits (for producers, retailers and consumers) provided by complying with private standards.

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Annex XXIX (contd)

Appendix IV

FINAL REPORT – OIE QUESTIONNAIRE ON PRIVATE STANDARDS

Executive Summary

The OIE convened an expert *ad hoc* Group on private standards for sanitary safety and animal welfare to examine the current and possible future problems and benefits presented by private standards for sanitary safety and animal welfare in regard to international trade. In this context, sanitary safety covers animal production food safety and animal health including diseases transmissible to humans. The *ad hoc* Group developed a questionnaire that was sent to all OIE Members and to relevant organizations having an official agreement with the OIE.

In total 68 Members (39% of the 175 OIE Members) and eight international or regional organisations replied to the questionnaire. Some two thirds of the 175 OIE Members are developing countries or countries with 'in transition' economies. Based on the OECD system for classifying economic development, 44% (30) of the 68 responses are from developing countries and 56% (38) from developed countries.

The five OIE regions (Europe; Africa; Americas; Asia, Far East & Oceania; and the Middle East) account for 49%, 16%, 15%, 15% and 6% of the responses, respectively. The consolidated submission of the EU Member States accounts for 82% of the responses from countries of the OIE region of Europe.

The replies provided by OIE Members are analysed in section three of this report.

The international and regional organisations that replied to the questionnaire comprise four industry groups, two international animal welfare organisations and two intergovernmental regional organisations. Their replies are discussed in section four of the report. Their answers vary widely, making it difficult to draw statistically clear conclusions in section four.

Nearly all (96%) responding OIE Members agree that a clear distinction needs to be made between private standards for sanitary safety and private standards for animal welfare. Many respondents (72%) agree that private standards in international trade have arisen due to a lack of official standards in some areas.

Nearly all respondents (97%) agree that the implementation by OIE Members of animal welfare standards should be strengthened and that the OIE PVS Tool should put greater emphasis on the implementation of the OIE animal welfare standards.

Nearly all respondents agree that private standard setting bodies should do more to promote the harmonization of their standards (91% of respondents) and that there should be closer collaboration between private standard setting organizations and the OIE (97% of respondents). Many OIE Members emphasize the need for broad collaboration and harmonization between international organizations and private standard setting bodies.

Private standards for sanitary safety

Most respondents (82%) agree with the general statement that private standards for sanitary safety either have created or may create significant trade problems for exports from their countries. A few respondents had no opinion or disagree with this statement. Responses from all regions are broadly consistent.

The problems most commonly identified are 'compliance costs', 'lack of basis in science or risk assessment', 'lack of transparency', 'over-prescriptive nature of private standards' and 'inadequate consultation with relevant stakeholders'.

Annex XXIX (contd)

Appendix IV (contd)

Overall, 62% of respondents consider that private standards for sanitary safety have created or may create significant benefits for their country and other respondents either have no opinion (16%) or disagree (22%). However, there are significant differences between developing and developed countries, with 87% of developed countries seeing real or potential benefits while only 30% of developing countries agree with this statement.

The benefits that are most commonly mentioned are 'market access opportunities including niche markets', 'filling the policy gap left by lack of relevant international standards', 'meeting the needs or concerns of stakeholders that are not addressed by OIE standards' and 'facilitating the implementation of public standards'.

Respondents give 33 examples of problems with private standards for sanitary safety or animal welfare. In most cases, there is insufficient information for detailed analysis and the OIE is following up on several examples with the respondents.

Where respondents provided a degree of specificity, the examples of problems with private standards for sanitary safety in the first answer concerned:

- requirements for *Listeria* spp for cooked poultry products;
- BSE related requirements concerning the age of animals from which meat is obtained, not respecting the BSE status of the exporting country;
- Bluetongue requirements for meat.

Private standards for animal welfare

In addition to calling for greater efforts by OIE Members to implement the OIE animal welfare standards and for more emphasis on animal welfare in the OIE PVS Tool, most respondents (74%) agree that private standards and certification can be a useful aid to the implementation of official standards. Nearly all respondents (97%) agree that although animal welfare is not covered by the WTO SPS Agreement, the OIE should continue to develop animal welfare standards and most respondents (76%) agree that OIE animal welfare standards would have increased legitimacy if the WTO SPS Agreement covered animal welfare.

Overall, 46% of respondents agree that private animal welfare standards create or may create problems. However, the responses of developed and developing countries are quite different, as shown in the table below.

The most significant problems cited are 'lack of harmonization between different private standards' and 'lack of basis in science or risk assessment'.

Overall, 64% of respondents consider that private animal welfare standards create or may create benefits. The support for this viewpoint was similar to the level of support for the proposition that private standards can provide benefits (62% of respondents agreed on this point). Again, the responses of developing and developed countries are quite different. Nearly all developed countries (89%) could see benefits of private animal welfare standards but 40% of developing countries do not agree.

The benefits/potential benefits that are most commonly mentioned for private standards are 'market access opportunities including niche markets', 'meeting the needs or concerns of stakeholders that are not addressed by OIE standards', 'facilitating the implementation of public standards' and 'creating and improving links between producers and retailers'.

In the cases where respondents provided a degree of specificity, the examples of problems with private standards for animal welfare in the first answer concerned:

- duck stocking density;
- transport requirements;
- slaughter requirements.

Differing opinions on private standards for sanitary safety versus those for animal welfare

For both sanitary safety and animal welfare, two thirds of respondents agree that private standards can provide benefits. This is different in the case of problems presented by private standards, where a majority of respondents (82%) can see problems with private standards for sanitary safety versus 46% that see problems or potential problems with private standards for animal welfare. If the responses of the 27 EU Member States are excluded, 76% of the total respondents agree with the statement that private standards for animal welfare create or may create problems.

The opinions of developed and developing countries on private animal welfare standards differ significantly, as shown in the table below.

OECD classification and number of responses	**Private Standards for animal welfare**			
	create problems		**create benefits**	
	agree	**disagree**	**agree**	**Disagree**
Developed country (36)	13%	**76%**	**89%**	0%
Developing country (28)	**87%**	10%	30%	40%

1. Background

OIE Members have become increasingly concerned about the effects of private standards for sanitary safety and animal welfare on their international trade interests. These concerns were reflected in the discussion at the 76th OIE General Session, May 2008, and Resolution XXIII, calling for the OIE to undertake some work on this question and to provide advice to Members. In particular, developing countries have expressed concerns that private standards may lack transparency, are not always based on science or risk analysis, can be costly to implement and could potentially undermine the official international standards of the OIE and the Codex Alimentarius Commission (CAC).

A working group of the WTO SPS Committee is examining this issue and the OIE continues to provide input relevant to its mandate. Although animal welfare is not currently covered by the SPS Agreement and therefore is not addressed by the SPS Committee working group, this issue remains very important for the OIE and its Members as the OIE is the intergovernmental organisation responsible for preparing standards according to the mandate granted by its Members.

The Codex Alimentarius Commission (CAC) discussed private standards for food safety at its General Assembly in July 2009. The CAC has received a report on this issue but has not provided specific advice to Members to date and, like the OIE, continues to collaborate with the SPS Committee's working group on the issue.

Annex XXIX (contd)

Appendix IV (contd)

The OIE convened an *ad hoc* Group on private standards for sanitary safety and animal welfare to examine this issue. In this context, sanitary safety covers animal production food safety and animal health. The *ad hoc* Group developed a definition of a private standards and a questionnaire to obtain current information from OIE Members on the current and potential difficulties and opportunities presented by private standards for international trade.

The *ad hoc* Group defined a private standard as follows.

'Private Standard': commercial requirements developed, owned and implemented by non governmental entities, with which suppliers must comply to have access to specific markets for animals and animal products. They sometimes include sanitary safety and animal welfare issues. OIE standards as an example of official standards are: elaborated democratically and according to an agreed framework; based on science and risk analysis and regularly reviewed; adopted, published and applied transparently; non discriminatory, but take into account the needs of developing countries and for sanitary safety, consistent with the rights and obligations of WTO members as established under the WTO SPS Agreement. Private standards may share some or many of the above features.

The questionnaire was structured to obtain specific and practical information from OIE Members and international organisations on private standards for sanitary safety and for animal welfare, recognising that the legal basis of official standards in these two domains is different and that the OIE should take account of this fact in developing future strategies.

2. Methods

The questionnaire (Appendix 1) was distributed to the 175 OIE Delegates and to representatives of relevant organisations that have official agreements with the OIE, namely the livestock and food production sector, animal welfare and regional intergovernmental organisations. Respondents were initially asked to reply by the end of September 2009 but this deadline was extended to the end of November 2009 at the request of some OIE Members.

The OIE questionnaire comprises 6 sets of questions. Section one includes general questions about private standards. Subsequent sections ask questions about private standards in two specific domains, i.e. sanitary safety and animal welfare, recognising that the legal basis for official standards in regard to these two domains differs. Sanitary safety, in this context, covers animal health and zoonoses and animal production food safety. The questionnaire contains several questions about the role that the OIE should play with regard to private standards. Most of these questions are 'closed' (i.e. answer yes, no or 'no opinion') and some are 'open' i.e. that invite respondents to give specific examples and comments.

The data provided by respondents were entered into a spreadsheet and analysed. Section 3 of this report analyses the responses of OIE Members to the questionnaire and section 4 describes the responses of international and regional organisations.

3. Responses of OIE Members

In total 68 Members (39% of the 175 OIE Members) replied to the questionnaire. Some two thirds of the 175 OIE Members are developing countries or countries with 'in transition' economies. Based on the OECD system for classifying economic development, 44% (30) of the 68 responses are from developing countries and 56% (38) from developed countries.

The five OIE regions (Europe; Africa; Americas; Asia, Far East and Oceania; and the Middle East) accounted for 49%, 16%, 15%, 15% and 6% of the total number of responses, respectively. The European Commission provided a consolidated submission on behalf of the Member States of the European Union (EU), which accounts for 82% of the responses from the OIE region of Europe.

Four countries of the Middle East region responded to the questionnaire. Although this represents 31% of the 13 countries in the region, the small number of replies makes it difficult to provide a statistically reliable analysis for this region.

Table 1 shows the numbers of Members that responded. Table 2 lists responding Members in each of the five OIE regions. Table 3 shows the classification of responding countries based on the OECD system of classifying economic development.

Table 1: OIE Members that replied to the questionnaire

OIE Region	Number of Members	Number of Respondents	% of Members in the region	% of total respondents
Africa	51	11	22%	16%
Americas	29	10	34%	15%
Asia, Far East & Oceania	31	10	32%	15%
Europe*	51	33 (7 submissions)	65%	49%
Middle East	13	4	31%	6%
TOTAL	**175**	**68**	**39%**	**100%**

* Includes a submission from the European Commission on behalf of the 27 EU Members.

Table 2: Regional distribution of OIE Members that replied to the questionnaire

Region	Respondents	Total respondents
Americas	Argentina, Brazil, Canada, Chile, Costa Rica, Dominican Republic, Haiti, Paraguay, USA, Uruguay	10
Africa	Algeria, Cameroon, Gabon, Guinea-Bissau, Mali, Morocco, Niger, Senegal, Sudan, Swaziland, Tunisia	11
Asia, Far East and Oceania	Australia, Cambodia, China, Japan, the Maldives, New Caledonia, New Zealand, Singapore, Taiwan, Thailand	10
Europe	Armenia, Bosnia/Herzegovina, Croatia, Norway, Switzerland, Turkey, EC on behalf of 27 Member States (Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom)	33
Middle East	Kuwait, Saudi Arabia, Syria, Egypt	4

Annex XXIX (contd)

Appendix IV (contd)

Table 3: Development classification based on the OECD system of OIE Members that replied to the questionnaire

Developing country: 30 (44%)	Developed country: 38 (56%)
Argentina, Brazil, Chile, Costa Rica, Dominican Republic, Haiti, Paraguay, Uruguay	Canada, USA
Algeria, Cameroon, Gabon, Guinea-Bissau, Mali, Morocco, Niger, Senegal, Sudan, Swaziland, Tunisia	Australia, Singapore
Cambodia, China, the Maldives, Thailand	Japan, New Caledonia, New Zealand, Taiwan
Armenia, Bosnia/Herzegovina, Croatia, Turkey	Norway, Switzerland, Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom.
Saudi Arabia, Syria, Egypt	Kuwait

3.1 General Statements about private standards for sanitary safety and animal welfare (section 2 of the questionnaire)

In section 2 of the questionnaire respondents were asked to give their opinion on seven statements about private standards and international trade. Table 3 shows the percentage of Members in each of the five OIE regions that agree with the statements.

Table 3: Percentage of respondents that agrees to the state ments in section 2

OIE Region	2.1	2.2	2.3	2.4	2.5	2.6	2.7
Africa	100%	64%	100%	100%	73%	100%	73%
Americas	90%	40%	100%	90%	50%	100%	40%
Asia, Far East, Oceania	80%	50%	80%	90%	60%	80%	40%
Europe	100%	91%	100%	100%	88%	100%	97%
Middle East	100%	75%	100%	100%	50%	100%	100%
Total	**96%**	**72%**	**97%**	**97%**	**74%**	**97%**	**76%**

In general it can be concluded that most Members in all five OIE regions agree to these statements. In the Americas region, two of the statements (2.2 and 2.7) do not receive support from more than 50% of respondents. In the Asia, Far East & Oceania region 50% of respondents do not support statement 2.7.

1) Statement 2.1: A clear distinction needs to be made in the approach towards private standards in the areas of sanitary safety and animal welfare.

Most respondents (96%) agree that a clear distinction needs to be made in the approach towards private standards in the areas of sanitary safety and animal welfare. Two respondents disagree.

2) Statement 2.2: Private standards in international trade are due to a lack of official standards in some areas.

Many respondents agree (72%) but there are some differences between OIE regions. Almost all European respondents (91%) agree to the statement while 60% of respondents from the Americas disagree with the statement.

3) Statements 2.3 and 2.4: The implementation by OIE Members of animal welfare standards should be strengthened and the OIE PVS Tool should put a greater emphasis on the implementation of the OIE animal welfare standards.

Nearly all respondents (97%) agree that the implementation by OIE Members of animal welfare standards should be strengthened and that the OIE PVS Tool should put greater emphasis on the implementation of the OIE animal welfare standards.

4) Statement 2.5: Private standards and certification can be a useful aid to the implementation of official standards.

Overall, 74% of respondents agree with this statement. However, the support was weaker from the countries of the Americas and the Middle East (50% agree) than from OIE Members in the other regions.

5) Statement 2.6: Although animal welfare is not covered by the WTO SPS Agreement, the OIE should continue to develop animal welfare standards

Most respondents (97%) agree that although animal welfare is not covered by the WTO SPS Agreement, the OIE should continue to develop animal welfare standards.

6) Statement 2.7: OIE animal welfare standards would have increased legitimacy if animal welfare was covered by the WTO SPS Agreement.

Overall, most respondents (76%) agree. However, the response rate is variable and less than 50% of respondents from the regions of the Americas and Asia, Far East and Oceania, agree. However, in these two regions several respondents expressed no opinion, so even in these regions the number of respondents agreeing to the statement is higher than the number disagreeing.

Comparisons of replies from developed and developing countries.

To further analyse responses received from the five OIE regions, a comparison of responses from developed and developing countries (according to the OECD system for classification of economic development) was made (see Table 3a). The most significant differences between developed and developing countries were in the replies to statements 2.2 and 2.5. This helps to understand but does not fully explain the differences between OIE regions.

Annex XXIX (contd)

Appendix IV (contd)

Table 3a: Comparison of replies between developed and developing countries (based on the OECD classification of economic development).

	Developed country								
	2.1	**2.2**	**2.3**	**2.4**	**2.5**	**2.6**	**2.7**	**7.1**	**7.2**
agree	95%	**89%**	100%	97%	**89%**	97%	82%	95%	97%
no opinion	3%	3%	0%	0%	11%	3%	11%	3%	3%
disagree	3%	8%	0%	3%	0%	0%	8%	3%	0%
	100%	100%	100%	100%	100%	100%	100%	100%	100%
	Developing country								
agree	97%	**50%**	93%	97%	**53%**	97%	70%	80%	93%
no opinion	0%	7%	3%	3%	20%	0%	20%	3%	3%
disagree	3%	43%	3%	0%	27%	3%	10%	10%	0%
	100%	100%	100%	100%	100%	100%	100%	93%	97%

3.2 Opinions on problems and benefits related to private standards (sections 3 to 6 of the questionnaire)

In sections 3 to 6 respondents were asked to express their views about current and potential problems and benefits that private standards represent. They were asked to detail possible problems and benefits and give concrete examples of problems, where possible.

Table 4 shows the percentage of respondents agreeing and disagreeing on the question of problems and benefits relating to standards for sanitary safety.

Table 5 shows the percentage of respondents agreeing and disagreeing with statements about the potential problems and benefits presented by private animal welfare standards. The cells with a clear majority (66% or more) of responses are highlighted in bold print.

In Tables 4 and 5 the responses of developed and developing countries (based on the OECD classification) are compared (also see Table 2).

Table 4: Opinions on problems and benefits of private standards for sanitary safety

OIE Region	**Private standards for sanitary safety**			
	create problems		**create benefits**	
	agree	**disagree**	**agree**	**Disagree**
Africa	**82%**	9%	45%	36%
Americas	60%	20%	30%	60%
Asia, Far East & Oceania	**70%**	10%	40%	10%
Europe	**97%**	3%	**88%**	9%
Middle East	50%	0%	25%	25%
Total (64)	**82%**	7%	62%	22%

OECD classification and number of responses	**Private standards for sanitary safety**			
	create problems		**create benefits**	
	agree	**disagree**	**agree**	**Disagree**
Developed countries (36)	**84%**	8%	**87%**	3%
Developing countries (28)	**80%**	7%	30%	47%

Globally, 82% of respondents agree that private standards for sanitary safety create or may create problems and 62% of respondents agree that these private standards may also create benefits.

If the responses of developed and developing countries are compared, both groups clearly agree that private standards for sanitary safety create or may create problems. However, opinions differ on whether private standards for sanitary safety can present possible benefits. While 87% of developed countries can see benefits, only 30% of developing countries share this opinion and 47% do not see potential benefits.

The most important problems cited are 'compliance costs', 'lack of basis in science or risk assessment', 'lack of transparency', 'over-prescriptive nature of private standards' and 'inadequate consultation with relevant stakeholders'.

The most important benefits cited are 'market access opportunities including niche markets' 'addressing the gaps in relevant international standards', 'meeting the needs or concerns of stakeholders that are not addressed by OIE standards', 'facilitating the implementation of public standards' and 'promotion of corporate social responsibility'.

Table 5: Opinions on problems and benefits of private standards for animal welfare

Regions	**Private Standards for animal welfare**			
	create problems		**create benefits**	
	agree	**disagree**	**agree**	**Disagree**
Africa	**91%**	9%	36%	36%
Americas	60%	20%	30%	40%
Asia, Far East & Oceania	60%	10%	40%	20%
Europe	15%	**85%**	**91%**	6%
Middle East	**100%**	0%	**67%**	0%
Total	46%	47%	64%	18%

OECD classification and number of responses	**Private Standards for animal welfare**			
	create problems		**create benefits**	
	agree	**disagree**	**agree**	**Disagree**
Developed (36)	13%	**76%**	**89%**	0%
Developing (28)	**87%**	10%	30%	40%

Overall, 46% of respondents agree with the statement that private animal welfare standards create or may create problems. Reflecting the economic development of countries in each OIE region, the responses of the five regions differ significantly, with 91% of respondents from Africa and all respondents from the Middle East agreeing with this statement, while 85% of the European respondents disagree with this statement.

A comparison of the responses of developed and developing countries provides more information on OIE Members' views on this point. Most developed countries (76%) disagree that private standards for animal welfare create or may create problems. However, most developing countries (87%) see problems.

Annex XXIX (contd)

Appendix IV (contd)

Overall, 64% of respondents consider that private animal welfare standards create or may create benefits. Views of regions vary. Some 40% of respondents in the Americas do not agree and Africa is divided on this question, with 36% of respondents agreeing, and 36% disagreeing. Nearly all developed countries (89%) see potential benefits of private animal welfare standards but 40% of developing countries do not agree. It is noteworthy that 27% of the responding developing countries responded 'no opinion', perhaps reflecting a lack of understanding or a need to better explain this question.

Where problems are cited, those most commonly mentioned are 'lack of harmonization between different private standards' and 'lack of basis in science or risk assessment'.

Benefits mentioned most commonly relate to 'gaining market access opportunities, including niche markets', 'meeting the needs or concerns of stakeholders that are not addressed by OIE standards', 'facilitating the implementation of public standards' and 'creating and improving links between producers and retailers'.

Respondents provided 33 examples of problems with private standards for sanitary safety and animal welfare. However, few of the examples given are specific and practical and the remainder is still largely theoretical. The OIE is taking steps to collect additional information from some respondents.

3.3 Opinions on problems and potential problems of private standards for sanitary safety (questionnaire section 3)

Based on replies on section 3 of the questionnaire, most respondents (83%) agree with the general statement that private standards for sanitary safety either have created or may create significant trade problems for exports from their countries. A few respondents had no opinion or disagree with this statement. Responses from all regions are broadly consistent.

The questionnaire listed 15 possible problems related to private standards for sanitary safety and respondents were requested to indicate the most important (the 'top five problems') for their country. The five problems most commonly identified are shown in Table 6. The problems mentioned by the largest number of respondents (15%) are 'compliance costs' and 'lack of basis in science or risk assessment'. Three other problems i.e. 'lack of transparency', and 'inadequate consultation with relevant stakeholders' and 'over-prescriptive nature of private standards' are considered to be amongst the three most serious problems by 14%, 13% and 13% of respondents.

Table 6: Opinions on problems associated or potentially associated with private standards for sanitary safety

Importance	Problem	%
1, 2	Compliance costs (e.g. certification, auditing)	15%
1, 2	Lack of basis in science or risk assessment	15%
3, 4	Lack of transparency	14%
4, 5	Inadequate consultation with relevant stakeholders	13%
4, 5	Over-prescriptive nature of private standards	13%

Respondents also identify significant concerns in the following areas:

- private standards may pose a problem for fair competition if they are abused by retailers to create competitive distortions and/or mislead the public;
- private standards may create confusion, depending on who requires the private standards;
- the lack of dispute resolution mechanisms for private standards;
- private standards should meet the WTO SPS and OIE minimum standards;
- private standards could create a new form of protectionism.

Respondents give 20 examples of specific problems arising from private standards for sanitary safety. In most cases, there is insufficient information to support detailed analysis and the OIE is following up several examples with respondents.

In the cases where respondents provided a degree of specificity, the problems concerned:

- requirements for *Listeria* spp for cooked poultry products;
- BSE related requirements concerning the age of animals from which meat is obtained, not respecting the BSE status of the exporting country;
- Bluetongue requirements for meat.

3.4 Opinions on problems and potential problems of private standards for animal welfare (questionnaire section 4)

The responses to this question are significantly different from the responses to the questions in section 3, which addresses sanitary standards, many respondents agreed (46%) and disagreed (47%) (with the general statement that private standards for animal welfare either have created or may create significant trade problems for exports from their countries.

There are significant differences amongst OIE regions in the responses to this question. Most respondents from Europe (85%) disagree that private standards for animal welfare are or may be problematic. Respondents from the other four regions largely agree with the statement.

The questionnaire listed 15 possible problems that may arise in relation to private animal welfare standards and respondents were asked to identify the five most significant problems or potential problems for their country. The responses are shown in table 7. The problems most commonly mentioned are "lack of basis in science or risk assessment" and "lack of harmonization between different private standards". Respondents also considered "lack of transparency", "lack of harmonization between different private standards" and "compliance costs (e.g. certification, auditing)" to be important problem areas.

Table 7: Opinions on problems associated or potentially associated with private animal welfare standards

Importance	Problems	%
1, 2	Lack of harmonization between different private standards	12%
1, 2	Lack of basis in science or risk assessment	12%
3	Lack of transparency	11%
4, 5	Inadequate consultation with different stakeholders	9%
4, 5	Compliance costs (e.g. certification, auditing)	9%

Other concerns raised by respondents include the assertion that lack of objective outcome based measures and harmonised risk assessments in animal welfare make it difficult to compare levels of standards, including private standards.

Respondents give 13 examples of specific problems arising from private animal welfare standards. In most cases, there is insufficient information for detailed analysis and the OIE is following up several examples with respondents.

In the cases where respondents provided a degree of specificity, the problems concerned:

- duck stocking density;
- transport requirements;
- slaughter requirements.

Annex XXIX (contd)

Appendix IV (contd)

3.5 Opinions on benefits or potential benefits of private standards for sanitary safety (section 5 of the questionnaire)

Respondents were asked whether they consider that private standards for sanitary safety have created or may create significant benefits for their country. A majority of respondents (64%) indicates that they agree and other respondents either have no opinion (14%) or disagree (22%). Again there are significant differences amongst regions. Most (88%) European respondents are of the view that there are real or potential benefits while 56% of respondents from the Americas disagree.

The questionnaire listed nine potential benefits of private standards for sanitary safety and respondents were asked to indicate the five points that they consider to be most important to their countries. The responses are listed in Table 8. The benefits that are most commonly mentioned are "market access opportunities including niche markets" and "filling the policy gap left by lack of relevant international standards".

Table 8: Opinions on benefits ~~arising~~ or potential benefits of ~~arising from~~ private standards for sanitary safety

Importance	Benefits	%
1	Market access opportunities including niche markets	19%
2	Filling the policy gap left by the lack of relevant international standards	18%
3	Meeting the needs or concerns of stakeholders that are not addressed by OIE standards	18%
4	Facilitating the implementation of public standards	17%
5	Promotion of corporate social responsibility	14%

Respondents identified the following additional benefits that they believe to be important:

- the possibility of increased transparency in establishing private standards, allowing organisations to go beyond government minimums with company auditing of private standards providing an additional layer of oversight; increasingly, private standards are more clearly written and less vague than public standards;
- process orientated private standards which define codes of good practice may help producers to get in line with internationally agreed official standards and thus create new market opportunities.

3.6 Opinions on benefits or potential benefits arising from of private standards for animal welfare (section 6 of the questionnaire)

Respondents were asked if they consider that private animal welfare standards have created or may create significant benefits for their country. Like the responses to section 5 of the questionnaire, which deals with sanitary standards, 65% of respondents indicate that they agree with this statement. Remaining respondents have no opinion (17%) or disagree (17%) that private standards for animal welfare have real or potential benefits. However, 40% of respondents in the African region do not agree with the statement.

The questionnaire listed ten potential benefits of private animal welfare standards and respondents were asked to indicate the five benefits that are they consider to be most important for their country. The benefits/potential benefits that are most commonly mentioned are: 'market access opportunities including niche markets', 'meeting the needs or concerns of stakeholders that are not addressed by OIE standards', 'facilitating the implementation of public standards' and 'supporting continuous improvement of global animal welfare', with 14% of respondents identifying each of these.

Thirteen per cent of respondents considered that 'filling the policy gap left by lack of relevant international standards' and 'price premiums' were also significant benefits or potential benefits for their country.

Table 9: Most important benefits arising or potentially arising from private standards for animal welfare

	Benefits	**%**
1, 2, 3, 4	Market access opportunities including niche markets	14%
1, 2, 3, 4	Meeting the needs or concerns of stakeholders that are not addressed by OIE standards	14%
1,2, 3, 4	Facilitating the implementation of public standards	14%
1,2, 3, 4	Supporting continuous improvement of global animal welfare	14%
5, 6	Filling the policy gap left by lack of relevant intemational standards	13%
5, 6	Price premiums	13%

Respondents also listed the following benefits or potential benefits:

- the ability to go beyond government standards;
- increased engagement of private sector in international science-based standards development process;
- increased accountability and transparency on the part of the food animal production centre;
- improved food quality and worker safety;
- contribution to sustainable development by promoting higher animal welfare standards;
- creation of market opportunities for small scale farmers and producers.

3.7 OIE policy on private standards (section 7 of the questionnaire)

Overall, most respondents (91%) agree that private standard setting bodies should do more to promote the harmonization of their standards and nearly all (97%) consider that there should be closer collaboration between private standard setting organizations and the OIE.

Respondents suggest actions that could facilitate collaboration between private standard setting organizations and the OIE as follows:

- Invite identified private standard setting bodies to participate in the OIE through formal agreements;
- Ensure that the OIE standards for both sanitary safety and animal welfare are prominently identified and accessible on the OIE homepage. This enables those involved with private standard development to have easy access to relevant internationally recognised standards.
- Continue to actively promote and increase awareness of existing international standards.
- Encourage OIE Members to communicate with private standard setting organizations to ensure that those organizations are familiar with OIE standards
- Continue to develop standards where there are gaps in existing international standards.
- Ensure transparency in the development of international standards so that the organisations developing private standards can more easily see what information was used to develop the international standards.

Annex XXIX (contd)

Appendix IV (contd)

Respondents made similar comments with respect to the steps that the OIE could take to prevent private standards having a negative effect on the implementation of official standards, i.e. to improve communication between private and official standard setting bodies and to increase awareness and understanding of international standards. Some respondents call for more transparency in the development of international standards.

Respondents recommend that the OIE work more closely with other international standard setting bodies and the WTO SPS Committee to address the issue of private standards with a view to facilitate collaboration and reduce confusion about standards.

Respondents were asked to make suggestions, based on their national experience, on how to deal with the problems that private standards present for international and, where relevant, regional trade. The respondents who answered this question emphasize the need for broad collaboration and harmonization between international organizations and private standard setting bodies. They also emphasise the need for transparency in the development of both international and private standards.

4. Results from international and regional organisations

Table 10 shows the eight international and regional organisations that responded to the questionnaire: two animal welfare organisations, four international industry organisations and two intergovernmental regional organisations. The international animal welfare organisations comment on private standards for animal welfare but do not express views on private standards for sanitary safety.

Table 10: Responses from international and regional organisations

International animal welfare organisations	World Society for the Protection of Animals (WSPA); Compassion in World Farming (CIWF).
International industry organisations	International Dairy Federation(IDF); International Federation of Agricultural Producers (IFAP); Internationa1 Meat Secretariat (IMS); Intentional Poultry Council (IPC).
Regional governmental organisations	Union Economique et Monetaire Ouest Africaine(UEMOA); Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA).

The numbers of the respondents are too small and the responses provided by the organisations are too variable to draw statistically reliable conclusions. Nevertheless, the replies show some interesting trends.

4.1 International animal welfare organisations

The two animal welfare organisations that responded to the questionnaire agree that there needs to be a clear distinction between private standards for sanitary safety and animal welfare. They consider that the OIE should put greater emphasis on the use of the OIE PVS tool for implementing animal welfare standards and that OIE members should strengthen the implementation of animal welfare standards. In general, these organisations would like to see the OIE increase its development and implementation of animal welfare standards. The animal welfare organisations consider that private standards can be a useful aid to the implementation of international standards. However they did not agree that private standards in international trade are due to a lack of official standards in some areas.

The animal welfare organisations disagree with the statement that private standards for animal welfare create or may create problems. They agree strongly that private standards for animal welfare offer benefits to countries with regard to trade. They generally disagree that private standard setting bodies should do more to promote the harmonization of their standards and they agree that the OIE should foster closer collaboration with private standard setting organisations.

4.2 International industry organisations

The four international industry organisations that replied to the questionnaire agree that there should be a clear distinction between private standards for sanitary safety and animal welfare. The majority does not consider that the growth of private standards in international trade is due to a lack of official standards. The industry organisations agree that the OIE should improve and strengthen the development and implementation of animal welfare standards. The industry organisations have differing views on whether private standards and certification can be useful to aid the implementation of official standards.

The attitude of these organisations to private standards is generally negative. They consider that private standards for sanitary safety and for animal welfare create problems or potential problems. However, private animal welfare standards may also create benefits.

The organisations differ on whether private standard setting bodies should do more to harmonise their standards and on whether the OIE should collaborate more closely with private standard setting bodies.

4.3 Intergovernmental regional organisations

The two intergovernmental regional organisations that responded to the questionnaire are from South America and West Africa. The replies provided by these organisations were generally consistent with those provided by the countries in the relevant regions. However, like the international industry organisations, the intergovernmental regional organisations do not consider that private standards in international trade are due to a lack of official standards, nor do they agree that the OIE PVS Tool should put a greater emphasis on the implementation of animal welfare standards.

The two intergovernmental regional organisations agree that private standards for sanitary safety and animal welfare should be clearly distinguished and that private standards in both areas have the potential to create problems for countries in their respective regions. These organisations have no opinion on or do not recognise potential benefits of private standards for sanitary safety or animal welfare.

The two organisations strongly agree that private standard setting bodies should do more to harmonise their standards and that there should be closer collaboration between private standard setting bodies and the OIE.

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Annex XL

Original: English
October 2009

REPORT OF THE SECOND MEETING OF THE OIE *AD HOC* GROUP ON TRADE IN ANIMAL PRODUCTS

Paris, 15 October 2009

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The OIE *ad hoc* Group on Trade in Animal Products met at the OIE Headquarters from 15 October 2009.

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

1. Introduction

In introducing the agenda, the Chair of the *ad hoc* Group, Dr Brückner, reminded members of the *ad hoc* Group that the main objective of this meeting was to review the report "Qualitative Assessment of the commodity risk factor for spread of foot and mouth disease associated with international trade in deboned beef" (the OIE/DfID Review, Annex III) and propose any modifications that were considered to be pertinent. The report of the *ad hoc* Group and Dr Paton's report, with proposed modifications, would be submitted to the Terrestrial Animal Health Standards Commission (the Code Commission) for consideration of appropriate next steps.

Dr Vallat joined the *ad hoc* Group for a brief discussion on the importance of international trade in animal products ('commodities') for OIE Members. He thanked all participants as well as donors supporting this group and ~~He~~ informed the Group that this topic is mentioned in the OIE 5th Strategic Plan, along with clear reference to the need for all OIE Members to comply with the OIE standards for international trade, based on the consensual adoption of these standards by the World Assembly of Delegates. Also pertinent to this topic, the 5th Strategic Plan recommends that Veterinary Services be recognised as a Global Public Good. The OIE, in collaboration with partners and donors, will continue to support reinforcement of the capacity of Veterinary Services through the use of the OIE Tool for Evaluation of Veterinary Services (OIE PVS Tool) and relevant follow up activities (e.g. PVS Gap Analysis and veterinary legislation missions). Implementation of the OIE standards depends, *inter alia*, on Veterinary Services meeting the OIE standards for quality, as set out in Chapters 3.1. and 3.2. of the Terrestrial Animal Health Code (the *Code*).

2. Update on developments since the last meeting of the *ad hoc* Group

The group noted that some of the recommendations from the previous meeting have already been resolved, including measures for BSE (beef and beef products), CBPP (milk and milk products) and CSF (pork and pork products). The Group also noted that the Code Commission had proposed to delete chapters on delisted diseases (bovine cysticercosis and Techovirus encephalomyelitis) in its September 2009 meeting. Some outstanding items are listed in table 1 below.

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Concerning FMD, the Group agreed on the approach taken by the Code Commission and recommended to address as a top priority the inclusion of compartmentalization in Code chapters. Other items should be addressed later, based on the scientific evidence available. However, the Group emphasized the importance of measures other than pasteurization (e.g. lactoperoxidase) in treating milk products for developing countries.

The Group recommended that the Code Commission continue working to improve the *Code* presentation and to make it more user friendly.

Table 1: Status of recommended actions from first meeting of *ad hoc* Group on Trade in Animal Products ('Commodities')

Commodity	Disease (article)	Issue	Next steps
Beef	RVF (Article 8.11.11.)	risk on viraemic animals	TAHSC with experts
	bovine brucellosis (Article 11.3.6.)	beef as a safe commodity, trade of cattle for slaughter	AHG in Nov09
	CCHF	chapter development	AHG in Oct09
Milk and milk products	FMD	provisions for unpasteurized milk (cheese, sour milk)	TAHSC with ref lab experts
	bovine brucellosis	risk mitigation measure development	AHG in Nov09
	Lactoperoxidase treatment	effectiveness to inactivate animal pathogen	Seeking information
Sheep and goat milk	All chapters except scrapie	article development	TAHSC/SCAD/S&T/ITD
Pork and pork products	FMD	article review	TAHSC / paper review?
	ASF	chapter formatting	TAHSC/ITD
	SVD	chapter revision	AHG in Feb10
	PRRS	guidance document	AHG
	Porcine circovirus	diagnostic tests	BSC
	Rinderpest	pig susceptibility	TAHSC with experts

3. Discussion and validation of the research review and qualitative risk assessment by experts (the OIE/DfiD Review)

Noting that the OIE/DfiD Review had been circulated to members of the *ad hoc* Group before the meeting, Dr Brückner invited Dr Paton to present the main conclusions and recommendations. Dr Paton outlined the process for conducting the study, which was managed by teleconference between the three collaborating authors. He explained that the group looked at the risks associated with deboned beef, pork and mutton but as data are relatively extensive for beef compared with pork and mutton, it was decided to concentrate on deboned beef.

Dr Paton explained that there remain some key questions regarding 1) the infective dose of FMDV for pigs infected via the ingestion of beef (assumed to be the most relevant exposure pathway in an importing country); and 2) the extent to which tissues (such as fat, bone marrow and lymphatic tissue) that may harbor FMDV may be present in deboned beef. Dr Paton noted that the survival of FMD virus in matured deboned meat *per se* is not in question provided the pH is checked but there is some evidence that FMD virus may survive in other tissues that may be present in residual amounts in deboned beef.

Dr Donaldson observed that the animals presenting the highest risk are those that are incubating FMD, particularly towards the end of the incubation period (when the virus load is highest), as these animals are not likely to be detected at ante mortem inspection.

The conclusions and recommendations of the study were discussed in detail.

The OIE/DFID Review calls for the establishment of more detailed protocols for ante and post mortem inspection to address the risk of FMD transmission. It was agreed that the OIE International Trade Department would review existing chapters of the *Code* and provide advice to the Code Commission on appropriate revision of the text. The existence of the Codex Alimentarius Code of Hygienic Practice for Meat (CHPM) and the need to keep the Codex informed of any developments in this regard was noted.

The OIE/DFID Review indicates that while deboned beef is a very low risk commodity with respect to the spread of FMD, neither data on the safety of trade in deboned beef to date nor a risk assessment of the survival of FMDV during the preparation of deboned beef according to the procedures set out in the *Code* provide conclusive evidence that the risk is negligible without the application of additional risk mitigation measures that reduce the likelihood of infected cattle being presented for slaughter.

The OIE/DFID Review also finds that some of the current provisions in the *Code* on risk management for FMDV in deboned beef (including measures applied to the cattle and to the meat) are too general and leave too much room for interpretation as to their effective implementation. For example Article 8.5.23, point 1b reads: "have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation. More information could be provided on the vaccination schedule and associated controls that are recommended.

The Group discussed the recommendation of the OIE/DFID Review relating to the FAO/OIE Progressive FMD Control Pathway, supporting the recommendations of the OIE/FAO Global Conference on FMD (Paraguay, 24-26 June 2009). It was acknowledged that the application of the principles of the FAO/OIE Progressive FMD Control Pathway could help to demonstrate adequacy of mitigation measures in support of beef exports. However, members of the group also expressed concern regarding a recommendation to follow a pathway that has not yet been clearly defined. If such a pathway is to be used, it should be limited to practical guidelines for countries to follow when wishing to reach an improved status for FMD. Such pathway must be based on and limited to the *Code* provisions. The pathway is to assist countries in the self assessment of their situation as regards the control of FMD, but cannot constitute a different approach for recognition of a country's FMD status.

The OIE/DFID Review notes that the current *Code* chapter on FMD does not provide specific recommendations on surveillance measures and risk management in countries/regions that are not FMD free. Rather, the *Code* states that the use of deboning, maturing and pH testing deboned beef should be used for the purposes of trade in deboned beef from FMD infected countries where cattle are vaccinated. The current guidance on surveillance in the *Code* provides for establishing the FMD freedom of countries/zones but does not provide sufficient guidance to countries or regions that are not free from FMD.

Dr Paton noted that although data on survivability of the FMD virus types Asia 1 and SAT 1, 2 and 3 are lacking, he would not expect that these viruses would behave very differently to the other strains of FMDV that have been well studied. Dr Amanfu recommended conducting research into this question as it is possible that the SAT strains are more fragile than other FMDV strains under certain conditions, both in terms of thermolability and in terms of resistance to reduced pH. It may be possible to reduce the holding period that is currently applied to beef exports from FMD infected countries on the basis of more definitive information on the survivability of the SAT virus strains. This question should also be reviewed for the Asia strain of FMDV. No decision can be taken on this in advance of specific scientific studies.

Following Dr Paton's presentation of the conclusions and the recommendations of the OIE/DfID Review, the *ad hoc* Group discussed key points in detail.

Recommendation 1: More specific guidance should be developed on mitigation measures that will provide adequate assurance that FMDV infected animals, particularly those in the early stages of infection and possibly incubating the disease, are not presented for slaughter at export abattoirs in regions that are not officially FMD-free.

The Group discussed at some length Recommendation 1 (a) regarding the isolation of cattle during the three weeks prior to slaughter. This is an important step as it addresses the risk of infected cattle being slaughtered while incubating FMD, potentially resulting in the production of meat containing FMDV. Dr Thiermann reminded the Group that the current provisions in the *Code* for deboned beef exports from non FMD free countries/zones already calls for the isolation of cattle within the 30 days prior to export. However, this provision is not generally used by OIE Members as a basis for approving imports from countries that are not FMD free. Some members of the Group considered that the term 'isolation' should be used rather than the word 'quarantine' as 'quarantine' implies holding in a quarantine station and this measure was not warranted. Cattle need to be isolated to ensure that they are not exposed to infection and to ensure that if they were already infected at the time of entering the isolation period, clinical signs would have developed before they are sent to slaughter. The report of the OIE/DFID Review was modified accordingly.

Recommendation 1 (b) refers to other options for reducing the weight of challenge, such as specified measures of surveillance and vaccination to control FMD in the vicinity. The word 'vicinity' was defined as 'areas that are epidemiologically related to the source of the animals', to reflect that the epidemiology of the disease should be taken into account and that proximity is not the sole (nor the most important) consideration.

Recommendation (e) was modified by replacing 'Competent Authority and their veterinary services' with 'Veterinary Authority'.

Recommendation 2: More specific guidance should be developed on mitigation measures required at export abattoirs in regions that are not FMD-free. This guidance should encompass both procedures to be followed and measures by which their implementation can be monitored.

All three points [(a), (b) and (c)] were accepted with one modification to point (c) ('Veterinary Authority' to replace 'Competent Authority and their veterinary services').

Recommendation 3: Further research

The *ad hoc* Group generally supported the relevance of all recommendations [(a) to (f)] but considered that the reasons for undertaking this research should be explicitly stated. It was agreed that research on the key points (a) to (c) inclusive could help to demonstrate the safety of the current *Code* provisions and encourage OIE Members to adopt these provisions. In addition, further research could also help to establish a scientific rationale for developing new provisions in the *Code*. However, the Groups also warned of the difficulty of reaching definitive conclusions on risk, even if further research is conducted .A caveat should be added to warn of the difficulty of reaching definitive conclusions on risk, even if further research is conducted.

4. Conclusions

The Group endorsed the conclusions of the OIE/DFID Review. The Review finds that deboned beef, by itself, is not a 'negligible risk' commodity in the same sense, for example, that milk and dairy products present a negligible risk for BSE. However, application of the relevant provisions in the *Code* results in a commodity (suitably sourced, matured, deboned beef) that is safe for trade and OIE Members should be encouraged to apply these provisions wherever relevant.

The Group supported the conduct of research as proposed in the study, with a particular focus on the SAT 1, 2 and 3 viruses, as this could help to address restrictions that are currently applied, and may not be justified, for beef exports from African countries.

The Group also agreed that countries and regions should be encouraged to follow the FAO/OIE Progressive Control Pathway for FMD, where appropriate, as this could help to facilitate trade in commodities by supporting compliance with *Code* provisions.

The group noted that following further progress in the development of the concept of safe trade in commodities, the Director General might consider reconvening the group to address any needs that may be identified by the Terrestrial Code Commission. It was suggested that other issues related to deboned meat as a safe commodity, not necessarily applicable to FMD only, should be further investigated to facilitate decision-making on trade in specific commodities.

It was generally agreed that the OIE/DFiD study should be placed in the public domain and that there was value in publishing it either in the OIE Scientific and Technical Review or in another appropriate publication. Dr Kahn confirmed that the study and the report of the *ad hoc* Group would be in the public domain as an annex to the report of the Terrestrial Code Commission's February 2010 meeting. She also undertook to ascertain other possibilities for publication of the report, in the OIE Review, another publication or on the OIE internet site.

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…/ Appendices

MEETING OF THE OIE *AD HOC* GROUP ON TRADE IN ANIMAL PRODUCTS (COMMODITIES)

Paris, 15 October 2009

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Annex II

MEETING OF THE OIE *AD HOC* GROUP ON
TRADE IN ANIMAL PRODUCTS (COMMODITIES)
Paris, 15 October 2009

Adopted agenda

1. Welcome from the Director General
2. Adoption of the agenda
3. Update on developments since the last meeting of the ad hoc Group, including relevant conferences and meetings and feedback from Code Commission meeting of September 2009.
4. Discussion and validation of the research review and qualitative risk assessment by experts
5. Recommendations for the Terrestrial Code Commission
6. Future work of the Group

Annex XL (contd)

Annex III

Qualitative assessment of the commodity risk factor for spread of foot-and-mouth disease associated with international trade in deboned beef

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Abstract

The risk that imported livestock and their products may introduce foot-and-mouth disease virus (FMDV) restricts trade in these commodities from parts of the world where FMDV has not been eradicated. This reduces investment and development of the livestock sector in many developing countries as well as export trade opportunities and global food supply. This review focuses on the risks associated with trade in deboned beef (DB) from foot-and-mouth disease infected cattle, countries or zones. A definition of DB is provided along with a description of the procedures required for its preparation within abattoirs. A review of the available evidence is presented for circumstances under which DB can be contaminated with FMDV and some figures are provided for the amount of this commodity that has been traded from FMDV-infected regions. Additional mitigating measures to reduce the risk of FMDV contamination of DB are discussed, particularly pre-slaughter measures, such as surveillance, quarantine and vaccination. It is clear that a combination of pre-slaughter and slaughterhouse measures has resulted in a commodity (DB) with a negligible risk of transmitting FMD. Nevertheless, it is concluded that the current evidence does not provide absolute assurance that abattoir procedures for producing deboned beef can on their own result in a commodity with a negligible risk of transmitting FMDV without complementary measures to reduce the likelihood of slaughtering infected cattle. The main areas of uncertainty are the amounts of residual FMDV-harbouring tissues within DB, and our understanding of what constitutes a safe level of contamination. More detailed guidance should be developed to specify what mitigating measures are needed in support of the export of DB from regions that are not officially FMD-free. Generic or ambiguous guidance that leads to differences in interpretation can give rise to obstacles to trade and should be avoided. Further data to evaluate the safety of DB might be provided by a study of the amounts of residual lymph node and bone marrow tissues within DB.

Introduction

International Trade Standards set by the World Organisation for Animal Health (also known as the Office International des Epizooties, OIE) aim to prevent the spread of animal diseases that can have devastating health and economic consequences, thus facilitating safe trade in animals and animal products. As specified within the World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) Agreement, OIE standards must balance safety considerations against the need to promote trade and avoid discriminatory measures that are not based on scientific evidence. The role of livestock products as trade commodities and the importance of fair market access for developing countries have been discussed by Perry, *et al.* (2005). Scoones and Woolmer (2008) have considered different approaches to achieving market access for beef from southern Africa.

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Annex III (contd)

The global demand for meat currently outstrips supply and over the past two decades beef exports have become significant sources of export revenue and jobs for developing countries. In 2006, more than 70% of global meat was produced in developing countries (DC). However, Least Developed Countries (LDC) with the potential to produce quality meat still have impediments to access regional and international markets (Perry *et al*., 2005). This is despite tariff barriers that are frequently low or non-existent for LDCs. Barriers to trade, imposed by importing countries, are sometimes based on perceived rather than actual risk and in such cases may not reflect internationally agreed upon trade standards. Such barriers can limit the capacity of Developing and LDC to export high value livestock and animal products. This has a knock-on effect in reducing investment in the livestock industry and the availability of products for both internal and external consumption. Impacts of animal diseases on global livestock and meat markets as well as challenges for livestock producers, industries and policy-makers in a context of rising demand for locally produced and imported livestock products have been reviewed by Morgan and Prakash (2006). Global risks of infectious animal diseases and factors affecting emergence or spread of livestock diseases have been reviewed by CAST (2005). This report has pointed out that despite enormous progress in scientific knowledge and improvements in sanitary standards in livestock production, several FMD outbreaks caused by international spread of the disease have resulted in major economic losses in recent years.

Foot-and-mouth disease (FMD) has been considered a sufficiently serious infectious animal health problem for most developed countries to have expended a great deal of effort on its eradication. These countries, or zones within them, have the status of FMD-free, with or without vaccination, approved by the OIE. If they do not vaccinate their livestock against FMD prophylactically, their animals are highly susceptible to infection from any introduced form of the disease and their own exports can then readily pass on newly acquired infection to third countries. In contrast, many DCs and LDCs lack the resources to eradicate the disease, have endemic or sporadic occurrence of the disease and do not have the OIE FMD-free status. FMD-free countries attempt to protect their livestock industries against introduction of FMD virus (FMDV) by regulating imports of FMD susceptible animals and their products, since it is known that infected animals as well as some of their infected products can introduce FMDV and give rise to outbreaks of the disease. As different types and/or strains of FMDV occur in different parts of the world, there is also logic in preventing the spread of infection between countries from different regions that are not FMD-free. Consequently, FMD is a significant barrier to trade in both live animals and many of their products and even for animal products that do not pose a direct risk of spreading disease. Facilitating access to international markets will assist with poverty alleviation by increasing revenue, jobs and food security in LDCs but should be brought about with safeguards against increasing the risk of spreading disease.

The risk of instigating an outbreak of FMD in an importing country through a traded animal product is a combination of the likelihood of (1) the animals from which the product is derived being infected with FMDV at the time of slaughter, (2) the likelihood of FMDV surviving during preparation, storage and transportation of the commodity, (3) the probability of FMDV infected product reaching susceptible animals in sufficient quantity and causing an outbreak of FMD, and (4) the volume of trade. A variety of measures can be used to mitigate the first three of these risks and the OIE Code provides guidelines on what measures are appropriate for trade in different commodities between countries at different stages of FMD control and eradication. Where scientific evidence demonstrates that it is safe to trade specific animal products that have been processed in a manner which precludes the presence, or removes or inactivates the disease agent of concern then international regulations should be adapted to enable these products to be traded. Alternatively, a combination of measures to reduce both the likelihood of slaughtering infected animals and FMDV survival thereafter may be appropriate.

In the UK, some outbreaks of FMD were attributed to imports of frozen bone-in meat from FMD infected countries in South America, notably the large outbreak in 1967/8. However, research suggested that the risk of this recurring could be greatly reduced by restricting imports to deboned beef from areas with a systematic vaccination regime. This was the basis for the UK to permit imports of beef from Argentina in 1969, and since that time, very large quantities of this product have been imported without any evidence that this has given rise to outbreaks of FMD (Astudillo, *et al*., 1997b; de las Carreras, 1993). The OIE has set up recommendations for safe trading of beef as will be described later on in this review, The EU, probably the largest importer of DB has also developed stringent rules to allow safe importation of this commodity (EU Council Directive 2002/99/EC).

This review focuses on the risk of international trade in deboned beef (DB), and the extensive evidence base, historical experience and past and current processing technologies to assess the risk of spreading FMDV by trading this product from FMD affected areas. The consistency of current international trade standards of OIE to the scientific evidence is also assessed.

Foot-and-mouth disease

FMDV infects cattle, buffalo, pigs, sheep, goats and various wildlife species and is a major cause of productivity loss. It exists as seven serotypes that do not engender cross-protective immunity, as well as many intra-serotypic strains that may also incompletely cross-protect (Anonymous, 1937). The virus spreads rapidly by multiple routes and is difficult and expensive to control. Hence, its occurrence correlates inversely with economic development and it is most common in Africa, the Middle East and parts of Asia and South America. Countries with a livestock surplus have a strong incentive to control the disease in order to facilitate exports of animals and their products. However, for many there are major obstacles to be overcome in meeting the FMD criteria which would enable such exports. For example, the FMDV strains circulating in Africa, Asia and South America are almost entirely distinct and consequently vaccines must be tailored regionally. The greatest diversity of serotypes and strains occur in Africa, but control efforts are least developed in many countries of the continent. There are competing priorities and limited resources and in countries with poor prospects for FMD control there is little incentive to conduct surveillance in order to determine the variety and predominance of different FMDV strains affecting livestock and wildlife populations. Thus, the range of tailored vaccines is probably inadequate as well as the quantities available and the resources and political will required to organise and sustain effective control campaigns. This is in contrast to the successful control and eradication schemes carried out in continental Europe and South America which have often relied upon mass vaccination, requiring a high proportion of the cattle population to be repeatedly immunised for many years.

The pathogenesis of FMDV has been reviewed (Alexanderson *et al*., 2003). Susceptible livestock are most commonly infected by FMDV through the oropharynx, although the virus can also enter through abrasions in the skin. After replication at the portal of entry, the virus drains to the local lymph nodes and then the bloodstream leading to viraemia, widespread dissemination throughout the body and viral shedding in many bodily secretions. The virus reaches high titres in the stratified epithelia of the mouth, feet and udder associated with the development of painful vesicles that rupture and release large amounts of virus into the surrounding environment. Virus replication in heart muscle can occur in young animals; evidence for replication in skeletal muscle is less convincing. The incubation period between infection and the onset of clinical signs may be from 2-14 days depending upon dose, but most commonly is 3-5 days. Virus may be present in a variety of tissues and bodily fluids and excretions prior to the onset of clinical signs. Whereas cattle and pigs usually develop obvious clinical signs of

Annex XL (contd)

Annex III (contd)

FMD, the disease is often much less easily recognised in small ruminants. Systemic antibodies appear rapidly, from 5 days after infection, and are associated with clearance of virus from the circulation. Virus persists longer at the site of lesions and in a high proportion of cattle, low levels of the virus can be detected in the oropharynx beyond 28 days after infection and up to three and a half years post infection. These persistently infected cattle are known as FMDV carriers. Carrier cattle do not readily transmit infection to other susceptible animals but the risk that they pose in this regard has not been quantified with certainty.

OIE Recommendations on Trade in Beef

One way to facilitate beef exports from countries that are not FMD-free is to establish one or more FMD-free zones in which animals are completely segregated from those in adjoining infected zones. The current OIE requirements for trading beef from FMD-free zones have been harmonised with those for countrywide freedom and no longer require deboning of meat from cattle. Compartments, in which animals are separated by management, rather than mainly geographical barriers have also been proposed (Scott *et al*., 2006), but their implementation by OIE for FMD is still under review. Alternatively, the OIE recommends that beef can be exported as a safe commodity from countries or zones that are not FMD-free, subject to certain precautions to reduce the likelihood of infected animals being slaughtered and providing that certain procedures are followed during preparation of the commodity. The requirements are given in Article 8.5.23 of the OIE Terrestrial Animal Health Code (TAHC) and include the general need for an official FMD control programme, involving compulsory systematic vaccination of cattle and the following specific conditions:

For fresh meat of cattle (*Bos taurus* and *Bos indicus*) and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera) Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of meat:

1. comes from animals which:

    a) have remained in the exporting country for at least 3 months prior to slaughter;

    b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;

    c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to slaughter;

    d) were kept for the past 30 days in an establishment, and that FMD has not occurred within a ten-kilometre radius of the establishment during that period;

    e) have been transported, in a vehicle which was cleansed and disinfected before the cattle were loaded, directly from the establishment of origin to the approved abattoir without coming into contact with other animals which do not fulfil the required conditions for export;

    f) have been slaughtered in an approved abattoir:

        i) which is officially designated for export;

        ii) in which no FMD has been detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched;

g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after slaughter;

2. comes from deboned carcasses:

a) from which the major lymphatic nodes have been removed;

b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following slaughter and in which the pH value was below 6.0 when tested in the middle of both the *Longissimus dorsi*.

Otherwise, in the case of meat products of domestic ruminants and pigs for importation from FMD infected countries or zones, it is recommended that the meat is processed to ensure the destruction of the FMD virus – i.e. fresh meat cannot be traded. In this context, fresh meat means all edible parts of an animal (apart from the head, feet and viscera) that has not been subjected to any treatment irreversibly modifying its organoleptic and physicochemical characteristics. This includes frozen meat, chilled meat, minced (ground) meat and mechanically recovered (deboned) meat.

Abattoir Procedures and Post Mortem Changes

For the purpose of this review DB comes from veterinary inspected cattle transported and slaughtered as prescribed in Article 8.5.23 of OIE TAHC. Carcasses have been aged (matured) at refrigeration temperatures until ultimate pH has been reached and have been fabricated (by meat cutting) to obtain a prescribed fresh (not processed) refrigerated or frozen beef item. A processed product refers to one that has been subjected to a food preservation treatment other than chilling and freezing (e.g. curing, heating, dehydration, ionising irradiation, etc). DB mainly corresponds to muscle tissue, after deboning, including fat cover, connective tissue, small vessels and nerves as well as all tissues which were not removed during slaughtering and fabrication procedures. A brief description of common, correct slaughtering and fabrication procedures is pertinent to this review.

The process of slaughtering involves transport of animals to an abattoir, holding and ante-mortem inspection with no evidence of clinical disease in a lairage, stunning, bleeding out, hide removal, eviscerating, halving (splitting the beef into sides), post mortem inspection with no macroscopical evidence of disease, chilling of the carcasses, fabrication (final deboning) and packaging. The extent to which these processes lead to removal of infection with FMDV have an important impact on the risk of final product contamination. Since inspection of the final product does not reveal how procedures have been followed during pre-harvest and post-harvest stages and its preparation, adequate Food Safety and Quality Assurance Schemes (FS&QAS), including traceability and auditing of the process are vital (CODEX, 2005; Dagg, *et al*., 2006; Caporale *et al*., 2001; McKean, 2001).

After death, anaerobic glycolysis takes place in muscle tissues and stored glycogen is converted to pyruvate, which is then reduced to lactic acid resulting in a fall in pH, ultimately to a value of 5.6 - 5.7 (Foegeding, *et al*., 1996). Puolanne *et al*. (2002) have calculated that a decline in pH from 7.0 to 5.5 (ultimate pH) requires the formation of 60 to 80 mmol lactic acid per kg muscle tissue depending on the muscle tissue and the animal species. This has an important impact on FMDV survival because the virus is inactivated by acid conditions; as well as an extremely important influence on food safety and

Annex XL (contd)

Annex III (contd)

quality of the final product (deboned meat). The accompanying depletion of ATP is responsible for *rigor mortis* (stiffening of the muscle) which normally takes 6 – 12 hour for beef muscle. Glycogen can be depleted by several pre-slaughter stress conditions including exercise, fasting, hot and cold temperatures and fear (Lister, *et al.* 1981), resulting in reduced muscle tissue acidification and improved survival conditions for FMDV. Good transportation conditions, handling and animal welfare practices are crucial to obtain DB with an ultimate pH value of 5.8 or lower after ageing or maturation (EU, 2002). There is approximately 1% glycogen in the muscle tissue and this will generate 1.0 to 1.1% lactic acid. For each 1% lactic acid formed the pH will be lowered by approximately 1.8 pH units. Nonetheless, both the rate of pH fall and the ultimate pH achieved are influenced by factors such as, species, type of muscle in an animal, genetic variability between animals, administration of drugs which affect metabolism, environment prior to slaughter (feeding, stress), post-mortem temperature - increased temperature increases rate of pH decline - and electrical stimulation of excised muscle increases rate of pH decline (Ockerman, 1996).

Bachrach *et al*., (1957) studied rates of inactivation of tissue culture derived type A FMDV at various pH levels. At 4ºC, and pH 6.0, infectivity was lost at a rate of about 90% per minute. Bachrach et al (1957) found that inactivation rates were biphasic resulting in a very low level of residual virus that is rather pH stable. However, it is generally accepted that FMDV is totally inactivated at pH 6.0 or below after 48 hr at a temperature of 4ºC (Pharo, 2002). pH changes may occur at different rates in different muscles, a measurement of pH 5.8 in the *Longissimus dorsi* (LD) muscle has been used as a proxy to indicate non-survival of FMDV in the carcass (CEC, 1986). Extensive LD muscle pH data showed that 66,220 out of 694,719 beef carcasses had a pH equal to or greater that 6.0 at 24 hr post slaughter (USDA, 2002).

General requirements for safe preparation of meat are described in the Codex Alimentarius Code of Hygienic Practice for Meat (CODEX, 2005). These guidelines emphasise the importance of a risk-based approach tailored to food safety issues, local threats and the needs of importers. The Codex is therefore not prescriptive concerning specific mitigations for FMD, such as the precise nature of ante-mortem and post-mortem inspection procedures. Beef carcasses and beef cuts, from exporting, slaughtering and fabrication commercial facilities, have been extensively studied and characterized from the hygienic, keeping quality and food safety stand-points (Lasta, *et al*., 1992; Rodríguez, *et al*., 2000). Furthermore, best practices for handling vacuum-packed beef cuts have been developed (AMI 2003). Meanwhile, some markets apply specific hygiene rules for food of animal origin to ensure a high level of food safety and health protection (EU, 2004).

Commercial beef slaughtering operations for exporting markets are fully mechanized and procedures are carried out at different stations on an assembly line. This enshrines the principle of moving the carcass always forward aiming to avoid cross contamination. Each carcass bears an identification or bar code which helps to retrieve information on slaughter date, origin of animal, type of animal, carcass characteristics, and other production and quality attributes. On the slaughter floor, the feet, head, and hide (all of which can harbour FMD infectivity) are removed at the very beginning of the process. This first stage of the slaughtering line is known in the meat industry as the "dirty zone". After evisceration (at the "intermediate zone"), beef carcasses are split into right and left sides at the "clean zone" to ensure rapid cooling in the chilling room. It is crucial to run all slaughtering procedures under proper FS&QAS (i.e. SSOP's, GMP's and HACCP). Adequate traceability procedures must ensure that each particular carcass, head and viscera (the three items are moved separately along the slaughter floor in different conveyor lines) bear the same identification tag at the slaughter floor level to facilitate Veterinary Inspection as well as further FS&QAS carried out by the industry.

Immediately after leaving the killing/slaughter floor, beef carcasses are kept in the chilling rooms at appropriate refrigeration temperatures (carcasses will begin chilling within one hour from bleed-out). The chilling room should be designed according to the number of animals that are slaughtered so as to provide not only enough room for storage but also adequate conditions of air movement and temperature transfer among beef carcasses. Carcass chilling is crucial for safety and quality. Refrigeration temperatures will reduce carcass surface moisture to produce unfavourable conditions for microbial growth as well as slow down microbial growth rate. Moreover, chilled beef will be easier to handle for cutting and will preserve quality characteristics as well. The beef muscle ageing (maturation) process crucial for FMDV inactivation via pH drop is also temperature dependant. Early ageing (24 – 36 hr post slaughter) also starts muscle protein denaturation improving tenderness and eating quality. Under most common commercial practices, ageing will continue after beef cuts have been prepared and packaged and kept under refrigeration as will be briefly described below. For the purpose of this review, DB has been considered adequately aged after muscle tissue has achieved its ultimate pH (5.8 or below). pH is measured in each LD immediately before the carcass is broken in quarters and consequently before entering the deboning room at a pH control station. pH measurement is carried out according to a specified protocol (i.e. electronically measured, with daily calibration of instruments, proper registration chart/notebook, etc) and under the audit of the Veterinary Inspection Service (VIS).

The process of carcass fabrication starts immediately after carcasses leave the chilling room and takes place in the deboning room where beef cuts are obtained under environmental refrigeration temperatures (usually <10ºC). Carcass temperature (usually between 4 and 7ºC) and pH (5.8 or below) are controlled before entering into the deboning room to ensure compliance with Veterinary Service Inspection Authorities and specifications of importing countries. Each carcass side or half is divided into quarters. The forequarter, composed of specified wholesale cuts, is usually the heavier quarter. The hindquarter, also composed of specified wholesale cuts is the most valuable quarter based on market prices. There are several methods used to break specific wholesale units down into smaller retail market units. Local or international preferences, industry market capabilities, merchandising trends, as well as many other factors may determine the optimal cutting procedure to produce any particular fresh beef item. Cutting beef quarters for exporting markets is an area in which a variety of options are utilised by meat cutters at the industry level. Photographs, diagrams, anatomical references as well as a summary of the main cutting descriptions are commonly utilized in explaining cuts of beef for trading purpose (IPCVA, 2008). For DB preparation, as it was defined above, all bones as well as major blood vessels, visually identifiable lymph nodes, blood clots and specified amounts of fat tissues are removed according to market or commercial specifications before final packaging. From the stand-point of FMD risk mitigation procedures, specific VIS stations eliminate – as far as is practically possible - lymph glands, fragments of bones and any other suspected tissue at the deboning room level. Adequate traceability procedures at deboning and packaging rooms ensure that each particular beef item corresponds to a particular carcass. All deboning, packaging, chilling or frozen storage as well as labelling and shipping procedures should be under Veterinary Inspection as well as further FS&QAS carried out by the meat industry. There are protocols that cover non-compliance with a specified product (i.e. carcasses with a pH reading equal or higher than 6.0 should be properly identified, separated in a different cooling facility, and not exported. These carcasses are diverted to local/domestic markets). If FMD is eventually detected in a herd at the slaughterhouse level it is excluded for export markets. Depending on the amount, localization and extension of lesions in organs or carcasses they are diverted to local market or condemned if necessary. After slaughter of a FMD herd proper cleaning and sanitation procedures (facilities, personnel) are carried out with approved FMDV inactivation agents. The whole process should be under VIS rules and audit.

Annex XL (contd)

Annex III (contd)

Literature review on FMDV survival in fresh meat

There is a considerable body of literature on the amount of FMDV detectable in the tissues, secretions and excretions of different species of animals during infection. However, many variables may affect these values, including differences in host species and breeds, types and strains of FMDV, stage of infection and methodology used to make measurements. Virus persistence in animal products after slaughter depends upon many of the same variables and especially on changes in pH that take place in different organs and tissues under different conditions. Although the subject has been reviewed on numerous occasions, the number of publications that provide actual data on virus survival in cattle carcasses, collected and stored so as to mimic beef abattoir slaughtering processes, is relatively few and much of the literature is not easy to access. Table 1 summarises the most important of these where detailed methodologies are available. None of the in-depth studies has involved serotypes Asia 1 or any of the South African Territory (SAT) serotypes (in general, the thermal stability of the Asia 1 FMDV serotype is relatively high and that of SAT serotypes is relatively low (Doel & Baccarini, 1981)). In most cases, cattle were slaughtered a few days after direct inoculation with FMDV and mostly when showing clinical signs of disease. Such studies may represent a worst case scenario for peak FMDV contamination. The majority of these studies involved cattle that had not been vaccinated against FMD. In one major study, however, large numbers of vaccinated cattle were used (NASNRC, 1966). Since the cattle had received at least six vaccinations with a vaccine strain homologous to that used for subsequent challenge, but were killed at peak viraemia this study provides a best case scenario for the likely reduction in levels of viral contamination associated with FMDV infection in vaccinated animals. Reviews of FMDV survival in meat are summarised in Table 2. FMDV survival in various beef processed items as well as virus behaviour and stability under different thermal and non-thermal processes have been extensively studied notably in North and South America in the ´80s and ´90s (Blackwell, *et al*., 1982; Blackwell, *et al*., 1988; García Vidal, *et al*., 1988; Lasta, *et al*., 1992; Vermeulen, *et al*., 1993; Masana, *et al*. 1995a; Masana, *et al*. 1995b; Pagliaro, *et al*. 1996). These studies provide relevant experimental data on FMDV thermal stability, further insight on pH effect, as well as additional FMD-safe processing treatments for international trade for various edible beef items.

Usually, the methods used to detect FMDV survival in meat products have been by inoculation of test material, either into cattle, guinea-pigs, mice or cell cultures. These cannot be considered as natural routes of infection or ones that mimic the most likely form of risky exposure following importation of deboned beef, which is ingestion, especially by pigs. The titres of virus reported in different studies are not directly comparable due to differences in the sensitivity of the test systems used. A minority of the studies also fed animal products to small numbers of pigs. The results are also not directly comparable in that the studies involved a wide variety of serotypes and strains of virus but the individual and/or comparative characteristics of these viruses in respect of thermal and pH sensitivity are unknown or unstated.

The conclusions of these studies are that the acidification of skeletal muscle that takes place during maturation of the carcass is normally sufficient to inactivate all FMDV in this tissue, even when cattle are killed at the height of viraemia. Since it is known that the required level of acidification cannot be guaranteed under all circumstances, measuring of the pH of the carcass can be used to ensure that it has occurred. This is the basis for the current requirements concerning maturation and pH assessment of beef carcasses (EEC, 1986; OIE, 2008).

In contrast, other tissues and organs that may harbour FMDV do not undergo acidification and in these tissues the virus can survive the maturation process and subsequent low temperature carcass storage. These include blood, heads, feet, viscera, bones and major lymph nodes, all of which can be removed during the processing of the carcass. Under commercial beef operation conditions FS&QAS are in place in order to control and to eliminate these defined non-muscle tissues. However, residual blood, fragments of bones and small lymph nodes are likely to remain in the cuts. FMDV in bone tissues would most likely be found in the bone marrow rather than the bone itself. There are no available data to quantify amounts of fragments of bones or lymph node tissues that remain in a specified beef cut (USDA, 2002).

Immunisation of cattle by repeated vaccination using vaccines closely matched to the challenge strain of FMDV confers a high degree of protection upon infection. It has been shown to greatly reduce the level of virus present in lymph nodes (NASNRC 1968) and presumably also in other parts of the animal and its products.

Risk associated with FMDV survival in animal products

Table 3 lists and comments upon the risk assessments reviewed in this study.

The risk associated with FMDV survival in animal products depends not only on the quantity of surviving virus but on the likelihood and route of exposure to susceptible animals, the species of susceptible animal, the amount of the material inoculated, inhaled or ingested and the number of animals that are actually exposed (Sellers, 1971; Sutmoller and Vose, 1997). This makes it difficult to establish a threshold level of FMDV contamination of a commodity, below which it could be considered as representing a negligible risk.

Ingestion of contaminated animal products by pigs is one of the most likely routes by which an imported, contaminated meat product could start an outbreak of FMD, although other means are possible and some infections of cattle in the UK in 1967 have been attributed to their exposure to personnel who had been handling contaminated, imported meat (Sellers, personal communication). Due to their higher susceptibility to inhalation of FMDV, Sellers (1971) suggested that ruminants might be infected by sniffing contaminated materials rather than by eating them. From feeding FMDV contaminated materials to relatively small numbers of pigs, the minimum oral dose of FMDV to infect pigs has been estimated at around 10^5 tissue culture infectious doses (Sellers, 1971; Donaldson, 1997) This was deduced from a small number of rather disparate studies, mostly not involving titration of the challenge dose, and in which results were not always consistent (Table 4). Actual data on how readily pigs become infected by ingestion of FMDV contaminated carcass material is very scarce (Table 4) and there appear to have been no studies in which material equating to DB as a commodity has been fed to pigs.

Considering the daily feed intake of a pig, Sellers (1971) concluded that at a virus concentration of less than 10 $ID_{50}g^{-1}$, the amount of product needed to be ingested by a pig to establish infection would exceed its daily feed intake. This assumes that an effective dose can be acquired cumulatively, whereas the relationship between concentration, volume and total effective dose is poorly understood. An added complication arises due to non-homogeneous commodity contamination. For example, if a small fragment of bone within a large amount of meat had a virus concentration above 10 $ID_{50}\,g^{-1}$ within the

bone fragment, there might still be insufficient virus in total to infect pigs through ingestion. The physical nature of the food may also be important since it has been shown that infected bone marrow was infectious to pigs only if crushed bones were incorporated into the feed. It was presumed that crushed bones facilitated infection through causing oral abrasions (Anonymous, 1927) which suggests that animals with pre-existing oral lesions might also be more susceptible to infection by FMDV. Finally, Sutmoller and Vose (1997) were of the opinion that doses below those normally considered the minimum for establishing infection still have a certain low probability to cause infection and begin an outbreak. However, this argument assumes that the material would be fed to a very large number of pigs some of which would have greater susceptibility than average. In the case of a small fragment of contaminated bone within a large consignment of meat, there would be insufficient material to be eaten by many pigs.

Practices within an importing country such as vaccination against FMD or prohibitions on swill feeding of pigs also militate against, but not necessarily negate, the risk from contaminated, imported animal products.

Information on trade in beef in relation to FMD dissemination

Beynon (1968) reported that between 1954 and 1967, 54% of primary outbreaks of FMD that occurred in England were attributed to imported meat, bones and meat wrappers. Similar figures are provided by a Welcome Trust Witness Seminar on the 1967/8 UK FMD outbreaks recorded in 2001. However, these outbreaks predate the introduction of requirements for deboning and maturation of carcasses imported from South America as well as introduction of the ban on all swill feeding to UK pigs. Valarcher *et al*. (2008) in their review of the origins of FMD outbreaks within Europe in the last 20 years, record only a single case attributed to beef importation and this concerned the outbreaks in Albania in 1996. In this case, the import permit on the beef consignment stated that it was deboned, but in fact it was bone-in.

Blajan and Callis (1991) noted that more than 100,000 tons of boneless beef were imported into the European Community in 1989 from South America and Southern Africa. Furthermore, between 1968 and 1990, 500,000 tons of boneless meat had been imported into the UK from Argentina. There is no evidence that this led to any outbreaks of FMD. FMD risk mitigation procedures that have been in use in South America for more than 30 years have contributed to the development of a safe and highly technical and specialized beef exporting industry.

Total DB exports from Argentina were more than 9,271,850 tons (product/shipping weight) between 1965 and 2008; while exports of DB to FMD-free countries such as the UK, in the same period, were 913,608 tons; 1,230,207 tons to Germany and 769.973 tons to Chile (Otaño, 2009). These trade figures are summarised in Figures 1-5. Deboned beef exports expressed as equivalent carcass weight for Brazil were 21,325,000 tons, while Uruguay exported 4,247,000 tons expressed as equivalent carcass weight.

It is interesting to analyze exports from Argentina to the UK between 1963 and 1995, since vaccination was not applied in the UK. It is possible to estimate the number of steers slaughtered in order to obtain one ton of DB shipped to the UK. For type A cuts (special cuts from hindquarter) it is assumed that one animal provides between 18 and 20 kg. Hence, it will be necessary to slaughter between 50,000 and 55,000 steers to obtain 1,000 tons of DB (SENASA, 1994). For the year 1991, 42,837 tons were exported, from approximately 214,000 beef cattle corresponding to 7,130 troops of cattle – one troop is approximately 30 steers. Steers slaughtered for the export trade historically came from the "Pampa region", particularly from its central fattening areas. Notably, this Pampa region, described as a Secondary Endemic zone, from the FMD standpoint, used to have the largest number of annual FMD outbreaks in Argentina (Dillon, 2009). Therefore, it is very likely that some DB was shipped to the UK after being obtained from FMDV infected animals. If such has been the case, no evidence has been found that an outbreak of FMD had occurred in the UK due to this commodity trade. Reported FMD outbreaks in Argentina are summarized in Figure 6.

Figure 7 provides figures for DB imports into the EU from countries that do not have OIE FMD-free country status. However, there is no differentiation between imports from FMD-free regions and regions that are not free. As well as large-scale imports from South America, smaller scale imports also took place from southern Africa (Botswana, Namibia, Zimbabwe and South Africa). Further information on this trade is available from a recent workshop on transboundary animal disease and market access, see: http://www.steps-centre.org/ourresearch/vetscience.html. These southern African countries used similar principles of separating FMD-endemic from free areas by fencing and movement restrictions, biannual vaccination of cattle in proximity to infected African buffalo and active clinical surveillance (Thomson, 2008). However, their exports to Europe were mostly (apart from Zimbabwe) only permitted from OIE recognized FMD-free zones. A further precaution was and is that DB from southern Africa could/can not be imported into Europe until three weeks after the source animals were slaughtered, allowing time for recognition of any recent outbreaks that could affect the safety of the commodity. Since the time to ship to Europe exceeds three weeks, the precaution fits well with the export process.

According to a study by PANAFTOSA and Tuskegee University (PANAFTOSA, 1995; Table 3), the risk of DB spreading FMD internationally following a reintroduction of FMDV into Uruguay or Argentina during the 1990's was exceedingly small, providing that outbreaks would have been limited in number and rapidly brought under control.

Risk Assessment

A risk assessment strictly adhering to OIE guidelines will focus on conditions in the exporting as well as the importing country. Information needed to conduct a risk assessment of this nature will include information on the exporting country's Veterinary Service, disease surveillance, eradication and control programmes, zoning systems, incidence and/or prevalence of disease, existence of disease-free areas and areas of low disease prevalence, animal demographics, farming and husbandry practices, geographical and environmental characteristics including rainfall and temperature, etc (OIE, 2004).

The above-mentioned information (inherently specific to a particular country) is not available due to the broad scope of this project that includes all infected countries, zones and compartments globally. Furthermore, this information need not be applicable when focussing on a specific commodity and therefore it was decided to use a commodity risk factor approach. Following this approach, each commodity that is handled in exactly the same manner would have the same commodity risk regardless of the status of the country or zone or compartment of origin. For this purpose, it is presumed that the animal producing the commodity is infected (worst case scenario) and every step in the slaughtering and storing process is evaluated in order to determine how much the infection is reduced by each process (Metcalf *et al*., 1996).

It should, however, be noted that all the factors mentioned above, especially disease prevalence, are key factors that need to be taken in account when determining the risk of infected animals actually arriving at the slaughter plant. Also, most of these factors are critical control points that have the potential to decrease the probability of infected animals being presented for slaughter and thus reducing the risk associated with the final product.

Annex XL (contd)

Annex III (contd)

Methodology:

The commodity risk factor approach described by Metcalf *et al* (1996) was used to determine the risk associated with trade in deboned beef from FMD infected animals, countries and zones.

A scenario tree was used to identify the risk pathways, to ensure a logical chain of events and to identify information requirements (Figure 8).

To adhere to the principles of the SPS Agreement, which states that risk must be assessed according to the SPS measures which might be applied, the standards set by the OIE TAHC were used where applicable, for example maturation standards as described in Article 8.5.23 was used in the risk evaluation.

The risk of each of the six events in the scenario tree and ultimately the risk associated with the final product were qualified using data obtained through an extensive literature review process.

The following terms were used to describe the risk / likelihood estimates (OIE, 2004):

Term:	**Oxford Dictionary Definition:**
Average	The usual amount, extent, rate
Extremely	Outermost, furthest from the centre; situated at either end; utmost; the highest or most extreme degree of anything
High	Extending above the normal of average level
Highly	In a high degree
Insignificant	Unimportant; trifling
Low	Less than average, coming below the normal level
Negligible	Not worth considering; insignificant
Significant	Noteworthy; important; consequential
Remote	Slight, faint

Possible risk mitigations (quarantine and vaccination) and their influence on the commodity risk factor were evaluated from data acquired through the literature review.

Assessment of the commodity risk factor:

Event 1 (Disease not detected during ante-mortem inspection):

Key points at the ante-mortem inspection stage:

- Cattle from Veterinary Inspected farms arrive at slaughter facility pens.
- Traceability registers as well as sanitary documentation are analyzed for each cattle group (usually one truck carries a group of approximately 30 animals).
- Cattle should be transported and handled according to Veterinary Inspection Service (VIS) rules. Cattle should be allowed to rest, and be provided with *ad libitum* water as well as feed when appropriate.

- A systematic procedure should be followed to consistently inspect animals involving a thorough visual examination as part of an official VIS scheme. Veterinarians should be able to walk around the animal holding facility to check for any abnormal movement or symptoms.

- When necessary (i.e. VIS detect any abnormality) animals should be individually examined and rectal temperature, mouth and feet are checked for visible lesions by VIS.

- Trucks, floors and pens should be properly cleaned and sanitized under VIS procedures.

Fact:

- During a study by Cox et al (1961), high virus titres were found in lymph nodes, 24 hours post-inoculation and before any clinical signs were observed.

- A study by McVicar and Sutmoller (1976) showed that viraemia was detected before the onset of clinical signs in some animals.

- Different studies indicated that considerable amounts of virus were recovered from the mucosae and lymphoid tissues of the pharyngeal region of cattle for periods of up to 3-9 days before the detection of viraemia and/or clinical signs (Burrows, 1968; Burrows *et al*., 1981; Sellers *et al*., 1968).

- Alexandersen *et al*. (2003) reported that FMDV could be detected in serum, pharyngeal fluid, saliva, nasal swabs and milk prior to the first appearance of macroscopical lesions. Viral titres in serum averaged 103.2 TCID50/ml the day before onset of clinical signs, peaking at 104.9 and 105.3 on the day of and day after first clinical signs respectively.

- Infection of Chinese yellow cattle with O PanAsia FMDV failed to cause clinical disease although these cattle were able to transmit infection to susceptible in-contact animals (Kitching, 2002; Huang *et al*., 2000).

Opinion:

- Pyrexia of 40°C for 1-2 days precedes vesicle development (Kitching, 2002). During this time, cattle show only non-specific signs of malaise. Vesicle development is often accompanied by other visible signs such as drooling of saliva, grinding of teeth and lameness.

- In endemic regions in cattle that have partial natural or vaccinal immunity, clinical signs may be mild and may be missed (Kitching, 2002).

- In clinically sick cattle, the likelihood that lesions will be missed is low (Astudillo *et al*., 1997a). However infected animals in the incubation period present a high risk (Sutmoller 2001).

The available evidence suggests that there is a low risk that infected cattle, showing pathognomonic clinical signs will be missed during ante-mortem inspection, however, the risk should be considered as high when animals presented for slaughter do not show detectable clinical signs (for example cattle in the incubation period partially immune animals and cattle infected with a mild strain of the virus). The levels of virus present in animals peak at around the time of onset of clinical signs, but significant levels of virus may be present before this time.

Annex XL (contd)

Annex III (contd)

Event 2 (Disease not detected during post-mortem inspection):

Key points at the post-mortem inspection stage:

- After killing the animals, each carcass is subjected to a macroscopic examination of all organs and tissues and when necessary microscopic and lab analysis are carried out. Thorough inspection of the feet and mouth including the tongue and buccal surfaces is essential.

- Post-mortem inspection is carried out by properly trained professionals of the VIS.

- Head, viscera and carcass must carry the same identification tag until the VIS is finished at slaughter level.

- Post-mortem inspection includes visual observation, palpation and excision of lymphoid glands and organs.

- Feet, hoofs, tongue, gums are carefully examined. Feet and hoofs are rapidly removed from the killing floor.

- Carcasses are released for either fresh or processing markets according to the VIS decision. When necessary, carcasses or their parts are subjected to condemnation.

- Immediately after finishing slaughtering, carcasses are sent to appropriate chilling rooms to allow ageing and muscle pH drop.

Fact:

- Considerable amounts of virus were recovered from the mucosae and lymphoid tissues of the pharyngeal region of 21 of 23 cattle killed before the onset of viraemia and in many of these and other animals for periods of up to 3 days before slaughter or the detection of viraemia and/or clinical signs (Burrows *et al*., 1981).

Opinion:

- Astudillo *et al*. (1997a) estimated that the post-mortem inspection process would be at least five times more sensitive than the ante-mortem inspection on account of the thorough individual inspection of each carcass.

- Carrier cattle are unlikely to have scars on the tongue or foot epithelium and will escape detection at the farm of origin and at ante-mortem or post-mortem inspection (Sutmoller, 2001).

Compared to ante-mortem inspection, post-mortem inspection has an enhanced probability of detecting macroscopic lesions but a reduced probability of detecting non-specific signs of illness such as lameness and depression that are the main, albeit poor, indicators at the onset of illness due to FMD. A systematic procedure should be followed to consistently inspect high risk tissues.

Event 3 (Infected tissue not removed during slaughter):

Key points at removal of specified organs:

- The head, as well as viscera, are handled in different lines (pulley systems) from corresponding beef carcass. The three elements though bear the same tag identification.
- Tonsils are eliminated (not used for any food purpose).
- Pharynx and throat are longitudinally excised, visually inspected and by palpation, the presence of lesions are investigated. They can be used for pet food.
- When necessary samples (pharyngeal or lymph nodes) are taken for lab studies.

Fact:

- The pharynx is a major site of primary and secondary FMDV replication during acute infection and along with pharyngeal and other lymph nodes is the major site of FMDV persistence in cattle (reviewed by Alexandersen *et al*., 2003; Juleff *et al*., 2008)
- The dorsal surface of the soft palate and the pharynx was indicated as the main sites for virus persistence and multiplication. Virus was recovered from these sites, from 41 out of 54 cattle killed 14-196 days after infection (Burrows, 1966).
- The quantity of virus present in the pharynx of acutely infected animals is high (up to $10^{7.4}$ $TCID_{50}$/ml), but in convalescent animals the amounts of virus are much less (~10-100 $TCID_{50}$/ml) (Alexandersen, 2003) and therefore carrier animals do not readily infect other susceptible animals through contact (Tenzin *et al.*, 2008).

Opinion:

- Superficial mechanical contamination of beef by virus present in the throat is a risk to be considered. With proper slaughtering techniques and destruction of the pharyngeal area, mechanical contamination poses a negligible risk for the international beef trade (Sutmoller, 2001).

The successful removal of potentially infected tissue (e.g. head, feet, pharynx, etc), will reduce the risk of contamination of the final product. The risk that these tissues will not be removed completely depends entirely on the meticulous execution of this step of the slaughtering process. An adequate FS&QAS with proper documentation, and critical control point management, should be put in place to ensure removal of potentially infected tissues.

Event 4 (Virus survives maturation at temp above 2°C, minimum 24 hours with pH below 6):

Key points at ageing stage including pH measurement:

- Beef carcasses are allowed to start ageing at refrigeration temperatures (usually for a 24/48hr period). Refrigeration temperatures (cooling room and carcasses) and time frame are usually Critical Control Points in a commercial facility that follows a FS&QAS.

Annex XL (contd)

Annex III (contd)

- Before entering into the deboning room each carcass is subjected to a standardised pH measurement. Ultimate pH (5.8 or lower) is tested for the *Longissimus Dorsi* (LD) muscle of each beef carcass. Good correlation has been found between the pH level of LD muscles and many other beef muscles of the same carcass. LD is a standard comparator muscle of beef with regard to pH.

- pH measurements are usually carried out by industry QA specialists and audited by the VIS. Instruments for pH measurement should be inspected and calibrated daily. Adequate forms and documentation are kept as evidence of proper procedure and product attribute.

Fact:

- Virus in muscles may be accounted for by either the direct infection of the tissues or by its presence in the capillary beds and vessels because of viraemia (Cottral *et al*., 1960).

- A study by Cottral *et al* (1960) included muscle pH curves that showed that the virus population in muscles was probably greatly reduced within eight hours, but infectious virus may have persisted in the superficial portions of the muscles for nearly 48 hours, since the pH was still 6.0 or higher in some areas.

- Prolonged survival of the virus in muscle tissue is only likely if the pH is above 6.2 (Henderson & Brooksby, 1948).

- The pH level reached by the meat of normal animals depends on at least two factors: the glycogen content of muscle at point of death and the buffering capacity of the muscle. In animals where the activity before slaughter was prolonged and severe, the pH may be very high. Exercise, stress and certain disease conditions may also inhibit lactic acid formation (Bate-Smith, 1948).

- FMDV was found in both fresh and ripened (72 hours at 4C) haemal nodes (Cox *et al*., 1961).

- In samples of bone marrow taken from cattle during the acute stage of infection (48 hours post infection), FMDV survived at 1-4C for as long as 210 days. In similar samples of lymph nodes and hemal nodes, virus persisted for 120 days (Cottral, 1969).

- Lymph nodes that were examined by Cottral *et al* (1960) maintained pH readings between 6.4 and 6.9, a favourable range for virus survival (at 4C for 72 hours).

- Lymph nodes and blood clots in large vessels, even though in close proximity to the muscles, do not develop the degree of acidity that is present in the muscle tissue and the pH of a lymph node does not become sufficiently acid to inactivate the virus (Henderson & Brooksby, 1948).

- Liver, kidney, rumen, lymph node and blood from disease cattle have all been shown to be highly infective and to remain so if stored frozen (Henderson & Brooksby, 1948).

- Virus was detected in the ripened lymph nodes (from carcasses hung for 72 hours at 3-6 C) from all animals infected 32 hours prior to slaughter (NASNRC. 1966).

- A study by Garcia-Vidal *et al* (1983) showed that virus was not detected in muscle at pH 6.0 or below. The minimum pH value in which the virus was present was pH 6.4.

Opinion:

- Further research has been advised to investigate the effect of pre-slaughter stress on the depletion of glycogen stores and subsequent reduced pH drop in FMD-infected sheep (Ryan *et al*., 2008), but there is also little information on how this may impact upon FMDV survival in cattle carcasses. However, this potential problem is controlled by pH checks on beef during DB preparation.

- No data are available on the kinetics of virus inactivation in meat at pH 6.0 (Astudillo *et al*., 1997a).

The most important factor for post-slaughter inactivation of the virus in the carcass is pH. Virus might be present in muscle tissue at slaughter as a result of viraemia or direct infection and a variety of conditions exist where the desired pH to inactivate virus might not be reached. The risk of virus surviving maturation at temperatures above 2ºC, for minimum 24 hours can thus be considered significant, unless a pH of less than 6.0 is reached during that time. Measuring the pH in the middle of both *Longissimus dorsi* muscles, as described in the OIE Code, will ensure that the muscle pH has decreased sufficiently to inactivate FMDV. However, it was shown that the pH in lymph nodes, bone marrow and haemal nodes often does not reach the required value to inactivate virus. Therefore, the risk of virus surviving in a carcass at this point of the slaughter process is still significant.

Event 5 (Virus not eliminated during deboning and removal of lymph nodes):

Key points at deboning stage:

- Carcass fabrication, deboning and beef cut preparation should be carried out by professionals and skilful meat cutters at commercial facilities.

- Beef cuts and specified fresh beef items are prepared according to market specifications.

- Meat cutting is carried out under FS&QAS and VIS schemes.

Fact:

- Human error cannot be completely ruled out during the deboning process. Blood clots, bone chips and pieces of large vessels or parts of lymph nodes might not be removed completely (Astudillo *et al*., 1997a; Cottral *et al*., 1960; Sutmoller 2001).

- Muscles taken from the vertebrae may be particularly contaminated with bone, because they are near the point where the carcass is split (Cottral *et al*., 1960).

Annex XL (contd)

Annex III (contd)

- FMD virus can survive 120 days at 1-4°C in lymph nodes and 210 days at 1-4°C in bone marrow (Cottral, 1969).

- The amount of surviving FMDV in bone marrow has been found to be sufficient to infect pigs by the oral route when fragments of bone were included in the material fed to the pigs (Table 4 and Cox *et al*., 1961).

- The virus may survive and be demonstrable in commercially boned cured or uncured meat, if the meat were obtained from an area where foot-and-mouth disease is present. It was concluded by Cottral et al (1960) that meat derived from animals infected with foot-and-mouth disease was not rendered free of the virus by the usual commercial procedures of ripening, boning, salting and storage.

- FMDV was found in both fresh and ripened (72 hours at 4C) haemal nodes, which are difficult to remove from meat during trimming (Cox *et al*., 1961).

Opinion:

- Maturation and deboning of the carcass will eliminate most of the virus, but beef from cattle slaughtered in the incubation period is likely to pose a considerable risk (Sutmoller, 2001).

The evidence shows that there is a low risk that all virus will not be removed during the process of deboning and the removal of lymph nodes. Since the amount of residual lymph node and bone tissue is unclear, and even though FMDV in bone tissues would most likely be found in the bone marrow rather than the bone itself, the risk of viable virus still being present at this point of the slaughter process is thus not demonstrably negligible. Whether DB prepared from an infected animal contains enough FMDV to infect susceptible animals by natural routes of exposure has not been directly measured.

Event 6 (Cross-contamination of clean product or packing materials):

Key points at environmental, packaging and related stages:

- Processes and operations at meat industry facilities are designed and carried out to avoid cross-contamination. A forward-moving "conveyor-belt system" ensures that clean products are not allowed to move back or have contact with a zone containing products at an earlier and potentially contaminated point of processing. Adequate cleaning procedures and sanitation schemes must be in place.

- FS&QAS and VIS schemes must be in place to avoid cross-contamination.

Fact:

- Virus can survive for at least four days in infected blood splashed on carcass surfaces (Cottral *et al*., 1960).

- The survival of FMDV on or within various contaminated objects would be shorter for free virus than for virus within cells from epithelial lesions. Also the amount of protective colloids and tissue debris as found in mucous from the nasal and salivary discharges of infected animals would lengthen the survival time. According to Cottral (1969), sunlight, temperature, pH changes and relative humidity will also have an influence. Virus can for example survive on a meat cloth (at 4°C) for 6 weeks (Cottral, 1969).

- FMD virus remained infectious for approximately 33 to 398 days on meat packaging materials experimentally contaminated with infected bovine tissues. The contaminated materials were stored at 4 C with an average relative humidity of 85% (Gailiunas *et al*., 1969).

- Sutmoller and Vose used binomial modelling to illustrate that when sufficient numbers of susceptible animals are exposed to products which have low levels of contamination (and even if all individual animals receive less than the so-called minimum infective dose) there is still a chance of infecting one animal from the group, which is likely to start an epidemic with a highly infectious disease such as FMD (Sutmoller & Vose, 1997).

Opinion:

- The slaughter of viraemic cattle creates an additional hazard of gross environmental viral contamination of the slaughterhouse facilities. It seems reasonable to assume that contamination of personnel and products leaving the premises, including packaging material and vehicles, cannot be excluded (Sutmoller 2001).

- In their review article Sutmoller *et al* (2003) address the concern regarding mechanical contamination of a carcass with "carrier virus" from the pharyngeal area. They conclude that because of antibodies in blood and other fluids and additional measures which may be applied during slaughter and processing (e.g. for BSE) the risk is negligible.

It has been shown that when clean product or packing materials come in contact with contaminated blood, other fluids, etc., the clean product can be contaminated with virus and have the potential to transmit disease. The risk of this happening depends on the hygiene procedures of the slaughtering process and the virus concentrations on the contaminated materials.

Final commodity risk qualification:

As mentioned previously, for the purpose of the commodity risk factor approach, it was presumed that the animal producing the commodity is infected. For this reason, the initial risk started off as high, whereas under field conditions it might be very low due to other pre-slaughter risk mitigation procedures such as surveillance, vaccination, quarantine, etc. not discussed so far.

Cattle showing pathonomonic clinical signs have a high probability of being detected during ante-mortem or post-mortem inspection and therefore constitute a low risk. However, infected cattle that do not show overt clinical signs associated with FMD, e.g. partially immune cattle, cattle infected with a mild strain of the virus, breeds of cattle that do not show obvious clinical signs or animals early in the incubation period, introduce additional risk to the process. Preclinical viraemia represents the highest risk.

Annex XL (contd)

Annex III (contd)

The removal of potentially infected tissues and organs, for example the head, feet, pharynx, etc., followed by maturation of the carcass according to the standards in the Code, will mitigate the risk, although not entirely. It was shown that the FMDV can survive maturation in the lymph nodes and bone marrow and that these tissues might not be completely removed during the mitigation processes. Therefore until more evidence on the amount of residual lymph node and bone tissue become available, the risk associated with deboned beef cannot be ascribed a negligible rating.

Cross-contamination of clean product and packing materials is an additional possibility. The related risk will depend on the likelihood of cross-contamination happening in a specific abattoir and the viral levels on the contaminated product.

Overall, the risk associated with deboned beef, when only considering OIE recommended risk mitigations applicable to the slaughtering process, although low, cannot be completely ignored based on current knowledge. Some additional measures to mitigate the risk outside the slaughtering process are discussed below. A combination of pre-slaughter and slaughterhouse measures has been shown to be very effective in reducing risk to negligible levels.

Effect of pre-slaughter risk mitigations on commodity risk factor:

Scenarios for additional risk mitigation measures are summarised in Figure 9.

Surveillance:

Early detection of disease in the source herds, accompanied by appropriate control measures is extremely important and will significantly reduce the risk of selecting infected animals for slaughter. Surveillance programmes need to be designed according to the disease situation in the country of origin and should adhere to the principles of Chapter 1.4 (Animal Health Surveillance) and Articles 8.5.40 to 8.5.46 in the TAHC.

Vaccination:

Fact:

- Cattle develop an effective immune response within 3-5 days after vaccination (Doel *et al*., 1994).

- Vaccination can reduce the number of infected animals and the risk of slaughtering viraemic cattle in the pre- or sub-clinical stage of disease. For example, the findings of a study by Orsel *et al* (2005) indicate that single vaccination in a population of calves can reduce transmission and that it might be sufficient to eradicate the virus during an epidemic of FMD.

- During a series of experiments organized by the Argentine-United States Joint Commission on FMD it was shown that multiple vaccination markedly reduced the chance of recovering virus from lymph nodes at the time of slaughter, of cattle exposed to virus by tongue inoculation 32 hours previously (NASNRC, 1966).

- Neutralising antibodies induced in vaccinated animals are probably the best guarantee for meat, blood, lymph nodes, bone marrow and organs being free of virus (NASNRC, 1966; Sutmoller & Casas Olascoaga, 2003).

- Vaccinated ruminants will continue to carry live FMD virus in their pharynx after contact, regardless of the development of clinical or sub-clinical disease (Kitching, 1998). Doel *et al* (1994) showed that a large number of cattle (at least 11/28) given O1 Lausanne vaccine became persistently infected when challenged.

- McVicar and Sutmoller (1976) during their study concluded that the high virus titres seen in vaccinated cattle in the absence of obvious clinical signs suggest that partly immunized cattle, after exposure to virus, may become inapparent virus shedders and therefore dangerous sources of infection.

- Experiments to demonstrate transmission of FMD virus from carriers to susceptible in-contact animals have been unsuccessful (Van Bekkum *et al*., 1959; Sutmoller & Barteling 2004; Kitching, 1998).

- Where FMD outbreaks were controlled by consistent vaccination with a qualified vaccine the disease did not re-occur. There are also no documented cases where cattle vaccinated with a qualified vaccine caused new outbreaks. Therefore, the risks posed by vaccinated carriers must be an acceptable, "close to zero" risk (Barteling & Sutmoller, 2002).

- Emergency protective vaccination will reduce the risk of encountering recently infected animals, whereas the risk posed by carriers established prior to vaccination would not be significantly altered by vaccination (Have, 2003).

- Circulating antibodies, whether acquired passively or actively, do not prevent the establishment of FMDV infection in the pharyngeal area in cattle, but it will prevent detectable viraemia. The risk of meat from carrier animals being contaminated is thus negligible or close to zero, because there will be no virus in the bloodstream, muscles, lymph glands or other organs (Sutmoller, 2001; Sutmoller *et al*., 1968).

- According to Sutmoller *et al* (2003) in countries where FMD was controlled by the use of systematic vaccination of the cattle population only, transmission of disease from carrier cattle to non-vaccinated or other susceptible species has not been observed. Also, in situations in which, after a period of "freedom of FMD", vaccination was discontinued there has been no case of FMD linked to the existence of carriers. Only circumstantial historical evidence exists to implicate carrier animals as the source of an outbreak, however there are numerous cases in which large numbers of convalescent cattle introduced into non-protected herds did not cause new outbreaks.

- Subclinically infected vaccinated cattle can transmit infectious levels of FMDV to susceptible animals for up to seven days post-infection (Donaldson and Kitching, 1989).

- Effective vaccination requires the vaccine strain to be antigenically matched (i.e. correct serotype and strain) to the challenge strain against which protection is required in the field (Paton *et al*., 2005). This requires knowledge of the circulating field viruses to which vaccinated livestock may be exposed. This is feasible in some parts of the world, where effective surveillance has ensured that the range of locally circulating field viruses has been properly documented and where well-matched vaccines are available. However, it is difficult to achieve in regions where there is considerable or unknown antigenic diversity amongst circulating field viruses and use of well-matched vaccine strains cannot be guaranteed (OIE/FAO Reference Laboratory Network Report, 2008).

Annex XL (contd)

Annex III (contd)

Opinion:

- For vaccinated animals, an antibody test of a blood sample at the time of slaughter could provide a high margin of assurance of the absence of virus from the carcass (Sutmoller & Casas Olascoaga., 2003).

- Thompson *et al* (2009) suggests that a single vaccination at three weeks prior to slaughter is sufficient, while Sutmoller & Casa Olascoaga (2003) advocate double vaccination.

- Sutmoller *et al* (2003) concludes that transmission from carrier animals must be a very rare event and it is not known whether it happens by a special set of circumstances or whether it is merely an infrequent stochastic phenomenon, or both.

- Sutmoller *et al* (2003) addresses the concern that meat, meat products and milk from vaccinated FMD carriers are a risk for FMD free regions, zones or countries and states that apart from the regular risk reduction processes that are applied to meat and meat products, the vaccinated animal offers even less risk. The neutralizing antibodies in the vaccinated animal are the best guarantee that meat, blood, lymph nodes, bone marrow, organs, etc. will be free of FMDV.

- Antibodies to vaccine viruses may not protect against infection with viruses that are not closely related antigenically to the vaccine strain of virus.

- High yielding dairy cows in the Middle East are not always protected from high level challenge with FMDV despite vaccination every ten weeks with vaccine produced under European standards containing eight strains of virus (Kitching, 2002).

- The progressive control pathway for FMD recommended by OIE/FAO under the umbrella of the Global Framework for control of Transboundary Animal Diseases (GF-TADS) requires as a first step, that countries that are not free of FMDV should identify the types and strains of circulating viruses. This requirement might be made a prerequisite for those countries wishing to export deboned-beef.

The protective effect of vaccination with an efficient vaccine, applied according to acceptable international standards will very significantly reduce the probability of animals becoming infected and thereby reduce the risk of infective animals being presented for slaughter. However, if infection of vaccinated animals occurs, virus replication can take place, albeit often at reduced levels compared to unvaccinated animals, with or without the appearance of obvious clinical signs. Vaccinated and infected animals can also become virus carriers regardless of whether they show clinical signs of infection. Neutralising antibodies in correctly vaccinated animals are likely to ensure that meat, blood, lymph nodes, bone marrow and organs are free of virus. Vaccination is therefore a very valuable mitigation measure, provided that vaccines closely matched to the challenge strain of FMDV are used and applied correctly. Serology could be used in conjunction with vaccination as an additional safe guard to ensure that protective antibody levels are indeed obtained.

Quarantine:

Fact:

- For the purpose of the OIE *Terrestrial Code*, the incubation period of FMD is 14 days (OIE, 2008) and a 3 week quarantine period should thus suffice.

- The incubation period depends on the species, dose, route and strain of virus. For within farm spread: the incubation period can vary from two to ten days. While for between-farm spread by the airborne route the range is four to 14 days, depending on the infecting dose (Donaldson, 1987).

Opinion:

- Thompson et al (2009) suggest that a 3 week quarantine period will create the opportunity for any animals in the batch of cattle destined for slaughter to manifest disease. Any suspicion of disease should result in all the animals being discarded.

- Since FMD has a short incubation period, infection of the animals either at the farm of origin or in transit would probably be visible during ante-mortem inspection, with lesions on at least a few animals (Astudillo *et al*., 1997).

Given that the risk associated with DB described above is mainly as a result of slaughtering animals in the incubation period, a 3 week pre-slaughter quarantine will be a valuable mitigation measure providing that undetected infection of cattle does not occur during quarantine.

Waste product management:

The institution of a ban on the feeding of waste products (swill) to pigs is an important risk mitigation measure. This measure will ensure that any residual FMDV that might have entered through the importation of DB will not establish or spread in the importing country and will thus pose no risk. The success of this mitigation measure is however dependant on the ability of the country to enforce such a ban.

Previous risk assessments performed on deboned beef:

Several risk assessments, models and reviews regarding the safety of trade in DB have been published (Astudillo *et al*., 1997; Metcalf *et al*., 1996; Sutmoller, 2001; Sutmoller & Casas Olascoaga, 2003; Yu *et al*., 1997 and others mentioned in Table 3). Whereas the risk assessment in this review only focused on the commodity itself for reasons already mentioned, most of the other assessments focused on specific countries and could thus include conditions in the importing as well as in the exporting country. The final risk rating of these assessments can therefore not be compared to the final rating of this review, which only took risk mitigations during the slaughter process into account. It is however noteworthy that the risk in most of these assessments was negligible when including additional mitigation measures (such as vaccination, surveillance, cattle originating from free zones, etc).

However, the paper by Sutmoller and Olascoaga (2003) reviewed previous risk assessments and concluded that the risk mitigation methods recommended in the TAHC will effectively eliminate FMDV from beef, but in viraemic cattle, this elimination may not be complete and virus in organs from these animals will not be affected by maturation and deboning (with reference to Cottral *et al*., 1960). Furthermore, in the paper by Sutmoller (2001) the risk mitigation measures were reviewed and the author classified the risk associated with viral survival after treatment of carcasses (according to OIE recommendations) as moderate for animals in the incubation period.

Annex XL (contd)

Annex III (contd)

Metcalf et al (1996) used example data to describe the application of risk assessment to international trade in animal products and thus no source was referenced for the data used. The process of estimating the source and commodity risk factors was described. In this example the commodity risk factor was calculated to be negligible, but no explanation was given on how the probability estimates (for example the probability of virus not eliminated during deboning and removal of lymph nodes) were determined and the animals presented for slaughter were assumed to be vaccinated. Although this paper is an excellent model for conducting similar risk assessments, it is difficult to evaluate the value of the quantitative results for the specific commodity risk factor in this review; since extensive supporting evidence for the estimated probabilities is lacking and a pre-slaughter mitigation was taken into account.

Early detection of disease in the source herds is one of the most important risk reduction factors featuring in all the risk assessments.

From these assessments it can be concluded that the risk associated with DB when only applying the risk mitigations associated with the slaughtering process cannot be considered negligible, but when applying additional risk mitigation measures, such as described in Article 8.5.23 of the TAHC, the risk can be classified as negligible.

Discussion

FMDV survives poorly in bovine muscle tissue and even in experiments where cattle were slaughtered at the peak of viraemia, FMDV did not survive the changes associated with *rigor mortis* and carcass maturation (Henderson and Brooksby (1948). Certain conditions may reduce post mortem acidification of muscle and might therefore be expected to contribute to improved FMDV survival. Studies have confirmed that not all beef carcasses reach the required level of post mortem acidification (USDA, 2002), but no data were found to validate or refute the effect of this on FMDV survival. This could be studied, although it may be considered that the testing of the pH of meat provides sufficient assurance that acidification has been adequate, even if the practice of testing the *Longissimus dorsi* muscles may not totally guarantee the pH fall of all other beef muscles. In contrast, FMDV survives in other tissues that do not become acidic, such as blood, lymph nodes and bone marrow (Henderson and Brooksby, 1948). The practice of bleeding out carcasses and removal of bones and major lymphatic glands reduces the risk of residual FMDV survival in boneless beef, but would not be expected to eliminate these tissues entirely leaving a residual but unquantified risk of FMDV survival. The risk posed by a low level of residual virus is difficult to assess because few studies have examined the susceptibility of pigs (or other susceptible species) to infection by plausible infection routes such as ingestion of contaminated carcass materials. In general, relatively high doses of virus are needed to infect pigs reliably by the oral route (Sellers, 1971) and this would suggest that risk due to deboned beef would be very low. However, without information on the amounts of non-muscle tissue present in deboned meat and also on the probability of any low level of contamination being able to initiate downstream infection through exposure to susceptible animals, it can be concluded that deboned beef is a very low risk commodity with respect to spread of FMD, but it cannot be concluded that the risk is negligible without other complementary risk reduction measures.

Alternative evidence for the safety of DB when exported from FMD infected countries is the data showing that very large quantities of this product have been shipped from South America to Europe without causing FMD outbreaks – even during periods of FMD outbreaks in South American countries (Astudillo, *et al*. 1997b). Furthermore, the fact that outbreaks were regularly attributed to beef imports prior to this precaution being introduced is highly suggestive of a beneficial impact from the measure. However, this does not provide categorical evidence for the absolute safety of the commodity, since other risk mitigation measures such as quarantine, surveillance and vaccination were also in operation that ensured a very low level of virus circulation in the livestock sector servicing the export industry. Smaller, but still very significant quantities of deboned beef have also been exported to Europe from Southern Africa, but in this case the exports have been mostly from FMD-free zones. The question therefore remains as to what extent virus circulation needs to be understood and controlled before DB becomes an acceptable risk.

The current OIE Terrestrial Animal Health Code requires a number of additional measures to reduce the likelihood of an infected animal being presented for slaughter at an export abattoir. Thomson *et al*. (2009) have recommended an alternative procedure whereby animals would be held in a quarantine facility for at least three weeks prior to slaughter and vaccinated against FMD on entry to the facility. Furthermore, they recommended that the farms from which the animals were sourced, the quarantine facility and the abattoir should be operated so as to comply with the requirements of a FMD-free compartment as defined by the OIE, operating under an integrated bio-security system. Requirements of the existing OIE Code with respect to abattoir procedures and commodity preparation and deboning were endorsed, meanwhile other measures to minimize impact of food borne hazards at both production and industry levels (i.e. veterinary drug residue programs, pathogen reduction programs, application of FS&QAS, etc) were also stressed. Perry *et al*. (2005) have stated that the commodity based approach needs to be translated into practice for specific products from specific regions of developing countries in order to gain trading opportunities for those products. Moreover, they suggest further development of specific guidelines for defined livestock priority commodities from developing countries. These matters are under consideration by the OIE (OIE, 2008).

Although optimal vaccination greatly reduces the levels of FMDV in infected animals, it can be anticipated that as vaccination becomes less effective, for example due to low potency, single dose, long or very short interval before challenge or poor antigenic match to challenge strain, then the protection conferred will diminish towards that of an unvaccinated animal. Therefore, vaccination as a mitigation measure will only be effective if suitable vaccines are used and this requires both a surveillance system to ensure that the vaccine strain is tailored to the threats from locally circulating field isolates of FMDV and a system of accreditation to ensure adequate potency and correct application. This justifies the requirement in the OIE Code for vaccination to be part of an official control scheme. The alternative model of Thomson et al (2009) might be compatible with this requirement provided that some system of local surveillance and accreditation can be provided. The Progressive FMD Control Pathway recently promoted by FAO/OIE provides a possible approach to establish credible surveillance and risk management without FMD freedom (Rweyemamu *et al*., 2008; Paton *et al*., 2009). The Pathway encompasses six stages, the first four of which cover steps towards FMD freedom. Stage 0 is the starting point, stage 1 is reached when risks have been identified and a control strategy developed and stage 2 is when critical risks have been managed. Stage 1 or 2 might be considered as the minimum requirement for compatibility with exporting deboned meat to FMD-free countries.

Annex XL (contd)

Annex III (contd)

Most beef exporting countries that maintain ongoing vaccination for FMD control (i.e. South American countries) have achieved a well mechanized and highly specialized industry through 40 years of safe trading DB mainly to the EU. However, as new beef exporting actors may enter in the international arena they will need to upgrade their operations to be able to respond to market opportunities as well as to face new challenges which in turn impact the whole international sector. For instance, recent studies on pre-slaughter management (i.e. before and during transport to slaughter, during handling at livestock markets, and at the time animals are put-up for slaughter within abattoirs) draw attention to pre-slaughter stress, food safety and quality issues affecting the final product (Gregory, 2008). Therefore, it will be helpful to understand these trends and to develop new guidelines for defined beef items intended for international safe commodity trade, as has been suggested by Perry, et al (2005).

Conclusions

1. Several countries that have not had countrywide FMD freedom have used a combination of measures to (i) reduce the likelihood of infected animals being presented for slaughter at export abattoirs, and to (ii) minimise FMDV survival during the slaughter process and the preparation of DB. This combination of measures has proved extremely successful in eliminating risk associated with trading DB.

2. Existing best practice for preparation of DB in export abattoirs provides a high level of risk mitigation against contamination of the commodity by FMDV Nonetheless, harmonised protocols for procedures such as ante mortem and post mortem inspection could be established as guidance for new players.

3. Deboned beef is a very low risk commodity with respect to spread of FMD. However, neither data on the safety of trade in the commodity to date nor a risk assessment of the survival of FMDV during the preparation of the commodity under currently recommended procedures provide conclusive evidence that the risk is negligible without measures that reduce the likelihood of infected cattle being presented for slaughter.

4. The current OIE *Terrestrial Animal Health Code* comprises both specific and general recommendations for minimising the risk of FMDV contamination of exported DB. Whereas general guidance is non-prescriptive and leaves open the possibility of utilising a range of specific measures that might be balanced and effective, it also suffers from the disadvantage of being open to different interpretations as to what is necessary and this may act as a major impediment to trade. For example, the requirement that there should be an official control programme for FMD does not give details of what is required in this regard. Other measures than those proposed in the Code might provide a similar or sufficient level of risk reduction, but those that rely on application of the principles of compartmentalisation for FMD are weakened by the lack of detail on what this would entail.

5. Vaccination has the potential to be a very effective mitigation measure to ensure the safety of deboned beef, but it is reliant on the effective use of appropriate vaccines and this requires an adequate knowledge of the strains of FMDV that are most likely to threaten the vaccinated cattle population. Post-vaccination serology could add to the assurance that vaccination has been effective. Single or double dose vaccination can provide an effective level of immunisation, although immunisation is stronger after two rather than one vaccination.

6. The Progressive FMD Control Pathway recently promoted by FAO/OIE could be developed to provide a possible approach to establish credible surveillance and risk management without FMD freedom.

7. The competence of the National Veterinary Services will always be critical, both for surveillance and vaccine selection, and for enforcement of mitigation measures including those carried out before, during and after slaughter.

8. Food Safety and Quality Assurance Schemes (i.e. SSOPs, GPMs, HACCP, traceability, etc) at the livestock and meat industry level are crucial to provide enhanced monitoring and controlling procedures in a sector that combines many mechanized operational stations with others based on qualified human labours.

9. Actual data on virus survival in cattle carcasses, collected and stored so as to mimic beef abattoir slaughtering procedures are scarce with respect to FMDV serotypes, Asia 1 and SAT 1-3.

10. There is no agreed threshold level for safe FMDV contamination of a commodity such as deboned beef, and the minimum dose of FMDV within deboned beef that can infect pigs by ingestion is poorly understood.

11. Information was not found on the amount of residual blood clot, lymph node and bone tissue within deboned beef.

12. Information was not found on the survival of FMDV in deboned beef from carcasses where the normal acidification of skeletal muscle had not occurred nor on FMDV survival in fat tissues (other than bone marrow and infected blood splashed on beef carcass surfaces).

13. It was difficult to combine the data on safely traded deboned meat with that on FMDV occurrence within the relevant exporting and importing countries in order to estimate the proportion of this meat that had come from infected cattle. However, while very large volumes of DB have been imported into countries which have OIE freedom from FMD without vaccination there is no direct evidence that they have caused disease, even though some unknown proportion has almost certainly involved cattle infected with FMD, even if only as carrier animals.

Recommendations

1. More specific guidance should be developed on mitigation measures that will provide adequate assurance that FMDV infected animals, particularly those in the early stages of infection and possibly incubating the disease, are not presented for slaughter at export abattoirs in regions that are not officially FMD-free.

Annex XL (contd)

Annex III (contd)

The FMD Progressive Control Pathway of the Global Framework for the progressive Control of Transboundary Animal Diseases (GF TADs) could provide a useful framework to guide the implementation of the necessary measures that should encompass both procedures to be followed and measures by which their implementation can be monitored, including the circumstances of disease risk escalation under which the trade would be suspended. Guidance should include:

a) Options for isolating animals that are three weeks or less away from slaughter so that they do not become exposed to infection and/or are not incubating FMD at the time of slaughter.

b) Other options for reducing the weight of challenge, such as specified measures of surveillance and vaccination to control FMD in the areas that are epidemiologically related to the source of animals ("in the vicinity").

c) Procedures to survey the antigenic variants of FMDV that are circulating in the vicinity, including neighbouring regions, in order to validate the protective immunity likely to be provided by use of particular FMDV vaccines.

d) Vaccination between 4 and 12 weeks prior to slaughter for all cattle destined for presentation at export abattoirs, using vaccines that comply with OIE norms.

e) Recommendations on enforcement and accreditation procedures including the role of the Veterinary Authorities in supervising and approving the arrangements.

2. More specific guidance should be developed on mitigation measures required at export abattoirs in regions that are not FMD-free. This guidance should encompass both procedures to be followed and measures by which their implementation can be monitored. It should include:

a) Procedures and measures to regularise ante mortem and post mortem inspection, including specific guidelines based on best practices in the beef industry.

b) Specific guidelines should be developed for the preparation of specified beef commodity items (beef cuts, beef trimmings, ground meat, etc) to provide adequate assurance that FMDV is not present in such commodities.

c) Enforcement and accreditation procedures including the role of the Veterinary Authority regarding procedures, measures and guidelines outlined in 2.a. and 2.b.

3. Further research and investigation are recommended to better understand the following points:

a) The behaviour and survival of FMDV in bovine fat tissues.

b) The amounts of residual bone marrow, lymph node and blood clot in DB.

c) The effective oral dose of FMDV for pigs.

d) The relative contribution of "pre-slaughter" versus "at-abattoir" control measures aimed at reducing the likelihood of FMDV contamination of DB exported from zones that were not OIE free. A more detailed retrospective study from one or more countries where detailed records are available might be developed to analyse the likelihood that DB from infected animals were actually exported.

e) The survival in carcasses of a wider range of serotypes and strains, including especially Asia1 and SAT viruses.

f) Gaps in availability of suitable vaccine strains for some regions.

Removal of uncertainty over some of these issues, particularly items (c) and (d) above might lead to a downgrading of the FMD risk associated with DB. However, the difficulty of quantifying the levels of specified residual tissues in DB and of establishing a safe threshold for FMDV contamination of DB should not be underestimated.

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Table 1. Studies of FMDV survival in meat and other tissues[10]

Number of infected animals slaughtered and FMDV serotype	Stage of infection at slaughter	pH measure-ments	Tissues examined	Period of storage of tissues	FMDV assay system	Outcome	Conclusions	Study authors and date
Unknown number of infected cattle or method of infection. Also examined FMDV survival in carcasses of pigs and guinea-pigs	Height of pyrexia	Not reported	Long bone marrow, juice from pressed muscle and heart blood. Also examined FMDV survival on carcass surfaces following contamination by fluids containing FMDV.	Trade freezing (10 to15°F or -12 to -9° C) or chilling (28-30° F or - 2 to - 1°C)	Inoculation of cattle, pigs or guinea-pigs or feeding to pigs	Marrow and heart blood were infective to cattle after 42 d storage. Juice from pressed muscle was not infective after 11 d storage. 4 pigs fed marrow were not infected. In a separate experiment with bones of infected pigs, marrow plus crushed bone but not marrow alone were infective for pigs orally.	FMDV survives in bone marrow but not muscle. Bone spicules enhance infectivity of marrow for pigs by the oral route.	Stockman *et al*., 1927 (Second Progress Report of the FMD Research Committee)
10 cattle infected by contact in 3 experiments involving different "strains" of FMDV. Some cattle found to have insufficient levels of viraemia for further study	At expected peak of infectivity based initially on rising temperature, but predictions not always correct. Some cattle had early macroscop-ic lesions.	Not reported	Tail, kidney, liver, tongue, cheeks, heart, skirt, gall, sweetbread, brain, bone-marrow, muscle, tendon, fat, fascia, hide, carcass "drip", carcass "wrappings"	Carcasses dresse quartered and coo at -1°C, then store at -2°C. Conditions made to mimic "as closely as possible those of the very large trade in imported beef"	Mainly by intramusc-ular inoculation of pigs with a 20 ml tissue emulsion	Various tissues as well as carcass wrapping materials soaked in blood from one of the infected cattle were infective for pigs on one or more occasions after intramuscular inoculation at up to 40 d after slaughter of the cattle. Crushed bones fed to pigs after 40 d storage also transmitted disease to pigs by the oral route.	Variable results obtained with same materials from different cattle. Sometimes muscle and carcass drip was infective for pigs by inoculation even after storage. Sometimes stored bone marrow with crushed bones was infective for pigs orally. No maturation of carcasss above freezing point.	Andrews *et al*., 1931 (Fourth Progress Report of the FMD Research Committee)

[10] The studies cited were carried out on cattle, except for one, particularly representative of commercial husbandry and slaughter conditions, that involved lambs (Gomes, et al., 1994)

6 cattle infected with serotypes “O” or “A”	2 d after tongue inoculation when fever and unruptured vesicles present	pH ≤ 6.2 considered critical to virus inactivation. pH maintained above this in all tissues other than muscle	Beef, defibrinated blood, liver, kidney, rumen pillars, lymph node	From fresh to 2 mths at 4ºC and up to 6 mths at -10ºC to -20ºC	Titration in cattle by tongue inoculation (mainly) or feeding to pigs (liver and lymph node)	Virus only recovered from meat within 24 hrs after slaughter or from quick frozen meat thawed in buffer. Defibrinated blood was virus positive after 6 wks at 4ºC. When liver and lymph nodes with low virus titre fed to 30 pigs, a small number became infected	Virus survives in lymph nodes and possibly blood in otherwise “safe” carcasses rendered non-infective by acidity of rigor. Results based on cattle killed at height of infection when clinical signs apparent.	Henderson & Brooksby, 1948
7 cattle FMDV infected with serotype “A”	30-35 hrs after inoculation (?tongue) when showing typical clinical signs of FMD	Peak acidity of muscle attained at 72 hrs after death and greater in deep than superficial musculature. Lymph nodes have pH 6.4-6.9 after 72 hrs at 4ºC.	Citrated blood, muscle (*supraspinatus and semitendinos-us*), blood clots, bone marrow, lymph nodes,	Salted fresh meat stored at 33 d at 4ºC. Deboned quarters ripened at 20ºC for 1 hr and then stored at 4ºC for 24 hrs. Uncured and salt cured meat stored in barrels for 16-50 d at 1ºC. Forequarters stored up to 73 d at 4ºC.	Titration in cattle by tongue inoculation	Boned meat contains lymph nodes and large blood vessels. Occasionally, large blood clots are present and also fragments of bone, especially in muscles taken from the vertebrae near the point where the carcass is split.	Meat derived from FMD infected animals was not rendered free of FMDV by ripening, boning, salting and storage	Cottral *et al.*, 1960

2 donor steers were inoculated with FMDV Vallee A type, strain 119. 10 swine for feeding experiment	20 hours and 9 d post inoculation respectively	Not reported	Lymph nodes, haemal nodes, muscle tissue and bone marrow	Fresh and ripened (72 hours at 4ºC and 194 d at 1ºC)	Inoculation of cattle and feeding to pigs	Virus was detected in the lymph nodes and haemal nodes of the steers (both 20hrs and 9 d post inoculation), while the animals showed no signs of infection. Pigs fed marrow supernatant with bone fragments developed FMD within 5-6 d. Pigs fed the same material without the bone fragments did not have signs of infection during 15 d of observation.	Meat from animals in the stages just preceding and shortly after the regression of signs of FMD would be hazardous to export from countries where FMD is present. Bone fragments increased infectivity to pigs.	Cox *et al.*, 1961
2 cattle infected by intradermolingual inoculation with type “A” or “C”	31 or 38 hrs after inoculation when showing typical clinical signs of FMD	Details not reported	Blood, kidney, spleen, liver, lung, brain, bone marrow, lymph nodes, heart, stomach, intestine, rumen, tongue, muscle, parotid salivary gland, testicle, uterus	Chilling for 2 or 8 d and freezing for 60, 120 or 210 d	Calf kidney cell culture inoculation	Muscle was initially FMDV positive in one animal but not after storage. Blood, bone marrow, lymph nodes and a variety of other tissues were frequently positive after storage up to 210 d	FMDV survived in blood, bone marrow and lymph nodes but not muscle. Other tissues in which FMDV survived are normally removed from deboned meat.	Savi *et al.*, 1961
12 cattle infected with serotype “O” Method of infection unknown	Unknown. 10 carcasses said to be derived from cattle slaughtered at the time of general development of sickness	The pH averaged 01.-02 higher in tissues of diseased cattle compared to normal animals	Blood, skeletal muscle, cardiac muscle, liver, spleen, kidneys, lymph nodes, medulla, rumen, bone marrow, fat	Held at 10-12ºC for 24 hrs, then at 2-7ºC. Tissues examined 2, 24, 48, 72 hrs and 9 d after slaughter. Two carcasses stored for 81 d at -20ºC and lymph nodes stored for 687 d at -30ºC.	Inoculation of guinea-pigs, tissue cultures and in one case, cattle. Guinea-pig inoculation the least sensitive.	Non-muscle tissues not acidified during post mortem change and retained infectivity despite inactivation in muscle (one animal positive at 2 hrs after slaughter only)	The main sites for FMDV survival in carcasses are blood, lymph nodes bone marrow and fat. FMDV could not be detected in muscle tissue after 2 d storage. Lymph nodes became non-infective at 9 d post-slaughter when carcasses chilled, but retained infectivity if carcasses frozen	Wisniewski, 1963

57 cattle infected with serotypes “O”, “A” and “C”. 14 repeatedly (≥6x) vaccinated and 5 unvaccinated cattle per serotype.	32 hrs after tongue inoculation (the time of peak viraemia in unvaccinated cattle). No secondary lesions at slaughter.	No Ph differences between vaccinated and unvaccinated cattle at time of slaughter. After cask curing, meat Ph was 5.3-6.7	Fresh and “ripened” lymph nodes were collected. Meat was boned and cut for curing in casks, by salting with sodium chloride, sodium nitrite and sodium nitrate mixture at 4.5 kg per 100 kg meat.	Carcasses hung at 4°C for 72 hours. Curing was at 4°C for approximate-ly one month	Inoculation of cattle, mice and tissue cultures. Feeding to pigs.	By cattle inoculation, fresh, ripened and cured lymph nodes from unvaccinated cattle were FMDV positive; 1/42 vaccinated cattle had a fresh lymph node with detectable FMDV. Cured lymph nodes fed to 30 pigs – 10 per serotype. None of the pigs developed FMD.	Multiple vaccination markedly reduced the chances of FMDV infection of lymph nodes. One month’s storage also reduced virus survival in lymph nodes from unvaccinated cattle. The level of immunity developed by the vaccinated cattle in this experiment would be hard to guarantee under field conditions.	NASNRC, Argentine-US Joint Commission on FMD, 1966
54 Cattle were infected by tongue inoculation with either serotypes A, SAT1 or SAT3	Cattle killed 14-196 d post infection.	Not measured	Saliva, oesophageal/ pharyngeal fluid and various post mortem specimens (turbinates and posterior part of the nasal septum, tongue, pharynx, soft palate, oesophagus, trachea and bladder)	All samples were held at room temp and assayed for infectivity within 2-3 hours after collection or of the slaughter of the animal	Plaque assay, mouse inoculation and serum neutralizatio n tests	Virus was recovered from 41 / 54 cattle killed, 14-196 d after infection. The chief sites of virus multiplication based on the frequency of virus recovery and infectivity titres were the dorsal surface of the soft palate and the pharynx.	The mucosae of the pharynx and the soft palate are the main sites of virus multiplication in the bovine carrier animal.	Burrows, 1966
12 cattle (milking cows), 9 sheep and 10 pigs were exposed (in isolation) to cattle infected by inoculation with serotype O strain	Samples taken daily from 1 – 13 d post exposure	Not measured	Samples taken from blood, milk, pharynx, rectum and prepuce or vagina	No storage	Inoculation into tissue cultures	Virus was recovered from pharyngeal samples from the majority of animals for several d before clinical disease was evident. Virus was also recovered from the blood, milk, rectal and preputial or vaginal swabs before clinical lesions were apparent.	Some animals were possible sources of infection for periods up to five d (cattle and sheep) and up to 10 d (pigs) before disease was diagnosed in the animals concerned.	Burrows, 1968

4 susceptible bulls placed in isolation with 4 steers inoculated on the tongue with serotype O, strain	Samples were collected daily	Not measured	Samples were collected from the pharynx, saliva, blood, rectum and prepuce	No storage	Inoculation in tissue culture	In three bulls virus was recovered from one or more sites before the appearance of lesions.	Virus was found in the pharynx in bulls up to 9 d before any clinical signs were noted. Ante- and post-mortem infection will thus not identify these potential sources of virus.	Sellers *et al.*, 1968
15 cattle infected with serotypes “A”, “O”, “C”.	Inoculated by intralingual or intramusc-ular routes and killed at peak of viraemia	Not reported	Blood, prescapular lymph nodes, internal iliac lymph nodes, vesicular epithelium and tallow collected	Tissue smears applied to packageing materials. After drying, specimens stored at 4ºC and 82-88% relative humidity	Inoculation of ground smears into tissue cultures	FMDV survived for at least 5 weeks in all smears. Smears of ground lymphoid tissues harboured 2 log units of virus after 7 weeks.	FMDV survives on meat packaging materials longer than the durability of chilled beef or the time needed to transport animal products between continents	Gailiunas *et al.*, 1969
56 cattle were exposed to serotypes A and O using different methods (direct contact, indirect contact, feeding, intranasal spray and lung inoculation).	2 to 6 d post exposure	Not reported	Extensive samples including lymph nodes, serum, soft palate, pharynx, trachea, tonsils, nasal cavities, bronchi, lung, tongue, oesophagus, heart muscle, etc.	Most samples were assayed for virus within 6 hours of collection, but some were held at -70ºC for several d	Inoculation into different tissue cultures	45 cattle were sampled after slaughter, 6 were apparently not infected, 23 were infected and examined before the onset of viraemia, 12 were viraemic and 4 were exhibiting early signs of disease. Virus was recovered most regularly and in the greatest amounts from the dorsal surface of the soft palate, the retropharyngeal lymph nodes, the pharynx and the tonsils, and least frequently from the lungs, bronchial lymph nodes and the nasal mucosae.	The distribution and amounts of virus in the tissues of 23 cattle killed before the onset of viraemia indicated that the pharyngeal area was the most likely site of initial infection and virus growth.	Burrows *et al.*, 1981

9 cattle (6 -18 months old). FMD strains O_1 Campos and A_{24} Cruzeiro were used. Animals were slaughtered at 24 and 72hs post infections.	Animals were infected by intrader mal injection (tongue) and nasal instillation. Virus suspensions of $10^{5.67}$ LD_{50} (Campos) and $10^{4.6}$ LD_{50} (Cruzeiro) were used.	Electronic measurem - ents of pH in *Longissimus dorsi* (LD) (infected), *Biceps femoris* (BF) and *Psoas major* (PS) (non-infected) muscles. Samples were analyzed at 2, 4, 8, 12, 24 and 30 hr post slaughter.	Blood, lymph nodes and LD muscles.	Samples were kept at refrigeration temperatures and analyzed between 2 and 30 hr post slaughter.	Inoculation into suckling mice and in vitro assay using BHK cells.	45 LD muscles samples from infected animals were assayed for FMDV infectivity. FMDV was not detected at a pH value of 6.0 or below. A pH reading of 6.04 was the lowest value found from FMDV LD infectivity stand-point. The experimental study was also designed to consider influence of electrical stimulation on pH drop of beef carcasses using a set of 20 healthy carcasses.	Confirmed early research findings of Henderson and Brodsky (1948) with regard to FMDV inactivation in infected beef muscles. Electrical stimulation produced a pH drop to a value of 6.0 at 4 hr post slaughter in BF and PS from healthy, non infected beef muscles.	García Vidal *et al*., 1982
8 heifers (18 - 30 months old) were inoculated (intralingual & intramuscular) with FMDV serotype O_1 (aprox 10^5 $TCID_{50}$/ml). The study considered electrical stimulation (ES) effects on pH and FMDV in carcass and offals.	At slaughter (36 – 40 hr after the inoculation) all animals had classical symptoms of FMD. 2 heifers were used as control (No ES treatment applied).	pH values measured by direct probe and iodo-acetate homogenate s. Samples considered: different muscles, offals and bone marrow	Tongue, M. masseter externus, M. masseter internus, heart, pillars of diaphragm, lung, liver, kidney, LD muscle, M. semimembranosu s (S), M. extensor carpi radialis ECR), lymph nodes (cervicales superficiales), bone marrow (humerus).	Samples were collected at 1, 2, 3, 4, 6, 24 and 48 hr post mortem (pm) under refrigeration (2ºC). Temperatures were measured by a digital probe thermometer in the LD, S and ECR muscles and in the offals.	Samples collected at 3, 24 and 48 hr were inoculated into baby mice. Virus isolation and tritration were performed in pig kidney cells.	FMDV recovered from masseter muscles, lymph nodes and ECR muscle. No virus was demonstrated in the heart. High concentrations of FMDV in the blood at slaughter. Virus was demonstrated in a few samples of skeletal muscle at 4 hr pm. pH values of heart were remarkably low in both infected and control animals ES had no effect on pH of lymph node, bone marrow and offals.	Underlines risk associated with meat containing lymphatic tissues. Recommended pH measurement should take place in each carcass before deboning. Proposed LD muscle as representative of skeletal muscle. A pH value of 5.8 or below in the LD is acceptable as indicating non-survival of FMDV. pH determinations should be made after 24 hr storage.	CEC, 1986.

9 cattle raised in a free FMD free area, unvaccinat-ed, free of specific antibodies. FMDV strains O_1 (Campos), A_{79} (Argentina), and C_3 (Resende) originally isolated in field outbreaks in Argentina.	3 groups of 3 animals were inoculated with 20,000 LD_{50} of each strain intrader -mally in the tongue. Animals were killed at 72 hr post inoculation, when viraemia is normally present.	Mean pH of 1,296 samples were measured in triplicate from samples collected from carcasses stored at 1ºC for 2 and 7 d.	Tissues analyzed were lymph nodes, blood clots, bone marrow (ribs) and muscles (*Longissimus dorsi*, *Semitendinos-us*, *Biceps brachii*, masseter).	Maturation/ Ageing: One-half of a carcass from each animal was stored at 1ºC for 2 d, while the other half was stored for 7 d at the same temperature.	Intramusculari inoculation into suckling mice. In vitro assay using primary cultures of bovine fetal thyroid cells. Final assessm-ent was made by intraderm-al inoculation of cattle	Clear cut differences were observed between muscle (pH below 6) and lymph node (LN), blood clots (BC) and bone marrow (BM) values (mean pH above 6). No significant changes of pH were observed after maturation (2-7d). LN (2d):6.3; (7d):6.4 BC (2d):6.5; (7d):6.6 BM (2d):6.8; (7d):7.0	The virus was most frequently detected in bone marrow samples and less frequently but with comparable numbers of positive samples, in lymph nodes tissue and blood clots. It does not seem necessary to prolong maturation beyond 2 d, as suggested by the infectivity detected in LN, BM and BC. Highest titre virus survival was in BM.	Lasta *et al*,, 1992.
25 lambs (~ 3 mth old). Virus O_1 Campos. Animals were intrad-e rmally inoculated in the tongue ($10^{5.6}$ ID_{50}). 100 healthy (non-infected) lambs were used as controls for pH measure-ments.	24 hr post infection temperatur-e, clinical examinatio-n and blood samples were taken. Slaughter was performed at 48, 72, 96, 120hrs and 15 and 30 d post infection (PI).	In LD muscle. Temperat-ure was recorded on *Longissimus Dorsi* (LD) and *Semimem* *branosus* (SM) muscles.	LD, SM. Lymph nodes (from muscle tissue areas and viscera), tonsils, heart, oesophagus, lungs, liver, spleen, kidney.	Samples were aged and after finishing maturation were frozen. Carcass ageing was done at 4ºC for a 24 hr period. LD and SM were kept frozen for 4 mths at -20ºC.	Titration of muscle, organs and lymph glands were performed in duplicate.	In animals slaughtered in febrile state at 48, 72, and 96 hrs post infection (HPI) the virus was detected before and after maturation in the LD and SM muscles, that did not reach a pH of <6.0 during ageing. No virus was found before or after ageing of carcasses in those animals slaughtered at 120 hr PI, 15 or 30 d PI. Kidney had the highest virus concentration. Lymph glands and tonsils also had high virus concentrations.	Virus detected in LD and SM muscles after maturation as well as after froz en storage (4 mths). Virus detected in glands and organs at 48, 72, 96 and 120 hr PI. Virus not detected in organs or glands of animals slaughtered at 15 or 30 d PI. In normal, healthy, non-infected sheep, pH of carcasses reached values of 5.96 after 6 hr and 5.36 after 24 hr of ageing at refrigeration temp.	Gomes *et al*., 1994

Table 2. Reviews which include consideration of of FMD virus survival in meat

Authors	Year of Publication	Title	Summary
Cottral, Cox & Baldwin	1961	The survival of FMDV in cured and uncured meat	Introduction to their own work provides a valuable review of earlier literature.
Cottral	1969	Persistence of FMDV in animals, their products and the environment	Tabulates the extremes for the earliest detection of FMDV and its longest reported persistence in living animals as well as virus survival in animal tissues and fluids and on various objects.
Roberts	1970	FMD, its relation to meat and meat processing	Literature review on FMDV in animal products with focus on treatments for virus inactivation. Identified problem of no established threshold of FMDV contamination below which a product could be considered safe.
Sellers	1971	Quantitative aspects of the spread of FMDV	Collated data on FMDV production levels, survival and required doses for infection. Considered that figures for level of FMDV contamination in air or feed must be combined with amount actually breathed in or eaten to establish minimum dose for infection.
Callis & McKercher	1978	Dissemination of FMDV through animal products	Concluded that main risk from deboned beef is residual lymph nodes, blood and bone fragments and that vaccination can reduce risk.
Blackwell	1979	Internationalism and Survival of Foot-and-Mouth Disease Virus in Cattle and Food products	In depth historical and scientifically based descriptions of FMD outbreaks in USA, Canada and Mexico, related to animal products trade including food items from South American countries.
Garcia-Vidal, Lazaneo, Correa, Urrestarazu, Huertas & Heidelbaugh	1983	Review of recent progress of the meat Institute of Uruguay on the development of industrial methods to inactivate Foot-and-Mouth disease virus in meat and meat products.	This review paper showed that virus was not detected in muscle at pH 6.0 or below. The minimum pH value in which the virus was present was pH 6.4.
Blackwell	1984	Foreign animal disease agent survival in animal products: recent developments	General review of factors contributing to survival of pathogens in different products and of effects of different commodity processing treatments.

Authors	Year of Publication	Title	Summary
Donaldson	1987	Foot-and-Mouth Disease: the principal features.	Describes the FMD virus, distribution, mechanisms of spread, routes of infection and pathogenesis. Gives information on the incubation period, organs that have been shown to contain high quantities of virus during acute disease and post-mortem pH changes.
USDA	1991	FMD emergency disease guidelines	Tabulated, referenced data on FMDV survival in different materials and from different species.
US General Accounting Office	2002	Foot-and-Mouth Disease. To protect U.S. livestock, USDA must remain vigilant and resolve outstanding issues.	Describes importance of the livestock industry to the US agricultural sector and economy. Relevance of protecting US livestock from FMD and measures for preventing FMD from entering the US are evaluated. Summarized survival time of the FMD virus in selected products and by-products.
Alexandersen, Zhang, Donaldson & Garland	2003	The pathogenesis and survival of FMD	Summary data on infective doses by various routes and on kinetics of virus replication, load and clearance.
Scott Williams	2003	Persistence of Disease Agents in Carcasses and Animal Products	Summary of persistence and inactivation of FMD virus associated with different agents and environments. Described behaviour and persistence in different matrices, elements and foods (carcass and meat products, skin, hides and fibres, semen/embryos, faeces).
Ryan, Mackay, & Donaldson	2008	Foot-and-mouth-disease virus concentrations in products of animal origin	Review collected data for the concentration of FMDV in animal tissues during the vireamic stage of the disease and in animal products derived from infected animals. The inactivation-resistant fraction of FMDV must be taken into account when estimating the efficiency of thermal or pH-dependant reduction of virus load. The significance of this is related to the initial virus load, the nature of the product and the treatment it undergoes. If the critical control points (deboning, removing lymph nodes and blood) are achieved, the risk to an exposed animal of becoming infected from beef chilled for 72 hr post-mortem is negligible (drop in pH should be monitored).

Table 3. Commentaries and risk assessments for FMD safety of meat

Authors	Year of Publication	Title	Summary
Van Bekkum, Frenkel, Frederiks & Frenkel	1959	Observations on the carrier state of cattle exposed to foot-and-mouth disease virus.	A rather large proportion of cattle, which have recovered from FMD, may still harbour the virus in the saliva for several months. The virus may be demonstrated in material collected from the oesophagus by inoculation into unweaned mice or susceptible cattle. After contact with clinical cases vaccinated animals may develop a similar carrier state without having shown symptoms of the disease. In these experiments susceptible oxen kept in contact with such carriers remained unaffected, even if the oral cavity was swabbed with infective saliva. No cases of FMD occurred in vaccinated or unvaccinated cattle or in unvaccinated pigs, if such animals were introduced into a herd known to contain carriers or if they were kept on the same premises with such animals.
Brooksby	1961	International trade in meat and the dissemination of FMD	Factors to be considered in assessing the risks in relation to FMDV infected meat. Concluded that an absolute prohibition should be placed on importation of meat from areas with exotic strains of FMDV.
Sutmoller, McVicar & Cottral	1968	The epizootiological importance of foot-and-mouth disease carriers.	From these experiments it was concluded that nearly all infected cattle become carriers and the carrier state in cattle is probably a normal sequel to infection. Susceptible cattle always had viraemia, usually accompanied by fever, while cattle that had received antiserum prior to virus inoculation did not. Viraemia was prevented even in cattle with a very low level of passively acquired antibody. Circulating antibodies, whether acquired passively or actively, do not prevent the establishment of FMDV infection in the pharyngeal area in cattle, but it will prevent detectable viraemia.
McVicar & Sutmoller	1976	Growth of foot-and-mouth disease virus in the upper respiratory tract of non-immunized, vaccinated and recovered cattle after intranasal inoculation.	Non-immunized, vaccinated and recovered cattle were inoculated intranasally with various doses of FMD virus. Samples of oesophageal pharyngeal fluid were taken periodically for up to 7 d after inoculation and virus titres of these samples were plotted as pharyngeal virus growth curves. The extremely mild clinical syndrome exhibited by some of the vaccinated cattle after virus inoculation could easily have been missed under field conditions. Virus titres in OP fluid samples taken 2-4 d after inoculation from the four vaccinated steers with a low pre-exposure serum titre were as high as those seen in the non-immunized cattle. The high virus titres seen in vaccinated cattle in the absence of obvious clinical signs suggest that partly immunized cattle, after exposure to virus, may become inapparent virus shedders and therefore dangerous sources of infection.
Blajan & Callis	1991	International trade and FMD	Data on trade in animals and their products show that large amounts of exports from infected countries have taken place without causing outbreaks in the countries of destination.
MacDiarmid	1991	The importation into New Zealand of meat and meat products: A review of the risks to animal health	The review examined the potential risks posed by each type of meat & meat-based product. Regarding boneless beef and FMD, the paper stressed the relevance of ensuring that only animals free from FMD should be slaughtered, originating from regions free of FMD as well as the importance of checking on the pH of boneless beef. Comments (quoted) “There is no evidence that boneless beef has ever been the origin of a FMD outbreak. Thirty four primary outbreaks occurred in the EC during the period 1977 to 1987. Eight of these originated from outside the Community and were probably due to imports of meat which had not been deboned. Thirteen of the outbreaks were most probably due to faulty FMD vaccines or laboratory escapes and 13 remain of unknown origin”.

Authors	Year of Publication	Title	Summary
Doel, Williams & Barnett	1994	Emergency vaccination against foot-and-mouth disease: Rate of development of immunity and its implications for the carrier state	The study was undertaken as part of a larger programme to determine the rate with which protective immunity could be expected to develop in animals given emergency vaccines and the extent to which these animals would shed virus and spread the disease by direct or indirect contact. Two experiments demonstrated that oil- or AL(OH)3/saponin-adjuvanted vaccines made from inactivated virus antigens held in the International Vaccine Bank were capable of protecting cattle 4 or more d after vaccination. A large number of cattle (at least 11/28) given O1 Lausanne vaccine became persistently infected when challenged. Animals challenged only a few d after vaccination appeared more likely to become carriers on the basis of ease of virus recovery and possibly would pose a greater risk to healthy contact animals than those from which it was more difficult to isolated virus by probang.
Pan American Foot-and-Mouth Disease Center & Tuskegee University School of Veterinary Medicine	1995	Assessment of the risk of foot-and-mouth disease introduction into the CARICOM countries through the importation of meat from Argentina and Uruguay	Cooperative effort between the Pan American FMD Centre and the School of Veterinary Medicine, Tuskegee University, US. This study examines the risk of beef importation by CARICOM (Caribbean) countries. Quantitative Risk Assessment (QtRA) model was based on rules and procedures for exporting deboned beef to the European Community (EC). The study states that this protocol has been very effective, since deboned beef coming from millions of beef cattle has been imported by EC countries, even during times of extensive FMD outbreaks in South America countries. UK imported in this period more than one million tons of deboned beef and still remained free of FMD. This QtRA study concluded that the risk of introducing FMD for CARICOM countries by exporting deboned beef from Mesopotamia region of Argentina and from Uruguay was exceedingly small.
Callis	1996	Evaluation of the presence and risk of FMDV by commodity in international trade	Summarises policy changes on importation of meat and meat products into UK and Europe after 1968 and notes that no outbreaks were associated with this trade thereafter.

Authors	Year of Publication	Title	Summary
Metcalf, Blackwell & Acree	1996	Application of Risk Assessment to International Trade in Animals and Animal Products	Disease risk factors associated with the trade in animals and animal products can be grouped in three categories: source risk factors, commodity risk factors and destination risk factors. Each of these broad categories can be treated separately. Commodity risk factors are often made more complex than necessary by the tendency to mix source and commodity factors together in evaluating the risk of the commodity. To determine the commodity risk factor it is necessary to begin with the premise that the commodity is infected with the disease agent of concern and examine each step of the processing, handling and storing of the commodity in order to determine how much the infection is reduced by each process.
Yu, Habtermariam, Wilson, Oryang, Nganwa, Obasa, Robnett	1997	A risk assessment model for FMDV introduction through deboned beef introduction	A basic quantitative risk assessment model is used to determine the risk of FMD introduction through beef based on the prevalence of FMD-infected cattle in herds as well as the prevalence of infected herds in the exporting country. Mitigations taken into account were farm-level inspection, ante-mortem inspection, post-mortem inspection, chilling and deboning. The model showed that the early stage (lower prevalence) of an FMD outbreak may impose a high risk of FMD virus introduction. However, this risk decreases again at higher prevalence due to higher likelihood of detection during ante- and post-mortem inspections. Small sample sizes during inspections increased risk considerably.
Vose	1997	Risk analysis in relation to the importation and exportation of animal products	Review of modelling techniques applicable to quantitative risk analysis for trade in meat. Discusses need to model variables that are not accurately quantified and problem of accuracy in dealing very low risk. Comparison of scenario pathways and simulation for quantitative risk analysis in relation to dangers associated with animal products.
Sutmoller & Vose	1997	Contamination of animal products: the minimum pathogen dose required to initiate infection	Highlights residual risk when products are contaminated with less than the minimum infective dose due to non-zero risk from any infectious dose and impact of multiple exposures. Problem of estimating lower threshold of minimum infecting dose in absence of data from experimental challenges with very large numbers of animals. A modelling approach suggested.
Astudillo, Sutmoller, Saraiva & Lopez	1997a	Risks of introducing FMD through the importation of beef from South America	Describes post 1968 mitigation measures for export of meat to Europe from S America. Quotes estimate that > 1 million tons of deboned frozen meat safely imported to UK (SENASA, 1994). Provides estimates of the likelihood of FMDV survival at each risk mitigation stage (probability values for each event in scenario pathway) and concludes a 1 in 1 million chance of getting FMDV in meat, assuming that the mitigation measures are adhered to. Considers that no data is available on the kinetics of FMD virus inactivation in meat at a pH of 6.0. Combination of low regional risk of FMDV infection with efficient risk mitigation ensures safety of products.

Authors	Year of Publication	Title	Summary
Astudillo, Cané, Geymonat, Sathler, Garay Roman, Sutmoller, Zottele, & Gimeno	1997b	Risk assessment and risk regionalisation, based on the surveillance system for foot and mouth disease in South America.	Describes two examples of risk assessments for international trade, i.e. bovine embryos and beef as a way of proposing regional risk evaluation of FMD in South America. Utilize the model developed by PANAFTOSA and Tuskegee Univ. Sch. Vet. Med. to analyze meat trade. Authors stress that in respect to trade in beef from infected FMD countries, it is not only the deboning and maturation processes that is relevant but also the overall safety provided from an efficient animal health surveillance and information system as well as efficient procedures in selecting herds and abattoirs.
Kitching	1998	A recent history of Foot-and-Mouth disease.	A review article on the FMD outbreaks internationally from 1991 – 1997. States that there is a reluctance to use vaccination as control measure since ruminants will continue to carry live FMDV in their pharynx after contact, regardless of the development of clinical or sub-clinical disease. However, experiments to demonstrate transmission of FMD virus from carriers to susceptible in-contact animals have been unsuccessful.
Sutmoller	2001	Importation of beef from countries infected with foot-and-mouth disease: a review of risk mitigation measures	Outlines OIE Code requirements and a risk pathway to analyse risk associated with beef trade. Considers four disease stages of FMD and the hazard and mitigation for each. Concludes that not all virus is eliminated from infected animals by deboning and maturation and that animals incubating FMD without clinical signs pose the main risk. Highlights dangers of cross-contamination between carcasses and from oropharynx. Emphasises importance of antibodies in neutralising FMDV in meat and other tissues.
Barteling & Sutmoller	2002	Culling versus vaccination: challenging a dogma in veterinary (FMD) science.	Discuss the pros and cons of culling or vaccination as control methods for FMD. Maintains that where FMD outbreaks were controlled by consistent vaccination with a qualified vaccine the disease did not re-occur and there are no documented cases where cattle vaccinated with a qualified vaccine caused new outbreaks. Therefore concludes that the risk posed by vaccinated carriers is an acceptable, "close to zero" risk.
Pharo	2002	FMD: an assessment of the risks facing New Zealand	Broad review of the pathogenesis and transmission of FMD and hazards posed for international trade. Cites Bachrach *et al.* (1975) on rate of inactivation of FMDV by acidic conditions: 90% per min at pH 6 and 90% per sec at pH 5. Considered that oral infection of pigs is the most likely outbreak scenario.
USDA	2002	Risk assessment –Importation of fresh (chilled or frozen) beef from Uruguay. Animal Plant Health Inspection Service, APHIS. United States Department of Agriculture, USDA.	A quantitative risk assessment (RA) to evaluate the likelihood of FMD introduction through importation of beef from Uruguay. Mitigations considered in the assessment included: a) Commodity imported is deboned prime beef cuts from carcasses that are maturated for 36 hr at a temperature between 2 to 10ºC. b) Beef originated from animals in herds certified to have been vaccinated with oil-adjuvant vaccine. c) All animals pass both ante- and post-mortem inspections. d) All carcasses are pH tested in the LD muscle and the pH must be less or equal to 5.8. The RA found that the likelihood of importing fresh or frozen, maturated, and deboned beef infected with FMD virus would not exceed 1.03×10^{-4} or 1 in 9,700 chances (95% confidence level).

Authors	Year of Publication	Title	Summary
Have	2003	An assessment of guidelines for treatment of meat from a FMD vaccination zone.	A report of the Research Group of the Standing Technical Committee of the EC for the control of FMD. Concludes that the current requirements for the heat treatment of meat from FMDV vaccinated animals, although based on empirical data, can be considered to provide a high degree of safety when applied to low-level contaminated products such as meat from vaccinated animals.
Sutmoller, Barteling, Casas Olascoaga & Sumption	2003	Control and eradication of foot-and-mouth disease.	In this review article the authors address the concern regarding mechanical contamination of a carcass with rrier virus" from the pharyngeal area. They concluded that because of antibodies in blood and other fluids and asures applied during slaughter and processing (e.g. for BSE) the risk is negligible. They also stated that in ntries where FMD was controlled by the use of systematic vaccination of the cattle population, transmission of ease from carrier cattle to non-vaccinated or other susceptible species has not been observed. Also, in situations in ch, after a period of "freedom of FMD", vaccination was discontinued there has been no case of FMD linked to the stence of carriers. Only circumstantial historical evidence exists to implicate carrier animals as the source of an break, however there are numerous cases in which large numbers of convalescent cattle introduced into non-tected herds did not cause new outbreaks.
Sutmoller & Casas Olascoaga	2003	The risks posed by the importation of animals vaccinated against foot-and-mouth disease and products derived from vaccinated animals: a review	Repeats many of the arguments from previous paper in 2001. Advocates double vaccination of cattle prior to slaughter and use of serology at abattoirs to check antibody status. Highlights danger of non-industrial processing of small ruminants leading to risk of carcass contamination from pharynx.
Thomson *et al.*	2004	International trade in livestock and livestock products: the need for a commodity-based approach	Proposed an alternative commodity based approach for international animal health and food safety standards based on the fact that different commodities pose different risks when it comes to the dissemination of human and animal pathogens. They concluded that this approach would improve access to international markets for all countries, especially for those LDCs.
Orsel, Dekker, Bouma, Stegeman & de Jong	2005	Vaccination against foot and mouth disease reduces virus transmission in groups of calves.	The study investigated whether single vaccination against FMDV could significantly reduce virus transmission in groups of calves compared to transmission in groups of non-vaccinated calves. The findings suggested that single vaccination in a population of calves could reduce transmission and that this might be sufficient to eradicate the virus during an epidemic of FMD.
European Food Standards Agency (EFSA)	2006	Assessing the risk of FMD introduction into the EU from developing countries	Considered that illegal imports are a greater risk than those from countries with an established and regulated trade with Europe. Recommended additional research on virus survival in tissues and animal products, specifically: (1) the effects of pre-slaughter stress upon pH drop; (2) virus strain variability in survival; (3) the effect of vaccination on amount and distribution of FMDV in animal products. Some data on meat imports are given, but insufficiently stratified for use in this review.

Authors	Year of Publication	Title	Summary
Hartnett and 9 others	2007	A quantitative assessment of the risks from illegally imported meat contaminated with FMDV	Even where swill feeding is banned there is a residual risk of pigs and also wild boar gaining access to imported meat products. An estimate of thefuture frequency of FMD infection in GB livestock was made of 0.015 cases of infected animals per year (between 0.0017 and 0.053 with 90% certainty). Imports from the region Near and Middle East account for 47% of this risk and 68% of the risk is attributed to bone-in and dried de-boned products.
Thomson, Leyland & Donaldson	2009	De-boned beef – an example of a commodity for which specific standards could be developed to ensure an appropriate level of protection for International trade	Proposals on additional risk mitigation procedures to eliminate/reduce the increase in risk that results from slaughtering animals in the incubation stage. Vaccination and a 3 week pre-slaughter quarantine period are suggested, combined with a compartmentalisation approach to biosecurity.
Sutmoller & Barteling	2004	Discussion paper on the risks posed by FMD carriers occurring amongst vaccinated cattle.	Discussed the risk posed by vaccinated carriers and reviewed historical evidence to that effect. Stated that under a variety of experimental conditions, transmission of FMD from recovered as well as vaccinated carriers has not been demonstrated.

Table 4. Experiments describing oral infection of pigs with FMDV

Authors	Serotype	Inoculum	Volume & route	Dose	Dose calculation	No. exposed	No. infected	Comments
Sellers, 1971 – citing Stockman et al 1927	unknown	unknown	unknown	$10^{5.4}$ (according to Sellers 1971, but not found in original report)	Log_{10} infectious units or ID_{50} according to Sellers 1971	7	5	Original report describes several experiments where pigs fed with carcass tissues did or did not become infected, but there is no information on the dose of virus
Sellers, 1971 – citing Andrews *et al.*, 1931	O 39	unknown	unknown	$10^{5.2}$ (according to Sellers 1971, but not found in original report)	Log_{10} infectious units or ID_{50} according to Sellers 1971	5	1	Original report describes several experiments where pigs fed with carcass tissues did or did not become infected, but there is no information on the dose of virus
Sellers – citing Henderson & Brooksby, 1948	O ASJ	bovine lingual epithelium (6 pigs) & liver, kidney and lymph nodes (30 pigs)	Unknown volume smeared on feeding troughs	$10^{5.0}$ (30 pigs) & $10^{6.5}$ (6 pigs) (according to Sellers 1971, but not in original report)	Log_{10} infectious units or ID_{50} according to Sellers 1971	30 6	2 1	
Cox *et al.*, 1961	A 119	Bone marrow with (n=5) or without (n=5) bone fragments	75 ml as feed	$7.5 \times 10^{5.5}$ ID_{50}	Cattle tongue titration	10	5	Only those fed bone marrow including bone fragments became infected (similar to findings of Stockman *et al.*, 1927 and Andrews *et al.*, 1931)
Nathans*, 1965	Pig adapted C strain	unknown	Oral instillation	5 pigs given $10^{2.4} – 10^{4.6}$ 7 pigs given $10^{5.4} – 10^{6.6}$	Suckling mouse LD_{50}	12	2/5 and 7/7	Further details also tabulated in Sellers, 1971
Terpstra, 1972	O_1 Weerselo	Vesicle suspension in medium	2 ml by oral instillation	$10^{4.6} – 10^{7.5}$	Suckling mouse LD_{50} (add ~1log to convert to bovine thyroid cell culture ID_{50})	4 received $10^{4.6} – 10^{5.4}$ and 7 received $10^{6.0} – 10^{7.5}$	0/4 receiving low dose and 7/7 receiving high dose	

* Original article not seen, used citation of Terpstra, 1972

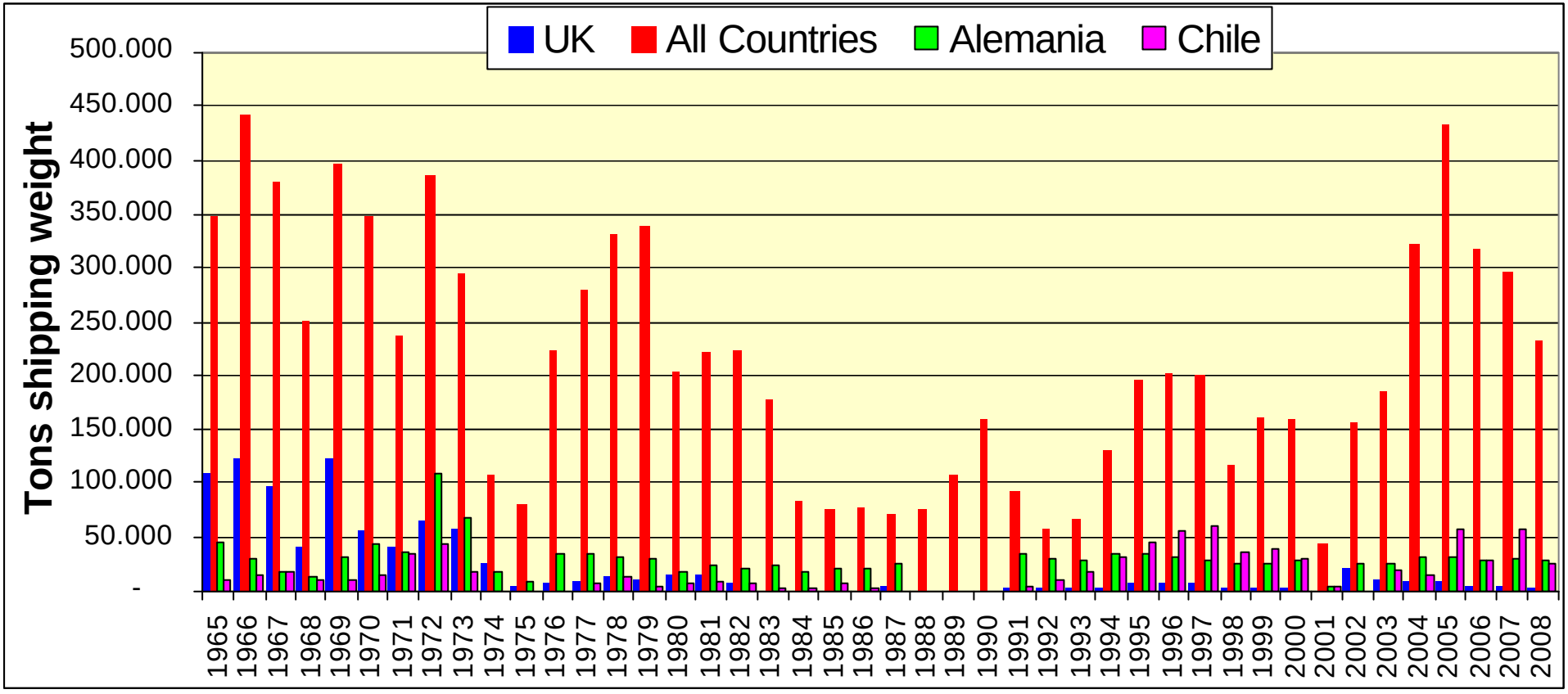


Figure 1. Deboned beef exportation from Argentina to All Countries. Years 1965 -2008. Figures are based on data found at the former Argentine National Meat Board archive and the current Argentine National Directorate of Agrifood Market, SAGPyA, statistic series.
(C. Otaño, Personal Communication)

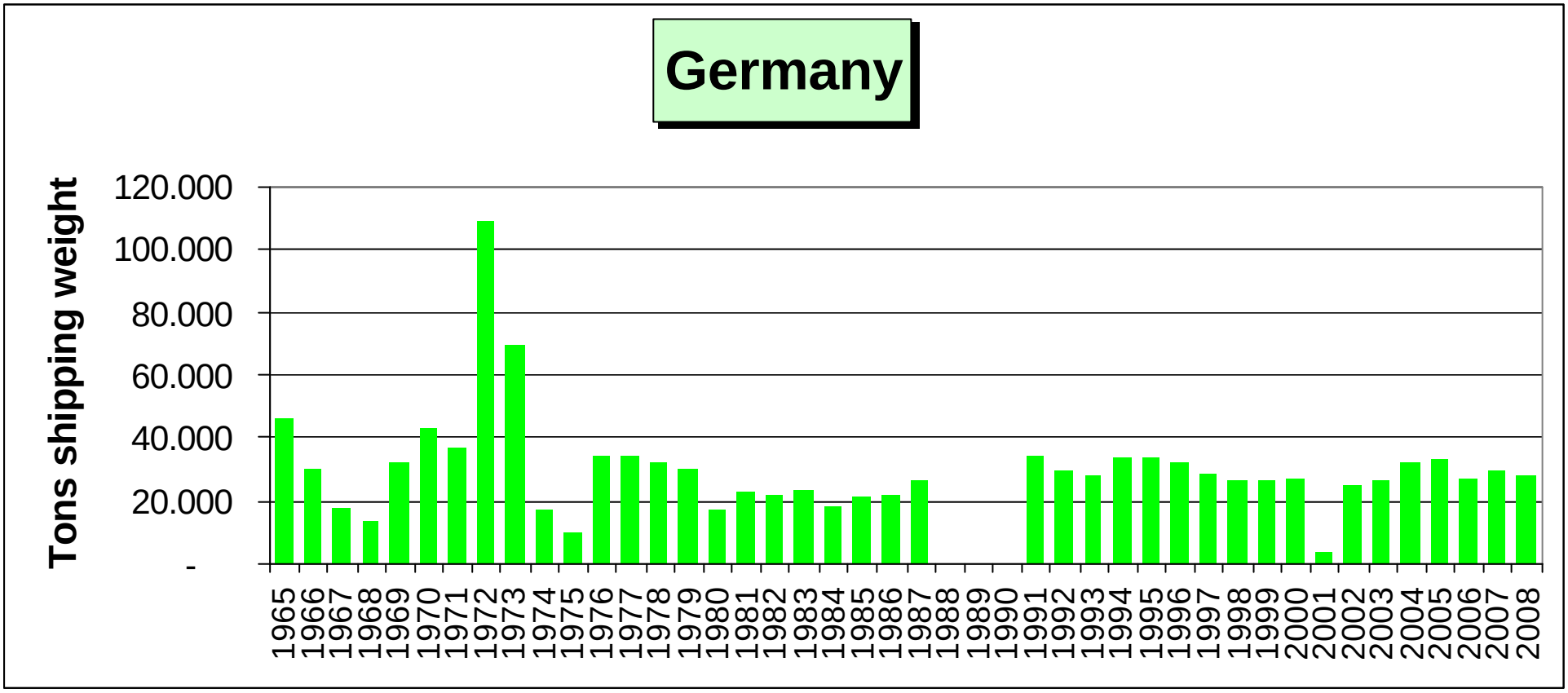


Figure 2. Deboned beef exportation from Argentina to Germany. Years 1965 -2008. Figures are based on data found at the former Argentine National Meat Board archive and the current Argentine National Directorate of Agrifood Market, SAGPyA, statistic series.

(C. Otaño, Personal Communication)

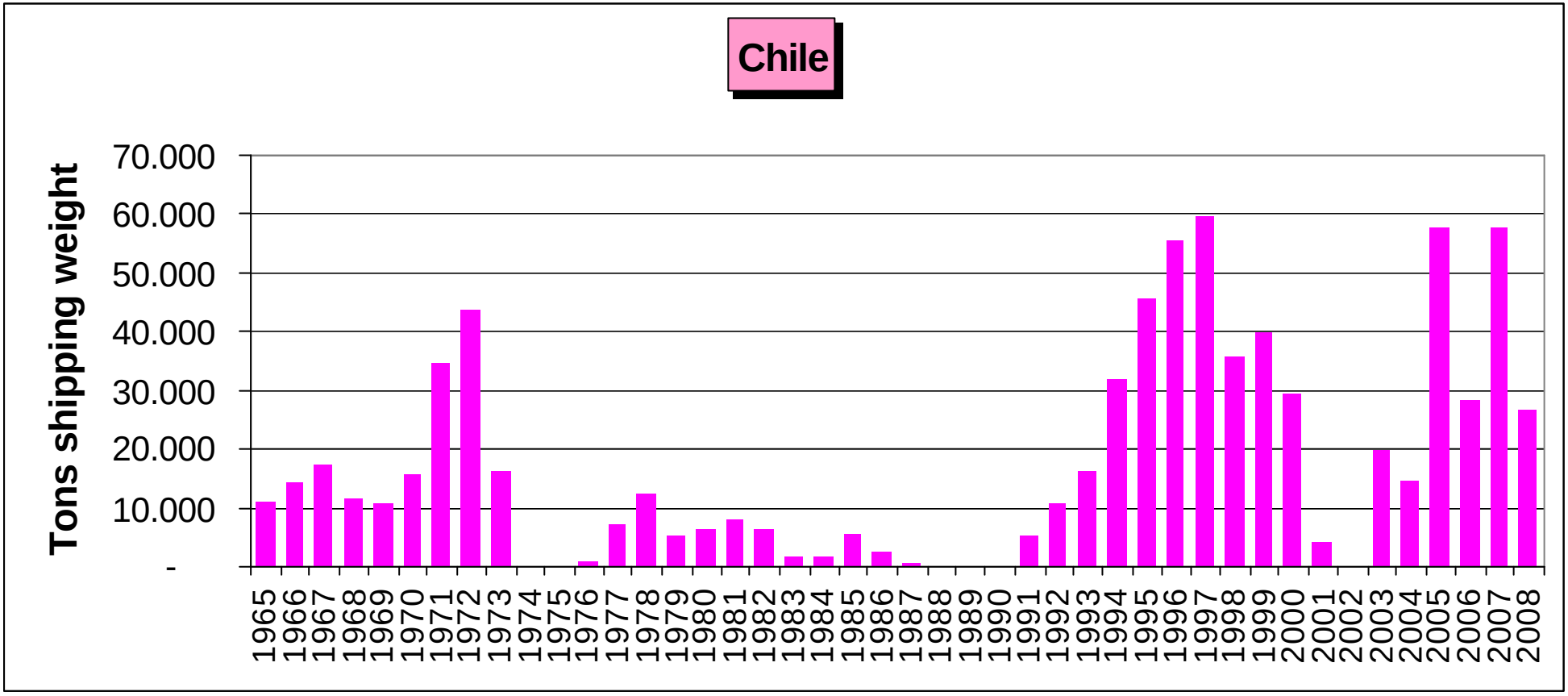


Figure 3. Deboned beef exportation from Argentina to Chile. Years 1965 -2008. Figures are based on data found at the former Argentine National Meat Board archive and the current Argentine National Directorate of Agrifood Market, SAGPyA, statistic series.

(C. Otaño, Personal Communication)

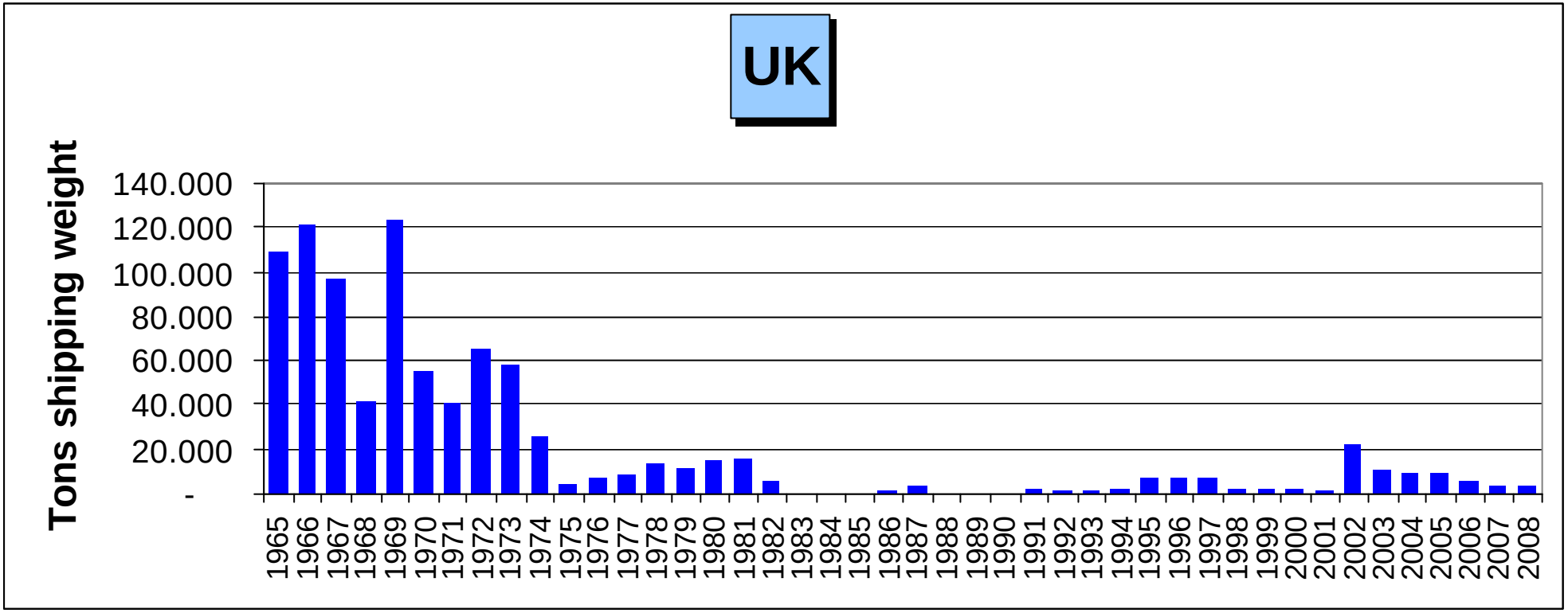


Figure 4. Deboned beef exportation from Argentina to the UK. Years 1965 -2008. Figures are based on data found at the former Argentine National Meat Board archive and the current Argentine National Directorate of Agrifood Market, SAGPyA, statistic series.

(C. Otaño, Personal Communication)

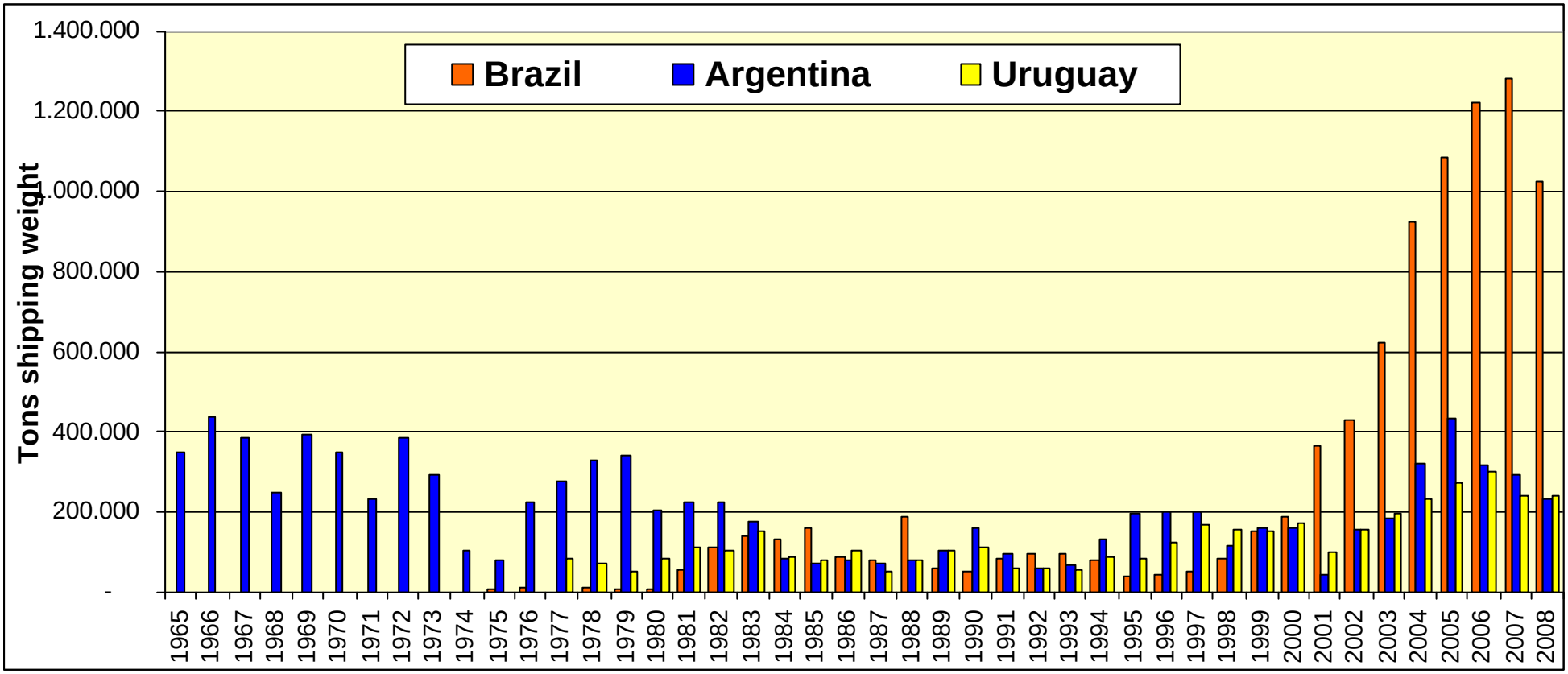


Figure 5. Deboned beef exportation from Argentina, Brazil and Uruguay. Years 1965-2008. Figures are based on data provided by the Argentine National Directorate of Agrifood Market, SAGPyA. (C. Otaño, Personal Communication)

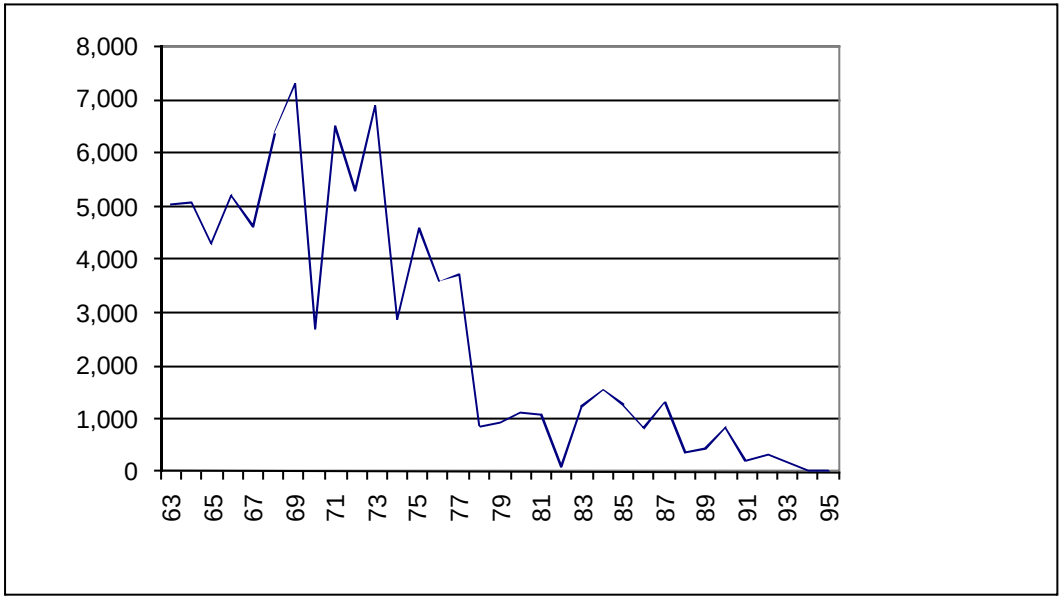


Figure 6. Argentina, FMD Reported Outbreaks. Between years 1963 and 1995. Figures are based on data provided by the Argentine National Directorate of Animal Health, SENASA. (Dillon, J., Personal Communication).

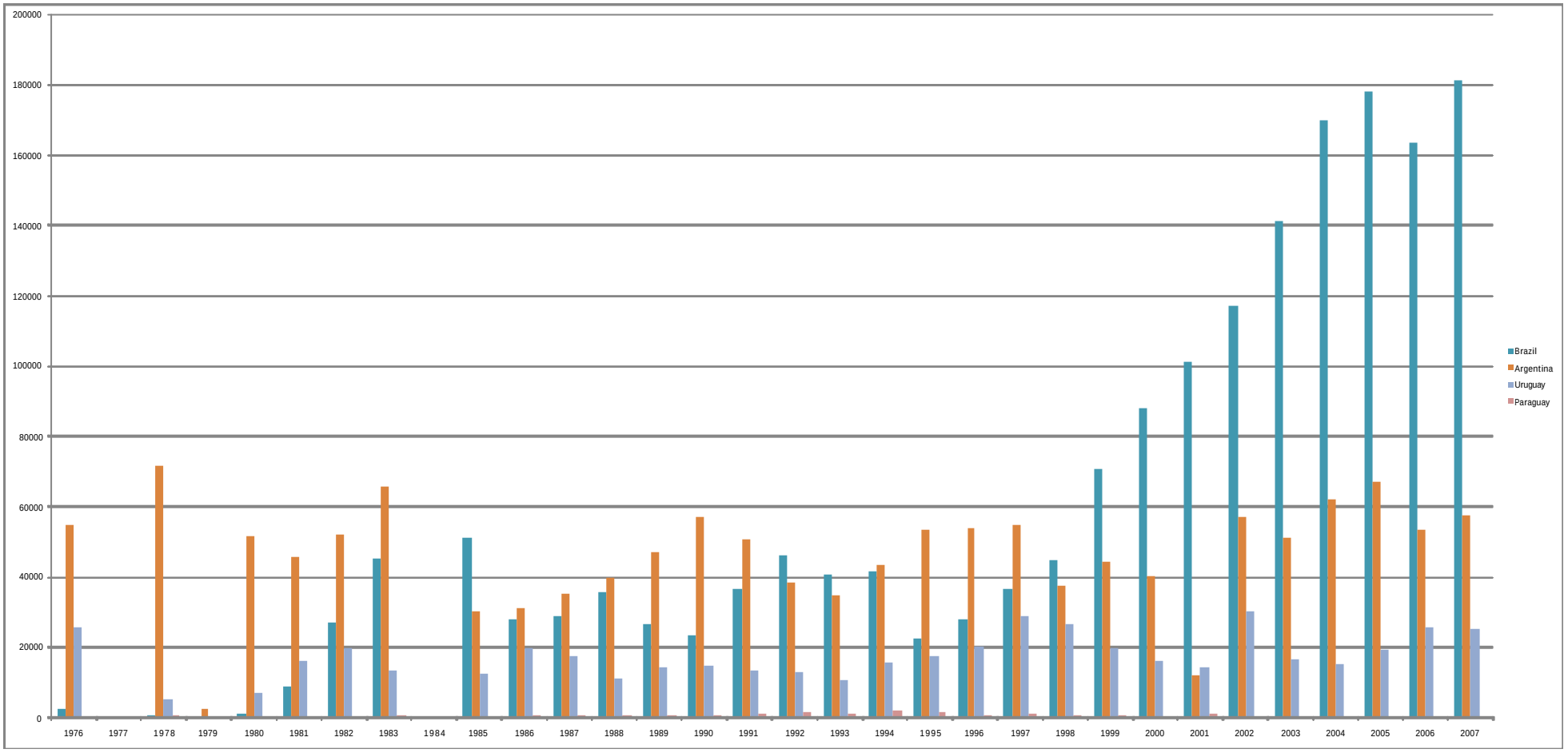
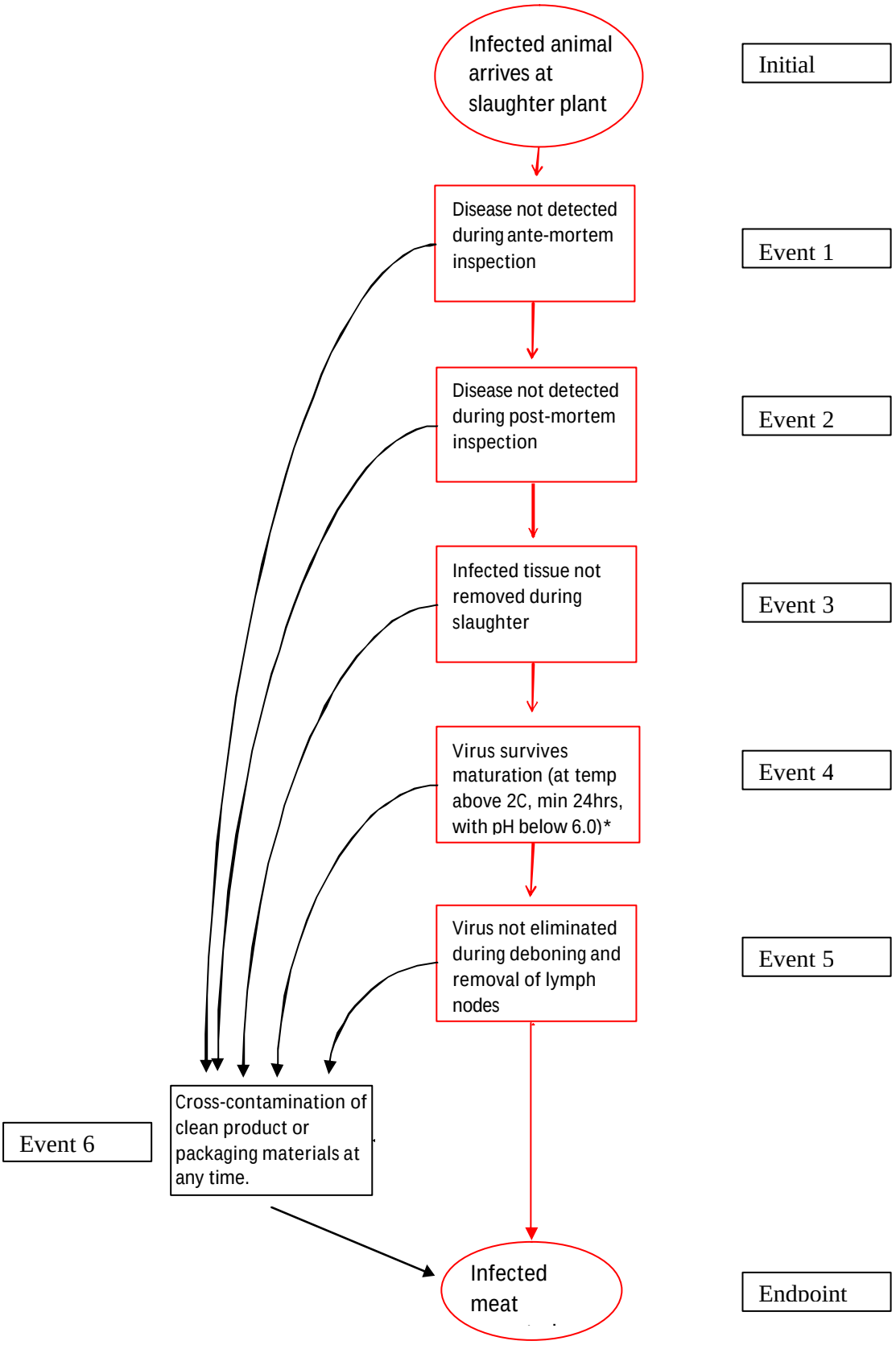


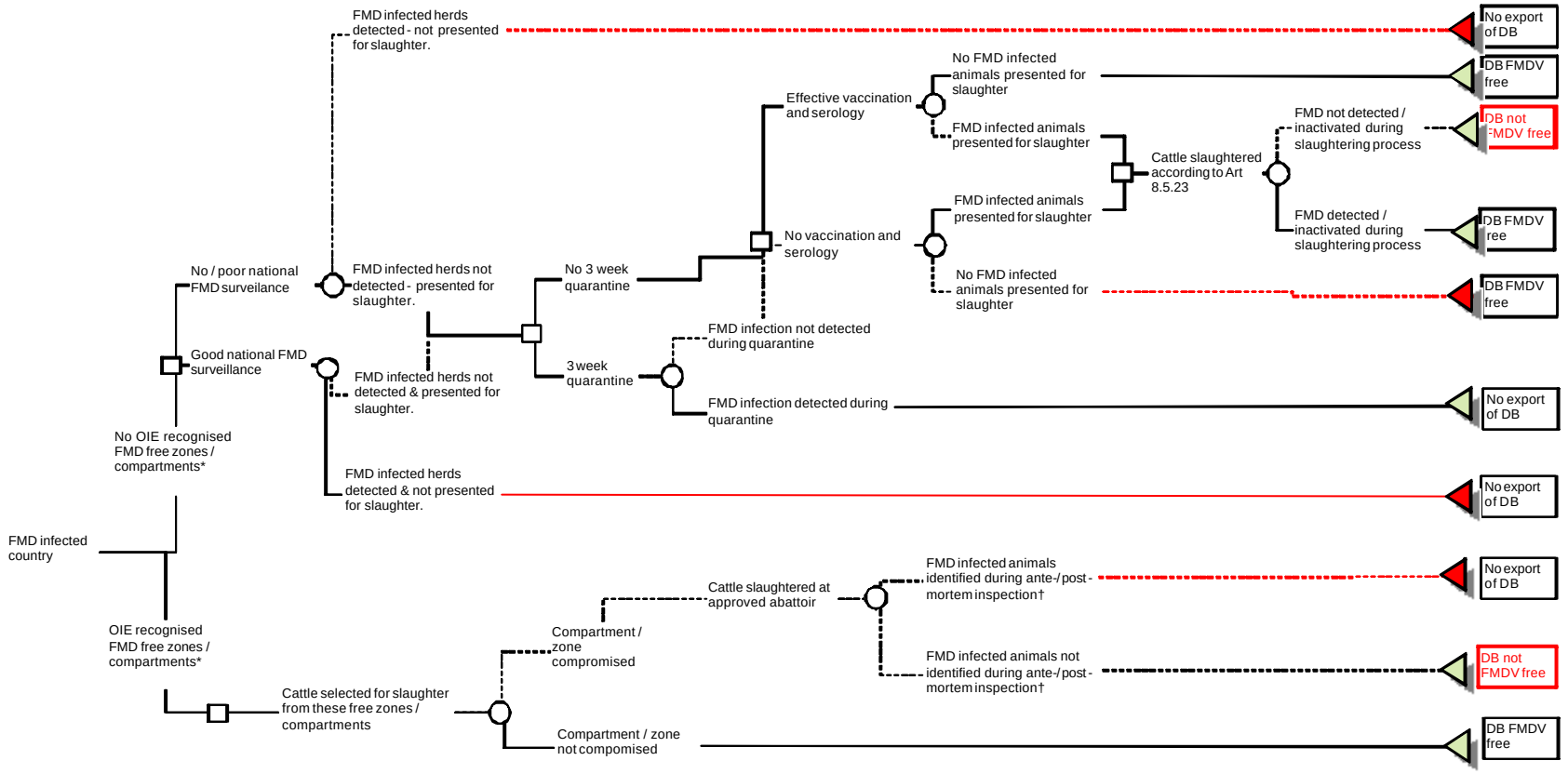
Figure 7. Fresh deboned beef imports into the European Union, 1976-2007.
Units are tons. Data not found for 1977 and 1984. 1976 to 1987 figures are based on carcase weight equivalent figures found in the Meat and Livestock Commission (now AHDB)'s archive. They have been converted to a boneless weight to enable comparison to be made with the 1988-2008 series (Battho H, Personal Communication).

Fig 8: Risk Assessment Scenario Tree at Slaughterhouse



*According to standards in Article 8.5.23 of Code

Fig 9. Scenarios for safe preparation and export of deboned beef



*Recommedations for FMD free compartments still being developed. Assume that the same recommendations as for free zones, will apply for trade in fresh meat.

†The only recommendation for the slaughtering process for cattle from FMD free zones. Art 8.5.20 (without vaccination) & Art 8.5.21 (with vaccination).

lower probability pathways

decision node

chance node

outcome node

DB deboned beef

Annex XLI (contd)

Item	Annex	Chapter	Title	Provided for comments	GS78
1	III	11.4. 11.10. 12.4. 12.12. 12.13. 15.2. 15.6.	Bovine cysticercosis Dermatophilosis Epizootic lymphangitis Horse mange Horse pox Atrophic rhinitis of swine Teschovirus encephalomyelitis	Sep09	A
2	IV	5.6.	Glossary Border posts and quarantine station in the importing country	Sep09	A
3	V	1.2.	Criteria for listing disease		A
4	VI	1.4.	Animal health surveillance	Sep09	A
5	VII	1.5.	Surveillance for arthropod vectors of animal disease	Sep09	A
6	VIII	1.6.	Status for OIE listed diseases	Sep09	A
7	IX	2.1.	Import risk analysis	Sep09	A
8	X	3.1. 3.2.	Veterinary services Evaluation of veterinary services	Sep09	A
9	XI	4.2.	Design and implementation of systems to achieve animal traceability	Sep09	A
10	XII	4.3. 4.4.	Zoning and compartmentalisation Application of compartmentalisation	Sep09	A
11	XIII	4.5. (> 4.6.) 4.6. (>4.5.) 4.7. 4.8.	Collection and processing of bovine, small ruminant and porcine semen General hygiene in semen collection and processing centres Collection and processing of in vivo derived embryos of livestock and horses Collection and processing of in vitro produced embryos/oocytes from livestock and horses	Sep09	A
		4.10.	Collection and processing of laboratory rodent and rabbit embryos/ova	Sep08 /Mar&Sep09	A
12	XIV	4.12.	Disposal of dead animals		A
13	XV	5.1. 5.2.	General obligations related to certification Certification procedures	Sep09	A
14	XVI	6.3.	Control of hazards of animal health and public health importance in animal feed	Sep09	A
15		6.4.	Biosecurity procedures in poultry production	Sep09	E
	XVII	6.5. 6.6.	Prevention, detection and control of *Salmonella* in poultry *Salmonella* enteritidis and *Salmonella* typhimurium in poultry	Sep09	A
16	XVIII	6.7.	Introduction to the recommendations for controlling antimicrobial resistance	Sep09	A
17	XIX	new	Use of animals in research and education	Mar&Sep09	A
		7.3. 7.4. 7.5. 7.6. 7.7.	Transport of animals by land Transport of animals by air Slaughter of animals Killing of animals for disease control purposes Guidelines on stray dog population control	Sep09	A
18	XX	8.1.	Anthrax	Mar&Sep09	A
19	XXI	8.2.	Aujeszky's disease	Sep09	A
20	XXII	8.3.	Bluetongue	Sep09	A
21	XXIII	8.5.	Foot and mouth disease	Mar&Sep09	A

Annex XLI (contd)

22	XXIV	8.11.	Rift Valley fever	Sep09	A
23	XXV	8.16.	West Nile fever	Sep09	A
24	XXVI	10.4.	Avian influenza	Sep09	A
25	XXVII	10.13.	Newcastle disease	Sep09	A
26	XXVIII	11.6.	Bovine spongiform encephalopathy	Sep09	A
27	XXIX	11.7. 11.8.	Bovine tuberculosis Bovine tuberculosis of farmed cervidae	Sep09	A
28	XXX	11.9.	Contagious bovine pleuropneumonia	Sep09	A
29	XXXI	11.11.	Enzootic bovine leukosis	Sep09	A
30	XXXII	11.13.	Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis	Sep09	A
31	XXXIII	11.14.	Lumpy skin disease		A
32	XXXIV	12.7. 12.10.	Equine influenza Equine viral arteritis	Sep09	A
33	XXXV	14.9.	Scrapie	Sep09	A
34	XXXVI	15.3.	Classical swine fever	Sep09	A
35		new	Control of hazards of animal health and public health importance in heat treated pet food	Sep09	E
36		8.9.	Paratuberculosis		E
37		8.10.	Rabies		E
38		8.15.	Vesicular stomatitis		D
39		9.1. 9.2. 9.3. 9.4. 9.5. 9.6.	Acarapisosis of honey bees American foulbrood of honey bees European foulbrood of honey bees Small hive beetle infestation (*Aethina tumida*) *Tropilaelaps* infestation of honey bees Varroosis of honey bees		E
40		11.3.	Bovine brucellosis		E
41		15.5.	Swine vesicular disease	Mar09	E
42			Porcine Reproductive and Respiratory Syndrome		E
43		new	Communications	Sep08/09	E

A: for adoption at 78GS, E: under experts consultation (ad hoc Group/SCAD/BSC etc.), D: deferred at Mar10

List of abbreviations	
APFSWG	Animal Production Food Safety Working Group
AWWG	Animal Welfare Working Group
CAC	Codex Alimentarius Commission
CISA	Comité Interamericano de Sanidad Avícola
CVP	Comité Veterinario Permanente del CONOSUR
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
HPNAI	highly pathogenic notifiable avian influenza
IBR/IPV	infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis
ICFAW	International Coalition for Farm Animal Welfare
IETS	International Embryo Transfer Society
NAI	notifiable avian influenza
NSP	non structural proteins
OIRSA	Organismo Internacional Regional de Sanidad Agropecuaria
PPR	peste des petits ruminants
PRRS	porcine reproductive and respiratory syndrome
SCAD	Scientific Commission for Animal Diseases
USA	United States of America
VS	Veterinary Services
WHO	World Health Organization