a) Evaluation of the request from three Member Countries for the establishment of a zone free from FMD where vaccination is not practised

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of three Member Countries for the establishment of an FMD free zone where vaccination is not practised. The Commission determined that the following zones fulfilled the conditions to be considered as FMD free zone without vaccination in accordance with Article 8.5.4. of the *Terrestrial Code:*

- The summer pasture zone in the province of San Juan in Argentina;
- The regions of Lima, Lambayeque, La Libertad, Ancash and parts of Piura and Cajamarca in Peru, with the understanding that this new zone would be merged to the existing zone as recognised in Resolution No. 14 adopted at the 80th General Session, to constitute a single free zone where vaccination is not practised.

The application of the third Member Country was not approved by the Commission and the dossier was referred back to the applicant Member Country, inviting the country to fully observe the provisions in Article 8.5.4.

Two members of the Commission excused themselves from the meeting during the discussions on the applications for FMD disease status of their respective home countries.

b) Evaluation of the request from three Member Countries for the establishment of a zone free from FMD where vaccination is practised

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of three Member Countries for the establishment of a FMD free zone where vaccination is practised. The Commission determined that the following zones fulfilled the conditions to be considered FMD free zone with vaccination in accordance with Article 8.5.5. of the *Terrestrial Code:*

- The regions of Chaco and part of Valles in Bolivia;
- The regions of Tumbes and parts of Piura and Cajamarca in Peru.

In the case of the third application, the Commission, after a meeting with a Delegation from the applicant Member Country, decided, in line with Resolution 25 of the 80th General Session, to request the Director General to mandate an expert mission to the country to enable the Commission to make an informed decision, taking into account the findings of the mission.

c) Evaluation of the request from two Member Countries for the endorsement of their official control programme for FMD

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of two Member Countries for the endorsement of their official control programme for FMD. The Commission determined that the official control programme of Bolivia fulfilled the conditions to be endorsed by the OIE in accordance with Article 8.5.48. of the *Terrestrial Code.* The application of the other Member Country was not approved by the Commission and the dossier was referred back to the applicant Member Country, inviting the country to fully observe the provisions in Article 8.5.48.

The endorsed report is attached as Annex 13.

3.12. *Ad hoc* Group on Peste des petits ruminants (PPR): 27-29 November 2012

The Commission noted the need of Member Countries in having the *Terrestrial Code* chapter on PPR revised to provide for official disease status recognition as well as for a Global Control Strategy for PPR. The development of the Global Control Strategy would be coordinated by the Working Group set up under GF-TADs[3] for FMD. In addition, the Commission was informed of the Bill & Melinda Gates' Foundation project to establish a pilot protocol for different vaccination strategies, establishing a PPR vaccine bank and strengthening the vaccine quality control system in West Africa.

The main isues discussed in amending the *Terrestrial Code* chapter included the questionnaire for official disease status recognition and the relevance of free status recognition with the involvement of wildlife for PPR. The Commission noted that there was published scientific evidence that suggested that wildlife did not play a significant role in maintaining PPR infection. However, the *ad hoc* Group had indicated that sampling animals other than the target population (domestic and captive wild sheep and goats) could be useful for sentinel surveillance purposes. The Commission requested the *ad hoc* Group by electronic consultation to clarify what actions should be taken when positives were found in wildlife in a free country or zone.

The Commission harmonised the amended chapter with other disease specific chapters in the *Terrestrial Code* and proposed several amendments. The main additions were in relation to Article 14.8.3 (PPR free country or zone), where the Commission included a provision for applicant countries to submit evidence of the system that would prevent the entry of the virus into the proposed free country or zone; and the specification that a containment zone does not follow the recovery pathway, since once the outbreaks had been resolved the restrictions on the containment zone would be lifted.

Two members of the *ad hoc* Group had also been responsible for the revision of the *Terrestrial Manual* chapter on PPR. The *ad hoc* Group provided comments on the revision of the requirements for vaccines and vaccination. The Commission recommended that this information was shared with the Biological Standards Commission.

The Scientific Commission endorsed the report of the *ad hoc* Group and discussed the revised version of Chapter 14.8 on PPR and accompanying questionnaires for official disease status. These documents were forwarded to the Code Commission for further processing of the draft revised chapters.

The endorsed report is attached as Annex 14.

3.13. Working Group on Wildlife Diseases: 12-15 November 2012

The Chairperson of the Working Group on Wildlife Diseases (hereafter the Working Group), provided an overview to the Commission on the recent activities of the Working Group as reflected in the report of the meeting held in November 2012 and to discuss future work of the Working Group. The Working Group recognised and appreciated the value of having a member of the Commission in the Working Group and pointed out the importance of maintaining this presence in future meetings. The Commission was also informed of the actions planned by some members of the Working Group for World Rabies Day 2013, in view of the implications of rabies on wildlife.

The Commission discussed the report of the Working Group and noted with appreciation the excellent work it had done in support of the objectives of the Commission and the OIE. The Commission supported the involvement of members of the Working Group in the establishment of an OFFLU group focused on influenzas in wildlife. The Commission also supported the proposal to dedicate a day, at the next meetings of the Working Group, to a brainstorming session with representatives from a range of relevant international organisations engaged in wildlife, biodiversity management and health. The

[3] OIE/FAO Global Framework for the progressive control of Transboundary Animal Diseases

Commission noted the reference to and importance of Appendix III of the report of meeting of the *ad hoc* Group on Wildlife Disease Notification from July 2008 providing the basis for the current version of the list of pathogens in wildlife for voluntary reporting. The Commission suggested that the OIE provide easy access to this Appendix III and the current list on the OIE website. The Commission requested the Working Group to address, at its next meeting in November 2013, Member Country comments on relevant articles of draft disease-specific chapters in relation to the implication of wildlife and surveillance (e.g. Article 1.4.6., update of Chapter 14.8. on PPR, revision of Chapter 15.2. on CSF of the *Terrestrial Code*). The Commission further requested the Working Group to explore possible ways for the OIE to address the challenges of the management of Trans-Frontier Conservation Areas related to disease status and animal movements, and to provide its view to the Commission.

The Commission was informed by the Scientific and Technical Department on the training of National Focal Points for Wildlife. It was indicated that the third cycle of this training would start in November 2013 and that the focus could be on risk assessment, *WAHIS-Wild* and validation of diagnostic tests. This could provide an opportunity to Member Countries to develop more specific priority-setting approaches based on needs and concerns in order to provide a better focus in their surveillance activities.

The report of the Working Group was adopted (81 SG/13 GT)

■ Programme and priorities

The following *ad hoc* Groups were identified as pending work from the Commission and as potential new work:

3.14. *Ad hoc* Group on Glanders

The Commission recommended that an *ad hoc* Group be convened during the second half of 2013, if there was sufficient justification and rationale for including Glanders in the list of diseases for official status recognition. In this new work, both experts on Glanders diagnostics and control as well as those from the *ad hoc* Group on the temporary movements of high health, high performance horses would be consulted by the OIE. The Commission emphasised the importance of timely communication and consultation between several *ad hoc* Groups and Specialist Commissions on this cross-over subject.

3.15. *Ad hoc* Group on Rift Valley Fever (RVF): tentative date 4-6 June 2013

The Commission was informed about the consultation process with experts on the justification for an update of the RVF *Terrestrial Code* chapter. Four experts had provided a consolidated report with their arguments, highlighting the reasons why an update to the *Terrestrial Code* chapter was recommended. The experts also pointed out the inconsistency amongst *Terrestrial Code* chapters of several vector-borne diseases and suggested that when making a revision, achieving harmonisation between these chapters also be considered.

The Commission took note of the proceedings from the RVF inter-regional conference for East Africa and Middle East, held in November 2012 in Mombasa, which had just been finalised and which contained important information, also worth considering by an *ad hoc* Group to be set up for RVF.

3.16. *Ad hoc* Group on International Horse Movements: 24-26 April 2013

The Commission was informed on the development of work in relation to equine diseases relevant to the 'temporary movement of "high performance, high health" horse subpopulations. The events/activities that had taken place since the first joint OIE/FEI conference in Guadalajara in 2011 were summarised. These activities now culminated into a 3-year Collaboration Agreement between OIE and FEI under which funds would be available to carry out a 3-year work programme.

While the work was to be guided by an *ad hoc* Group to meet for the first time on 24 – 26 April this *ad hoc* Group should report to this Commission as well as to the Code and Biological Standards Commissions.

Furthermore, the Commission was informed that the requested baseline document on "Biosecurity Guidelines" and a "Definition" for these particular "high health, high performance" horses had been produced in close collaboration with a consultant and this would form the basis of work for the first meeting of the *ad hoc* Group. It was also noted that the 3-year agreement had some funding for selection, research and development on diagnostic tests and vaccines for equine diseases.

The draft Terms of Reference and provisional agenda for the *ad hoc* Group meeting were endorsed by the Commission.

3.17. *Ad hoc* Group on Harmonisation of the *Terrestrial Code* Chapters on Infection with Bluetongue Virus, Infection with African Horse Sickness Virus and Infection with Epizootic Haemorrhagic Disease Virus: tentative dates 20-22 August 2013

The Commission reiterated its previous decision on the need to convene an *ad hoc* Group to harmonise all three chapters on vector borne diseases caused by Orbivirus and transmitted by Culicoides, taking into consideration Member Country comments, the latest revised chapters endorsed by the Commission for 'case' and 'infection' definitions and also the *Terrestrial Code* chapter on vector surveillance.

The draft Terms of Reference and provisional agenda for the *ad hoc* Group meeting were endorsed by the Commission.

3.18. *Ad hoc* Group on Tuberculosis: tentative dates 9-11 April 2013

The Commission noted the need to combine the *Terrestrial Code* chapters on Tuberculosis into a single chapter in view of the pathogen-oriented approach followed in the *Terrestrial Code*. The Commission discussed this matter with the Code Commission and agreed that they would wait Member Country comments on the revised chapter on Brucellosis before starting to harmonise the approaches. Nevertheless, the Commission recommended that an *ad hoc* Group be convened to discuss some requests by the Biological Standards Commission and by the Code Commission on the latest scientific information in relation to gamma interferon tests as well as on the development of DIVA tests given that vaccination for tuberculosis was currently not an option considered.

The Code Commission and the Scientific Commission agreed that representatives from both Commissions should be present at this *ad hoc* Group meeting.

The draft Terms of Reference and provisional agenda for the *ad hoc* Group meeting were endorsed by the Commission.

3.19. *Ad hoc* Group on PRRS: tentative dates 9-11 July 2013

The Commission had requested an expert opinion at its last meeting to take a scientifically sound decision to recommend the development of a *Terrestrial Code* chapter on PRRS as had been requested by Member Countries. Following the opinion of experts that there was now sufficient scientific knowledge to allow the drafting of a *Terrestrial Code* chapter on PRRS, the Commission recommended that an *ad hoc* Group be convened.

The draft Terms of Reference and provisional agenda for the *ad hoc* Group meeting were endorsed by the Commission.

4. Official disease status

4.1. Brazil's BSE Risk Status

The Commission was advised that Brazil, which had been granted a negligible BSE risk status in May 2012, had detected the first case of BSE in its territory and submitted the immediate notification to the OIE in December 2012. It was also noted that the OIE had requested Brazil to provide all relevant information to the Commission at the current meeting.

The Commission was informed by a Delegation from Brazil on the sequence of events leading to the delay in the notification to the OIE of the first case of BSE in their country. The Commission decided, in accordance with the standards of the OIE *Terrestrial Code*, not to withdraw the "negligible risk" status of Brazil.

The Commission also affirmed that the identification of this single case of BSE was not putting the country's or its trading partners' animal and public health at risk, notably because the animal was destroyed and no parts of it had entered the food or feed chain.

The Commission, however, noted with concern that there had been a considerable delay before Brazil sent the clinical samples for a confirmatory diagnosis to an OIE Reference Laboratory. The Commission therefore agreed that it needed more detailed information on the procedures in place for processing samples and the improvement of the surveillance system in the country so as to further monitor the continuous compliance by Brazil with the relevant provisions of the *Terrestrial Code* to be respected for the sustainable maintenance of its official status for BSE.

At its next meeting in September 2013 the Commission should again assess the additional information to be provided by Brazil.

4.2. Evaluation of the request from a Member Country for the establishment of a zone free from FMD where vaccination is not practised

The Commission evaluated an application from a Member Country that was received after the meeting of the *ad hoc* Group on evaluation of FMD official disease status had taken place. After discussions with the Director General, the Commission decided to apply the provisions of Resolution No. 25 adopted at the 80th General Session - as part of the evaluation of the Member Country dossier - and requested the Director General to mandate an expert mission to the country to enable the Commission to make an informed decision, taking into account the findings of the mission.

4.3. Revision of the questionnaires (harmonisation between country and zone) for the annual reconfirmation of disease status

The Commission endorsed the revision of the forms for the annual reconfirmation for FMD and CBPP free status as proposed by the Scientific and Technical Department. The wording was harmonised between the diseases, and between the forms for free zones and free countries.

4.4. Guidance on preliminary evaluations made by the secretariat and the experts evaluating Member Country applications

The Commission agreed that the Scientific and Technical Department should document the good practices already implemented by some *ad hoc* Groups for the evaluation of Member Countries disease status into a standard generic procedure so that such practices be systematically followed. Such procedure would support the experts from *ad hoc* Groups in their task, and improve the transparency and objectivity in the work of the OIE in this area.

5. Matters of interest for consideration

5.1. Rinderpest

The Commission was provided with the latest information on the rinderpest post-eradication activities. The second meeting of the Joint OIE/FAO Advisory Committee on Rinderpest had taken place in October 2012 and a further meeting was scheduled for February 2013. The Committee was working to develop guidelines to ensure safe destruction of rinderpest virus (RPV) containing material and criteria to evaluate research proposals that involve the manipulation of RPV containing material. For the evaluation to take place, laboratories and other institutions should submit a completed application form to the Committee. On the advice of this evaluation, FAO and OIE would have to reach a decision on whether to authorise the research. Once the research application criteria had been in place, the moratorium of RPV research would be lifted and the Committee would evaluate each application based on the criteria.

Furthermore, the Committee was also developing criteria to evaluate applications from laboratories and other institutions wishing to host an approved facility in which RPV containing material would be stored. The application forms for different categories of containment facilities were under development.

The Committee would also provide its view on an international contingency plan as the tool through which the different players interact; such a plan should be consistent with the provisions of the *Terrestrial Code*. The Commission wished to be kept informed of the progress being made by the Committee.

Finally the Commission was informed about advocacy activities and funding related to rinderpest.

5.2. Opinion on the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents: feedback from experts on Leptospira serovars candidates for listing and on the comments received by a Member Country

The Commission decided to refrain from providing an opinion on which diseases should remain listed since it was clear from the extensive comments (some of them conflicting) from Member Countries that this issue needed to be discussed thoroughly before identifying a way forward.

5.3. Emerging diseases

Some of the recent examples of emerging diseases had identified the need to revise the definition of "emerging diseases" as it appeared in the Glossary of the *Terrestrial Code* especially in relation to the duration of time under which a disease would remain classified as "emergent" and to the notification obligations of Member Countries. An internal technical group constituted at the OIE Headquarters had preliminary discussions on this issue. Its preliminary findings and proposals, while still under debate, were presented to the Commission.

The Commission was of the opinion that a listed disease should be also considered as emerging when it appeared in a new geographical area– for example, the occurrence of BTV8 in Europe. At the same time, the Commission took note of the fact that unjustified barriers to trade could sometimes be enforced, as result of notification to the OIE. In view of this, the Commission proposed that instead of stating that the definition of emerging diseases would exclude listed diseases, some wording is added to the definition to indicate that either the definition excluded listed diseases for notification purposes, or that listed diseases were covered elsewhere.

The Head of the OIE Animal Health Information Department joined the Commission meeting. He delivered a presentation to indicate that, for the majority of OIE listed diseases, a case definition had not been defined in the *Terrestrial Code*. He suggested that all disease specific chapters in the *Terrestrial Code* be harmonised to include, in the first article, the name of the pathogenic agent, the diagnostic procedure which determine a case on the basis of the *Terrestrial Manual*, and the conditions for notification (differentiating between the species that would have an impact on trade for that particular disease from the species that would not).

The Commission supported the proposal for a change in the first article of the disease chapters in the *Terrestrial Code* and also indicated that the chapters revised during the current meeting by the Commission had been amended accordingly in relation to case and infection definitions.

5.4. Decision on the publication of a paper on the background information related to bee diseases

The Code Commission requested the Scientific Commission to consider the publication of the paper 'Background to the *Terrestrial Code* chapters on bee diseases' that had been presented to the Code Commission as an annex to the report of the meeting of the *ad hoc* Group on Diseases of Honey Bees endorsed by the Scientific Commission at its last meeting. The paper contained very useful background information but its format and nature was not appropriate for inclusion in the *Terrestrial Code*. The Scientific Commission recommended that the paper be published in the OIE website, as a stand-alone document, under "Our scientific expertise" once the chapters on bee diseases had been adopted by the World Assembly of Delegates.

5.5. Schmallenberg virus in semen

At the recent findings on the infectious Schmallenberg virus and its genome detection in cattle semen in experimental studies, the OIE had contacted the experts of the *ad hoc* Group on Schmallenberg virus and requested that the OIE Technical Factsheet be updated. There was some debate on the need to keep the appendix of the technical factsheet, considering that on-going studies seemed to demonstrate a low impact of the disease and that the endemicity of the situation had led to the discontinuation of notification to the OIE by countries that previously detected the infection. The Commission considered that the information in the appendix was still needed, especially given new research findings that could update the information about Schmallenberg virus. The Commission agreed on the revised technical factsheet.

6. OIE Collaborating Centres

6.1. Collaborating Centre in Cuba

At its previous meeting, the Commission had requested the applicant country to provide a summary of proposed activities and services with clear objectives and had suggested a suitable title to the proposed Collaborating Centre that would better reflect the expertise described in the dossier.

The Commission examined the re-submitted dossier and decided that, for harmonisation across all three OIE official languages, the most appropriate title should be "Collaborating Centre for the Reduction of the Risk of Disasters in Animal Health".

The Commission agreed to confirm the designation of the Collaborating Centre, which had been approved on a temporary basis, with the recommendation that the Centre also manage other disasters that would have an impact on the health and welfare of animals and not only those caused by pathogenic agents.

6.2. Collaborating Centre in New Zealand

The Commission evaluated a new application for a Collaborating Centre for Veterinary Epidemiology and Public Health in the Asia-Pacific region. The Commission recommended that the New Zealand centre be recognised as "Collaborating Centre for Veterinary Epidemiology and Public Health", noting that the mandate of a Collaborating Centre was global and not limited to a specific region.

7. Liaison with other Commissions

7.1. Issues with the Terrestrial Animal Health Commission

A joint meeting between the President and a Vice-President of the Code Commission with the Scientific Commission took place on Friday 8 February 2013. The minutes of the joint meeting will be published in the Code Commission report. Below is a summary of the main points discussed:

a) Rabies: new *Terrestrial Code* article proposed by the Code Commission

Consistent with the OIE, WHO and FAO's efforts to work on a global strategy for rabies control in collaboration with other key partners, the Code Commission had revisited the *Terrestrial Code* chapter on Rabies and had proposed the re-insertion of an article that would allow countries to self-declare freedom in dog populations.

The Commission noted that the *ad hoc* Group on Rabies that developed the amended chapter on rabies for the *Terrestrial Code* in 2011 had proposed a similar article and suggested to the Code Commission that the wording proposed by the *ad hoc* Group be used for this article. The Code Commission agreed to this proposal after a joint discussion on the matter, with the condition that the wording should clearly indicate that the provision was for public health purposes and not for trade purposes.

The Director General of the OIE suggested that the agreed article between the two Commissions be proposed for adoption at the forthcoming General Session in May 2

b) *Terrestrial Code* chapters with Member Country comments

The Commission received from the Code Commission the Member Country comments on *Terrestrial Code* Chapters 6.9 (responsible and prudent use of antimicrobial agents), 8.3 (Bluetongue), 8.12 (Rinderpest), 9.1-9.6 (Bee diseases), and the draft chapter on Epizootic Haemorrhagic Disease. The Commission provided its opinion to the Member Country comments and forwarded the revised chapters back to the Code Commission, noting that some of the comments on Bluetongue and Epizootic Haemorrhagic Diseases would be dealt with at a later stage by the *ad hoc* Group on Harmonisation of African Horse Sickness, Bluetongue and Epizootic Haemorrhagic Diseases and would thus be revisited by the Commission at its next meeting in September 2013.

Regarding the comments on the chapters on bee diseases, views of the relevant *ad hoc* Group had been sought by correspondence. The main changes/replies to the comments were (1) to remove eggs from the safe commodities for American and European Foulbrood (chapters 9.2. and 9.3.) although it was highlighted that for American Foulbrood a risk analysis had been conducted by New Zealand concluding that eggs were safe (http://www.biosecurity.govt.nz/files/regs/imports/risk/honey-bee-genetic-material-ra.pdf) and that this position had also been supported by other Member Countries, (2) to propose a higher level of irradiation in the articles 7, 8 and 9 of the chapter on European Foulbrood (Chapter 9.3.) based on a scientific publication (Hornitzky MAZ [1994]). Commercial use of gamma radiation in the beekeeping industry. Bee World 75, 135-142), (3) to highlight that the different levels of irradiation for mites and beetles (chapters 9.4. to 9.6.) were based on the recommendations developed by the International Plant Protection Convention (IPPC): IPPC (2003) Guidelines for the use of irradiation as a phytosanitary measure, FAO, Rome, Publication No. 18. April 2003, and (4) to change the definition of varroosis (Chapter 9.6.) stating that varroosis is a disease caused by varroa mites and highlighting however the importance of viruses in the disease. The Commission endorsed the ad hoc Group changes to the chapter and forwarded it to the Code Commission.

The Commission did not have enough time to address the Member Country comments on antimicrobial agents and suggested that, in view of the importance of the issue for public health as well as of the forthcoming OIE Global Conference on Antimicrobial Resistance in March 2013, these comments be given the highest priority to be reviewed by the Code Commission and if an expert review was required to address any of them, the comments be forwarded to the President of the Scientific Commission for further circulation among relevant experts. Two clarifications on Chapter 6.9 of the *Terrestrial Code* required input from the experts. The proposals from the experts, endorsed by the President of the Scientific Commission, related to: a) the merging of sub-articles 1 (Marketing authorisation), 2 (Submission of data for the granting of the marketing authorisation) and 3 (Marketing authorisation approval) into a single sub-article called "Marketing authorisation" in Article 6.9.3 (Responsibilities of the Competent Authority); and b) changes to sub-article 1 of Article 6.9.8 (Responsibilities of animal feed manufacturers) based on Member Country comments.

c) Sharing of documents between Commissions

The Code Commission requested that the *ad hoc* Group meeting reports were shared between the Scientific and Technical Department and the International Trade Department of the OIE as soon as they were finalised and approved. The Scientific Commission requested that all of the Member Country comments of a scientific nature be shared between the International Trade Department and the Scientific and Technical Department as soon as they were received. The two Commissions agreed that, for traceability purposes, the Scientific Commission would provide the Code Commission with the revised chapters with the changes indicated in relation to the last version considered by the Code Commission (published in the Code Commission report with Code Commission changes included) in which the version (Scientific Commission meeting of month/year) would be specified.

To facilitate communication between the two Commissions on the work in progress, a summary table of the Commission decisions/actions relative to *Terrestrial Code* chapters was included in the Commission's report as Annex 15.

7.2. Issues with the Biological Standards Commission

The reports of the *ad hoc* Group meetings on PPR and AHS would be shared with the Biological Standards Commission as they contained information relevant to the work of that Commission. In addition, the Scientific Commission requested the Biological Standards Commission to kindly provide the latest scientific updates within its mandate on tuberculosis, Rift Valley Fever and glanders in view of the potential *ad hoc* Group meetings that would be convened in the near future.

8. Country missions of the Commission

The country visits of the Commission projected for the near future were prioritised. The mission on FMD control in the southern African region had been postponed several times and should thus be scheduled as a priority followed by missions related to pending country applications for official disease status.

9. Any other business

9.1. FAO intervention on Post Vaccination Monitoring (PVM) for FMD

Dr Samia Metwally, Animal Health Officer, FAO, was invited to this meeting to provide detailed information on the working group she had been leading on FMD Post Vaccination Monitoring (PVM), in which a number of virologists, diagnosticians, epidemiologists, statisticians and field veterinarians were being involved. Dr Metwally had been tasked to develop this work by the OIE/FAO FMD Reference Laboratory Network, in liaison with the OIE and to develop guidelines for PVM. At the last meeting of the Commission, it was recommended that an OIE *ad hoc* Group with nominees from both FAO and OIE be convened to assist in the production of the guidelines for PVM. However, since the last meeting of the Commission, the working group led by Dr Metwally had made a significant progress in the development of the guidelines, which were presented at the OIE/FAO FMD Reference Laboratories network meeting in Jerez, Spain, in October 2012. In this context, the Commission was requested to express an opinion on establishing an expert panel under the auspices of GF-TADs, instead of convening an OIE *ad hoc* Group.

Dr Metwally gave a presentation to the Commission in which she summarised the objectives of this initiative, its link to the Global FMD Control Strategy and explained the different parts of the outline of the Guidelines. She stated that a number of country contributions had already been received (e.g. China, India), others were expected (Kenya, SADC, Brazil) shortly and that the draft document was to be reviewed by an expert panel (i.e; GF-TADs expert group). This expert panel would be coordinated jointly by FAO and OIE, and would meet in April/May 2013. Ideally, the goal of reviewing the document should be attained with one single meeting. The Guidelines would then be validated through pilot implementation in countries and the document would be revised as necessary.

The Commission took note that the Belgium Institute was involved in the DISCONVAC project and that one of the project outputs was also a PVM guide that would be shared with the OIE and FAO. A synergy between the two initiatives was proposed.

The Commission requested to have an opinion on the list of experts that would participate in this initiative. Dr de Clercq would represent the Commission at the expert panel (i.e.GF-TADs meetings) on FMD-PVM.

9.2. Information on the global FMD situation by the OIE/FAO World Reference Laboratory for FMD

The Head of the Pirbright Institute's World Reference Laboratory (WRL) for FMD was invited to the meeting of the Commission to provide details on the latest advances in FMD control and to make a presentation on the FMD serotypes' worldwide distribution and trends. The need for different control strategies adapted to the regional needs and using tailored vaccines was highlighted. There had been increased activity of serotypes Asia 1 in the Middle East and SAT-2 in North Africa during the year 2012. A high quality of vaccines used against FMD was of paramount importance to achieve effective control.

A summary of the outcomes of the meeting of the FMD Reference Laboratory Network that had taken place back to back with the EU FMD meeting in October 2012 in Jerez, Spain was also provided. The Commission was informed that the Pirbright Institute had been designated as the global coordinating laboratory for the OIE/FAO Global Control Strategy for FMD as well as for laboratory testing training.

The Commission informed the representative of Pirbright on the FMD PVM work that would be carried out under GF-TADs and on the development of an OIE World Assembly Resolution on global data sharing for FMD, which would be presented at the 81st General Session as a follow up of the Global Conference on FMD Control held in Bangkok in 2012.

10. Adoption of the report

The Commission briefly reviewed the main decisions taken during the week to make sure that they were appropriately recorded in the report. The Commission agreed to circulate the draft report electronically for comments before adoption.

The next meeting of the Commission will be from 2 to 6 of September 2013.

.../Appendices

Annex 6

Original: English
November 2012

MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) RISK STATUS EVALUATION OF MEMBER COUNTRIES

Paris, 27 – 30 November 2012

A meeting of the *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk status evaluation of Member Countries (hereafter the Group) was held at the OIE Headquarters from 27 to 30 November 2012.

1. Opening

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department, welcomed the Group. Dr Miyagishima congratulated the Group for the important work made at its previous meeting in September 2012 to address the challenges faced by Member Countries with small cattle populations with respect to the current surveillance requirements in the *Terrestrial Animal Health Code* (*Terrestrial Code*). He thanked the Group for having considered every single option to address this subject in order to converge on the most scientific, feasible and realistic approach. He requested the Group to propose an amendment to the Chapter of the *Terrestrial Code* accordingly for consideration by the Scientific Commission for Animal Diseases (Scientific Commission) in February 2013.

Dr Miyagishima emphasised that the OIE process for granting official recognition of disease status was under scrutiny by the applicant Member Countries and other OIE partners. In accordance with the OIE Standard Operating Procedures (SOPs) governing official recognition of disease status, he recommended the Group to produce a detailed report in order to give clear understanding to the applicant Member Countries on possible information gaps and/or specific areas that should be addressed in the future. Dr Miyagishima acknowledged that the Group had always found a consensus in the past when evaluating applications. Should a consensus not be reached for a given dossier, the Group should record in its report all views and opinions with detailed rationale behind. Dr Miyagishima reminded the Group that the Scientific Commission was responsible to undertake, on behalf of the World Assembly of the OIE, the assessment of OIE Member Countries applications by considering the report of the Group, including analysis of the dossiers, findings and recommendations.

Dr Miyagishima also informed the Group that for this meeting the OIE had allowed a Member Country to dispatch its experts at the OIE Headquarters to clarify issues relating to the evaluation of its dossier in case the Group considered that a face-to-face interaction with the applicant Member Country would be necessary. In this respect, he reminded the Group that as a matter of principle, the presence of experts from applicant Member Countries at the OIE Headquarters was not actively sought and the request and provision of information through telecommunication was the approach preferred by the OIE. Nevertheless a physical meeting between the Group and the representatives of an applicant Member Country could be considered on a case by case basis, after consultation of the Director General of the OIE.

Finally, the Group was reminded of the standing OIE policy concerning declaration of interest and confidentiality of information statements, noting that the members of the Group had already signed and were bound by confidentiality undertaking. Dr Miyagishima invited experts who were in the situation of a potential conflict of interest to voluntarily withdraw from the discussion on specific dossiers in question.

2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group adopted its agenda of the meeting. Dr John Kellar was appointed Chair of the meeting and Dr Martial Plantady acted as rapporteur.

The agenda and list of participants are provided as Appendices I and II, respectively.

3. Review of current BSE Chapter of the Terrestrial Code to accommodate Member Countries with a small bovine population according to the conclusion reached at the September meeting

Based on the conclusion reached at its September 2012 meeting, the Group amended Article 11.5.22. of the *Terrestrial Code* in order to accommodate Member Countries with a small bovine population..

4. Evaluation of requests from Member Countries for the evaluation of BSE risk status

Experts of the Group, in pairs, had accepted to conduct a preliminary analysis of the dossiers of individual applicant Member Countries (as allocated by the OIE Headquarters) prior to the meeting. The experts presented their key findings to the plenary, which proceeded with in-depth discussion, dossier by dossier, on the applicant Member Country's compliance with the provisions on BSE risk status in the *Terrestrial Code*. Where necessary, messages were sent electronically to the applicants requesting missing information. All contacted Member Countries provided requested information to the Group in time. In addition, the Group held a face-to-face meeting with representatives of one applicant Member Country to seek clarification on a number of points.

4.1. Bulgaria

In February 2012 Bulgaria submitted a dossier seeking a 'controlled BSE risk' status and an update in October 2012. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

Points specifically noted by the Group were summarised in the following discussion.

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Bulgaria during the interval covered by the assessment was not negligible.

- *Risk of recycling and amplification of the BSE agent*

  The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in Bulgaria's cattle population during the interval covered by the assessment.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group determined that the awareness programme met the requirements of the *Terrestrial Code.*

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 1998 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code.*

- *Laboratory examination*

  The Group determined that the arrangements for laboratory examination met the requirements of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual).*

- *Appropriate level of control and audit of the feed ban*

  The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country

No BSE case had been recorded in Bulgaria.

e) Compliance with conditions for 'controlled BSE risk' status - Article 11.5.4.

Based on the information provided, the Group accepted Bulgaria's request for 'controlled BSE risk status'. Additionally, the Group noted that Bulgaria has also met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    'Controlled BSE risk' or 'negligible BSE risk'

4.2. Costa Rica

In October 2012, Costa Rica submitted a dossier seeking a BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

Points specifically noted by the Group were summarised in the following discussion.

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Costa Rica during the interval covered by the assessment was not negligible.

- *Risk of recycling and amplification of the BSE agent*

  The Group considered that the conclusion of the exposure assessment was that the risk of recycling and amplification of the BSE agent if it were present in Costa Rica's cattle population during the interval covered by the assessment was not negligible.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code.* The Group noted in 2011 and 2012 a considerable increase in the number of surveillance samples attributed to the clinical suspect stream, while accessions in the other streams remained within the ranges established in preceding years.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group determined that the awareness programme met the requirements of the *Terrestrial Code.*

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 2001 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code.*

- *Laboratory examination*

  The Group determined that the arrangements for laboratory examination met the requirements of the OIE *Terrestrial Manual* including the 2011 introduction of immunohistochemistry.

- *Appropriate level of control and audit of the feed ban*

  The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country

No BSE case had been recorded in Costa Rica.

e) Compliance with conditions for 'controlled BSE risk' status - Article 11.5.4.

Based on the information provided, the Group recommended that Costa Rica be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    'Controlled BSE risk'

    The Group acknowledged improvements recently accomplished and under way in the areas of surveillance, specific risk materials (SRM) removal, feed mill line dedication and laboratory diagnostics. These improvements had contributed to acquisition of controlled BSE risk status.

The Group noted a considerable increase in the number of accessions attributable to the clinical suspect surveillance stream in 2011 and 2012, in the absence of a parallel increase in other streams. While the focus on clinical suspects was in keeping with guidance in the *Terrestrial Code* Chapter, in the absence of a parallel increase in other streams it could signify less than adequate specificity in the attribution of accessions by surveillance stream. The Group recommended that Costa Rica review the criteria whereby accessions were attributable to the clinical suspect stream.

The Group noted a considerable concentration of accessions in the 4 to 7 years age category which commanded the greatest number of surveillance points per accession. This could signify less than adequate specificity in the attribution of accessions by age. The Group recommended that Costa Rica also review the criteria whereby the age of tested animals was established.

4.3. Israel

In September 2012, Israel submitted a dossier seeking a 'negligible' or 'controlled' BSE risk status and an update in October 2012. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Israel during the interval covered by the assessment was negligible.

- *Risk of recycling and amplification of the BSE agent*

The Group considered that the conclusion of the exposure assessment was that the risk of recycling and amplification of the BSE agent if it were present in Israel's cattle population during the interval covered by the assessment was negligible.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1992 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the OIE *Terrestrial Manual*.

- *Appropriate level of control and audit of the feed ban*

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country

The Group noted that Israel had so far one case of BSE born in September 1992. The indigenous case was born more than 11 years preceding the submission of the dossier. Therefore, Israel had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE case during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided, the Group recommended that Israel be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    'Negligible risk'

4.4. Italy

In accordance with the established procedures, the participating expert from Italy withdrew from the meeting during the discussions on the Italy's dossier by the Group.

The Group recalled that in 2007 the OIE received a dossier from Italy to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group at that time was that Italy should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. Italy had been listed as a Member Country having a 'controlled BSE risk' status since May 2008.

In October 2012, Italy submitted a dossier seeking a negligible BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Italy during the interval covered by the assessment was not negligible.

- *Risk of recycling and amplification of the BSE agent*

The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in Italy's cattle population during the interval covered by the assessment.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code.*

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code.*

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1992 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code.*

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual.*

- *Appropriate level of control and audit of the feed ban*

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country

The Group noted that Italy had so far 145 cases of BSE. The youngest birth cohort reported as affected by BSE was born in 2001, meaning that all indigenous cases were born more than 11 years preceding the submission of the dossier. Therefore, Italy had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided, the Group recommended that Italy be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    'Negligible BSE risk'

4.5. Japan

In accordance with the established procedures, the participating expert from Japan withdrew from the meeting during the discussions on Japan's dossier by the Group.

The Group recalled that in December 2008 the OIE received a dossier from Japan to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that Japan should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. Japan had been listed as a Member Country having a 'controlled BSE risk' status since May 2009.

In September 2012, Japan submitted a dossier seeking a negligible BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

Points specifically noted by the Group were summarised in the following discussion.

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Japan during the interval covered by the assessment was negligible.

- *Risk of recycling and amplification of the BSE agent*

The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in Japan's cattle population during the interval covered by the assessment.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code.*

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code.*

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1996 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code.*

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual.*

- *Appropriate level of control and audit of the feed ban*

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country

The Group noted that Japan had so far 36 cases of BSE. The youngest birth cohort reported as affected by BSE was born in January 2002, meaning that all indigenous cases would have been born more than 11 years prior to May 2013. Therefore, Japan would have met the provisions of Article 11.5.3. point 3 b) in May 2013 when the final decision would be made by the World Assembly. All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided, the Group recommended that Japan be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    'Negligible BSE risk'

4.6. The Netherlands

The Group recalled that in February 2007 the OIE received a dossier from the Netherlands to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that the Netherlands should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. The Netherlands had been listed as a Member Country having a 'controlled BSE risk' status since May 2008.

In February 2012, the Netherlands submitted a dossier seeking a 'negligible BSE risk status' followed by an update in October 2012. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered the Netherlands during the interval covered by the assessment was not negligible.

- *Risk of recycling and amplification of the BSE agent*

  The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in the Netherlands' cattle population during the interval covered by the assessment.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 1990 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

  The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual*.

- *Appropriate level of control and audit of the feed ban*

  The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country

The Group noted that the Netherlands had so far 95 cases of BSE. The youngest birth cohort reported as affected by BSE was born in February 2001, meaning that all indigenous cases were born more than 11 years preceding the submission of the dossier. Therefore, the Netherlands had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided, the Group recommended that the Netherlands be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    'Negligible BSE risk'

4.7. Slovenia

The Group recalled that in 2007 the OIE received a dossier from Slovenia to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that Slovenia should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. Slovenia had been listed as a Member Country having a 'controlled BSE risk' status since May 2008.

In September 2012 Slovenia submitted a new dossier seeking a negligible BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Slovenia during the interval covered by the assessment was not negligible.

- *Risk of recycling and amplification of the BSE agent*

The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in Slovenia' s cattle population during the interval covered by the assessment.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code.*

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code.*

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1995 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code.*

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual.*

- *Appropriate level of control and audit of the feed ban*

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country:

The Group noted that Slovenia had so far 8 cases of BSE. The youngest birth cohort reported as affected by BSE was December 2000, meaning that all indigenous cases were born more than 11 years preceding the submission of the dossier. Therefore, Slovenia had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided, the Group recommended that Slovenia be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

- Status

'Negligible BSE risk'

4.8. United States of America

In 2006 the OIE received a dossier from the United States of America (USA) to evaluate the BSE risk status of the cattle population of the USA in accordance with the *Terrestrial Code.* The Group recommended that the USA should be regarded as having met the requirements for recognition as complying with the *Terrestrial Code* as a Member Country with 'controlled BSE risk'. The USA had been listed accordingly since May 2007.

In July 2012, the USA submitted a new dossier seeking a negligible BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

Points specifically noted by the Group were summarised in the following discussion.

a) Section 1: Risk Assessment — Article 11.5.2. point 1

The Group considered that the national risk assessment conducted in 2006, updated in 2009 and 2010 on a national basis and in 2012 on a regional basis, was robust and comprehensive, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 11.5.2. of the *Terrestrial Code.*

- *Risk assessment for introduction of the BSE agent*

The Group acknowledged that 7 years and 8 years had lapsed, respectively, since the USA introduced mitigation measures against import risk associated with live cattle and bovine material from Canada. The Group noted the robust national risk assessments associated with those mitigation measures and the recent regional assessment. The Group agreed that while the USA permitted live cattle imports for slaughter and breeding from birth cohorts starting in 1999, in fact, imports for slaughter had been born in 2003 or later and imports for breeding had been born in 2005 or later. The Group noted that 4 cases of BSE had been detected (one imported from Canada; three indigenous atypical cases) since 2003. The year of birth of the last indigenous case was 2001. The Group could not reach a consensus on the interpretation of this information.

Several members of the Group were of the view that the release risk during the interval of the assessment, while very low, was not negligible. They questioned the results of the BSurvE assessment whereby the BSE prevalence by birth cohort was established for Canadian cattle. They also questioned the integrity of the importation process, considering that live cattle imports could violate the rules governing their disposition by virtue of inadequate identification, age determination and oversight. These members of the Group agreed that the import conditions for imported cattle from controlled BSE risk countries were not following Article 11.5.8. of the *Terrestrial Code* (cattle selected for export were born after the date from which the ban on the feeding of ruminants with MBM and greaves derived from ruminants was effectively enforced). Citing the 2007 meeting report of the Group on atypical BSE, these members of the Group considered the atypical BSE case diagnosed in 2012 as a continuing indigenous BSE challenge to an imperfect feed ban.

Other members of the Group held the view that the release risk was negligible. These members of the Group considered that more than 8 statutory years had lapsed since ruminant MBM was imported from Canada with minimal BSE scrutiny and more than 7 statutory years had lapsed since live cattle had been imported from Canada with minimal BSE scrutiny. They credited the phased reintroduction of imports from Canada as reflecting mitigation measures commensurate with their assessed risk, in accordance with Article 2.1.5. of the *Terrestrial Code*. They reminded the Group that Member Countries lacking adequate national identification systems (such as Brazil, New Zealand, Argentina) at the time of assessment had been approved by the OIE as negligible BSE risk. The same Member Countries determined the age of animals using dentition instead of national identification. In their view, the Group should apply consistency in respect of these facts.

These members of the Group considered the atypical BSE case diagnosed in 2012 as epidemiologically unrelated to the classical BSE epidemic against which the USA feed ban was directed. They further considered that atypical BSE was a naturally occurring transmissible spongiform encephalopathy of rare prevalence and did not constitute a significant threat to the control of classical BSE, based on the report provided to the Scientific Commission by the Group in September 2012. The members considered furthermore that, given the age (born in 2001) of the 2012 case, even if the report provided to the Scientific Commission in September 2012 was not taken into consideration because of it not yet having been endorsed by the Scientific Commission, the 2012 BSE case was not a consideration by virtue of the fact that cattle infected by the BSE agent but born more than 11 years before should not be considered in the release risk assessment (Article 11.5.3. of the *Terrestrial Code*).

- *Risk of recycling and amplification of the BSE agent*

The Group agreed that since 1997 the USA had prohibited the use of MBM (except poultry origin and pure porcine or equine MBM) in ruminant feed. The Group acknowledged the introduction in April 2009 of a prohibition on the use of certain SRM (achieving a 1-log reduction in BSE infectivity via removal of brain and spinal cord of animals over 30 months of age) for animal feed. The Group acknowledged the exclusion of 77 % of fallen stock from rendering; the industry's estimation that 99 % of MBM production occurred in dedicated facilities; an average of 2-log reduction in BSE infectivity in rendering; the diversion of 31 % of MBM to pet food; the processing of livestock feed in dedicated facilities in 98 % of feed mills; the raising of cattle on 80 % of premises without pigs or poultry. The Group acknowledged the conducting of 26,000 tests in the feed chain, 50 % of which tests were applied to feed destined for ruminants.

The Group agreed that the effectiveness of a ruminant-to-ruminant feed ban did not exceed 65 % based on experience in other countries. The Group acknowledged that rendering parameters in the USA were not mandatory in the manner of those applied in the other countries already assessed as negligible risk (several European Union members and Japan for example).

The Group could not reach a consensus on the interpretation of this information.

Several members of the Group considered that 23 % of fallen stock was still being processed in rendering plants. They also considered that the information provided on the relative distribution of rendering parameters among renderers was based on estimation primarily from industry (secondarily from the USA's Food and Drug Administration) and 10 % of the renderers used a 0-1 log reduction-method. These members of the Group considered that until October 2009 SRMs and other inedible offal were rendered for non-ruminant feed. They considered that potentially infective ruminant material (vertebral column, tonsils and ileum) could still be recycled into the feed chain following the imposition of the modified SRM ban at that time. These members of the Group considered that the removal of SRMs in rendering plants seemed difficult due to the diverse number of options and to the absence of an accurate determination of age. They considered that approximately 30 % of MBM domestically produced for feeding

purposes was mixed ruminant/non ruminant MBM. They considered that the effectiveness of the feed ban could therefore be questioned regarding its ability to prevent recycling and amplification of the BSE agent. They considered that on the 20 % of farms where cattle cohabit with swine or poultry or both, there were no preventive measures (other than a warning label on feed bags) applied to prevent ruminants from having access to feed for monogastric animals (which contain SRM). These members of the Group considered that to take the average log reduction for every step was not a realistic worst case assumption; they considered that under realistic worst case assumptions the risk of recycling and amplification is not negligible.

Other members of the Group considered that the efficacy of the feed ban should be commensurate with the assessed release risk (Article 2.1.5. of the *Terrestrial Code*). They acknowledged a feeding system incorporating the removal of 77 % of fallen stock; the dedication of 99 % of rendering plants to only ruminant or only monogastric species; the achievement of a weighted average reduction in BSE infectivity of 2-logs by rendering; and that the diversion of 31 % of MBM production to pet food and the dedication of 99 % of feed mills to only ruminant or to only monogastric species led to a net linear reduction in infectivity exposure of $7x10^{-7}$ until and including 2008 and with the addition of a partial SRM ban in 2009 a net linear reduction of $7x10^{-8}$. These members of the Group considered that this conclusion is supported by: the results of 26,000 tests conducted throughout the feed chain; and a BSurvE model assessment showing a marked decline in BSE prevalence upon the imposition of the 1997 feed ban. These members, referring to the importance of applying consistency, considered that the combination of these measures was no less robust than those of other Member Countries already assessed by the OIE as having negligible BSE risk (such as New Zealand, Australia and many South American countries in which human consumption of SRM had been accepted as a mitigation measure without monitoring).

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group accepted that surveillance on a national basis had been undertaken at a level 20 times higher than the minimum requirements for retained controlled BSE risk status or achievement of negligible BSE risk status. The Group agreed that surveillance on a regional basis directed at 2 regions most exposed to Canadian BSE risk met or exceeded *Terrestrial Code* requirements on a zone basis. The Group agreed that the level of surveillance applied had been sufficient to detect 3 cases of atypical BSE and an imported case of BSE from Canada.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1986 and concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

The Group noted that the arrangements for laboratory examination met the minimum requirements of the *Terrestrial Code*.

- *Appropriate level of control and audit of the feed ban*

The Group referred to the findings of the exposure assessment and its interpretation by parts one and two.

d) BSE history in the country

The Group noted that the USA had so far 4 cases of BSE. One of them was proven to have been imported from Canada and the others were indigenous, atypical BSE cases. All indigenous cases were born more than 11 years prior to the submission of the dossier. Every effort had been expended in the country to trace all cattle which were reared with the BSE cases during their first years of life. For the last case (atypical BSE case born in 2001), 50 animals among 344 within its birth cohort were sold in 2007 and 2008 but could not be traced.

e) Compliance with Conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided and the nature of bovine husbandry in the USA, the Group reached consensus that birth cohorts born in and since 2009 represented negligible BSE risk. Several members of the Group were of the view that the USA would meet the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk' no earlier than 2016, provided that current measures are maintained. Other members of the Group were of the view that the USA currently met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended status*

  After extensive deliberation, the Group was not able to reach the consensus on the final recommendation to the Scientific Commission on the dossier of USA. Several members of the Group recommended 'controlled BSE risk', while others recommended 'negligible BSE risk'. Both opinions along with the detailed rationale for each component of the risk assessment would be conveyed to the Scientific Commission for its assessment and final conclusion on the recommendation to bring to the World Assembly of Delegates.

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    The Director General is referred to the findings above.

4.9. Other Member Country request

The Group assessed one additional request of a Member Country for recognition of 'negligible BSE risk' status which did not meet the requirements of the *Terrestrial Code*; the dossier was referred back to the corresponding Member Country.

5. Other matters

The Group agreed to bring to the attention of the Scientific Commission the challenges encountered by the Group in interpreting the rendering protocol incorporated in Article 11.5.19. of the *Terrestrial Code*, given the latitude provided by the risk assessment chapter (Chapter 2.1. of the *Terrestrial Code*) in respect of equivalent versus prescribed mitigation measures. Several members of the Group interpreted the provision of the Code as prescription of measures. Other members of the Group believed that within the Code equivalence in measures applied could be accounted for. To date, the Group had, by consensus and with guidance from the Scientific Commission, employed a degree of latitude in interpretation of the Code Chapter on BSE vis-à-vis the provisions of corollary chapters of the Code on surveillance and risk assessment. In this instance, consensus could not be reached within the Group in the approach to be taken.

Dr Miyagishima congratulated the Group for its hard work and recognised that it had employed every single means to reach conclusions based on a consensus. Dedication of the Chair, the rapporteur and all other experts of the Group to examine all data available in detail and interpret them objectively was recognised.

6. Finalization and adoption of the draft report

The Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report would be subject to a period of circulation to the Group for comments and adoption. The report was finalised by correspondence.

.../Appendices

OIEの定めるBSEステータスごとの主な要件（2013年）

ステータス	リスク評価	サーベイランス	リスク低減措置	認定を受けた国 2007年認定/2008年認定/2009年認定/2010年認定/2011年認定/2012年認定/2013年認定
無視できるリスク（25カ国）	実施	B型サーベイランス※を実施中 ※5万頭に1頭のBSE感染牛の検出が可能なサーベイランス（例：日本の飼養規模の場合15万ポイントが必要）	【BSE発生なし/輸入牛のみで発生】 ①報告・教育等が7年以上 かつ ②飼料規制※が 8年以上実施され、他のほ乳類由来の飼料による交差汚染について、適切な水準の管理及び査察が行われていること （※反すう動物由来肉骨粉の反すう動物への給与禁止） 【国内発生あり】 上記①かつ② ＋ 過去11年以内に自国内で生まれた牛で発生がないこと	アルゼンチン、ウルグアイ、オーストラリア、シンガポール、ニュージーランド フィンランド、アイスランド、ノルウェー、スウェーデン パラグアイ チリ インド、ペルー デンマーク、パナマ オーストリア、ベルギー、ブラジル、コロンビア イスラエル、イタリア、日本、オランダ、スロベニア、米国
管理されたリスク（27カ国）	実施	A型サーベイランス※を実施中 ※10万頭に1頭のBSE感染牛の検出が可能なサーベイランス（例：日本の飼養規模の場合30万ポイントが必要）	報告・教育等が行われており、また効果的な飼料規制が実施され、他のほ乳類由来の飼料による交差汚染について、適切な水準の管理及び査察が行われているが ①報告・教育等が7年未満 又は ②飼料規制が8年未満	カナダ、スイス、台湾 キプロス、チェコ、エストニア、フランス、ドイツ、ギリシャ、ハンガリー、アイルランド、ラトビア、リトアニア、ルクセンブルグ、マルタ、ポーランド、ポルトガル、スロバキア、スペイン、英国、リヒテンシュタイン、メキシコ 韓国 クロアチア、ニカラグア ブルガリア、コスタリカ
不明のリスク（その他の国）	無視できるリスク、管理 ・ ・ ・ スクのいずれにも該当しない場合			

※ 下線は、生原基で既に掲げている国

※ 以下は生原基では掲載しているがOIEステータスでは不明とされているもの
エルサルバドル、ケニア
コスタリカ、スワジランド
ナイジェリア、ニカラグア
ニューカレドニア
パキスタン、バヌアツ
ボツアナ、モーリシャス[6]

厚生労働科学研究費補助金（医薬品・医療機器レギュラトリーサイエンス総合研究事業）
分担研究報告書

ウシ等由来原料の基準の研究

研究分担者　飛梅　実　国立感染症研究所・感染病理部・主任研究官

研究要旨
国際獣疫事務局（OIE）により日本を含む複数国がBSEに対して「無視できるリスク国」に認定された。この結果を踏まえ、本研究では海外におけるウシ等由来原料に係る規制状況、国内の研究者等の国内規制に対する意見等について調査を行うとともに、医薬品等に用いる原料の基準について、改めてリスク評価を行い、原料基準のあり方の検討に資するため整理・検討する。同時に、原材料への他組織の混入を評価できる系の構築をめざし、生物由来原料を用いる最終製品の安全性確保に資する研究を行う。

A．研究目的

１：現在、反芻動物に由来する原料については、BSE 発生リスクに応じて、原料として使用可能な部位、原産国を定め、使用が規制されている。近年、国際獣疫事務局(OIE)において、日本、米国を含む複数国が新たに「無視できるリスク国」に指定された。これを踏まえ、医薬品等に用いる原料の基準について、改めてリスク評価を行い、原料基準のあり方の検討に資するため整理・検討する。

２：プリオン感染反芻動物では組織ごとの危険度が異なるため、原料として使用できる部位を規制することで最終製品の安全性を担保している。本研究では、使用部位規制の実効性を数値化することを目的とし、出発原材料への神経組織の混入をプリオン蛋白質（PrPc）等の神経組織特異的マーカーを指標として検出する系の作成を目指す。

B．研究方法

１：EU圏では科学運営委員会(Scientific Steering Committee：SSC)および欧州食品安全機関(European Food Safety Authority：EFSA ）が食品等のBSEのリスク評価を担っており、地理的 BSE リスク評価（geographical BSE risk：GBR)がなされてきた。現在では、国際獣疫事務局（World Organisation for Animal Health：OIE）でのリスク評価を基準とすることが確認されている。本研究では、SSCおよびEFSAでのGBRのリスク評価基準の推移、OIE基準への移行を文献的に調査し、医薬品等に用いる原料基準のあり方に対する提言の資料とする。

２：プリオンの前駆蛋白質であるプリオンタンパク質(PrP^c)は主に中枢神経系をはじめとした神経組織に分布する。このため、PrP^cを検出することで、評価試料中への神経組織の混入を評価できると考えられる。本研究では神経由来組織混入・残留の評価系へのプリオン検出エライザの応用について検討する。TSE 検査に用いられてきたプリオン検出エライザは高感度化が図られ、定量性も有している。PK（タンパク分解酵素)処理を省くことでプリオン蛋白質(正常型プリオン：PrP^c)を検出でき、製品または材料への神経系組織の混入の有無を判別できる。

（倫理面への配慮）
報告事項なし

C．研究結果

１－１）欧州委員会・科学運営委員会（SSC）　地理的BSEリスク評価（GBR）：SSC GBR

1998年欧州員会（EC）のSSCによりGBRが開発され、2003年まで使用された。この間、3度の改定を経ている。対象国より提供されたデーターを基にカテゴリーⅠ～Ⅳに分類している。

１－２）欧州食品安全機関（EFSA）地理的BSEリスク評価（GBR）：EFSA GBR

2003年にGBR評価の実施責任がSSCからEFSAへ移行されている。19か国を対象とした再評価およ

び新規評価にはSSC　GBRが用いられている。 EFSA GBR では侵入リスク評価、安定性評価、評価分類における変更がなされている。

１－３）国際獣疫事務局（OIE）でのリスク評価

2005年7月発行の欧州委員会TSEロードマップにおいて、BSEのリスク評価はOIEが主要な役割を果たすべきとの記載がなされ、2005年9月のCVO/EU議会においてBSEリスク分類はOIEガイドラインに基づく必要性があるとの見解が示された。OIEでは、OIE 陸生動物衛生規約第2 章3.13 章にBSEサーベイランスに関して収載している。OIE では各要件からカテゴリー１からカテゴリー３に分類している。

２）TSE 検査用エライザキットは、ニッピ社よりニッピブルが販売されている。プリオン蛋白質を指標とした実験的な原材料への神経組織の混入を調べるため、ニッピブルのマウスプリオン蛋白質への交差反応性を検討した。サンプルとしてスクレイピー感染マウス脳乳剤を用いた。その結果、ニッピブルはPK処理・未処理に関わらずマウス脳乳剤に反応した。この結果より、ニッピブルはマウスで増幅されたPrPscならびにマウスprionタンパク質への反応性を有することが明らかとなった。

D．考察および結論

１）欧州でのBSEリスク評価は、SSCでのGBR策定に始まり、EFSAによる改正が行われた。SSCおよびEFSAによるGBRは4段階で評価されていた。GBR評価では、カテゴリーⅢに分類された国でのBSE発症例、アクティブサーベイランスでのBSE症例が報告されておりGBR評価手法の妥当性が確認されている。　現在はOIEの定めるステータスが採用されている。OIEのBSEステータスは3つのカテゴリーに分類され、日本は2013年にBSEの「無視できるリスク国」に分類されている。本研究では今後、SSC、EFSA GBR の評価手法の経時的進展等について文献調査を進める。加えて、GBR での評価を受けた国の評価後のリスク変動にいての検索を進め、医薬品等に用いる原料基準のあり方に対する提言の資料とする。

２）TSE 検査用エライザキット　ニッピブルがマウスprion（PrPsc）およびプリオンタンパク質への反応性を有することが確認出来た。これにより、プリオン病発症マウス組織を用いて、プリオンタンパク質量に対するPrPsc量の計測が可能となる。今後、各組織におけるプリオンタンパク質量計測行い、神経組織の混入をプリオンタンパク質を指標として計測できるか否かについての検討並びに、プリオン病発症マウス組織でのプリオンタンパク質量当たりのPrPsc量の計測を行う。

E．健康危険情報

報告事項なし

F．研究発表

１．論文発表

1) Koga Y, Tanaka SI, Sakudo A, Tobiume M, Aranishi M, Hirata A, Takano K, Ikuta K, Kanaya S Proteolysis of abnormal prion protein with a thermostable protease from Thermococcus kodakarensis KOD1.. Appl Microbiol Biotechnol. 2013 Jul 24 published online

2. 学会発表

報告事項なし

G．知的財産権の出願・登録状況

１．特許取得

報告事項なし

２．実用新案

報告事項なし

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書　籍　名	出版社名	出版地	出版年	ページ
奥田晴宏, 川崎ナナ	16.7その他の医薬品と関連物質	日本化学会 辰巳　敬	第7版化学便覧応用化学編	丸善出版株式会社	東京	2014	1079-1084
北條浩彦, 清水則夫	基本編－原理と基本知識－ リアルタイムPCRを使った解析の基本 10プライマー／プローブの設計の手順②マルチプレックスPCRの場合	北條浩彦	原理からよくわかるリアルタイムPCR完全実験ガイド 最強のステップUPシリーズ	株式会社羊土社	東京	2013	72-74
清水則夫, 渡邊　健, 外丸靖浩	実践編－プロトコールを中心に－ Ⅳ章 遺伝子量解析 15 ウイルス感染症を診断する ウイルスゲノムの定性的検査と定量的検査	北條浩彦	原理からよくわかるリアルタイムPCR完全実験ガイド 最強のステップUPシリーズ	株式会社羊土社	東京	2013	192-202

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
小林　哲, 遊佐敬介, 川崎ナナ	ウイルス等感染性因子安全性評価に関する研究.	衛研報告	131	7-15	2013
遊佐敬介, 前田洋助, 高林　誠, 小林　哲, 苑宇哲	CHO細胞が産生するレトロウイルス様粒子とウイルス安全性.	医薬品医療機器レギュラトリーサイエンス	44(10)	852-856	2013
小林　哲, 遊佐敬介, 川崎ナナ	免疫抑制作用を有する各種薬剤の投与症例におけるウイルス感染プロファイルの比較およびリスク分析.	医薬品医療機器レギュラトリーサイエンス	submitted		

Nakano Y, Monde K, Terasawa H, Yuan Y, Yusa K, Harada S, Maeda Y	Preferential recognition of monomeric CCR5 expressed in cultured cells by the HIV-1 envelope glycoprotein gp120 for the entry of R5 HIV-1.	*Virology*	452	117-124	2014
Maeda Y, Terasawa H, Nakano Y, Monde K, Yusa K, Oka S, Takiguchi M, Harada S	V3-independent competitive resistance of a dual-X4 HIV-1 to the CXCR4 inhibitor AMD3100.	*Plos One*	9(2)	e89515	2014
日本PDA製薬学会 バイオウイルス委員会 SALLY分科会	第2章：生物薬品の品質，安全性の向上に関する検討 過去の事例に学ぶウイルス汚染の防止対策 －血漿分画製剤の感染事例とその対策.	*PHARM TECH JAPAN*	29(7)	45-50	2013
Yuan Y, Yokoyama K, Maeda Y, Terasawa H, Harada S, Sato Y, Yusa K	Structure and dynamics of the gp120 V3 loop that confers noncompetitive resistance in R5 HIV-1_{JR-FL} to maraviroc.	*Plos One*	8(6)	e65115	2013
Suzuki K, Hattori S, Marks K, Ahlenstiel C, Maeda Y, Ishida T, Millington M, Boyd M, Symonds G, Cooper DA, Okada S, Kelleher A	Promoter targeting shRNA suppresses HIV-1 infection *in vivo* through transcriptional gene silencing.	*Molecular Therapy - Nucleic Acids*	2	e137	2013
前田洋助	ケモカイン受容体変異とHIV感染抵抗性.	化学療法の領域	29	2466-73	2013
Kobayashi Z, Akaza M, Numasawa Y, Ishihara S, Tomimitsu H, Nakamichi K, Saijo M, Morio T, Shimizu N, Sanjo N, Shintani S, Mizusawa H	Failure of mefloquine therapy in progressive multifocal leukoencephalopathy: Report of two Japanese patients without human immunodeficiency virus infection.	*Journal of the Neurological Sciences*	324	190-194	2013
Yan J, Ng S-B, Tay J L-S, Lin B, Koh TL, Joy Tan J, Selvarajan V, Liu S-C, Bi C, Wang S, Choo S-N, Shimizu N, Huang G, Yu Q, Chng W-J	EZH2 overexpression in natural killer/T-cell lymphoma confers growth advantage independently of histone methyltransferase activity.	*blood*	121(22)	4512-4520	2013

Tachikawa R, Tomii K,Seo R, Nagata K, Otsuka K, Nakagawa A, Otsuka K, Hashimoto H, Watanabe K, Shimizu N	Detection of Herpes Viruses by Multiplex and Real-Time Polymerase Chain Reaction in Bronchoalveolar Lavage Fluid of Patients with Acute Lung Injury or Acute Respiratory Distress Syndrome.	*Clinical Investigations*		1-8	2013
Ito K , Shimizu N, Watanabe K, Saito T, Yoshioka Y, Sakane E, Tsunemine H, Akasaka H, Kodaka T, Takahashi T	Analysis of Viral Infection by Multiplex Polymerase Chain Reaction Assays in Patients with Liver Dysfunction.	*Internal Medicine*	52	201-211	2013
Yamaguchi T, Kanayasu-Toyoda T, Uchida E	Angiogenic Cell Therapy for Severe Ischemic Diseases.	*Biol.Pharm. Bull.*	36(2)	176-181	2013
Inoue Y, Kubota-Koketsu R, Ideno S, Nakamura H, Ono K, Okuno Y, Ikuta K	Induction of anti-influenza immunity by modified GFP carrying hemagglutinin-derived epitope structure.	*J. Biol. Chem*	288(7)	4981-4990	2013
Yasugi M, Kubota-Koketsu R, Yamashita A, Kawashita N, Du A, Sasaki T, Nishimura M, Misaki R, Kuhara M, Boonsathorn N, Fujiyama K, Okuno Y, Nakaya T, Ikuta K	Human monoclonal antibodies broadly neutralizing against influenza B virus.	*PLoS Pathogens*	8(10)	e77892	2013
Watanabe Y, Ibrahim M S, Ikuta K	Evolution and Control of H5N1.	*EMBO Reports*	14(2)	117-122	2013
Urayama T, Cameron R, Sato T, Yunoki M, Ikuta K	Misinterpretation in virus clearance studies of biological products due to an uncommon discrepancy between cytopathic effects and infectivity of human immunodeficiency virus (HIV).	*Biologicals*	41(2)	125-127	2013
Hirai I, Ebara M, Nakanishi S, Yamamoto C, Sasaki T, Ikuta K, Yamamoto Y	Jurkat cell proliferation is suppressed by Chlamydia (Chlamydophila) pneumonia infection accompanied with attenuation of phosphorylation at Thr389 of host cellular p70S6K.	*Immunobiology*	218(4)	527-532	2013

Tian Y S, Verathamjamras C, Kawashita N, Okamoto K, Yasunaga T, Ikuta K, Kameoka M, Takagi T	Discovery of novel low-molecular-weight HIV-1 inhibotors interacting with cyclophilin A using in silico screening and biological evaluations.	*J. Mol. Model*	19 (1)	465-475	2013
Li Y G, Siripanyaphinyo U, Tumkosit U, Noranate N, A-Nuegoonpipat A, Kurosu T, Ikuta K, Takeda N, Anantapreecha S	Chikungunya virus induces a more moderate cytopathic effect in mosquito cells than in mammalian cells.	*Intervirology*	56 (1),	6-12	2013
加藤(森) ゆうこ, 柚木幹弘, 生田和良, 萩原克郎	血液製剤の安全対策−プリオン除去の現状−	モダンメディア	59(9)	231-237	2013
高橋一恵, 大久保祐士, 古木理恵, 服部眞次, 浦山 健, 坂井薫, 柚木幹弘, 萩原克郎, 生田和良	由来の異なるE型肝炎ウイルスの熱感受性の違いについて.	血液事業	36(3)	679-685	2013
Higuchi H, Gondaira S, Iwano H, Hirose K, Nakajima K, Kawai K, Hagiwara K, Tamura Y, Nagahata H	*Mycoplasma* species isolated from intramammary infection of Japanese dairy cows.	*Vet Rec.*	172(21)	557	2013
Kikuchi Y, Ohnishi T, Furusawa H, Kawai T, Fukuda Y, Yokoyama H, Sugita-Konishi Y	ELISA Detection of *Kudoa septempunctata* in Raw *Paralichthys olivaceus* (Olive Flounder) using a Chicken Anti-*Kudoa* Antiserum.	*Biocontrol Science*	18	193-197	2013
Ohnishi T, Kikuchi Y, Furusawa H, Kamata Y, Sugita-Konishi Y	*Kudoa septempunctata* Invasion Increases the Permeability of Human Intestinal Epithelial Monolayer.	*Foodborne Pathog. Dis.*	10	137-192	2013
内田恵理子, 古田美玲, 菊池 裕, 窪崎敦隆, 遊佐精一, 宮原美知子, 佐々木裕子, 小原有弘, 大谷 梓, 松山晃文, 大倉華雪, 山口照英	細胞基材に対するマイコプラズマ否定試験のPCR法の見直しに関する研究.	医薬品医療機器レギュラトリーサイエンス	印刷中		
Koga Y, Tanaka SI, Sakudo A, Tobiume M, Aranishi M, Hirata A, Takano K, Ikuta K, Kanaya S	Proteolysis of abnormal prion protein with a thermostable protease from Thermococcus kodakarensis KOD1.	*Applied microbiology and biotechnology*	Jul 24	Epub ahead of print	2013