



Committee on Sanitary and Phytosanitary Measures

**ARTICLE 6 OF THE SPS AGREEMENT
QUESTIONS FOR DISCUSSION**

COMMENTS SUBMITTED BY OIE¹

Note by the Secretariat²

Addendum

Brazil, the European Union and the United States of America submitted a communication (G/SPS/W/311), circulated on 8 March 2019, requesting Members, as well as the IPPC and OIE, to review a set of questions and provide comments through the Secretariat by 10 May 2019. Subsequently, the co-sponsors of the submission invited all interested Members, as well as the IPPC and OIE, to submit replies to the questions contained in proposal G/SPS/W/311, as well as comments on the questions, by 14 June 2019.

This document provides the replies to the questions, and comments on the questions, as submitted by OIE. The questions in the proposal, as well as the replies received, will form the basis for discussions at the informal meeting on 17 July 2019.

In addition to the questions addressed to IPPC and OIE in document G/SPS/W/311, Ukraine submitted one question for the OIE as follows:

- Whether OIE takes (will take) into account the epizootic situation, which has an impact on the economic component and is aimed at trade facilitation while developing regionalization and disease status standards?

This question was subsequently sent to the OIE. At the OIE's request, the Secretariat sought further clarification on the question from Ukraine.

1 QUESTIONS FOR OIE REPRESENTATIVES

1.1. NOTE: most OIE responses are specific to the Terrestrial Animal Health Code, but please note that regionalization is also addressed in the Aquatic Animal Health Code.

Has the OIE revised their regionalization and disease status standards in recent years to clarify or elaborate provisions in response to Members' trade concerns? Are there any future plans to further revise these standards in the future?

1.2. OIE standards pertaining to regionalization and disease status are set out in the Terrestrial Animal Health Code (the Terrestrial Code) and the Aquatic Animal Health Code (the Aquatic Code), supported by diagnostic standards in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, and the Manual of Diagnostic Tests for Aquatic Animals.

¹ The compilation of comments from Members is available in document G/SPS/W/311/Add.1 and comments from the IPPC are available in document G/SPS/W/311/Add.3.

² This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights and obligations under the WTO.

1.3. OIE standards may be revised because of new scientific evidence, changes in the epidemiological situation of diseases or comments from member countries.

1.4. At the end of each chapter of the Codes and Manuals you can find when the chapter was first adopted and when it was last amended. For example, the Terrestrial Code, Chapter 4.3. on Zoning and compartmentalisation was first adopted in 1998 and last amended in 2018; Chapter 4.4. on the Application of compartmentalisation was first adopted in 2008 and last amended in 2012. The Aquatic Code, Chapter 4.1. on Zoning and compartmentalisation was first adopted in 1995 and last amended in 2010; Chapter 4.2. on the Application of compartmentalisation was first adopted in 2010 and last amended in 2016.

1.5. The rationale and details of amendments of new or revised standards adopted in the Codes and Manuals each year can be found in the respective reports of the Terrestrial Animal Health Standards Commission (Terrestrial Code), Biological Standards Commission (Terrestrial Manual) and Aquatic Animals Commission (Aquatic Code and Manual) made at the OIE General Session, which are publicly available at the OIE website (<http://www.oie.int/en/about-us/key-texts/final-reports-of-the-general-session/>). More detailed information regarding the development of these new and revised chapters is available in the respective reports of the Specialist Commissions which are available at: <http://www.oie.int/en/standard-setting/specialists-commissions-working-ad-hoc-groups/>.

1.6. The future revision of OIE standards is defined by the work programme of the Specialist Commissions, which are published as part of the Commissions' meeting reports. The last version of these programmes can be found as part of the February 2019 meeting report of each Commission, available at the OIE website (<http://www.oie.int/en/about-us/wo/commissions-master/>).

How are standards on surveillance linked to effective implementation of these standards?

1.7. The chapters in Section 1 of the Terrestrial Code are designed for the implementation of measures for the surveillance and notification of pathogenic agents. Chapter 1.4. on Animal health surveillance provides general recommendations on surveillance aimed at demonstrating the absence of disease or infection, determining the presence or distribution of disease or infection or detecting as early as possible exotic or emerging diseases. This guidance should be used when specific provisions are not included in disease-specific chapters.

1.8. Section 1 of the Terrestrial Code also includes information on the Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.) and standards for the application of official recognition by the OIE of free status for African horse sickness, bovine spongiform encephalopathy, foot and mouth disease, contagious bovine pleuropneumonia, peste des petits ruminants and classical swine fever.

1.9. The level of detail regarding recommendations for surveillance and the assessment of health status of a country, zone or compartment varies amongst disease-specific chapters.

Are there other underlying key standards that are pre-requisite and essential in order to implement successfully regionalization?

1.10. OIE's presentation to the WTO SPS Committee Thematic Session on Regionalization in 2017 fully outlined the relevant standards and the implementation challenges associated with regionalization (https://www.wto.org/english/tratop_e/sps_e/wkshop11july17_e/stone.pdf).

1.11. Implementation of successful regionalization is complex and elements essential for implementation are described in many different sections of the Codes. For example, chapters of Section 3 of both Codes are designed for the establishment, maintenance and evaluation of Veterinary Services and Aquatic Animal Health Services, respectively, and for communication, and in the case of the Terrestrial Code, also veterinary legislation. Many aspects of a quality Veterinary Service would be considered as essential for successful implementation of regionalization.

1.12. In addition to provisions in disease-specific chapters, some specific chapters to consider in the Terrestrial Code include Chapter 1.1. Notification of diseases, infections and infestations, and provision of epidemiological information, Chapter 4.3. Zoning and compartmentalisation and

Chapter 4.4. Application of compartmentalisation. Note there are equivalent chapters in the Aquatic Code.

1.13. Please note that depending on the disease, and whether it is officially recognized by the OIE, and the nature of the commodity, many other chapters may also need to be considered.

1.14. Complying with the relevant diagnostic standards in the Aquatic and Terrestrial Diagnostic Manuals are also required to fulfil some requirements.

Are there any plans to expand standards and procedures on recognition of disease-free status of member countries?

1.15. The OIE does not have plans to include additional diseases as part of the OIE official recognition procedure.

1.16. The OIE also endorses OIE member countries' official control programmes for foot and mouth disease, contagious bovine pleuropneumonia and peste des petits ruminants. Dog-mediated rabies will be included starting from 2020.

1.17. The OIE has developed Standard Operating Procedures (SOPs) to assist Members with the process relating to the official recognition of a specific disease status, for the official recognition of a risk status for bovine spongiform encephalopathy (BSE) or for the endorsement of a national official control programme. The SOPs currently apply to the official recognition of disease status for six OIE-listed terrestrial animal diseases, namely: African horse sickness, classical swine fever (CSF), contagious bovine pleuropneumonia, foot and mouth disease (FMD), peste des petits ruminants (PPR) and for BSE risk status.

1.18. OIE Members also have the possibility to self-declare their country or, a zone or a compartment within their territory, free from any disease. Should Members submit a request, the OIE offers to publish these self-declaration(s) on its website. However, the OIE will not publish self-declarations of freedom related to those diseases for which the OIE has put in place a specific procedure for official recognition of disease status.

How can OIE contribute to transparency on the use of the international regionalization standards?

1.19. Since 1998, the OIE has the mandate from the WTO to officially recognize disease-free areas of countries for trade purposes. The OIE has a procedure for the official recognition of disease status, a voluntary process, that applies to six diseases: African horse sickness, Foot and mouth disease, Bovine spongiform encephalopathy, Peste des petits ruminants, classical swine fever, contagious bovine pleuropneumonia and rinderpest.

1.20. A list of member countries with an official disease-free status are available on the OIE website at: <http://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/>.

1.21. Member countries may wish to make a self-declaration as to the freedom of a country, zone or compartment from an OIE listed disease or from other animal diseases. The member country may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. A list of OIE member countries that have met the OIE SOP for self-declaration are available at: <http://www.oie.int/en/animal-health-in-the-world/self-declared-disease-status/>.

Are there plans for developing any further materials or activities to enhance implementation of existing standards related to regionalization?

1.22. Although not a disease subject to the OIE Official Recognition Procedure, OIE intends to develop regionalization and compartmentalisation guidance specific to African swine fever, reflecting the international priority associated with this disease and in accordance with Resolution 33 passed during the 87th General Session.

1.23. Also available on the OIE website is a Checklist on the Practical Application of Compartmentalisation at:

http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/A_CMP_Checklist.pdf.

1.24. The OIE conducts regional training workshops on standards related to zoning and compartmentalisation according to the needs of member countries. Workshops have already been conducted on the implementation and application for disease-free zones (for FMD, CSF and PPR) and for containment zones in response to an outbreak. These workshops serve member countries in strengthening their knowledge on the principles for defining, establishing and maintaining zones complying to OIE standards. It also provides opportunities for member countries to share successful experiences and challenges encountered in establishing disease-free zones.

2 QUESTIONS FOR MEMBERS AND IPPC AND OIE REPRESENTATIVES

Are there ways for the SPS Committee to collaborate more effectively with OIE to strengthen implementation of international standards on regionalization and Article 6?

2.1. The OIE standards are science-based standards that have been developed and adopted by the World Assembly of Delegates, comprising the 182 OIE member countries. These standards include many provisions and guidance for the implementation of regionalisation. Each OIE member country is represented by an OIE Delegate. The OIE suggests SPS Committee members work with their OIE Delegate on these matters and engage in the OIE standard setting process.

2.2. Recently the OIE has undertaken an analysis of SPS notifications received through the WTO SPS notification mechanism. This work was undertaken in the context of the design of the OIE Observatory, which also intends to use this information on an ongoing basis. We found the data very difficult to analyse, due to data structure, format and quality issues associated with the reporting mechanism. We believe the WTO SPS Committee should re-examine this system, with a view to improving the utility of the reported data.

How have Members without elaborate SPS programmes relied on OIE work to facilitate safe importation of needed food products?

2.3. The Aquatic and Terrestrial Codes both include provisions for trade in 'safe' commodities, i.e. commodities that can be traded without import conditions regardless of exporting country's disease status.

2.4. In addition, the OIE's PVS Pathway is a capacity building mechanism to assist countries in implementation of OIE standards.
