



**Committee on Sanitary and Phytosanitary Measures**

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

COMPILATION OF COMMENTS SUBMITTED BY MEMBERS<sup>1</sup>

*Note by the Secretariat<sup>2</sup>*

*Revision*

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 IPPPC 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. Following the SPS Committee meeting in July 2019, Members were invited to submit additional comments by 6 September 2019.<sup>3</sup> The additional responses received from Argentina and Turkey have been incorporated in this revised compilation.

Japan requested clarifications to one of the questions contained in the proposal. Specifically, the last question addressed to Members in para. 3(a) of proposal [G/SPS/W/311](#) which reads:

- "How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?"

In response, the co-sponsors clarified the following:

- The first sentence of the question should be clarified to read: "How do you as an importing country use IPPC/OIE official pest- or disease-free country or zone status of an exporting country in implementing Article 6?..."
- The second sentence intends to ask whether an exporting Member has found the same international standard interpreted differently by its trading partners (e.g. importing Members).

This document provides a compilation of the replies to the questions, and comments on the questions, as submitted by the following Members: Argentina; Brazil; Canada; China; the European Union; Hong Kong, China; Japan; Mexico; Chinese Taipei; Turkey and Ukraine. The questions in the proposal, as well as the replies received, were the basis for discussions at the informal meeting on 17 July 2019 and will be further discussed in the context of the Fifth Review.

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<sup>1</sup> Comments submitted by the OIE and IPPC are available in documents [G/SPS/W/311/Add.2](#), [G/SPS/W/311/Add.2/Corr.1](#) and [G/SPS/W/311/Add.3](#), respectively.

<sup>2</sup> 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.

<sup>3</sup> The deadline was further extended to 13 September 2019.

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## 1 QUESTIONS FOR MEMBERS

### 1.1 Argentina

***What are your domestic procedures for establishing and maintaining pest- or disease-free status? What challenges have you encountered in implementing such procedures?***

1.1. Based on its experience as an exporting country regarding the process applied by importing countries or blocs to adopt the OIE's official recognition of a country or area as pest or disease-free, Argentina considers that it is necessary to highlight the following, taking as an example the recognition of areas free from foot and mouth disease (with or without vaccination) in our country.

1.2. Markets such as the European Union, Chile, the United States, Canada, Mexico and Japan, have applied their own assessment processes that are independent from the one carried out by the OIE, which generally involve on-site inspections or audits. In some cases, these processes have lasted over ten years and have required Argentina to bring the matter before the WTO, and deal with the delays and resources (human and financial) that this entails. However, these existing dispute settlement processes, and the ensuing penalties, do not necessarily facilitate trade.

1.3. In general, the main elements of this process that result in delays, costs and trade barriers are as follows:

1. The institutional and sanitary-related information required by the different countries or blocs (questionnaires) is not consistent. Each country requests different information and compiles this information differently.
2. These questionnaires are extensive. Given the length of time required for the replies to be drafted, translated and subsequently examined, updated and additional information often has to be provided.
3. The information provided must be translated into the language of the destination country or bloc. This process is costly and, depending on the language, may be complicated.
4. The assessment carried out by the importing country or bloc is contingent on its priorities and available resources.
5. The process involves different stages and time frames, depending on the importing country or bloc.
6. In most cases, the inspections conducted require logistical organization and the availability of funds.
7. The completion of such inspections is contingent on the priorities and available resources of the importing country or bloc. Sometimes, inspections are delayed for up to one year or more.
8. Once an inspection has been carried out, time is required to prepare preliminary reports, issue observations and draft the final report.
9. Following the approval of a report, some countries need to formalize the recognition granted through the adoption of a regulatory instrument, which means that it takes even longer for this recognition to take effect.

1.4. Furthermore, and as demonstrated above, these processes and time frames are not standardized. They are subjective and do not allow for predictability in terms of market openness. It can be concluded that such procedures not only depend on sanitary related factors but are also influenced by other political and trade components.

1.5. Regarding plant health, in Argentina, the procedures implemented to establish and maintain the status of areas that are free of or have low prevalence of fruit fly are in line with International Standards for Phytosanitary Measures (ISPM FAO) Nos. 30/2008 and 26/2006, respectively. These guidelines were incorporated into Argentine law through specific legislation on the matter.

1.6. In general, the difficulties that arise are related to time frames and the efforts involved in negotiating with importing countries to obtain their recognition of these areas, in addition to the

economic and financial efforts required for developing countries to achieve and maintain the necessary phytosanitary conditions.

***What kind of Committee activities and documents are most useful to you in your domestic consultations on implementation of Article 6?***

1.7. Not applicable.

***Have you used the Committee's Guidelines on Regionalization ([G/SPS/48](#)) in your efforts to seek recognition by another Member of your domestic control and enforcement systems for establishing and maintaining pest- or disease-free status? Are there areas of the Guidelines that could be improved?***

1.8. While the general considerations in the Guidelines state that, "Members should proceed with a recognition process without undue delay", it would be highly relevant to be able to agree on and establish maximum time limits for each of the stages of the process to recognize the phytosanitary status of an area, which are described in the section "Typical Administrative steps in the Recognition Process", in order to expedite the recognition process and avoid undue delays.

***How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?***

1.9. Regarding the fruit fly, in general, there have been no interpretation issues at the technical level. However, as mentioned above, there has been a long record of negotiations on the recognition of pest- or disease-free areas which have lasted over ten years. It would therefore be very beneficial to be able to establish maximum time limits for the different assessment stages, in order to rapidly obtain recognition without undue delay.

## **1.2 Brazil**

***What are your domestic procedures for establishing and maintaining pest- or disease-free status?***

1.10. The procedures followed by the Brazilian sanitary authority for the establishment and maintenance of disease-free areas or zones are based on those established by the OIE Terrestrial Code, Chapter 4.3 and on specific chapters for diseases with zoning.

1.11. Following these regulations, the internal rules for the establishment of regionalization and the rules for the transit of animals and products are published. The main procedures are:

- The extension and geographical limits of an area are clearly established by the Veterinary Authority on the basis of natural, artificial or legal limits and made public through official channels.
- Herds belonging to subpopulations of disease-free areas or zones should be recognizable through clear epidemiological separation of other animals and all other risk factors.
- Measures to ensure identification of the sub-population and to establish and maintain their health status through a biosafety plan are clearly documented and adequate to the eco-productive and epidemiological characteristics of the sub-population, including surveillance, movement controls, use of natural, artificial, or legal limits, spatial separation of animals, control of fomites and commercial practices of handling and management.
- Relevant goods must be identified in such a way that their movements are traceable and well documented and controlled.
- For compartmentalization, the biosafety plan should describe the partnership between private sector and the Veterinary Authority, as well as their respective responsibilities. It should also describe the standard operational procedures in order to provide clear evidence that surveillance, animal identification and traceability system and management practices

are appropriate to meet the compartmentalization definition. The biosafety plan should describe how the measures will be audited to ensure that risks are managed and reassessed regularly, and that the measures are adjusted accordingly.

***What challenges have you encountered in implementing such procedures?***

1.12. Regionalization is a very important principle for animal health management in Brazil, considering the large territorial extension and the geographical and environmental diversity in Brazilian territory. These factors represent major challenges, since they require large investments in livestock registration controls and movement of animals and products, with a view to guaranteeing adequate regionalization conditions. There is a need for strong structures and procedures by the veterinary services and for disease surveillance, including the early detection of diseases and also the demonstration of absence of infectious agents, as a way of ensuring the sanitary condition and the certification of goods from zones or regions.

1.13. In addition to these, another major challenge is to obtain recognition of disease-free zones or areas from importing countries, which often do not consider a recognition of health status from OIE, demanding efforts and costs to answer questionnaires from importing countries and organize missions and audits, sometimes without justified technical reasons.

***What kind of Committee activities and documents are most useful to you in your domestic consultations on implementation of Article 6?***

1.14. In the case of animal health, the Department of Animal Health of the Ministry of Agriculture, Livestock and Supply (DSA/MAPA) routinely applies the guidelines of the relevant international organizations, particularly the Terrestrial Code and other documents of the OIE. In that sense, it has not yet specifically used the documents published by the SPS Committee.

***Have you used the Committee's Guidelines on Regionalization ([G/SPS/48](#)) in your efforts to seek recognition by another Member of your domestic control and enforcement systems for establishing and maintaining pest- or disease-free status?***

1.15. In the case of animal health, the Department of Animal Health of the Ministry of Agriculture, Livestock and Supply routinely applies the guidelines of the relevant international organizations, particularly the Terrestrial Code and other documents of the OIE, as well as guidelines from the IPPC. In that sense, the Ministry of Agriculture, Livestock and Food Supply (MAPA) has not yet used the Guidelines on Regionalization ([G/SPS/48](#)) in its efforts to recognize disease- and pest-free areas in other countries.

***Are there areas of the Guidelines that could be improved?***

1.16. The procedures for the recognition of disease- and pest-free areas by importing countries should be harmonized with the procedures for recognition of regionalization status by the OIE and the IPPC, thus avoiding duplicate efforts by member countries in order to recognize disease-free areas. In the case of OIE official disease-free country or zone status, member countries should recognize the status granted by OIE.

***How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently?***

1.17. In the case of OIE official disease-free country or zone status, Brazil considers that most of the standards adopted by the Terrestrial Code and other OIE documents are properly interpreted and implemented by Brazil for the establishment of regionalization and safe trade in food.

1.18. These standards are always undergoing a revision process, with broad consultation and participation of the member countries, allowing advances in procedures and standards for trade. However, there are discrepancies in interpretation by countries and economic blocs. For example, some countries or blocs do not accept the health status recognized by the OIE for disease-free countries or zones.

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**Are there areas where additional clarification in the international standards or guidelines would be beneficial?**

1.19. The procedures for countries' recognition of regionalization in what regards disease- and pest-free areas should always be improved with the participation of importing and exporting countries.

**1.3 Canada**

1.20. Canada considers the topic of regionalization one that is important and timely. Canada submitted a paper ([G/SPS/GEN/1650](#)) to the Committee on its experiences and approaches to regionalization relating to animal diseases in October 2018. Canada supports the continued discussion of regionalization by the Committee, in particular through the questions for discussion identified in the proposal from Brazil, the European Union, and the United States of America in [G/SPS/W/311](#). Canada looks forward to engaging in a focused discussion based on these questions at the July 2019 informal meeting of the Committee. In advance of the July 2019 informal, Canada submits the following summary of its approach to regionalization.

Animal health

1.21. To prevent the spread of diseases and maintain international trade, Canada manages animal health risks by determining if zones are required based on the unique circumstances of each disease situation. Some factors that Canada includes in this determination are the nature of the disease, presence of the disease in wildlife or the environment, potential for disease spread and geographical features in the area (i.e., waterways, roads, terrain). Zoning is one tool within a suite of measures that Canada uses to respond to animal diseases domestically.

Plant health

1.22. Pest free areas (PFAs) are a tool within a suite of measures that Canada uses to domestically manage plant health risks and to maintain trade by preventing the spread of pests. For each situation, Canada determines if the establishment of pest free areas or areas of low pest prevalence is applicable based on the results of pest risk analyses and domestic surveys. Canada takes measures for the implementation of pest free areas or areas of low pest prevalence based on the relevant standards, guidelines, or recommendations adopted by the International Plant Protection Convention such as the International Standard for Phytosanitary Measures (ISPM) 4 *Requirements for the establishment of pest free areas* and ISPM 8 *Determination of pest status in an area*.

**1.4 China*****How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6?***

1.23. As a member of IPPC and OIE, China always respects and actively implements the rules and standards of IPPC and OIE relating to the Article 6. Based on the guiding principles and official recognition of OIE, China has recognized foot and mouth (FMD) free areas of some Members after scientific assessment.

1.24. Regarding the control and management of animal disease, China has been applying the regionalization instrument in accordance with the guiding principles of OIE and promoting continuous innovation in light of China's actual situation. In this regard, China has formulated and promulgated the construction requirements for establishing FMD free zone of vaccination. The construction of FMD free zones of some Members has been accomplished and some of them have been recognized as FMD-free zones by China after scientific assessment. Consultations with other Members on a memorandum of cooperation on the construction of FMD-free zones are under way.

1.25. In accordance with the OIE guiding principles, regionalization should also be treated and applied scientifically. For diseases of avian influenza and African Swine Fever etc., which are very difficult to be prevented from spreading by natural physical barriers, Members should be cautious to apply the regionalization management method.

## 1.5 European Union

### ***What are your domestic procedures for establishing and maintaining pest- or disease-free status? What challenges have you encountered in implementing such procedures?***

1.26. Within the European Union, goods, including live animals, plants, products of animal and plant origin, move freely among the EU member States. The relevant legislation (animal health, plant health, food safety) is harmonized at European Union level, it is legally binding for all the EU member States and lays down the requirements for intra-community trade, placing on the EU market and imports.

1.27. The European Commission, based on the information received from the EU member States and verified via on-site audits, takes regionalization measures, including the establishment and maintenance of pest- and disease-free status, in a science-based, harmonized and transparent way.

1.28. The criteria for regionalization are based on relevant international standards (OIE, IPPC) in line with Article 6 of the SPS Agreement. The disease status and related trade restrictions are published in the Official Journal of the European Union in the form of a Commission Decision that is legally binding and immediately applicable.

1.29. As an example, for ASF the overarching piece of legislation providing the tool for the control of African swine fever in the European Union is Council Directive 2002/60/EC of 27 June 2002. Within this framework, Commission Implementing Decision 2014/709/EU of 9 October 2014 covers the latest specific regionalization measures taken with respect to evolution of the African swine fever (ASF) in the European Union. This is complemented by working document SANTE/7112/2015,<sup>4</sup> which presents in a transparent manner guiding principles for the application of such regionalization measures and has been developed to lay down the principles and criteria for geographically and temporally defining ASF regionalization.

1.30. The animal and plant health situation in the European Union is periodically and frequently monitored through the Standing Committee on Plants, Animals, Food and Feed (PAFF) which plays a key role in ensuring that EU measures on food and feed safety, animal health and welfare as well as plant health are relevant, practical and effective. The PAFF Committee delivers opinions on draft measures that the Commission intends to adopt.<sup>5</sup> It is composed by representatives of all EU countries and presided by a European Commission representative. The PAFF Committee's mandate covers the entire food supply chain - from animal health issues on the farm to the product on the consumer's table - helping the European Union to deal effectively and timely with health risks at every stage of the production chain and changes as and when needed.

1.31. An overview of the EU regionalization system for animal health based on the example of Avian Influenza was presented at the thematic session on regionalization of July 2017. The presentation is available on the WTO SPS website.<sup>6</sup> Previously, a description of the application of Article 6 as regards animal diseases was presented by the European Union in document [G/SPS/GEN/1159](#) of 26 June 2012.

1.32. The basic EU plant health legislation (Regulation (EU) 2016/2031) deals with regionalization in the plant health area in relation to both the intra-Community trade and importation to the European Union. An overview of the EU system for regionalization in relation to plant health was presented at the thematic session on Pest-Free Areas of February 2018. The presentation is available on the WTO SPS website.<sup>7</sup>

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<sup>4</sup> [https://ec.europa.eu/food/sites/food/files/animals/docs/ad\\_control-measures\\_asf\\_wrk-doc-sante-2015-7112.pdf](https://ec.europa.eu/food/sites/food/files/animals/docs/ad_control-measures_asf_wrk-doc-sante-2015-7112.pdf).

<sup>5</sup> For more information see Comitology Register <http://ec.europa.eu/transparency/regcomitology/index.cfm?do=OpenData.list>.

<sup>6</sup> [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop11july17\\_e/gavinelli.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop11july17_e/gavinelli.pdf).

<sup>7</sup> [https://www.wto.org/english/tratop\\_e/sps\\_e/wkshop27feb18\\_e/arijs.pdf](https://www.wto.org/english/tratop_e/sps_e/wkshop27feb18_e/arijs.pdf).



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***What kind of Committee activities and documents are most useful to you in your domestic consultations on implementation of Article 6?***

1.33. All documents and activities of the SPS Committee are useful for the Commission services in their regulatory activities. Thematic discussions on animal and plant health issues, whether general or specific, are also very helpful in informing the EU regulatory activities in these areas and to learn about other Members' systems and procedures.

***Have you used the Committee's Guidelines on Regionalization (G/SPS/48) in your efforts to seek recognition by another Member of your domestic control and enforcement systems for establishing and maintaining pest- or disease-free status? Are there areas of the Guidelines that could be improved?***

1.34. The Guidelines are used regularly and systematically when the European Union and its Member States are seeking recognition and maintenance of the pest- or disease-free status of the European Union and/or certain parts of it for the purpose of export. The WTO SPS provisions and relevant guidelines are also taken into account when the European Union negotiates SPS provisions with other trade partners (free trade agreements or other sanitary/phytosanitary agreements).

1.35. The Guidelines, together with the specific OIE and IPPC standards, are generally considered as a good and clear basis for negotiations with trading partners on market access related issues, although on many occasions the procedure turned out to be slow and cumbersome. The European Union's experience is that the expedited process described under chapter IV of the guidelines is rarely used by some Members. In addition, the entire procedure for establishing pest and disease-free areas needs to be repeated after every outbreak, even when it is an outbreak of the same disease under similar circumstances.

1.36. The European Union is of the view that the guidelines do not need modification/improvement. Instead, what is required is their appropriate implementation by all Members.

***How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?***

**1.37. The European Union's experience as an importing Member:**

1.38. There is detailed legislation on the criteria of approval of a country or part of the country for import of live animals, plant and products to the European Union and the sanitary requirements to be met.<sup>8</sup> It is regularly revised in light of the animal health, plant health and food safety situation of the exporting country.

1.39. The application of regionalization requires confidence in the other Member's measures and policies on controlling animal and plant diseases. Previous knowledge on the animal and plant health situation in the given Member and the capacity to control and eliminate the disease outbreaks are determining factors. The main principle is that imported goods have to meet the same criteria as the ones produced in the European Union.

1.40. For plant health, the European Union accepts declarations from other Members on the pest free status provided they are based on IPPC standards. For animal health, the European Union asks for documentary evidence and carries out an evaluation both on paper and if appropriate in the form of on the spot audits.

1.41. The European Union recognizes the regionalization principle vis-à-vis trade partners with the objective of allowing trade to continue from disease-free areas, whilst restricting trade from affected areas. Thus, safe trade is maintained whilst risk of spread of disease is minimized.

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<sup>8</sup> <https://trade.ec.europa.eu/tradehelp/sanitary-and-phytosanitary-requirements>.

**1.42. The European Union's experience as an exporting Member:**

1.43. The European Union has a mixed experience as an exporting Member; only a few Members recognize fully the EU regionalization principles and measures; others only apply the regionalization principles partially and sporadically vis-à-vis the European Union or do not apply them directly. Consequently, when a major disease outbreak occurs in a member State of the European Union, trading partners ban the exports of relevant products from the entire territory of an affected member State, instead of targeting the affected area alone. Moreover, such a countrywide trade ban is often kept in place for several years without taking into account the improvements in the health status of the country/region there is no automatic re-opening after the country/region is declared free from the disease. Other trading partners apply regionalization principles partially (only for some diseases/member States) and/or very slowly.

1.44. The European Union will continue asking trading partners to recognize the regionalization measures as implemented in the European Union and thus to allow trade from areas not affected with animal diseases.

**1.45. International standards:**

1.46. The OIE Terrestrial Animal Health Code and the IPPC standards together with the WTO SPS Regionalization Guidelines are clear and provide a good basis for assessing trading partners' regionalization measures.

**1.6 Hong Kong, China*****What are your domestic procedures for establishing and maintaining pest- or disease-free status? What challenges have you encountered in implementing such procedures?***

1.47. The Department of Agriculture, Fisheries and Conservation (AFCD) is the competent authority of Hong Kong, China for the control of animals, plants and their products (except food products which is under the jurisdiction of Food and Environmental Hygiene Department). AFCD follows the recommendations of OIE with regards to reporting of animal diseases that are detected in the local territory, imposing sanitary controls to prevent the introduction of diseases and pathogens, enhancing the veterinary services (such as laboratory for equine disease testing, development of testing for exotic disease such as African Swine Fever), proposal of enhancing animal welfare standards through legislation.

1.48. There is legislation in place to ensure the report of notifiable diseases, import control of animals/plants and their products. There are also veterinary inputs (both from AFCD and veterinary consultants), liaison with OIE/ overseas competent authorities related to animal diseases to ensure AFCD is kept up-to-date with the local and global disease status. On the request by the importing countries/places, the overseas competent authorities are also invited for inspection and other relevant procedures to demonstrate the disease-free status of animals (e.g. racehorses) in Hong Kong, China.

***What kind of Committee activities and documents are most useful to you in your domestic consultations on implementation of Article 6?***

1.49. AFCD's mainly referred to the established OIE Terrestrial Animal Health Code, Terrestrial Manual in the development of import requirements for animals and animal products. The World Animal Health Information System of OIE is also referred to for world-wide diseases situation.

***Have you used the Committee's Guidelines on Regionalization (G/SPS/48) in your efforts to seek recognition by another Member of your domestic control and enforcement systems for establishing and maintaining pest- or disease-free status? Are there areas of the Guidelines that could be improved?***

1.50. No.



***How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?***

1.51. AFCD does consider the OIE official disease-free status in drafting import terms for various live animals from different member countries. In exercising Article 6 of the SPS Agreement, AFCD takes into account the OIE disease-free country or zone status of an exporting country in deriving the import requirements of different animal species.

1.52. On the phytosanitary side, AFCD recognizes 'pest free areas' and 'areas of low pest prevalence' established under various relevant International Standard for Phytosanitary Measures (ISPMs) (e.g. 4, 8, 10, 22, 26) as guided by the ISPM29 (Recognition of pest free areas and areas of low pest prevalence). These ISPMs produced by the Commission on Phytosanitary Measures of the IPPC are well written and no further clarifications are required. Nonetheless, no exporting country has ever claimed pest-free or low pest prevalence status when exporting plant commodities to Hong Kong, China and vice versa.

## 1.7 Japan<sup>9</sup>

### Japan's comments

1.53. Before concluding whether the guidelines on regionalization ([G/SPS/48](#)) are to be reviewed or not, Japan suggests for Members to check and discuss how the existing guidelines have been used in particular regionalization endeavors and whether the guidelines have actually been applied bilaterally because once we go into the detail of review of the guidelines, we could spend considerable time and resources to complete this activity.

### Japan's enquiries

1.54. About the last question for Members: "How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?"

- (Question 1) Is the 1<sup>st</sup> sentence of this question intended to be answered from the standpoint of exporting countries, instead of importing countries?
- (Question 2) Could you clarify the intention of the 2<sup>nd</sup> sentence of the same question? Please clarify whether this question is asking if:
  - 1) An exporting Member has found the same international standard interpreted differently by its trading partners (e.g. importing Members)? or
  - 2) An exporting Member has found that an importing Member interprets the same international standards differently in some cases?

***What are your domestic procedures for establishing and maintaining pest- or disease-free status? What challenges have you encountered in implementing such procedures?***

1.55. Concerning animal health, Japan recovers the disease-free status of the whole country after the occurrence of Foot and Mouth Disease (FMD) and Avian Influenza (AI) by implementing the countermeasures according to the criteria for recovering the disease-free status of OIE code.

1.56. For instance, FMD occurred in Miyazaki Prefecture in April 2010, which was the first case in Japan for the last 10 years. Because the rapid spread of the disease was observed in the eastern

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<sup>9</sup> Japan provided two submissions, the first submission included general comments, as well as a request for clarification of one of the questions. Please refer to the introductory paragraphs of this document for the clarification provided by the co-sponsors. The second submission responded to the questions indicated in [G/SPS/W/311](#).

part of the Prefecture despite the implementation of the movement restriction and stamping-out policy, over 210 thousand animals were culled eventually. Emergency vaccination was applied for the first time in Japan to contain the rapid spread in the zone (87 thousand animals were vaccinated and slaughtered). And then, Japan recovered the status of FMD free country where vaccination is not practiced in February 2011.

1.57. In regard of plant health, the movement of pests and their hosts from the limited infested area in Japan, African Giant Snails in Ryukyu islands for example, is restricted. Where pests that are newly introduced in Japan or that already occur in a part of Japan potentially cause enormous damage to farm crops, or are considered to prevent the export of plant from Japan, they are subject to official control, including surveillance of the pest occurrence, restriction on the host plants movement, and destruction of the host plants to contain or eradicate the pests. Japan succeeded in eliminating Oriental fruit flies and Melon flies from the whole country, and still maintains free status of both pests.

***What kind of Committee activities and documents are most useful to you in your domestic consultations on implementation of Article 6?***

1.58. For domestic and international transparency purposes, standard procedures for approval for import of products from other countries have been developed, taking into account the Guidelines on Regionalization ([G/SPS/48](#)), as well as relevant international standards such as Import Risk Analysis (Terrestrial Animal Health Code Chapter 2.1) of OIE.

1.59. International standards of OIE and IPPC are cited more often in domestic consultation regarding approval of imports of specific products from other countries than SPS Committee documents.

***Have you used the Committee's Guidelines on Regionalization ([G/SPS/48](#)) in your efforts to seek recognition by another Member of your domestic control and enforcement systems for establishing and maintaining pest- or disease-free status? Are there areas of the Guidelines that could be improved?***

1.60. Japan requests the importing country to inform us of the necessary process and the requirements to enable the export of Japanese products to the country in accordance with the Guidelines on Regionalization ([G/SPS/48](#)).

***How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?***

1.61. Instead of answering part of the risk assessment questionnaire from Japan (e.g. information on the disease outbreaks and responses taken during the past cases), the exporting country may use the dossier submitted to the OIE for application for recognition of animal disease free status. As for plants, IPPC does not officially recognize pest free status.

1.62. Regarding the question of the second sentence, the Japanese authority does not possess sufficient information to compare each country's interpretation of the international standards.

1.63. Lastly, the Japanese Government views that capacity building activities for Members, creating manuals or training materials that help establishing and maintaining the disease or pest free areas in accordance with the OIE or IPPC standards, for instance, and information-sharing on how the guideline is actually applied by Members would greatly contribute, rather than its further clarification and detailing, in order to promote implementation of regionalization.

1.64. The IPPC International Symposium for Pest-Free Areas and Surveillance held in Japan in October this year is one of such activities that aim to better understand pest-free areas and to develop the ability of Members.

## 1.8 Mexico

### ***What are your domestic procedures for establishing and maintaining pest- or disease-free status? What challenges have you encountered in implementing such procedures?***

1.65. **For animals:** We have a technical evaluation procedure for the recognition of animal disease-free and pest-free zones, which is available to the general public. This procedure was established in accordance with national laws and following the recommendations of the Terrestrial Animal Health Code - World Organization for Animal Health (OIE), Chapter 4.3.

1.66. Actions taken to maintain disease- or pest-free zones are based on the recommendations issued by the OIE in the Terrestrial Animal Health Code and the requirements contained in national legislation (release agreements and campaign-related laws). There is a federal budget for maintaining these zones. These funds are intended for implementing preventive and control measures.

1.67. Improvement of processes has posed a significant challenge for national veterinary services because the necessary information is dispersed in a wide range of sources and the recommendations issued by international agencies only consider a minimum of information.

1.68. **For plants:** Internal procedures for declaring and maintaining the status of disease-free or pest-free zones in Mexico are the Official Mexican Standards, which are listed below:

1. Mexican Official Standard NOM-069-FITO-1995 on the establishment and recognition of pest-free areas;
2. Mexican Official Standard NOM-023-FITO-1995 establishing the National Campaign Against Fruit Flies.

1.69. These procedures are thus in line with International Standards for Phytosanitary Measures (ISPM):

1. ISPM 26: Establishment of pest-free areas for fruit flies (*Tephritidae*);
2. ISPM 4: Requirements for the establishment of pest-free areas.

1.70. Some challenges faced in maintaining these zones are the costs involved and legal oversight.

### ***What kind of Committee activities and documents are most useful to you in your domestic consultations on implementation of Article 6?***

1.71. **For animals:** Workshops, courses, debates and directives or recommendations on implementation. Regionalization strategies led by other countries, as well as review and update of information generated by each Member regarding implementation of Article 6.

1.72. **For plants:** Reference to document [G/SPS/48](#), Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

### ***Have you used the Committee's Guidelines on Regionalization ([G/SPS/48](#)) in your efforts to seek recognition by another Member of your domestic control and enforcement systems for establishing and maintaining pest- or disease-free status? Are there areas of the Guidelines that could be improved?***

1.73. **For animals:** They have been used both for obtaining recognition and for conferring it.

1.74. Response time of veterinary services to produce the file conferring recognition or formulating comments on the same must be agreed, as well as the response time of the authorities entrusted with handling a request in order to evaluate the documents submitted.

***How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?***

1.75. **For animals:** It is used as part and parcel of the technical evaluation procedure for the recognition of animal disease-free and pest-free areas.

1.76. Implementation has been in conformity with the general principles established by the OIE. More technical and scientific information (including sources) on implementation is needed to make proper use of regionalization.

1.77. **For plants:** In practice, few countries request recognition of pest-free areas but when they do, the criteria used to analyze the information and grant recognition where necessary are established in ISPM 4, ISPM 26 and ISPM 29.

1.78. It is worth mentioning that the fact of recognizing a pest for the recognition of a pest-free area does not necessarily imply establishing phytosanitary measures for imports since in addition, a pest risk analysis must be carried out.

## **1.9 Chinese Taipei**

***What are your domestic procedures for establishing and maintaining pest- or disease-free status? What challenges have you encountered in implementing such procedures?***

The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu set up procedures to establish and maintain disease or pest-free areas in accordance with "Statute for Prevention and Control of Infectious Animal Disease" and "Plant Protection and Quarantine Act". Relevant implementing regulations are established to prevent and control the occurrence, transmission or spread of animal and plant diseases and pests.

1. To control domestic diseases and pests:
  - 1) When establishing each implementing regulation, the competent authority invites stakeholders from relevant authorities, industries, academia and research institutes to take part in discussions, as well as collecting views from industrial groups, farmers, private companies and official inspectors to seek and achieve consent.
  - 2) To draft measures to monitor and control animal and plant diseases and pests based on OIE and IPPC standards, and to establish implementing regulation in order to enforce laws with penalties to violators.
  - 3) To continue collecting views from stakeholders and to adjust or amend pertinent measures in order to establish or maintain disease or pest-free status.
2. Quarantine for importing animals, plants and their products:
  - 1) To prevent the introduction of exotic animal and plant diseases and pests, the competent authority has established procedures of inspection and quarantine requirements for importing animals, plants and their products, as well as the designated fields to conduct animal and plant quarantine.
  - 2) To consult with exporting country to proceed with desk review for risk assessment and to conduct on-site audit in order to recognize the animal and plant disease or pest-free status of exporting country and to make sure its SPS measures achieve our level of protection.
3. Challenges in implementing the above-mentioned procedures:
  - 1) As for the prevention and control of animal and plant diseases, because lands for farming and husbandry are limited, and the lands are utilized extensively, these situations increase the difficulty of disease prevention and control.

- 2) As for import quarantine, because the major part of agri-food consumption is imported from other countries, we need to prevent exotic diseases or pests being introduced into our territory along with trade. Therefore, we have to strengthen import inspection and review capacity in order to maintain our disease or pest-free status.

***What kind of Committee activities and documents are most useful to you in your domestic consultations on implementation of Article 6?***

1.79. It is helpful that Members share their experiences in establishing and maintaining disease-free areas in the thematic meetings or workshops held by the SPS Committee. Besides, the Committee should encourage Members and regional organizations to apply for holding regional workshops in order to resolve the problem about disease transmission and disease-free area establishment in the region.

***Have you used the Committee's Guidelines on Regionalization (G/SPS/48) in your efforts to seek recognition by another Member of your domestic control and enforcement systems for establishing and maintaining pest- or disease-free status? Are there areas of the Guidelines that could be improved?***

1.80. The Decision of guidelines to further the practical implementation of Article 6 approved by SPS Committee is valuable as a reference. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu has set up relevant review and recognition procedures based on relevant international standards, guidance and recommendations, and the recommendations of the Decision.

***How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?***

1.81. We establish the recognition of disease and pest-free area review procedure based on the OIE Terrestrial Animal Health Code and IPPC standards, mainly with ISPM 4 and ISPM 26. The exporting country must submit relevant technical information for us to review the case.

1.82. Besides, as for the phytosanitary recognition of pest-free areas, we recommend that IPPC should establish more detailed guidelines in this field for WTO Members' reference.

#### **1.10 Turkey**

***What are your domestic procedures for establishing and maintaining pest- or disease-free status? What challenges have you encountered in implementing such procedures?***

1.83. Ministry of Agriculture and Forestry has published "Directive Related with the Definition and Declaration of Zones Free from Notifiable Avian Influenza Disease" and "Free of Avian Influenza Disease Zones" in order to protect animal and public health, provide safe animal origin production and sustain international trade.

1.84. This Directive includes the definition of the zones that will be defined as zones free of avian influenza, in addition to the procedures for active and passive surveys for preserving the disease-free status, animal movements between the regions and the procedures to be followed in the zones where the disease-free situation is suspended in detail.

1.85. In Turkey, pest and disease-free zones are established in line with ISPM 4 (Requirements for the Establishment of Pest Free Areas), ISPM 6 (Surveillance Guide) and ISPM 26 (Establishment of Pest Free Areas for Fruit Flies (*Tephritidae*)). In the implementation of *Tephritidae* procedures, difficulties such as limited budget and human resources have been encountered.

**How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?**

1.86. As an importing country, in addition to the regionalization criteria defined by the OIE for the recognition of disease-free regions in the exporting countries, there are some other criteria that are evaluated. For instance, whether the disease reports of the concerned country are regular or not; if the requirements defined in the OIE Code for disease-freedom have been fulfilled or the procedures of self-declaration and regionalization specific to the relevant disease have been completed.

### 1.11 Ukraine

**What are your domestic procedures for establishing and maintaining pest- or disease-free status? What challenges have you encountered in implementing such procedures?**

#### Phytosanitary information

1.87. The main international documents describing the procedures for the establishment of pest-free areas, production places and sites by which Ukraine is guided are:

- WTO SPS Agreement;
- ISPM No. 4 Requirements for the establishment of pest free areas;
- ISPM No. 10 Requirements for the establishment of pest free places of production and pest free production sites.

1.88. Phytosanitary requirements of norms for objects of regulation (which will be exported to partner countries) concerning areas, production places and (or) sites free from definite pest - exports of such objects will be made exclusively from production places or production sites established in accordance with Article 31 of the Law of Ukraine "On Plant Quarantine" and the Procedure for the official establishment and/or maintenance of the status of a place of production or production site free of regulated pests, deprivation of such status, its renewal, and other conditions for the official establishment of the place of production or production site, approved by the order of the Ministry of Agrarian Policy and Food of Ukraine dated 7 August 2012 No. 487.

#### Problems

- Low awareness of agricultural producers about the procedures for the establishment of pest- free areas, production places and sites;
- Setting the boundaries of buffer areas.

#### Veterinary information

1.89. The Law of Ukraine "On Veterinary Medicine" defines in Article 22, development, introduction and approval of veterinary and sanitary measures. All veterinary and sanitary measures are based on international standards, guidelines and recommendations of relevant international organizations.

1.90. In order to control animal diseases, the State Service of Ukraine on Food Safety and Consumer Protection (SSUFSCP) and scientific institutions under the control of the SSUFSCP annually develop the Plan of anti-epizootic measures for the prevention main infectious parasitic animal diseases in Ukraine; the State plan of monitoring of infectious diseases on the territory of Ukraine is approved, and Procedure for carrying out monitoring researches on infectious diseases.

**What kind of Committee activities and documents are most useful to you in your domestic consultations on implementation of Article 6?**

1.91. Article 6 of the WTO SPS Agreement is used for the national (intra-state) harmonization of normative legal acts, for vertical as well as horizontal legislation. For example, the Order "On approving requirements for importing (sending) into the customs territory of Ukraine of live animals,



their reproductive material, food products of animal origin, feed, hay, straw, as well as by-products of animal origin and products of their processing" from 16 November 2018 #553, <https://zakon.rada.gov.ua/laws/show/z0346-19>.

***Have you used the Committee's Guidelines on Regionalization (G/SPS/48) in your efforts to seek recognition by another Member of your domestic control and enforcement systems for establishing and maintaining pest- or disease-free status? Are there areas of the Guidelines that could be improved?***

Phytosanitary information

1.92. Not used. However, the Competent Authority in Ukraine (SSUFSCP) is guided by ISPM No. 4 Requirements for the establishment of pest free areas and ISPM No. 10 Requirements for the establishment of pest free places of production and pest free production sites.

Veterinary information

1.93. Not used. However, in drafting regulations that are considered regionalization standards Health Code OIE Terrestrial Animal chapters 4.3 and 4.4 of the establishment in Ukraine compartmentalization mechanism.

***How do you use IPPC/OIE official pest- or disease-free country or zone status in implementing Article 6? In your efforts to seek recognition by another Member or Member(s), have you found that OIE or IPPC standards are interpreted and applied consistently? Are there areas where additional clarification in the international standards or guidelines would be beneficial?***

1.94. Ukraine based its SPS measures on the standards, directives and recommendations of the Codex Alimentarius Commission, the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC) in accordance with the requirements of the WTO SPS Agreement.

1.95. Some countries do not always take into account IPPC / OIE status of pest and animal disease freedom for a country or an area. They need to comply with the laws of the exporting country.

Phytosanitary information

1.96. Letters to the Members are sent with the request to recognize the territory of Ukraine as a free area from the quarantine organisms included in the list A1 of the List of regulated pests (quarantine organisms) approved by the Order of the Ministry of Agrarian Policy of Ukraine, 29 November 2006 No. 716 "On Approval the List of Regulated Pests".

1.97. In order to implement the phytosanitary requirements, it is proposed that agricultural producers and exporters establish sites and places of production free of pests, if such an action is required by the country of import.

1.98. Application form and procedure approved by order of the Ministry of Agrarian Policy and Food of Ukraine, 8 September 2012 № 487, the fee for the inspection of agricultural crops to detect quarantine organisms to provide and/or confirm the status of the place of production or production sites at the request of the person who produces the regulated objects by the Law of Ukraine "On Plant Quarantine" approved by the Resolution of the Cabinet of Ministers of Ukraine, 28 December 2011 No. 1348. In order to establish the status of the place of production or production site free from pest, the business operator is provided to the territorial authority of the SSUFSCP.

Veterinary information

1.99. Letters to the Members (Competent Authorities) are sent to the information on outbreaks of infectious animal diseases for their elimination and notification through international organizations (OIE, WTO) and bilaterally.

**Other comments**

1.100. Ukraine submits the following question to the OIE:

- 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?

**2 QUESTIONS FOR MEMBERS AND IPPC AND OIE REPRESENTATIVES****2.1 Argentina*****Are there ways for the SPS Committee to collaborate more effectively with IPPC and OIE to strengthen implementation of international standards on regionalization and Article 6?***

2.1 Section V of the guidelines contained in document [G/SPS/48](#) concerns monitoring, and encourages Member to inform the Committee when:

- a) *a request for recognition of pest- or disease-free area or area of low pest or disease prevalence is made; and/or*
- b) *a determination on whether to recognize pest- or disease-free areas or areas of low pest or disease prevalence is made.*

2.2 In order to obtain the recognition of pest-free areas by different countries, it would be very useful if the Committee encouraged countries to actively participate in monitoring activities to improve the implementation of Article 6 on regionalization.

2.3 It is important to note that the recognition of a disease-free country or area is only the beginning of the process of opening up a market, which determines the eligibility of its status for exportation. Recognition is generally followed by several (or all) the following steps:

1. Completion of a risk assessment, depending on the goods to be exported, in order to establish "sanitary import requirements".
2. Negotiation and agreement on the veterinary certificate to be issued.
3. Completion of the process for the accreditation of exporting establishments (such as livestock, production, processing and storage establishments). This step may involve a second inspection visit, which may be conducted via pre-listing or on an individual basis by establishment.

2.4 To eliminate delays in the process to adopt the OIE's official recognition of pest- and disease-free status, the following opportunities for improvement have been identified:

1. Identify, through the Observatory on the implementation of OIE Standards, of the constraints involved in the official OIE recognition process, as well as those faced by importing countries or blocs when adopting such recognition. This would allow for changes to be made to the process at the level of the OIE, and for cooperation and training instruments to be developed for importing countries and blocs.
2. Seek to ensure that, as a result of the above action, importing countries/blocs are able to automatically adopt official recognition by the OIE without delay.
3. Ensure that requests for information (questionnaires) are restricted to diseases for which there is no official recognition by the OIE, are standardized as far as possible, and take into account the validity of available material such as past audit reports and Performance of Veterinary Services (PVS) reports.
4. Create and establish enforcement and surveillance bodies at the WTO (step prior to dispute settlement and penalties).

2.5 Argentina considers that its strategy to address this issue could also be applied in the context of the Agreement on Trade Facilitation (Chapter on SPS), which concerns trade operators more directly.

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

2.6 Not applicable.

**2.2 Brazil**

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

2.7. The SPS Committee should seek greater commitment from Members towards recognition of health statuses established by the OIE or in accordance with the standards of IPPC without undue delay or, in case of non-recognition of the health status of a country or zone, justifying to the exporting party the scientific reasons for non-recognition.

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

2.8. In the case of animal health, the OIE standards are built on a broad process with free participation of the member countries and are usually based on a sound scientific basis and can therefore be considered reliable for the safe trade of food.

**2.3 European Union**

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

2.9. In 2018, the World Assembly of OIE Delegates adopted a resolution recommending the establishment of an Observatory on the implementation of OIE Standards by its member countries. Monitoring, identifying and analyzing difficulties faced by its member countries enables the OIE to ensure a more effective implementation of its standards, including regionalization. The European Union strongly supports this initiative and hopes that it will facilitate the good understanding and application of the regionalization principles worldwide.

2.10. The European Union also sees the benefits of similar initiatives to be carried out by IPPC. The European Union welcomes the activities of the IPPC regarding the development of a guide on pest-free areas.

2.11. In the opinion of the European Union, it is very important that OIE and IPPC continue to share regularly the state of play of their work on regionalization with the SPS Committee.

**2.4 Hong Kong, China**

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

2.12. No comment.

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

2.13. The Centre for Food Safety (CFS) is the food safety authority under the Food and Environmental Hygiene Department. It makes reference to the OIE recommendations for importation of meat for consumption when negotiating import protocols with a potential exporting country. CFS also adopts the concept of zoning and compartmentalization as recommended by the OIE to ensure the safety of imported food.

## 2.5 Japan

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

2.14. It would be beneficial for all the Members to share the examples of questions of importing Members which the exporting Members could not answer or the data the exporting Members did not have, in the aim of identifying the type of capacity building needed by Members, especially developing countries, for implementing pest or disease-free areas.

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

2.15. Not applicable.

## 2.6 Mexico

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

2.16. **For animals:** Yes, by encouraging the participation of persons with direct responsibility (in each country) for the understanding and implementation of regionalization in ISPM and OIE meetings. This would enable them to draft technical documents that contain real case studies and tried and tested alternative solutions, thus facilitating the understanding of each Member and building their capacity to identify, resolve and document problems and share success stories, which can then be incorporated into international standards.

2.17. **For plants:** Through IPPC meetings to which they are invited to participate. At these forums they can express the concerns of the Committee and of WTO Members.

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

2.18. **For animals:** The OIE's analysis is based on available scientific evidence.

2.19. **For plants:** In the case of Mexico, when phytosanitary requirements are negotiated for the export of produce to countries that do not have an SPS system or programme, the ISPM is the most important reference for facilitating formalities. This is where the importance of the IPPC's standard setting work and its capacity to remain updated come into play.

## 2.7 Chinese Taipei

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

2.20. No comment.

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

2.21. No comment.

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