



**Committee on Sanitary and Phytosanitary Measures**

**ANNUAL REPORT ON THE PROCEDURE TO MONITOR THE PROCESS  
OF INTERNATIONAL HARMONIZATION**

NOTE BY THE SECRETARIAT<sup>1</sup>

**1 INTRODUCTION**

1.1. At its meeting of 15-16 October 1997, the SPS Committee adopted a provisional procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations, as provided for in Articles 3.5 and 12.4 of the SPS Agreement. The Committee extended the provisional monitoring procedure in 1999, 2001, and 2003, and revised the procedure in October 2004.<sup>2</sup> In 2006, the Committee agreed to extend the provisional procedure indefinitely, and to review its operation as an integral part of the periodic review of the operation and implementation of the Agreement under Article 12.7.<sup>3</sup> The procedure was reviewed as part of the Third Review of the Agreement<sup>4</sup>, and again in the context of the Fourth<sup>5</sup> and Fifth Review.<sup>6</sup>

1.2. In November 2020, New Zealand submitted a proposal on the procedure to monitor the process of international harmonization ([G/SPS/GEN/1851](#)), followed by a subsequent proposal ([G/SPS/GEN/1877](#)) in February 2021. The Committee discussions on these proposals are detailed in Section 4.1 of this document.

1.3. The Committee has previously considered twenty-two annual reports on the monitoring procedure.<sup>7</sup> These reports summarize several standards-related issues that the Committee has considered and the responses received from the relevant standard-setting organizations. This current report includes the issues that were considered in the June and November 2020, and March 2021 Committee meetings.

**2 NEW ISSUES**

2.1. Since the 2020 Annual Report, four new issues have been raised under this procedure: (i) Codex Maximum Residue Limits and Risk Management Recommendations for Residues of Veterinary Drugs in Foods (CX/MRL 2-2018); (ii) Codex Alimentarius Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); (iii) Newcastle disease restrictions not consistent with the OIE international standard; and (iv) restrictions on exports of chocolate and cocoa products due to the lack of an international standard.

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<sup>1</sup> This document has been prepared under the Secretariat's own responsibility and is without prejudice to the position of Members or to their rights and obligations under the WTO.

<sup>2</sup> [G/SPS/14](#), [G/SPS/17](#), [G/SPS/25](#) and [G/SPS/11/Rev.1](#).

<sup>3</sup> [G/SPS/40](#).

<sup>4</sup> [G/SPS/53](#).

<sup>5</sup> [G/SPS/62](#).

<sup>6</sup> [G/SPS/64/Add.1](#).

<sup>7</sup> These were circulated as [G/SPS/13](#), [G/SPS/16](#), [G/SPS/18](#), [G/SPS/21](#), [G/SPS/28](#), [G/SPS/31](#), [G/SPS/37](#), [G/SPS/42](#), [G/SPS/45](#), [G/SPS/49](#), [G/SPS/51](#), [G/SPS/54](#), [G/SPS/56](#), [G/SPS/59](#), [G/SPS/60](#), [G/SPS/GEN/1332](#), [G/SPS/GEN/1411](#), [G/SPS/GEN/1490](#), [G/SPS/GEN/1550](#), [G/SPS/GEN/1617](#), [G/SPS/GEN/1710](#) and [G/SPS/GEN/1776](#).

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### **2.1 Codex Maximum Residue Limits and Risk Management Recommendations for Residues of Veterinary Drugs in Foods (CX/MRL 2-2018)**

2.2. At the June 2020 Committee meeting, the United States submitted its statement in document [G/SPS/GEN/1801/Rev.1](#).

2.3. Canada provided the following statement: Canada would like to thank the United States for raising the issue of the Codex Maximum Residue Limits and Risk Management Recommendations for Residues of Veterinary Drugs in Foods. Canada recalls the substantial effort to establish an international standard for ractopamine at Codex. The FAO/WHO Expert Committee on Food Additives (JECFA) conducted comprehensive risk assessments considering its toxicology, residues in and intake from food animals in 1993, 2004, 2006 and in 2010, and concluded that the recommended MRLs were safe for the consumption of muscle, liver, kidney and fat. The Codex Alimentarius Commission adopted MRLs for ractopamine in 2012 after discussing the issue for the previous four sessions. Non-adoption by Members of the ractopamine MRL, as well as other standards, recommendations and guidance established by Codex may unnecessarily increase costs for producers, processors and exporters, which results in higher prices for consumers around the world.

2.4. Paraguay provided the following statement: My delegation would like to thank the delegation of the United States for placing this item on the agenda. Paraguay has always supported and will continue to support the Codex work in this area. We urge all Members to follow the Codex recommendations to avoid the proliferation of non-tariff barriers to trade in agricultural products and of standards with which compliance may be impossible for developing countries that depend on exports of these products to sustain their economy and the subsistence of hundreds of thousands of people.

### **2.2 Codex Alimentarius Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003)**

2.5. At the November 2020 Committee meeting, the United States submitted its statement in document [G/SPS/GEN/1864](#), which highlighted the gaps between the regulatory procedures maintained by some Members for approval of genetically engineered (GE) food products and the Codex Guideline CAC/GL 45-2003. The United States regretted that some Members' requirements to conduct animal studies delayed the approval of, use of, and trade in useful and demonstrably safe products. The United States encouraged Members to eliminate those requirements, focus data requirements on the information necessary for conducting safety assessments, and consider Codex guidelines.

2.6. Argentina considered that Members should eliminate their requirements to routinely perform animal studies, which affected innovation and normal trade flows. Argentina reaffirmed the importance of following international, science-based guidelines.

2.7. Canada thanked the United States and reiterated the importance to base measures on international standards. Highlighting some of the conclusions of CAC/GL 45-2003, Canada underlined the importance of Members taking timely science- and risk-based regulatory decisions, taking into account the Codex food safety advice.

2.8. Paraguay expressed interest in sponsoring this item, highlighting the unnecessary costs and requirements resulting from differences between Codex and approval procedures established by some Members. Paraguay urged Members to contribute to international harmonization in order to facilitate trade.

### **2.3 Newcastle disease restrictions not consistent with the OIE international standard**

2.9. At the November 2020 Committee meeting, Turkey expressed its concern regarding the import restrictions imposed by some countries for heat-treated poultry meat from Turkey with regard to Newcastle disease. Turkey stated that paragraph 2 of Article 10.9.15 of the OIE Terrestrial Code indicated that heat-treated poultry meat was not an import risk. According to Turkey, some Members still imposed trade barriers for the heat-treated poultry meat products. Turkey referred to Article 3 of the SPS Agreement on harmonization and requested Members to follow the recommendations in Article 10.9.20 of the OIE Terrestrial Code.

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## **2.4 Restrictions on exports of chocolate and cocoa products due to the lack of an international standard**

2.10. At the November 2020 Committee meeting, Peru referred to the development and discussion of maximum levels of cadmium in chocolate and cocoa products within the Codex Committee on Contaminants in Foods (CCCF), as well as the importance of having an international standard for a sector that is of great social and economic significance to Peru. The lack of a Codex standard had led countries to adopt standards that were more trade restrictive than necessary.

2.11. Peru invited Members to coordinate with their respective health authorities, in order to achieve consensus by honouring the agreement to apply a criterion of proportionality when establishing, at the next CCCF meeting, maximum levels of cadmium for the following categories: (i) cocoa powder ready for consumption containing or declaring 100% total cocoa solids; and (ii) chocolate containing between 30% and 50% of total dry cocoa solids. Peru requested the secretariat of the Codex Alimentarius Commission (CAC) to ensure the development of science- and data-based standards. Peru also asked Members having already established maximum levels of cadmium for chocolate and cocoa products to review their standards on the basis of the findings presented within the CCCF and to inform their trade operators that these standards do not apply to cocoa beans.

2.12. Colombia indicated that this topic was of high interest for Colombia, given the implications in trade of chocolate and cocoa products. Colombia invited Members to take into account the considerations raised by Peru.

## **3 PREVIOUS ISSUES**

3.1. Since the 2020 Annual Report, there was further discussion on two issues previously raised under this procedure regarding: (i) ASF restrictions not consistent with the OIE international standard; and (ii) HPAI restrictions not consistent with the OIE international standard.

### **3.1 ASF restrictions not consistent with the OIE international standard**

3.2. At the June 2020 Committee meeting, the European Union submitted the following statement: Once again, the European Union must draw the attention of WTO Members to inconsistencies in the application of OIE international standards related to African swine fever. The OIE Terrestrial Code contains clear guidance for the identification, treatment and certification of tradable products. Yet, several WTO Members chose to ignore these recommendations that were developed, consolidated and adopted in the OIE with the support of these same Members.

3.3. Through the European Union's strict regionalisation policy, the European Union demonstrates every day in its single market that African swine fever can be managed effectively to make sure that legitimate and safe trade is not the cause of any outbreak. The European Union is highly transparent on its disease control measures and provides information through the websites of the EU Commission, of the member States, of the OIE and through bilateral contacts with trade partners. For example, weekly synthesis reports are published by the EU Commission.

3.4. The European Union would like to insist that WTO Members apply import measures that are consistent with the SPS Agreement and with international standards. The European Union continues to give high priority to this issue and stands ready to work with WTO Members to remove country-wide and scientifically unjustified bans. Given the large number of WTO Members affected by the disease, from EU member States to China, from Belarus to Malaysia, the European Union has suggested to organise a thematic session on the subject of African swine fever ([G/SPS/W/322](#)).

3.5. At the November 2020 Committee meeting, the European Union drew Members' attention to inconsistencies in the application of OIE international standards related to ASF. The European Union noted that several Members did not follow the OIE Terrestrial Code recommendations that had been developed and adopted with their support. The European Union had demonstrated in its single market that the disease could be managed effectively to ensure that legitimate trade was not the cause of any outbreak. The European Union was transparent on its disease control measures and provided information through many channels. ASF was a disease affecting many EU and non-EU countries.

3.6. The European Union welcomed the decision to organize a thematic session on ASF in March 2021. The objective would be to build confidence among Members to apply trade conditions consistent with the SPS Agreement and international standards. The European Union invited Members to work together to prepare the thematic session and work on the removal of country-wide and scientifically unjustified trade bans.

3.7. At the March 2021 Committee meeting, the European Union drew the Committee's attention to inconsistencies in the application of OIE international standards related to ASF. The European Union considered that many Members did not follow the OIE Terrestrial Code guidance for the identification, treatment and certification of tradable products. The European Union highlighted that it had, as well as other Members, demonstrated that ASF could be managed effectively to ensure that legitimate trade was not the cause of any outbreak. The European Union added that ASF was a disease affecting many EU and non-EU countries. The European Union invited Members to work on the removal of country-wide and scientifically unjustified trade bans.

### **3.2 HPAI restrictions not consistent with the OIE international standard**

3.8. At the June 2020 Committee meeting, the European Union submitted the following statement: The European Union appreciates the cooperation with those WTO Members that recognise the principle of zoning and accept the regionalisation measures put in place in the European Union. Many Members trust the European Union's effective and transparent system of control and eradication of animal diseases like avian influenza for many years now (and vice versa) and we do not experience any incident that would put this trust in question. On the other hand, there is still a significant number of WTO Members that disregard their obligations under Article 6 and Annex C of the SPS Agreement, in particular China, Korea and South Africa.

3.9. Country-wide bans after a disease outbreak are not scientifically justified. There is also no justification for WTO and OIE Members to wait one year or more to restore the disease-free status - instead of the three months defined by the OIE Code. The European Union successfully manages regionalisation measures in its entire territory, namely the single market of its member States. The veterinary services of all EU member States work in full transparency. Trade partners of the European Union can be reassured that it is at all times fully aware of the animal health situation in all member States.

3.10. The European Union reiterates its call to all WTO Members to respect their obligations on regionalisation under the WTO SPS Agreement; allow trade of all safe products from non-affected zones; lift all bans after regaining freedom 3 months after the application of stamping-out, cleaning and disinfection of all affected premises; refrain from imposing trade restrictions in case of HPAI in wild or captive birds; refrain from imposing trade restrictions in case of detected LPAI. The European Union has repeatedly explained the disease control and regionalisation measures taken in the event of an outbreak and offered bilateral structured dialogues to come to a solution with WTO Members. Unfortunately, these offers have not yielded concrete results so far.

3.11. The European Union appeals to WTO Members to respect the recommendations of international standard-setting bodies. These recommendations were developed and adopted with their support.

3.12. At the November 2020 Committee meeting, the European Union praised those Members that trusted the EU effective and transparent system of control and eradication of animal diseases such as AI. The European Union regretted that some Members disregarded their obligations under Article 6 and Annex C of the SPS Agreement. Country-wide bans after a disease outbreak were not scientifically justified, and there was no justification to wait one year or more to restore the disease-free status, instead of the three months defined by the OIE Terrestrial Code. The European Union reiterated its call to all Members to respect their regionalization obligations; allow trade of all safe products from non-affected zones; lift all bans after regaining freedom three months after eradication and re-instate trade conditions applicable to disease-free countries without delay; refrain from imposing trade restrictions in case of HPAI in wild birds; and refrain from imposing trade restrictions in case of detected LPAI. The European Union appealed to Members to respect the recommendations of ISSBs that had been developed and adopted with their support.

3.13. At the March 2021 Committee meeting, the European Union praised those Members trusting the effective and transparent EU system of surveillance, regionalization and eradication of animal diseases such as avian influenza. The European Union regretted, however, that some Members disregarded their obligations under Article 6 and Annex C of the SPS Agreement. Country-wide bans after a disease outbreak were not scientifically justified where effective movement controls were in place, and there was no justification to wait one year or more to restore the disease-free status, instead of the three months in the OIE Terrestrial Code. The European Union reiterated its call to Members to respect their regionalization obligations; allow trade from non-affected zones; lift bans three months after eradication and reinstate trade conditions applicable to disease-free countries without delay; refrain from imposing trade restrictions in case of HPAI in wild birds; and refrain from imposing trade restrictions in case of detected low pathogenicity avian influenza (LPAI). The European Union called on Members to respect the recommendations of ISSBs, which had been developed and adopted with their support.

3.14. The OIE provided an update regarding the relevant chapter of the OIE Terrestrial Code (Chapter 10.4), which had undergone extensive revisions to be proposed for adoption at its May 2021 General Session. The OIE highlighted some of the revisions, including a change to the title of the chapter (to refer to infection with HPAI viruses), a modification to the list of disease names in Chapter 1.3, and impacts on notification and surveillance requirements notably for LPAI, a new article on safe commodities, and a revision of the definition of poultry. The OIE pointed to the Terrestrial Code Commission Report of February 2021 (Part A) on its website, detailing the amendments.

## **4 OTHER ISSUES**

### **4.1 Procedure to monitor the process of international harmonization**

4.1. At the November 2020 Committee meeting, New Zealand presented its proposal submitted in [G/SPS/GEN/1851](#). New Zealand's proposal was in response to renewed discussion by the ISSBs on the use and impact of their standards. The IPPC had reported on the activities of the Implementation Review and Support System (IRSS), including a general survey on the IPPC and use of its standards. The OIE had initiated an Observatory project with the aim of assessing the implementation of standards, and what the impediments were to their implementation. Codex was exploring the issue in relation to its parent bodies (FAO/WHO), as significant funds were used to develop standards. New Zealand believed there was merit in promoting some discussion on what further role the Committee could play in assisting the ISSBs in monitoring the use of their international standards, as laid out in Articles 3.5 and 12.4 of the SPS Agreement. New Zealand suggested that the Secretariat invite Members and the ISSBs to propose ideas and suggestions on how the Committee could proactively explore this topic.

4.2. At the March 2021 Committee meeting, the Chairperson reminded the Committee that Members had had an opportunity to discuss New Zealand's submissions in [G/SPS/GEN/1851](#) and [G/SPS/GEN/1877](#) regarding the procedure to monitor the process of international harmonization at the informal meeting of the Committee of 24 March 2021. The Chairperson drew the Committee's attention to the summary of these discussions in his draft report on the informal meeting, which had been shared with Members to provide comments by the deadline of 23 April.<sup>8</sup>

## **5 RESPONSES RECEIVED FROM THE RELEVANT STANDARD-SETTING ORGANIZATIONS**

5.1. There have been no further responses received from the relevant standard-setting organizations since the last annual report.

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<sup>8</sup> The Chairperson's summary of the discussions on New Zealand's proposal held in the March 2021 informal Committee meeting is contained in Annex A of the summary report, [G/SPS/R/101](#).