

**Committee on Sanitary and Phytosanitary Measures**

**PROCEDURE TO MONITOR THE PROCESS  
OF INTERNATIONAL HARMONIZATION**

Draft Twelfth Annual Report<sup>1</sup>

Revision

The draft Twelfth Annual Report on the Procedure to Monitor the Process of International Harmonization was considered by the SPS Committee at its meeting of 29-30 June 2010. The Committee agreed to adopt the report subject to its revision to include information arising from discussions under the relevant agenda item at that meeting. The proposed revision was circulated to Members on 20 July 2010. Following comments by China and the United States, a new revision was circulated on 1 September, with a deadline for comments of 24 September 2010.

Japan has proposed further modifications to the report, as indicated below in paragraph 10. The Committee will be invited to adopt this revised report at its meeting of 20-21 October 2010.

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A. INTRODUCTION

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 adopted a revision of the procedure in October 2004.<sup>2</sup> On 28 June 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> This procedure was reviewed as part of the Third Review of the Agreement adopted by the Committee in March 2010.<sup>4</sup> The next such review is to be completed in 2013, and every four years subsequently.

2. The Committee has previously adopted eleven annual reports on the monitoring procedure.<sup>5</sup> These reports summarize several standards-related issues that the Committee has considered and the responses received from the relevant standard-setting organizations.

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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 or 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> 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 and G/SPS/51.

B. NEW ISSUES

3. Since the adoption of the Eleventh Annual Report in June 2009, one new issue was raised under this procedure. This issue is with regard to concerns relating to the lack of adoption of an MRL for ractopamine by the Codex Alimentarius Commission (Codex).

**Concerns on lack of adoption of MRL for Ractopamine by Codex**

4. At the meeting of the Committee of 28-29 October 2009, Brazil raised the issue of the lack of adoption of an MRL for ractopamine by Codex. The United States added that some Members had imposed ractopamine bans without sufficient scientific evidence to support them. Extensive discussions on this matter occurred during the last two Codex sessions and at the 18<sup>th</sup> session of the Codex Committee on Residues of Veterinary Drugs in Foods. Ractopamine had been approved by over 25 countries and the draft MRL was currently at Step 8 in the Codex process. Advice from JECFA to adopt the ractopamine MRL at Step 8 had been presented previously and adoption had been recommended in 2007 by the Committee on Residues of Veterinary Drugs in Foods. Australia, Canada, and the United States agreed with Brazil on the need for a rapid adoption of a Codex standard for ractopamine, to avoid further trading difficulties. Codex had not adopted the draft MRL for ractopamine at its 2009 session because of a request from China that JECFA conduct additional scientific review.

5. The European Union noted that in April 2009 the European Food Safety Authority (EFSA) had issued a scientific opinion regarding the harmfulness of this substance. China had also conducted a study on the effect of ractopamine on the tissue of pigs. Norway supported the intervention of the European Union and China, and stressed the need for JECFA to evaluate the latest data submitted by China before coming to a final conclusion.

6. The Codex representative confirmed that Codex had decided in July 2009 that JECFA should evaluate the Chinese studies before coming to a decision. It was agreed that JECFA would review the data that had not been previously reviewed before the next session of the Commission in July 2010.

7. At the meeting of the Committee in June 2010, the United States recalled the earlier discussions on this topic and explained that JECFA had recently concluded that the 2009 Chinese studies confirmed the validity of the proposed MRls. In light of the JECFA findings, the United States expressed strong support that the eight MRLs for ractopamine would be adopted at the July 2010 meeting of the Codex Alimentarius Commission. Canada, Brazil and South Africa agreed that there was scientific evidence to establish the MRLs at this time. The European Union stated that it was too early to prejudge the outcome of that discussion. China supported the position of the European Union and was of the opinion that Codex should continue its discussion based on science. The representative of South Africa noted that when the standard-setting process takes several years, it may encourage the emergence of private standards.

8. The representative of Chile indicated that this type of situation made clear the need for a procedure to voice a concern when a standard is held at Step 8 for several years.

C. PREVIOUS ISSUES

9. Since the adoption of the Eleventh Annual report, there was further discussion on one issue previously raised under this procedure. This issue is with regard to concerns raised relating to a draft regional standard of the North American Plant Protection Organization (NAPPO) entitled "Guidelines for Regulating the Movement of Ships and Cargoes Aboard those Ships from Areas Infested with the Asian Gypsy Moth" (RSPM N 33).

### **Concerns on regional standard of the North American Plant Protection Organization**

10. At the meeting of the Committee of 28-29 October 2009, China raised concerns, for the fourth time before the SPS Committee, about a regional standard approved by NAPPO on 10 August 2009. This standard provides NAPPO member countries (Canada, Mexico and the United States) with guidelines for risk management aimed at minimizing the entry and establishment of the Asian gypsy moth (AGM) in North America. It describes risk management options for ships which called on ports where the AGM is present, including China, Japan, Korea, Mongolia and Russia. It also describes measures necessary for cargo from or passing through infested areas destined to North America. Specific risk management options are adopted and applied by each NAPPO member country. China, Korea, and Japan reiterated their serious concerns regarding the trade impact of this regional standard. These Members China had previously suggested that this standard was inconsistent with Articles 2.2 and 5.6 of the SPS Agreement and that it had ambiguities regarding the technical application of the measure in different NAPPO countries and in different climatic conditions. The concern had been supported by Korea and Japan.

11. At the meeting of the Committee in March 2010, Korea stated that it had held technical consultations on this issue with Canada and the United States in February 2010. Korea hoped NAPPO countries would continue to have discussions with the concerned countries with a view to minimize the negative trade impact of this regional standard.

12. Canada noted that the NAPPO measure on AGM was being put in place to control the risk to North America's forests. NAPPO representatives had been diligent in ensuring that all concerned stakeholders, including the shipping industry, had been consulted. The standard would be phased in with full implementation taking place in March 2012. The standard had taken all possible SPS measures into consideration and had been developed to be no more trade restrictive than necessary to manage the risk. Furthermore, all NAPPO member countries were working with affected Members to come up with appropriate implementation plans and a number of Members had already participated in these meetings. The risk of the introduction of AGM to NAPPO member states was acute. In 2009, Canadian authorities had detected egg masses, each containing thousands of eggs, on ten ships travelling from the region.

13. The representative of Chile suggested that this topic should be addressed as a specific trade concern. The IPPC indicated that although regional plant protection organizations were recognized in the IPPC Convention and often regional organizations deposited a regional standard with the IPPC, this did not make it an international standard. The IPPC work programme included consideration of the need for an international standard on the movement of pests via ship containers and vessels. In such situations, the IPPC might use a regional standard as the basis for the development of an international standard.

14. This standard was distributed by NAPPO to the FAO/IPPC Secretariat and the Administrative heads of the Regional Plant Protection Organizations.

15. At the meeting of the Committee in June 2010, Chile again questioned whether it was appropriate to consider a regional standard under an agenda item that monitored the use of international standards. Chile and New Zealand suggested that this topic not be included in this report, but rather in the compilation of specific trade concerns (G/SPS/GEN/204/Rev.10). China maintained that this report should include all issues that had been discussed under this agenda item, so as to provide a complete record of the Committee's deliberations.

D. RESPONSES RECEIVED FROM THE RELEVANT STANDARD-SETTING ORGANIZATIONS

16. No further information has been provided by the relevant standard-setting organizations regarding other issues previously raised.

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