WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures

PROCEDURE TO MONITOR THE PROCESS OF INTERNATIONAL HARMONIZATION

Draft Thirteenth Annual Report[1]

Revision

The draft Thirteenth Annual Report on the Procedure to Monitor the Process of International Harmonization was considered by the SPS Committee at its meeting of 30 June - 1 July 2011. 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. This revision includes that information.

Members wishing to suggest modifications to this draft report are invited to submit their comments to the Secretariat (Gretchen.Stanton@wto.org) no later than **2 September 2011**. If no substantive objection to the report has been submitted by that date, the report will be considered to have been adopted.

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.[2] 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.[3] This procedure was reviewed as part of the Third Review of the Agreement adopted by the Committee in March 2010.[4] The next such review is to be completed in 2013, and every four years subsequently.

2. The Committee has previously adopted twelve annual reports on the monitoring procedure.[5] 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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[1] 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.

[2] G/SPS/14, G/SPS/17, G/SPS/25 and G/SPS/11/Rev.1.

[3] G/SPS/40.

[4] G/SPS/53.

[5] 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 and G/SPS/54.

B. NEW ISSUES

3. Since the adoption of the Twelfth Annual Report in October 2010, no new issue has been raised under this procedure.

C. PREVIOUS ISSUES

4. Since the adoption of the Twelfth Annual Report, there was further discussion on one issue previously raised under this procedure. This issue is with regard to the lack of adoption by the Codex Alimentarius Commission of standards relating to ractopamine.

Concerns on the lack of adoption of Codex standards relating to ractopamine

5. Brazil first raised the issue of the lack of adoption of an MRL for ractopamine by Codex at the meeting of the Committee of 28-29 October 2009. Brazil reported that extensive discussions on this matter had occurred during the previous two Codex sessions and at the 18th session of the Codex Committee on Residues of Veterinary Drugs in Foods. Adoption of the MRLs had been recommended in 2007 by the Committee on Residues of Veterinary Drugs in Foods. At the October 2009 meeting, the European Union, China and Norway stressed that it had been agreed in Codex that JECFA would evaluate the latest data submitted by China before the Codex Commission session in July 2010.

6. This issue was again raised at the SPS Committee meeting in June 2010, where Canada, Brazil, South Africa and the United States expressed strong support that the eight MRLs for ractopamine be adopted at the July 2010 meeting of the Codex Commission. China and the European Union reiterated their previous concerns that it was too early to prejudge the outcome of that discussion. The representative of Chile indicated that this type of situation made clear the need for a procedure to voice a concern when a Codex standard was held at Step 8 for several years.

7. At the meeting of the Committee of 30-31 March 2011, Brazil noted that the continuing failure of Codex to adopt MRLs for ractopamine raised the issue of the lack of respect of scientific principles by Codex. In 2008, Codex had decided to hold the proposals of MRLs for ractopamine at Step 8, and invited members to send further data to be analysed. To overcome the deadlock on the approval of ractopamine MRLs at the 33rd Session of the Commission in 2010, a "Friends of the Chair" group was established to discuss possible solutions focussing on JECFA risk management. There was no scientific justification for the delays in adoption of the standards.

8. Australia, Argentina, Canada, Chile, Colombia, Costa Rica, Mexico, New Zealand and the United States agreed with Brazil on the need for the immediate adoption of a Codex standard for ractopamine in order to ensure the protection of consumers, the promotion of international trade, food safety, and the maintenance of the role of Codex as an international reference organization in the area of food safety.

9. The Codex representative stated that the matter of ractopamine MRLs would be examined again at the next Commission, and hopefully members would be able to reach a consensus.

10. The European Union stated that JECFA had provided Codex with a risk assessment, however, discussions in Codex focused on risk-management. Norway and Switzerland agreed that while science was indeed a key element, risk managers also had to consider other factors that impact consumers' health. The European Union, as part of the "Friends of the Chair", had worked with ten other Members to actively search for a solution acceptable to all parties, and looked forward to making progress in advance of the July 2011 Codex Commission.

11. The Codex representative stated that the matter of ractopamine MRLs would be examined again at the next Commission, and hopefully members would be able to reach a consensus.

12. At the June 2011 meeting of the Committee, Costa Rica again raised concerns about the delays in the adoption of the proposed standard for ractopamine by the Codex Commission (G/SPS/GEN/1092). Maximum residue levels (MRLs) for ractopamine had been proposed, based on the safety assessment by the FAO/WHO Joint Expert Committee on Food Additives (JECFA), the advisory scientific body of the Codex. There were no scientific or procedural reasons to delay adoption of the standard for ractopamine. Costa Rica considered that this was a matter of major systemic importance, as there was a need to ensure that Codex standards were based on scientific analysis in order to guarantee the safety of international food supplies. The failure to adopt the standards cast doubts on the validity of JECFA, and discouraged Codex members, especially developing country members, from participating in the standard-setting process. Costa Rica stressed that Codex should base its decision on science, as this was important for protecting consumer health internationally, the promotion of consumption, and maintaining Codex as an international reference body in the area of food safety standards.

13. The United States recalled that the matter of approving MRLs for ractopamine would be considered for the fourth time by the Codex Commission the following week. The unjustified opposition by some countries to the adoption of a science-based international standard threatened the institutional integrity of Codex. Ractopamine was approved by 25 national authorities, including the United States, for use in the production of beef and pork. It has been used for 12 years in the United States with no adverse effects. JECFA, an independent panel of experts, had evaluated it numerous times and recommended MRLs for ractopamine in muscle, fat, kidney and liver tissues of cattle and swine. Science-based decision making allowed Codex to be free from national and political influences. Blocking this decision for non-scientific reasons created a dangerous precedent for countries to block other standards for reasons unrelated to food safety and consumer health protection. While the United States could understand that some Members did not want to approve the use of ractopamine at the national level, blocking the adoption of an international standard without scientific evidence was disruptive to the integrity of Codex. If international standards were no longer science-based, this could have adverse effects on the implementation of the WTO SPS Agreement, as it refers to Codex standards, and it would likely lead to the development of expensive private standards. Failure to adopt the MRLs at the next Codex meeting would undermine the scientific decision-making process and have adverse impacts on food security, sustainability and international trade in food.

14. Canada reiterated its support for the science-based standard setting process in Codex, while acknowledging that non-science factors may be considered in the risk management process where appropriate. In developing international food safety standards, the Codex process was based on sound scientific analysis and evidence provided by leading international scientists in the field, national experts, and independent scientific expert committees such as JECFA, JMPR, and JEMRA. Codex had been unable to reach a consensus in this case because there is an attempt to introduce into the Codex decision-making process regional consumer preferences which is not a legitimate factor in the global context and does not satisfy the Codex criteria for the consideration of other legitimate factors. Canada observed that the recommended MRLs were based on the scientific evaluation by JECFA and that all Codex procedures were followed, so there was no reason to further delay their adoption. The failure to adopt the standards could seriously impact the FAO/WHO scientific process on which Codex relies, undermine the integrity of the standard-setting process and lead to questioning the relevance of the Codex as a reference body under the SPS Agreement.

15. Brazil recalled that it had expressed similar concerns in the past. Given the exhaustive work by JEFCA, the non-adoption of MRLs could result in systemic problems that jeopardized Codex' role in food safety and posed a risk to the credibility of JEFCA and Codex. It was important that scientific data underpin decision-making to avoid trade barriers with no scientific basis, and to assist the

provision of safe food at reasonable cost, especially for developing countries. Brazil requested that these concerns be brought to the attention of Codex, FAO and WHO.

16. Argentina, Australia, Chile, New Zealand, Peru and the Philippines all shared the concerns that had been raised regarding the need to ensure that the basic principles and processes of Codex be respected. Chile noted that a great deal of work had been done to develop a strategic plan for Codex, in order to make the standard-setting process less cumbersome. However, the insistence on national preferences, in this case and in another that had dragged on for ten years, had exhausted the strength of the international standard-setting system. The Philippines stated that the establishment of a standard for ractopamine would allow countries, especially those with limited resources, to differentiate ractopamine from other substances that are unsafe or used illegally, therefore ensuring safe food supplies for consumers. Australia and New Zealand shared concerns that the failure to adopt the proposed standard could have broad implications for the integrity of the Codex standard-setting process.

17. The European Union stated that it was strongly committed to the role of science in the development of all international standards, as well as in its own legislation. However, it was imperative to understand the role of science as part of the risk analysis approach. The risk assessment by JECFA was valuable input for the Codex discussion, but the full range of factors had to be considered by Codex acting as risk managers, as was clearly stipulated in the Codex Procedural Manual. The European Union observed that their concerns on the use of ractopamine were supported by a significant number of other members, including China, which together with the European Union, constitute the largest producers and consumers of pig meat and which would thus be the most seriously impacted by the adoption of MRLs for ractopamine. Insofar as the relevance of Codex being put into question by delays in the adoption of such a standard, it was rather the adoption of a Codex standard when there was no consensus that would undermine the validity of Codex. The European Union was disappointed that some Members put more emphasis on the Codex mandate of facilitating trade rather than on the mandate of protecting the health of consumers. The European Union would make every effort to ensure that consumers remain at the centre of the Codex decision-making process.

18. China supported the statement of the European Union and highlighted that it was the largest consumer and producer of pigs in the world. Its ban was based on inadequate scientific evidence regarding ractopamine, and on the need to consider ractopamine residuals in lung tissue. China did not support the rush to adopt international standards where there was no consensus.

19. Switzerland and Norway shared the concerns of China and the European Union. Switzerland indicated that the work of the SPS Committee was based on existing standards, and as currently there was no standard for ractopamine, this issue should more appropriately be considered under Other Business. It was fundamental that Codex standards be based on scientific principles, and clear scientific conclusions, to ensure health. Overlooking divergent scientific conclusions and the lack of a consensus on this matter would create systemic concerns and jeopardize the role of Codex. Norway supported the use of science in the development of international standards, but observed that other elements also had to be taken into account in risk management decisions.

20. Costa Rica and the United States asked Members who had indicated that other factors should be considered in the adoption of Codex standards to elaborate on what these other factors were. The European Union replied that the SPS Committee was not the appropriate forum for the discussion of these factors but that all interested parties to the discussion on ractopamine were familiar with what these other factors were as extensive consultations had taken place on this matter. It was important that these factors be taken into account when the discussion took place in the appropriate forum, namely the Codex.

D. RESPONSES RECEIVED FROM THE RELEVANT STANDARD-SETTING ORGANIZATIONS

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