WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures

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

NOTE BY THE SECRETARIAT[1]

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.[2] 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.[3] The procedure was reviewed as part of the Third Review of the Agreement[4], and again in the context of the Fourth Review.[5]

1.2. The Committee has previously considered eighteen annual reports on the monitoring procedure.[6] These reports summarize several standards-related issues that the Committee has considered and the responses received from the relevant standard-setting organizations.

2 NEW ISSUES

2.1. Since the 2016 Annual Report, no new issues have been raised under this procedure.

3 PREVIOUS ISSUES

3.1. Since the 2016 Annual Report, there was further discussion on five issues previously raised under this procedure regarding: (i) IPPC phytosanitary certificate requirements for processed food products; (ii) use of the Codex international standard on glyphosate; (iii) BSE restrictions not consistent with the OIE international standard; (iv) HPAI restrictions not consistent with the OIE International Standard; and (v) application of ISPM 13 on notifications of non-compliance.

3.1 IPPC phytosanitary certificate requirements for processed food products

3.2. At the July 2016 Committee meeting, the United States reiterated its concerns regarding Members' use of phytosanitary certificate requirements for processed products, addressed in ISPM 32 on 'Categorization of Commodities according to their Pest Risk.' A key provision of ISPM 32 was 'intended use', which was defined as the declared purpose for which plant products or other articles were imported, produced or used. The intended use of a commodity might be for planting, processing or consumption and other uses such as decorative products and cut flowers. The United States noted that some intended uses of a commodity were associated with a higher probability of a regulated pest establishing than others. This might result in the application of

[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 and 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] The draft report of the Fourth Review is contained in document G/SPS/W/280/Rev.2.
[6] 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 and G/SPS/GEN/1490.

different phytosanitary measures for a commodity based on its intended use. The USDA-APHIS was currently examining its miscellaneous and processed products manual to update and clarify its guidance on processed foods and vegetable products covered by ISPM 32, Annex 1 to more closely reflect the intent of the standard. Additional work was underway on national- and regional-level guidelines by NAPPO. The United States would welcome an exchange of Members' experiences in implementing ISPM 32. Furthermore, the United States urged Members to employ a risk-based approach and to act in consistency with the guidance of ISPM 32, in that measures applied should be proportional to the pest risk identified for the intended use. In closing, the United States highlighted and applauded IPPC for a training session focused on better implementation of ISPM 32 held on 3 April 2016 in Rome, Italy.

3.3. Canada shared the concerns of the United States and encouraged Members to use international standards when establishing phytosanitary measures, including IPPC standards where these existed, and to support the principles as set out in ISPM 32. Canada encouraged Members to take into consideration factors such as the intended use of the commodity when establishing requirements.

3.4. New Zealand also shared the concerns raised and, as a Member that recovered costs from its exporters, requested unjustified activities and costs related to certification be avoided so as not to penalise exporters.

3.5. At the March 2017 Committee meeting, the United States reiterated its concerns, previously raised in the March and July 2016 Committee, regarding Members' use of phytosanitary certificate requirements for processed products, as set out in ISPM 32 on 'Categorization of Commodities according to their Pest Risk'. The United States recalled that it had outlined the key provisions of the standard, as well as highlighted the category of commodities defined as having been processed to the point where they did not remain capable of being infested with quarantine pests. The United States explained that in such cases, no phytosanitary measures should be required, and that such a commodity should not be deemed to require phytosanitary certification. The United States noted an increasing trend, where Members continued to require phytosanitary certifications for products sufficiently processed to mitigate any pest risk (e.g. dehydrated potatoes, frozen blueberries). The United States urged Members to follow the international standards, as set out in ISPM 32, in order to facilitate safe trade in plant products.

3.6. Canada shared the concerns of the United States and encouraged Members to use international standards when establishing phytosanitary measures, and to support the principles as set out in ISPM 32. Canada highlighted that this standard encouraged Members to take into account several factors, such as the method and the level of processing of the products prior to export, and the intended use of the commodity in establishing phytosanitary requirements.

3.7. Chile supported the concerns of the United States, noting that certifications were sometimes required in bilateral trade which went beyond the necessary authorizations, creating additional burden and infringing international standards. Australia and Mexico similarly echoed the concerns raised and encouraged Members to refer to IPPC ISPM 32 for guidance on the processed products that did not require phytosanitary certificates in trade.

3.2 Use of the Codex international standard on glyphosate

3.8. At the July 2016 Committee meeting, the United States reiterated its concern over the fact that some Members had already taken action, or were considering taking action, to no longer apply the Codex MRL for glyphosate. The United States understood that the measures being considered did not appear to be based on international standards or risk of exposure. The United States highlighted a recent JMPR report from May 2016 that had concluded that glyphosate was "unlikely to be genotoxic" and "unlikely to pose a carcinogenic risk to humans from exposure through diet." It was therefore important to distinguish these findings from that of IARC, which were based on hazard and not risk. The US EPA was currently re-reviewing glyphosate using all available data and would also seek external peer review of the US cancer assessment later in 2016. The United States stressed the importance of following international standards to minimize adverse impacts on trade, recalling Article 12 paragraph 4 of the SPS Agreement and the direction given in G/SPS/11/Rev.2. The United States also expressed its concerns with recent developments in the European Union, in particular not basing its import tolerance for glyphosate on Codex

standards, and the 18-month extension - as opposed to the usual 15-year reauthorization - of glyphosate use. This could have a significant impact on trade flows. The United States welcomed any update from Codex on these developments, particularly information on the May 2016 JMPR report and the steps that WHO had taken to clarify the relation between the JMPR and IARC reports.

3.9. Argentina, Canada and Brazil shared the concern of the United States and stressed the importance of following the Codex standard. They also noted the findings of the recent JMPR report and encouraged Members to take the guidance provided by JMPR and CCPR into consideration when developing, applying, re-evaluating or reauthorizing measures.

3.10. At the October 2016 Committee meeting, the United States again reiterated its concerns raised in the July 2016 Committee meeting regarding the use of the Codex international standard on glyphosate. The US EPA had recently published its review on glyphosate using all available data and would be seeking external peer review from a scientific advisory panel under the Federal Insecticide, Fungicide, and Rodenticide Act. The US EPA review had classified glyphosate as "not likely to be carcinogenic to humans at doses relevant for human health risk assessment." The US EPA was currently in the process of rescheduling the meeting of the fifth scientific advisory panel to ensure additional epidemiological expertise would be available to the panel. The United States stressed the importance of following international standards and basing SPS measures on risk assessments, recalling Article 12.4 of the SPS Agreement and the direction given in G/SPS/11/Rev.2. The United States invited Members to think of how the Committee could provide greater understanding of how risk-based regulation of pesticides could ensure food safety in trade.

3.11. Argentina, Australia, Brazil, Canada and New Zealand echoed the concern of the United States and stressed the importance of aligning national MRLs for glyphosate with the relevant Codex standard.

3.12. During the March 2017 SPS Committee, Argentina reiterated concerns that some Members were considering the possibility of rescinding the use of glyphosate and thereby no longer apply the Codex MRL. In particular, Argentina noted that although the European Commission had approved the extension of the authorization for glyphosate use until the end of 2017, there still remained concerns regarding the immediate impact on trade of agricultural products if the authorization was not further renewed. Argentina highlighted the JMPR report from May 2016 that had concluded that glyphosate was "unlikely to be genotoxic" and "unlikely to pose a carcinogenic risk to humans from exposure through diet". A recent European Chemical Agency (ECHA) publication, dated 15 March 2017, had also concluded that the available scientific evidence did not meet the criteria to classify glyphosate as being carcinogenic, mutagenic or toxic for reproduction. Argentina noted that the ECHA conclusion was in accordance with previous statements from the European Food Safety Authority (EFSA). Argentina recalled the obligations of Article 3 of the SPS Agreement, highlighting that Members had the obligation to base their food safety measures on Codex standards or on scientific evidence. No scientific evidence had been provided by the European Union to justify deviation from the Codex standard. Argentina urged the European Commission to take into account the Codex standard, the EFSA opinion and the ECHA risk assessment in its next decision on the renewal of the authorization of glyphosate use.

3.13. The United States also reiterated its concerns over the fact that some Members had already taken action, or were considering taking action, to no longer apply the Codex MRL for glyphosate. The United States understood that the measures being considered did not appear to be based on international standards or on risk of exposure. Multiple robust risk assessments had been undertaken by international and national authorities (e.g. JMPR, EFSA, ECHA) on glyphosate, none of which had found convincing evidence regarding a carcinogenic risk to humans. In addition, glyphosate was subject to a periodic registration review by the US Environmental Protection Agency (EPA), in order to ensure that pesticides containing glyphosate continued to meet the statutory safety standard for registration. The United States further informed that in 2016, the EPA had published a review of all available data on the potential carcinogenicity of glyphosate, where it had proposed to classify glyphosate as "not likely to be carcinogenic to humans at doses relevant for human health risk assessment". This review had included, but also extended beyond, the studies reviewed by WHO and the International Agency for Research and Cancer (IARC) which had assigned a classification of "probable human carcinogen" to glyphosate. The EPA review had been evaluated by an independent scientific advisory panel, which had released its report in March 2017. The EPA was now currently reviewing the panel's report, and other comments, before

making a final determination on the potential carcinogenicity of glyphosate. Draft human health and ecological risk assessments on glyphosate were also scheduled to be published later in 2017, for public comments. The United States underscored the importance of distinguishing between the assessments conducted by JMPR, EFSA, ECHA and the pending EPA risk assessment, from the report of IARC, which was based on an assessment of hazard only and not on risk. The United States further encouraged all Members to follow Codex glyphosate MRLs or to base SPS measures on science-driven risk assessments that incorporate realistic exposure scenarios.

3.14. Australia, Brazil, Canada, Chile and New Zealand echoed the concerns of Argentina and stressed the importance of following the Codex standard. The findings of the JMPR report of May 2016 were also noted and Members encouraged to take into account the guidance provided by JMPR and CCPR when developing, applying, re-evaluating or reauthorizing measures.

3.15. The WHO, on behalf of WHO and JMPR, confirmed the JMPR conclusions on glyphosate as outlined in the JMPR report of May 2016, and indicated that the process to review glyphosate was ongoing. The WHO further explained that JMPR would report to the CCPR in April 2017, and would not request a change in the MRLs for glyphosate.

3.3 BSE restrictions not consistent with the OIE international standard

3.16. At the October 2016 Committee meeting, the United States announced that in August 2016 the USDA Animal and Plant Health Inspection Service (APHIS) had published a Notice in the Federal Register that finalized the recognition of the OIE's negligible BSE risk designation for 14 countries. The United States noted that it was also recognized as negligible risk for BSE by the OIE, yet faced many restrictions on certain meat exports, inconsistent with this status. Some of these trade restrictions had been lifted in the past years and the United States called for the remaining BSE-related import prohibitions to be removed. The United States reminded Members that certain products such as protein-free tallow and blood products were deemed safe by the OIE regardless of a country's BSE risk status, and thus should not be subject to BSE-related import restrictions.

3.17. In the March 2017 Committee meeting, the United States reiterated its concerns that some Members maintained unjustified BSE restrictions that were inconsistent with the OIE international standards. The United States reiterated its commitment to aligning its import regulations governing BSE OIE guidelines and further recalled that in the October 2016 Committee, it had announced that the USDA's Animal and Plant Health Inspection Service (APHIS), had published a Notice in the Federal Register that finalized the recognition of the OIE's BSE negligible risk designations for 14 countries. The United States indicated that APHIS had published another Notice in the Federal Register on 23 January 2017, which indicated the preliminary concurrence with the OIE's risk designation for seven countries (Costa Rica, Germany, Lithuania, Mexico, Namibia, Romania and Spain) as negligible risk for BSE, and solicited comments on this proposed action by 24 March 2017. The United States noted that it was also recognized as negligible risk for BSE by the OIE, yet faced numerous unjustified restrictions on certain meat exports. The United States reminded Members that certain products such as protein-free tallow, and blood products were deemed safe by the OIE regardless of a country's BSE risk status and thus should not be subject to BSE-related import restrictions.

3.4 HPAI restrictions not consistent with the OIE international standard

3.18. At the October 2016 Committee meeting, the United States reminded Members that in April 2016 it had regained country-wide freedom from HPAI consistent with the OIE guidelines. The United States highlighted the importance of the stamping out and surveillance policies encouraged by the OIE guidelines as effective means towards guaranteed eradication of HPAI. Some AI-related restrictions on imports from the United States had been recently lifted, and the United States acknowledged Ecuador, Indonesia, Saudi Arabia and Turkey for their efforts. The United States urged Members to swiftly lift all remaining HPAI-related restrictions on US exports.

3.5 Application of ISPM 13 on notifications of non-compliance

3.19. In the March 2017 Committee meeting, Senegal raised concerns regarding the provisions contained in ISPM 13 on notifications of non-compliance, noting that non-conformity in relation to emergency actions was not well documented by Members. Senegal observed that in some cases, products that were judged to be in conformity by the relevant authority were then destroyed without the relevant exporting authority being informed. Senegal indicated that this breached the guidelines outlined in ISPM 13, which required the importing party to deliver a range of documentation, in the event of destruction, to the relevant competent authority. Senegal emphasized the importance of providing this information to the exporting country through the official channels, in order to ensure reliable flows of information and to maintain trust between authorities.

3.20. Burkina Faso and Seychelles supported Senegal's concern. In particular, Burkina Faso highlighted its similar experience in receiving late notifications of non-compliance from enquiry points, and in some cases not being informed.

4 RESPONSES RECEIVED FROM THE RELEVANT STANDARD-SETTING ORGANIZATIONS

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