

1 March 2023

(23-1401)

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Committee on Sanitary and Phytosanitary Measures

Original: English

WORKING GROUP ON APPROVAL PROCEDURES OUTCOMES AND RECOMMENDATIONS

NOTE BY THE WORKING GROUP

1 INTRODUCTION

1.1. Following the recommendation from the fifth review of the operation and implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), a Working Group on Approval Procedures (Working Group) was established with the goal of exploring:

- Key challenges of approval procedures that impact international trade and that the Committee on Sanitary and Phytosanitary Measures (SPS Committee) should seek to address;
- Principles of approval procedures that facilitate international trade while meeting the importing Member's appropriate level of sanitary or phytosanitary protection (ALOP) and the SPS Committee's role in highlighting these principles;
- Tools available and best practices to enhance the implementation of the obligations of the SPS Agreement as they apply to approval procedures; and
- Other topics raised by Working Group participants over the course of the Working Group.

1.2. As noted in the Summary of Process and Discussions for the Working Group (G/SPS/GEN/2097), there have been a number of outcomes and recommendations stemming from the exploration of these topics. Below is an overview of the Working Group discussions and the associated recommendations.

1.3. The various Working Group output documents, including this note, the Summary of Process and Discussions for the Working Group (G/SPS/GEN/2097), and the Collection of Available Tools and Resources (G/SPS/GEN/2098), do not represent a legal interpretation of the rights and obligations under the SPS Agreement and do not in any way exemplify a legal definition.

2 COLLECTION OF AVAILABLE TOOLS AND RESOURCES

2.1. Over the course of the Working Group, participants identified existing available tools and resources to enhance the implementation of the obligations of the SPS Agreement as they apply to approval procedures. A detailed summary of the discussions of the Working Group regarding this topic can be found in Section 2 of document G/SPS/GEN/2097. Tools and resources have been compiled in a reference document, the Collection of Available Tools and Resources (G/SPS/GEN/2098), organized by key themes. These themes include:

- Timing/Undue Delays and Communication/Information Exchange;
- Transparency;
- Justification of Approval Procedures;
- Harmonization with International Standards and Regulatory Cooperation; and
- General themes and other topics not classified.

3 KEY CHALLENGES ASSOCIATED WITH APPROVAL PROCEDURES

3.1. Additionally, Working Group participants discussed the key challenges of approval procedures that impact international trade and how the SPS Committee could seek to address them. A detailed summary of the discussions of the Working Group regarding this topic can be found in Section 3 of document G/SPS/GEN/2097. Participants explored the key challenges faced by Members that are summarized below.

3.1 Transparency; and communication or information exchange

3.2. Participants identified challenges with approval procedures that stem from:

- Unclear processes, including insufficient or unclear information on how to address data deficiencies, how to submit data that has been requested by the importing Member, how to provide follow-up information, how to request clarification, and how to request status updates and gain approval;
- Unclear timelines (i.e. sequence of events related to an approval procedure), deadlines (i.e. critical dates associated with the submission, evaluation, and completion of an approval procedure), and channels of communication (i.e. responsive points of contact within both the exporting and importing Member to address questions and comments from either party) associated with an approval procedure;
- Lack of adoption/use of international standards, guidelines, and recommendations or tools, including for the electronic exchange of certificates.

3.2 Justification and discrimination of approval procedures; and harmonization with international standards

3.3. Participants identified several challenges associated with approval procedures they felt were unjustified and/or discriminatory, as well as with harmonization of approval procedures with international standards, including:

- Approval procedures that do not appear to be based on scientific principles and risk assessments;
- Approval procedures that appear to be discriminatory, such as when requirements for imported products are more stringent or burdensome than for the same products produced under similar conditions in other countries or domestically; or the imposition of unjustifiable fees associated with an approval procedure;
- The lack of harmonization with international standards, guidelines, and recommendations, since approval procedures differing from these standards, guidelines, and recommendations can create difficulties and uncertainty for trade and decrease predictability; recognizing that Members may introduce or maintain measures resulting in a higher level of SPS protection if there is a scientific justification or as a consequence of the level of protection Members determine to be appropriate in accordance with the relevant provisions of Article 5 of the SPS Agreement;
- Instances where the implementation of an approval procedure aligns with a particular international standard, guideline, or recommendation in principle, but in application the approval procedure does not conform to, nor seems to be based upon, the referenced international standard, guideline, or recommendation. This creates uncertainty and negatively impacts trade.

3.3 Timing and undue delays; and other challenges

3.4. Delays in approval procedures, which some participants felt were undue, were also noted as a challenge. Delays slow down approvals, which restricts trade and negatively affects exporters and consumers. Delays in risk assessment procedures were highlighted as one of the main challenges with approval procedures. Participants identified the following challenges related to timing and undue delays:

- The timing of approval procedures, such as pre-market approval procedures, can vary between Members, which leads to asynchronous or misaligned approvals;
- The length of approval procedures can vary based on the Member and products involved, which results in unpredictability of the length of approval procedures;
- Limited technical or administrative resources result in delays in completion of approval procedures;
- Global challenges resulting in administrative constraints, such as the COVID-19 pandemic, can adversely affect international trade and approval procedures;
- Other challenges that can produce delays include lack of trust between parties and a lack of capacity to administer the required approval procedures in the competent authority of the importing Member.

3.5. Based on the discussions surrounding key challenges, the Working Group compiled concepts regarding how the SPS Committee could seek to address these challenges, which informed the discussions on principles of approval procedures.

4 PRINCIPLES OF APPROVAL PROCEDURES THAT FACILITATE INTERNATIONAL TRADE

4.1. Finally, Working Group participants discussed the principles of approval procedures that facilitate international trade while meeting the importing Member's ALOP, and the SPS Committee's role in highlighting these principles. A detailed summary of the discussions of the Working Group regarding this topic can be found in Section 4 of document G/SPS/GEN/2097. The principles of approval procedures highlighted by the contributions of participants include the need for:

- Science-based and risk-based SPS measures;
- Timely approvals;
- Transparency, communication (e.g. to provide status updates or request additional information or clarification), and publication of procedures, requirements, and standard processing periods, including procedure stages and deadlines;
- Non-discrimination between Members with the same SPS status;
- Harmonization with international standards in accordance with Article 3 of the SPS Agreement; and
- Equitable fees.

4.2. It is important to note that these principles are covered within the SPS Agreement, which is indicative of its continued applicability today, and that there is general agreement that there is no need to explore new obligations or to reopen the SPS Agreement.

5 CONCLUSION AND RECOMMENDATIONS

5.1. The work of the Working Group has facilitated a deeper conversation on the concepts surrounding approval procedures and has resulted in recommendations that will aid the SPS Committee in providing consistent guidance for Members who are developing or refining approval procedures.

5.2. As an outcome of these discussions, the Working Group makes the following recommendations:

- a. The Collection of Available Tools and Resources will be circulated and be kept up to date by the SPS Committee with the assistance of the Secretariat;
- b. Members should consider the use of SPS Committee mechanisms to facilitate discussions on the challenges and principles of approval procedures, and to further explore the need for additional guidance or tools to be developed. These mechanisms include, but are not limited to:
 - i. Agenda item 4(d) of the formal SPS Committee meeting on Operation and implementation of the SPS Agreement – Control inspection and approval procedures;

- ii. The upcoming sixth review process;
 - iii. The thematic groups established under the MC12 SPS Declaration work programme;
- c. Members are encouraged to further the implementation of Annex C of the SPS Agreement with respect to approval procedures;
- d. Members are reminded of the importance of key principles of the SPS Agreement, including those reflected in Annex C of the Agreement. Members are reminded of the importance of the following principles of approval procedures to facilitate international trade while meeting the importing Member's ALOP:
- i. Science-based, risk-based SPS measures in accordance with Articles 2.2, 3, and 5;
 - ii. Timely approval and no undue delay in approval procedures in accordance with Annex C.1(a), and information requirements limited to what is necessary in accordance with Annex C.1(c);
 - iii. Transparency, communication, and publication with respect to approval procedures in accordance with Article 7 and Annexes B and C:
 - Members are encouraged to make relevant information on approval procedures available on official websites, ideally in multiple languages, and to use e-tools to provide clear and timely information on approval procedures;
 - Members are encouraged to have up-to-date contact details of their SPS National Enquiry Points and National Notification Authorities available on the [e-Ping SPS&TBT Platform](#);
 - Members are encouraged to notify all new or changed approval procedures that are expected to have a significant effect on trade of other Members;
 - Members are encouraged to provide relevant information proactively at the start of the approval process, including with respect to the requirements for the approval procedure, anticipated processing period, steps of the approval procedure, and relevant deadlines and timeframes, as well as to provide regular status updates;
 - Members are encouraged to maintain an open and ongoing communication with applicants throughout approval processes; and
 - Members are encouraged, to the extent possible, to use international tools for the electronic exchange of certificates;
 - iv. Non-discrimination and consistent treatment of Members with the same SPS status in accordance with Article 2.3, Article 5.5, and Annex C.1(a);
 - v. Harmonization with international standards in accordance with Article 3 and Annex C; and
 - vi. Equitable fees in accordance with Annex C.1(f);
- e. Members are encouraged to engage in regulatory cooperation to maximize capacity and resources, to facilitate approval procedures, and to address asynchronous approvals; and
- f. Members are encouraged to adopt approval procedures that make use of modern technologies and practices, such as remote audits, and to work with relevant international organizations in this area.
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