WORLD TRADE ORGANIZATION

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WORKING GROUP ON APPROVAL PROCEDURES SUMMARY OF PROCESS AND DISCUSSIONS

NOTE BY THE WORKING GROUP

The Report of the Fifth Review of the Operation and Implementation of the SPS Agreement (Fifth Review Report)[1], adopted by the Committee on Sanitary and Phytosanitary Measures (SPS Committee) on 31 July 2020, contained several recommendations. This included a recommendation that "[f]ollowing the fruitful exchange of experiences and ideas at the November 2019 SPS Committee Thematic Session on Approval Procedures, the Committee should create a working group open to the participation of all Members and Observers to continue to examine the topic of approval procedures."[2]

The SPS Committee Working Group on Approval Procedures (Working Group) started its work in November 2020, along the lines of Canada's proposed guidance set out in document G/SPS/W/328/Rev.1, as updated by Canada and Paraguay in document G/SPS/W/328/Rev.1/Add.1. While it was initially foreseen that the Working Group would conclude its work in November 2021, the Working Group was extended until November 2022[3], and subsequently until March 2023.[4]

Twenty-five Members participated in the Working Group: Argentina, Belize, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, the European Union, Japan, Mexico, New Zealand, Norway, Paraguay, Peru, the Philippines, the Russian Federation, Singapore, South Africa, Switzerland, Chinese Taipei, Ukraine, the United Kingdom, the United States, and Uruguay.[5] The OECD was also a participant.

Canada and Paraguay acted as co-stewards to the Working Group. The Working Group worked electronically and met virtually (using WebEx) on the margins of the SPS Committee meetings as well as intersessionally, as required. Work was primarily conducted in English.

[1] G/SPS/64 and G/SPS/64/Add.1.

[2] See paragraph 3.12 of the Fifth Review Report (G/SPS/64).

[3] Canada's proposal for the Working Group contained in document G/SPS/W/328/Rev.1 indicated that the Working Group would conclude at the November 2021 SPS Committee meeting, unless the Working Group and SPS Committee agreed to extend the timeframe. At its meeting of 1 November 2021, the Working Group agreed that it would like to continue its work and extend its timeline for another year to allow the Working Group to continue its in-depth discussions on key challenges and address principles of approval procedures. At its November 2021 meeting, the SPS Committee agreed to extend the Working Group until November 2022.

[4] At its meeting of 7 November 2022, the Working Group agreed that it would like to continue its work and extend its timeline until March 2023 to allow the Working Group to finalise work on its output documents to be circulated to the SPS Committee. At its November 2022 meeting, the SPS Committee agreed to extend the Working Group until March 2023.

[5] The first meeting of the Working Group was open to all Members and observer organizations of the SPS Committee. Interested Members or observers wishing to join the Working Group were invited to sign up via the Secretariat. The Working Group was thereafter restricted to registered participants.

The Working Group conducted seven rounds of work, which mirrored the schedule of SPS Committee meetings.[6] Following each round of work, the co-stewards reported on the work at the informal meeting of the SPS Committee to keep Members appraised of the Working Group's progress.[7]

At the outset, the Working Group considered the process for its work as well as the topics that it would discuss.[8] The Working Group then focused on:

a. developing a common understanding of approval procedures for the purposes of the Working Group;

b. discussing tools available and best practices to enhance the implementation of the obligations of the SPS Agreement as they apply to approval procedures and compiling a collection of readily available tools and resources;

c. identifying key challenges of approval procedures that impact international trade and that the SPS Committee should seek to address;

d. identifying 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; and

e. discussing possible Working Group outcomes.[9]

This document is a factual account of the Working Group's work in these five areas. It complements the Working Group's note on Outcomes and Recommendations (G/SPS/GEN/2099).

[6] Following the SPS Committee schedule, these seven rounds of work took place in: (i) November 2020 – March 2021; (ii) March 2021 – July 2021; (iii) July 2021 – November 2021; (iv) November 2021 – March 2022; (v) March 2022 – June 2022; (vi) June 2022 – November 2022; and (vii) November 2022 – March 2023.

[7] The Chairperson of the SPS Committee reported on the discussions held at the informal SPS Committee meetings on this topic to the formal SPS Committee meetings. See Annex A of G/SPS/R/101, Annex A of G/SPS/R/102, Annex A of G/SPS/R/103, Annex A of G/SPS/R/104, Annex A of G/SPS/R/105, Annex A of G/SPS/R/106, Annex A of G/SPS/R/107, and Annex B of G/SPS/R/108. See also Section 4.4.2 and Annex B of G/SPS/R/100.

[8] Annex A provides an overview of the main topics for the Working Group's consideration, as they emerged from these initial discussions. Annex B describes the various phases for the Working Group as they were envisaged by the co-stewards following identification of these main topics.

[9] In addition, the Working Group liaised with the OECD on its related work on approval procedures, with the OECD providing regular updates and participants providing input on this OECD work project. The OECD work project on approval procedures conducted within its Joint Working Party on Agriculture was in the form of a three-part study: (i) part 1 to provide an overview of issues and current developments in the administration of approval procedures based on consultations with experts and literature review, which led to the identification of seven key issues faced by countries related to approval procedures; (ii) part 2 to evaluate the relative importance of these issues and possible trade implications based on an analysis of STCs and a questionnaire focusing on Members' positive developments and experiences; (iii) part 3 to highlight key findings of the study. Some Working Group participants provided input on and responded to the questionnaire to explore Members' positive developments and experiences with approval procedures. The OECD report, Sanitary and phytosanitary approval procedures, Key issues, their impact on trade and ways to address them, was published in February 2023.

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1 COMMON UNDERSTANDING OF APPROVAL PROCEDURES FOR THE PURPOSES OF THE WORKING GROUP

1.1. At the outset of the Working Group's work, a number of participants raised the topics of defining approval procedures, identifying the types of approval procedure that would fall within the scope of the Working Group, or developing a glossary. These early proposals led to discussions about the possibility and benefit of developing a common understanding of approval procedures prior to engaging on other topics (Section 1.1), with the Working Group agreeing on such a common understanding for the purposes of its work (Section 1.2).

1.1 Summary of discussions and proposals

1.2. Several proposals were put forward regarding defining approval procedures, developing a glossary, or identifying types of approval procedure. One such proposal was that the Working Group clarify the definition of the term "approval procedures". The term "approval procedures" meant the procedures to check and ensure the fulfilment of SPS measures, as reflected in Annex C of the SPS Agreement. Some Members, however, considered that approval procedures also included procedures for risk assessments under Article 5 of the SPS Agreement.

1.3. To support national and regional efforts to increase access to biotechnology products, one participant suggested that the Working Group develop a glossary of mutually agreed upon terms and definitions that would establish a baseline or common language for the SPS Committee on topics of mutual interest such as data portability, common application dossiers, unilateral and mutual recognition, history of safe use, and emergency use authorization. Commonly agreed language could serve as a starting point for future conversations to streamline and improve regulatory approaches to pre-market approvals. This proposal found some support in the Working Group to facilitate discussions on data portability, common application dossiers, the recognition of authorizations, and the management of low-level presence situations.

1.4. In addition, one participant proposed that the Working Group develop a common understanding of approval procedures, including the types of approval procedures and associated definitions. In some areas, Annex C was precise in its language as appropriate, while also providing a reasonable amount of flexibility so that its provisions applied to a wide range of regulatory approaches. However, this created the possibility of challenges and uncertainty in the implementation of the obligations of the SPS Agreement as they applied to approval procedures. Therefore, the Working Group could consider the types of approval procedures taken by Members, and how to enhance the implementation of the various types of approval procedures meeting the importing Member's ALOP while facilitating international trade. In agreeing with the proposal to consider the different types of approval procedures taken by Members and how to enhance their implementation, another participant highlighted the importance of this analysis for biotechnology products.

1.5. A related proposal was for the Working Group to work on definitions, classification of approval procedures, and basic criteria consolidation. Defining and grouping main approval procedures was seen as helpful to identify basic criteria to facilitate completion of the procedures. Criteria consolidation could also reduce the work involved for exporting Members in making submissions to each importing Member.

1.6. To provide parameters for future work, the co-stewards suggested that participants focus on identifying the scope of approval procedures. This could include, as appropriate, determining types/categories of approval procedures and their general characteristics. This work would be without prejudice to the rights and obligations of Members under the SPS Agreement, would not be used to develop an exhaustive list of approval procedures, and would not constitute legal definitions. The co-stewards suggested the scoping exercise in the hope that it would facilitate the work of the Working Group by establishing a collective knowledge and shared understanding of approval procedures that facilitate international trade while meeting the importing Member's ALOP. The co-stewards further suggested that the proposal to develop a glossary of terms and definitions in the field of biotechnology be revisited once the scope of approval procedures was clarified.[10]

[10] Some participants considered that the Working Group should avoid entering into detailed discussions on the specificities of individual approval procedures and definitions related to them. This was more within the realm of the role of the International Standard Setting Bodies (ISSBs). If the Working Group decided to work on a glossary, this glossary should have a broader scope, not only focus on biotechnology.

1.7. Several participants welcomed the co-stewards' proposed way forward. It was essential to establish a shared understanding of approval procedure before discussing key challenges and principles of approval procedures. A common understanding of approval procedures would have various benefits, including: (i) provide a reference framework and facilitating the discussions; (ii) help focus the discussions on the most important approval procedures given that Annex C was broad in scope; (iii) help identify whether to address all types of approval procedures or classify them in order to find common points for each group of approval procedures; (iv) increase Members' collective knowledge of approval procedures; (v) identify similarities between types of approval procedures taken by Members and their general characteristics; and (vi) enhance implementation of the obligations of the SPS Agreement as they apply to approval procedures. The co-stewards' clarification that exploring the scope of approval procedures would be without prejudice to the rights and obligations of Members under the SPS Agreement and would not constitute legal definitions was also welcomed by many. The common understanding would be developed solely for the purposes of facilitating the work of the Working Group and would be within the framework of Article 8 and Annex C of the SPS Agreement.[11]

1.8. Different types of approval procedures were proposed for the purpose of developing a common understanding. One participant referred to: (i) pre-market product approvals; (ii) certification; (iii) audits; and (iv) import checks. The different characteristics and impacts on food, animal, and plant trade of these approval procedures merited deeper examination. They were being proposed without prejudice to the rights and obligations of Members under the SPS Agreement and they did not constitute an exhaustive list of approval procedures. The participant noted initial characteristics of these types of approval procedures:

a. Pre-market product approval referred to approval procedures that required individual products to be assessed before they were permitted to be placed on the market as opposed to entire categories of products being approved such as when a pest risk assessment was conducted. Pre-market product approvals often applied to tools used in agriculture or food manufacturing and the applicant was usually the developer or manufacturer of the product, not normally the grower or exporter that needed to meet an importing Member's requirements and very rarely the exporting Member.[12] Pre-market approval procedures might vary between Members, leading to asynchronous or misalignment of approvals[13];

b. Certification referred to the issuing of end-use assurance documents that formally recognized that the importing Member was aware of, and had no immediate objections to, the proposed importation of specific goods by the stated importer, for the stated end-use and end-user. Certification might negatively impact trade when certification requirements were not limited to the extent necessary to meet the importing Members' ALOP or did not reflect the circumstances of risks to human, animal, or plant life or health, or where it was not recognized that assurances could be provided through means other than certificates;

c. Audits referred to official examinations of another Member's SPS measures. These were conducted to ensure a measure or group of measures' ability to provide required assurances and meet the ALOP of the importing Member. Audits generally focused on the control programme of the exporting Member and could include the review of their inspection and audit programmes, and on-site inspections of facilities. Audit provisions could be related to, but have obligations separate from, equivalency provisions. Audits could impact trade when there was lack of clarity, transparency, and predictability in the purpose and outcome of audits and in the audit processes;

d. Import checks were conducted to determine that imported products complied with the prescribed SPS requirements of the importing Member. This implied an inspection, examination, sampling, review of documentation, test, or procedure, including laboratory, organoleptic, or identity, conducted at the border or otherwise during the entry process

[11] One participant recalled that during the process of the fifth review of the SPS Agreement, many Members had emphasized that the result of the fifth review should not go beyond the obligations of the SPS Agreement. The discussions in the Working Group should focus on the implementation of the obligations of the SPS Agreement rather than create new obligations. This principle should be reflected in the Working Group's output documents.

[12] Canada's presentation at the 2019 Thematic Session on Approval Procedures was referenced. Examples of pre-market product approval procedures included: plant protection products and veterinary drug MRLs, which were established as part of an approval procedures for the product itself, and products of biotechnology.

[13] See para. 3.40. below.

by an importing Member or its representative to determine if a consignment complied with the SPS requirements of the importing Member. Import checks could impact trade when there was lack of clarity, transparency, and predictability in these processes, impact the integrity of the good more than necessary, and when import checks were more frequent than necessary based on risk.

1.9. Other participants referred to: (i) procedures for the recognition of pest/disease-free areas; (ii) procedures for the approval of genetically modified organisms (GMOs), with issues deriving from asynchronous approvals, resulting from the lack of operational capacity or undue delay (there were also cases in which the applicants were not always interested in submitting their requests in different markets at the same time, which could affect the regular international trade of grains)[14]; (iii) registration of certain food, such as formula for infants and young children; (iv) approval procedures of pesticide or veterinary drugs and additives or auxiliary substances; or (v) differential procedures for the approval of new food (novel foods) in accordance with the criteria established by some Members. Audit and inspection procedures were also mentioned, as well as laying down requirements for the certification and registration of products. Such a product registration procedure had the purpose of: ensuring that products placed on the domestic market (whether of domestic or foreign production) met the requirements regarding maximum residue limits (MRLs), additives, auxiliary substances, contaminants, general and nutrition labelling, etc.; being able to identify the manufacturer, importer, fractionator; and allowing for the product to be identified, tracked, and recalled by the public authority, if applicable.

1.10. Another participant suggested that the Working Group limit its work to approval procedures aimed at obtaining SPS market access, such as: (i) pest risk analyses for plant products; (ii) import risk analyses for animal products; (iii) animal health, plant health, and food safety control system audits; and (iv) administrative procedures related to the authorization of processing establishments for food and feed. The Working Group could identify and characterize the approval procedures most commonly applied by Members or those that were most important to trade, as well as their respective normal processing periods. This could be done by designing a survey to be circulated among Members, consulting the International Standard Setting Bodies (ISSBs) for a characterization of procedures for the SPS Committee's consideration, and having information collected directly from Members through, for example, some form of notification or trade policy review. Once this information obtained, especially on normal or expected processing periods, a definition of the term "undue delays" could be elaborated.

1.11. One participant put forward the following types of approval procedures: (i) approval of the import of plants, animals, and their products, i.e. the procedure carried out by the competent authorities in the SPS area to establish the SPS measures that will be applied to the import of plants, animals, and their products, as appropriate; (ii) approval of food and feed, approval of plant protection products (pesticides) and veterinary drugs, approval of food additives, and approval of GMOs, i.e. registration procedure prior to commercialization in the local market carried out by the competent sanitary authority according to the request presented by the manufacturer, importer, developer, or whoever corresponded; and (iii) approval of establishments, i.e. registration of establishments that manufacture food and feed that sold in the local market as well as the establishments authorized by the competent authority of the exporting Member, as they complied with the requirements of the importing Member.

1.12. Another proposal was that the Working Group be guided by what was contained in the WTO Analytical Index, specifically where reference was made to jurisprudence under Annex C of the SPS Agreement. Examples of approval procedures included: (i) the conduct of a risk assessment for a product; (ii) pest or disease-free area recognition processes; and (iii) procedures for the approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages, and feedstuffs. Another participant echoed the idea that WTO jurisprudence related to Annex C could provide guidance, and in this context referred to processes involved in equivalence determinations, import risk analyses, and pre-market approvals.

1.13. The Working Group further addressed whether its scope of work should include elements such as sampling and analytical capacity and the possibilities of finding common ground regarding methodologies for laboratories. Several participants understood approval procedures to include measures, such as sampling, testing, certification, and laboratory analysis, as they followed

[14] Another participant also referred to measures adopted by Members to manage approval asynchronies between Members that export and import GMOs, recognizing that some Members were not party to the Cartagena Protocol.

SPS approvals and consisted in control measures at the border when a commodity entered the importing Member's territory.[15] One participant referred to the review, through available documentary information, of recommended conformity assessment procedures (inspection protocols, laboratory tests, and/or analytical methodologies) applicable to the imported goods in port, in compliance with the SPS measures. Another participant further referred to national systems and procedures for approving the use of additives or for establishing tolerances for contaminants in foods, beverages, or feedstuffs. In this connection, one participant took the view that the Working Group needed to provide clear guidelines regarding laboratory work, while another stated that relevant methodologies needed to adhere to international recommendations.

1.14. Other views were shared, with one participant requesting that the inclusion of additional elements such as inspection, sampling, laboratory, or analytical capacity be decided at a later stage. Another participant noted that conformity assessment procedures, including inspection protocols, laboratory tests, and/or analytical methodologies were usually covered by the TBT Agreement rather than the SPS Agreement, and thus queried whether the Working Group would not extend its work beyond the scope of the SPS Agreement. Another participant underscored the importance of science-based measures, and noted that laboratory sampling and analysis procedures were within the scope of the SPS Agreement, considering that: (i) Annex C on control, inspection and approval procedures stated that such procedures included sampling, testing, and certification procedures; and (ii) Article 5 on risk assessment and determination of the ALOP required Members to ensure that their SPS measures were based on an assessment, as appropriate to the circumstances, of the risks to the life and health of individuals and animals and that in the risk assessment process, Members were required to take into account existing scientific evidence, relevant production processes and methods, as well as relevant methods of inspection, sampling, and testing.

1.15. Other participants expressed concerns regarding a possible common understanding of approval procedures. One participant cautioned that, while the Working Group may not intend to venture into legal definitions, developing a common understanding of approval procedures could nonetheless be construed as providing legal interpretations of the SPS Agreement or as listing or defining something that the SPS Agreement may have intentionally not listed or defined. Another participant cautioned against defining approval procedures in a way that would limit Members to predetermined procedures, disregarding their autonomy, and possibly generating major commercial problems considering the need for greater or lesser complexity of procedures in each Member. This issue could lead to even longer delays. Furthermore, standardization directly violated the principle of equivalence provided for the SPS Agreement, which was focused on obtaining expected results. While agreeing that the idea of classifying different types of approval procedures could help advance the work of the Working Group, some participants also worried that reaching an agreement regarding the classification of different types of approval procedures would involve lengthy discussions. The Working Group should not diverge its focus away from the key topics that it had been set to discuss. The Working Group should focus on implementation challenges and the tools and best practices that could be shared with Members to address these challenges, without creating additional obligations or definitions.

1.16. In light of these discussions, the co-stewards presented the following proposal regarding a possible common understanding of approval procedures:

> 1. The majority of WG participants value a common understanding to advance the objectives of the WG and to facilitate discussions among participants. Other participants also cautioned that any identification of a common understanding of approval procedures may possibly be interpreted as the identification of a legal definition.
>
> 2. Participants' submissions reveal general alignment in the parameters for the WG's understanding of approval procedures.

[15] Referring to the authorization process in its own country, one participant clarified that the process would begin with a request made by the competent authority of the country of origin concerned, which was subject to evaluation by an internal evaluation commission, and which resulted in the approval or not of the interested establishment. The approval of establishments was given through a process of consultation, evaluation, review of questionnaires and, when appropriate, audits to the competent authority and establishments in the country of origin. The authorization process was continuous and depended on the fulfilment of the sanitary requirements (which was verified through the control measures taken at the border inspection posts, such as documentary and physical inspection, sampling, and subsequent laboratory analysis) and on the renewal of the approval where applicable.

3. The descriptor of a common understanding of approval procedures below is generated solely for the practical purpose of advancing the objectives of the WG on approval procedures. It does not represent a legal interpretation of the rights and obligations of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) and does not in any way constitute a legal definition.

4. Many participants recalled that as per the SPS Agreement, "approval procedures" are any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures. Approval procedures may include the following:

- Approval of food and feed, and approval of the import of plants, animals, plant and animal products;
- Pre-market product approvals, approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages and feedstuff, approval of plant protection products (pesticides) and veterinary drugs, and approval of genetically modified organisms;
- Conduct of risk assessment for a product, Pest Risk Analysis, and Import Risk Analysis;
- Certification, authorization/approval of establishments, and animal or plant life and health and food safety control system audits;
- Pest- or disease-free area recognition and equivalence determination; and
- Import checks, sampling, laboratory analysis, and control measure.

This is not an exhaustive list of approval procedures.

5. This recommended approach strikes the appropriate balance to prevent protracted discussions that may unnecessarily delay the advancement of the WG's objectives and clarify the meaning of approval procedures for the purpose of the WG objectives.

6. With acknowledgement of a common understanding of approval procedures for the purpose of fulfilling the WG objectives, the participants can now identify key challenges of approval procedures that impact international trade that the Committee should seek to address. In undertaking this work, a number of participants suggest focusing on the types of approval procedures that pose the greatest challenges to international trade. Next, the principles of approval procedures that facilitate international trade while meeting the importing Member's appropriate level of sanitary and phytosanitary measures will be discussed.

1.17. Participants welcomed the co-stewards' proposal. They supported the idea that the descriptor of a common understanding of approval procedures did not represent a legal interpretation of the rights and obligations under the SPS Agreement and did not in any way constitute a legal definition. One participant suggested to indicate this principle clearly in the output documents of the Working Group. In addition, the Working Group engaged specifically on point 4 of the co-stewards' proposal, i.e. the illustrative list of approval procedures. One suggestion was to clarify that the list was for the purposes of the Working Group and had been developed to facilitate its work.

1.18. Taking into account comments received, the co-stewards presented a revised proposal for a common understanding of approval procedures, keeping the illustrative list of approval procedures, but clarifying that the illustrative list of approval procedures in their proposal was "[f]or the purposes of this WG" and "ha[d] been developed to facilitate the work of this WG". The co-stewards observed that having a common understanding would help guide the conversation, but that there was not an expectation that each of the items listed would be covered comprehensively by the Working Group.

1.19. Many participants welcomed the revised proposal. Other participants raised or reiterated concerns with the co-stewards' proposed illustrative list of approval procedures. One concern was that the illustrative list might broaden the scope of work too much. In this connection, one participant expressed doubts about including equivalence as well as sampling and laboratory analysis within the list and wondered if the approval of plant protection products would not rather fall under the

TBT Agreement. Another participant considered that the approval procedures listed were of different kinds, and included approval procedures that should be discussed in the context of provisions of the SPS Agreement other than Article 8 and Annex C. Procedures for risk assessment and pest-free area recognition conducted in order to establish SPS measures might sometimes be considered as a part of approval procedures, but these were provided for in other provisions of the SPS Agreement, such as Articles 5-6, and possibly entailed a large number of controversial aspects. If the Working Group were to lay all the elements on the table for consideration at one time, Working Group discussions would be scattered and would not efficiently lead to future work of the SPS Committee on this topic. The co-stewards should select the most appropriate elements of approval procedures among those listed in their proposal as a subject for discussion by the Working Group. The Working Group could give priority to discussing the implementation of import procedures under already established SPS measures.

1.20. Another query was whether the Working Group would be proposing this common understanding to the SPS Committee or proposing tools, best practices, or recommendations in the SPS Committee. One suggestion was that the Working Group could develop tools dealing with the most common concerns identified. Members could be consulted through a questionnaire, for example on the proper timing for different approval procedures. Based on this consultation, the Working Group could then move to discussing concrete proposals on how to address the main concerns with approval procedures.

1.21. Finally, one participant cautioned the Working Group against going too far in the exercise of identifying approval procedures. Approval procedures often consisted of internal processes and requirements for potential exporters, e.g. in the form of requests for various types of information used in importing Member's internal evaluation processes. If the goal was to publish a list of tools, the tools could be restructured around undue delay, information sharing, and related international standards. The Working Group needed to reflect on taking a step back and discuss general requirements spanning all types of approval procedures without trying to enumerate them. The Working Group could then further the conversation around some practical ways to address key issues, such as undue delays and issues pertaining to communication.

1.2 Agreed common understanding of approval procedures for the purposes of the Working Group

1.22. The co-stewards developed a revised common understanding of approval procedures, taking into account the various comments from participants on their proposed approach. The revised common understanding was developed for the purposes of the Working Group and to facilitate the discussions in the Working Group as follows:

> 1. The majority of WG participants value a common understanding to advance the objectives of the WG and to facilitate discussions among participants. Other participants also cautioned that any identification of a common understanding of approval procedures may possibly be interpreted as the identification of a legal definition.
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> 2. Participants' submissions reveal general alignment in the parameters for the WG's understanding of approval procedures.
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> 3. The descriptor of a common understanding of approval procedures below is generated solely for the practical purpose of advancing the objectives of the WG on approval procedures. It does not represent a legal interpretation of the rights and obligations of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) and does not in any way constitute a legal definition.
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> 4. Many participants recalled that as per the SPS Agreement, "approval procedures" are any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures. The 2019 Thematic Session on Approval Procedures highlighted a number of types of approval procedures, which WG participants may want to take into consideration in the work of this WG. The report of the Thematic Session is contained in document G/SPS/R/97/Rev.1. This is not an exhaustive list of approval procedures; it can facilitate the work of this WG and is without prejudice to the positions of Members or to their rights and obligations under the WTO.

5. The common understanding of approval procedures outlined above, provides participants with a basis for discussions as the WG moves forward to advance the WG's objectives. This common understanding does not require all participants to have the same position on the scope of approval procedures.

6. This recommended approach strikes the appropriate balance to prevent protracted discussions on the scope of the common understanding of approval procedures that may unnecessarily delay the advancement of the WG's objectives and clarifies the meaning of approval procedures for the purpose of the WG objectives.

7. If required, the WG can return to reflect on the common understanding of approval procedures for the purpose of fulfilling the WG's objectives. The common understanding of approval procedures outlined in this document may be revised, as needed.

1.23. The co-stewards noted that this revised proposal outlined a broader approach to the Working Group's common understanding of approval procedures. It aimed to address the concerns that had been raised by participants by providing a more flexible common understanding. In the absence of further comments, the Working Group was deemed to have reached consensus on this proposed common understanding of approval procedures for the purposes of its work.

2 TOOLS AVAILABLE AND BEST PRACTICES TO ENHANCE THE IMPLEMENTATION OF THE OBLIGATIONS OF THE SPS AGREEMENT AS THEY APPLY TO APPROVAL PROCEDURES

2.1. In the first two rounds of work, participants put forward tools and best practices to enhance the implementation of the obligations of the SPS Agreement as they applied to approval procedures (Section 2.1). The Working Group's work on this topic subsequently focused on developing a compilation of readily available tools and resources (Section 2.2).

2.1 Summary of initial discussions

2.2. Participants identified various best practices and approaches to enhance the implementation of the obligations of the SPS Agreement. Many participants referred to **transparency** in this context. As a transparency-related best practice, participants referred to compliance with the notification obligations of Article 7 and Annex B of the SPS Agreement. One participant proposed to encourage Members when submitting notifications to include the specific international standard that they are referencing. The participant also referred to: (i) having functional SPS National Enquiry Points (Article 7 and Annex B of the SPS Agreement) and encouraging Members to have up-to-date contact details for their SPS National Enquiry Points and National Notification Authorities available on the ePing SPS&TBT Platform to assist in knowing where to channel queries and to result in timely responses; and (ii) easily accessible established procedures, either posted on a website or available from the SPS National Enquiry Point. Most competent authorities of Members have official websites and Members should be encouraged to make their approval procedures available on websites.

2.3. The WTO notification system was seen as the cornerstone of the transparency provisions of the SPS Agreement, providing a user-friendly platform through which Members could notify other Members of new or significantly modified SPS measures. Presentations made during the 2019 Thematic SPS Workshop on Transparency and Coordination could serve as a reference for Members looking to strengthen their internal capacities to align with the SPS Agreement's transparency provisions, paying particular attention to the importance of timely notifications and of providing Members an opportunity for meaningful engagement so that comments could be considered.

2.4. In connection with **timing/undue delays** and **communication/information exchange**, one participant referred to document G/SPS/W/317, a submission from Brazil, Kenya, Paraguay, and the United States on enabling access to tools and technologies: towards safer and more sustainable agriculture through regulatory collaboration. Although set within the context of fall armyworm, this document provided a compilation of concepts that could be employed, on a voluntary basis, to improve and streamline regulatory processes, while safeguarding human, plant, and animal health. This compilation served as a resource for authorities with capacity constraints to help identify regulatory efficiencies that could lead to greater and faster market access. It referred to tools and technologies, although the general concepts were applicable to a variety of market access requests. These concepts included common application requirements, joint risk assessments, data portability, adaptation to regional conditions, unilateral recognition, mutual recognition, familiarity, history of

safe use, equivalence, and harmonization. Familiarity and history of safe use could be particularly relevant within the context of approval procedures, as they might allow Members to leverage previous experience (both direct and indirect) to inform and streamline internal evaluation processes. In this context, several tools from the Global Low-Level Presence Initiative were identified. The participant also referred to the APEC brochure, "A Trade Facilitative Approach to Pesticide MRL Compliance" and the Crop Life's Regulatory Harmonization webpage, as reflected in the compilation of readily available tools and resources. To the extent practicable, the voluntary adoption of these concepts to national regulatory frameworks could increase the relative speed and ease with which approvals could be considered, thereby reducing undue delays.

2.5. Other best practices put forward included **national coordination**. In many Members, approval procedures could entail more than one government agency or entity. National Coordination could help remove excess steps in the approval procedures and facilitate the harmonization of procedures among diverse agencies, in turn minimizing undue delays and unnecessary or burdensome steps or procedures.

2.6. Another area for best practices suggested by many participants related to the **use of international standards**. To the extent possible, Members should base approval procedures on international standards, guidelines, or recommendations. Additionally, where the lack of a measure and the capacity to specify one was causing a trade concern, importing Members should consider basing an SPS measure on international standards, guidelines, or recommendations until approval was established domestically. Harmonization of SPS measures with international standards, guidelines, or recommendations could facilitate approval procedures by ensuring that SPS measures were scientifically justified and by decreasing the likelihood of discrimination between and among trading partners.

2.7. **Setting of import tolerances/thresholds** was also addressed. Members could consider either establishing import-specific tolerance to assure food safety while facilitating trade when a product was not used domestically or establishing an appropriate threshold that provided for food safety or animal health or plant health protection. One participant also referred to import tolerances in the case of substances not regulated at national level but regulated by international standards.

2.8. The Working Group further discussed **regulatory cooperation** and **consideration of other Members' approvals**. On the topic of regulatory cooperation, Members could facilitate approval procedures by working jointly with other Members to maximize capacity and resources. This approach would be facilitated by Members following international standards, guidelines, or recommendations and risk assessment techniques developed by the relevant international organizations. In relation to the consideration of other Members' approvals, one participant stated that Members could consider taking into account the results or information from another Member's approval procedure as part of domestic approval procedures and to determine how to respond to a non-compliance.

2.9. In echoing these latter two suggestions, one participant considered the recognition of risk assessments to be a fundamental tool, especially in the approval process for biotechnology products. In that regard, the mechanism for the recognition of risk assessments carried out or authorizations given by other Members should ensure the exchange of complete information related to risk analyses to guarantee transparency and access to information and improve the implementation of approval procedures so that the ALOP is achieved, while facilitating trade. The participant further observed that many developing country Members did not have the conditions to properly implement the approval processes for commodities related to biotechnology products. Considering intellectual property rights and patents and that authorizations (including assessments) of biotechnology products were carried out on a case-by-case basis, as well as recognizing that the producer or importer / exporter was not in a position to easily obtain risk information, recognition mechanisms were required to include the consent of the biotechnology industry to proactively provide information to competent authorities, or to allow the exchange of information between competent authorities of trading partner Members adopting recognition strategies (i.e. common application dossiers).

2.10. Another suggestion was to develop **best practices to address asynchronous approvals**. The participant putting forward this suggestion recalled that an asynchronous authorization was a situation where there was a regulatory authorization for a product, such as an rDNA plant intended for food and feed use, in the country of origin and no corresponding authorization in a country of import. Asynchronous authorizations could delay commercialization of new products as well as create the potential for trade disruptions, for example, those arising from the low-level presence of unauthorized rDNA plants in food and feed shipments. The proposal was for the Working Group to

develop a consensus document of best practices to help reduce occurrences of asynchronous authorizations, recognizing that individual Members needed to devise measures consistent with their domestic legal requirements, and acknowledging that regulatory approaches should provide transparent and predictable timeframes for decision making, be science-based, be no more trade restrictive than necessary, and be consistent with relevant international obligations.

2.11. This proposal was echoed by others in the Working Group. One participant considered this to be of special interest for living modified organisms (LMOs). The participant suggested that the Working Group develop a section on best practices for the unilateral or mutual recognition of risk assessments. Another participant suggested that the Working Group lay down actions to improve asynchronous approval of GMOs, particularly regarding unnecessary requirements in the approval procedures which delayed commercial approvals. Regarding good practices, it would be helpful if the developers made joint and simultaneous presentations both in the exporting and importing Members, since the synchronization of approvals would facilitate the free circulation of products.

2.12. Other participants generally agreed that it would be helpful to identify a set of best practices to provide guidance for Members throughout the process of developing and establishing approval procedures. These discussions could focus on: use of and harmonization with international standards; regulatory cooperation, including recognition of joint risk assessments or third-country risk assessments to facilitate decision making and inform appropriate responses to non-compliance; and use of import tolerances and/or thresholds. Discussions in these areas could advance the understanding of ways in which Members could strengthen and streamline their approval procedures to facilitate safe trade. It would also help generate a general reference framework for the appropriate implementation of the different approval procedures, according to the principles included in Annex C, as well as address situations of non-compliance.

2.2 Collection of Available Tools and Resources (G/SPS/GEN/2098)

2.13. Over the course of the Working Group, many participants submitted ideas of readily available resources. The Working Group developed a collection of readily available tools and resources to enhance the implementation of the obligations of the SPS Agreement as they applied to approval procedures. In the process, the Working Group consulted with the ISSBs, with WOAH (founded as OIE) providing input on the collection.

2.14. The Working Group developed this collection with the understanding that it did not involve a substantive analysis and did not constitute an exhaustive list of tools and resources related to approval procedures. It was an evergreen document to be updated by the Working Group as it progressed with its work. The discussions relating to this collection of tools and resources focused on the types and individual resources to be added to the collection, how they should be grouped, the purpose of the collection, and how it could be complemented or improved.

2.15. Regarding the themes used for grouping the resources in this collection, one participant noted that some of them were topics (e.g. transparency and undue delay) while other resources were identified by sources. Another participant suggested to separate tools and resources from multilateral intergovernmental organizations from those of other organizations. Another question was whether some tools would benefit from appearing twice in the document when they were relevant to more than one theme. Eventually, tools were included in the compilation to feature only once in the document for simplicity and classified where they were deemed to be most useful.

2.16. In addition, one participant proposed that, when contributing to the list of available tools, participants should also identify the type of approval procedures or aspects of approval procedures that these tools related to or were relevant for. This was however not done consistently and was therefore not reflected in the collection.

2.17. One additional related proposal was to include guidelines of individual WTO Members on their own approval procedures and to create a repository of Member's approval procedures. Other participants acknowledged the usefulness of the suggestion but worried about the workload that would result from updating and maintaining a document containing Members' approval procedures. It was also queried whether including such information might change the purpose of the collection of available tools and resources. As an alternative, Members could provide concrete examples of the application of the tools and resources contained in the collection of available tools. The Working Group did not move ahead to implement these suggestions.

3 KEY CHALLENGES OF APPROVAL PROCEDURES THAT IMPACT INTERNATIONAL TRADE AND THAT THE SPS COMMITTEE SHOULD SEEK TO ADDRESS

3.1. The focus of the Working Group throughout several rounds of its work was on key challenges of approval procedures that impacted international trade and that the SPS Committee should seek to address. Discussions focused on challenges associated with:

a. timing and undue delays;
b. transparency;
c. communication or information exchange;
d. justification and discrimination of approval procedures;
e. harmonization with international standards; and
f. other challenges such as COVID-19.

3.2. To facilitate the discussions, the Working Group addressed a few key challenges at a time, staggering the discussions to address: challenges associated with "transparency" and "communication or information exchange" (Section 3.1); challenges associated with "justification and discrimination of approval procedures" and "harmonization of international standards" (Section 3.2); and "timing and undue delays" as well as "other challenges such as COVID-19" (Section 3.3).

3.1 "Transparency" and "Communication or information exchange"

3.3. Improving the communication and exchange of information among Members and increasing the transparency of the different stages of approval procedures were some of the main and most important challenges of approval procedures mentioned. One participant proposed that transparency of approval procedures be discussed in import risk analyses, while another considered that issues of transparency of procedures for sampling, testing and certification were the key challenges that the SPS Committee should seek to address.

3.4. On the issue of **transparency**, uncertainty of the steps of approval procedures and the lack of clarity as to the type of information required and the process to submit information, as well as undefined deadlines, were highlighted by various participants. The Working Group also discussed effects on trade of such challenges. For example, a participant noted that audits could impact trade when there was lack of clarity, transparency, and predictability in the purpose and outcome of audits and the audit processes. Building on this comment, another participant added that trade could be impacted when there was lack of clarity, transparency, and predictability in the times of realization and dictum of audits.

3.5. While acknowledging transparency-related challenges, one participant underlined that capacity constraints of developing country Members had to be taken into consideration. Transparency discussions should take into account technical and human capacities at domestic level.

3.6. Many participants also linked the discussion on transparency to that of timing and undue delays in approval procedures. In this context, one participant remarked that some Members failed to have a clear process for their approval procedures related to the importation of animals or animal products into their territory. The participant had for example been asked to complete a questionnaire and thereafter an audit of the farm's facilities had been conducted by the potential importing country. In addition, the competent authority of that country had evaluated its veterinary services. No report had been produced, despite repeated requests. This had created a great deal of uncertainty as to any additional steps or what might have been hindering the completion of the report.

3.7. One participant distinguished between exporting and importing points of view. The participant noted that from the exporting side, the main challenges were the lack of transparency, including the availability of the rules, unclear procedures, and vague time frame. The interpretation of the expression of "undue delay" could be considered as well in this context. In contrast, from the importing side, the main challenges were unclear and not sufficiently justified requests, as well as the lack of necessary data and guarantees.

3.8. In view of dealing with associated challenges, a participant suggested that the Working Group discuss minimum requirements for information necessary to complete the approval procedures. Another proposal was that the criteria for examining the completeness of the documentation should be clarified and that the applicant should be informed in a precise and complete manner of all

deficiencies in the context of paragraph 1(b) of Annex C of the SPS Agreement. Specifically, necessary documents and their contents should be announced to all applicants in advance as repeated requests for additional documents without advance announcement could lead to delays in the approval procedure. The same participant suggested that there be specific procedures to ensure that the competent body transmitted as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action could be taken if necessary as mentioned in paragraph 1(b) of Annex C of the SPS Agreement. The presentation of reasons and detailed explanations for the result of the procedure were important for an approval procedure to be implemented without undue delay. These proposals were echoed by another participant, who highlighted the importance of: (i) clarifying criteria for examining completeness of documentation; and (ii) announcing necessary documents to applicants in advance. These two recommendations were also linked to the WTO Trade Facilitation Agreement, which required Members to simplify their import processes and notify their standards of inspection.

3.9. Regarding **communication and information exchange**, the function of Members' National Enquiry Points was highlighted, as the entities responsible for the provision of answers to all reasonable questions from interested Members, as well as for the provision of relevant documents.

3.10. To facilitate further exchanges in the Working Group, the co-stewards provided a summary of the Working Group discussions and the 2019 Thematic Session on Approval Procedures relating to key challenges. On transparency and communication or information exchange, the co-stewards highlighted *inter alia* the following points from this summary:

a. A lack of transparency in approval procedures had been underlined as a challenge impacting trade, in particular when information on the rules and approval procedure processes was unavailable, the approval procedures were unclear, and the deadlines or timeframes were vague or undefined;

b. Challenges were experienced when the information required by the importing Member to complete their approval procedures was not readily available. Additionally, a lack of clarity, transparency, and predictability in audits and import checks could negatively impact trade;

c. The technical and human capacities at the country level had been highlighted as considerations that needed to be taken into account;

d. Difficulties with communication and information exchange had been noted as a challenge impacting trade, leading to situations where it was unclear what type of information or data was required, the process to submit the required information or data, the duration of different steps in the approval procedures, and the process to provide additional or follow-up information;

e. The lack of timely and objective responses also created uncertainty for trade. There may be challenges in receiving confirmation as to whether additional steps or information was required to complete the approval procedure, resulting in uncertainty on the overall status of the approval. Delays in communicating the result of the approval procedure in a timely manner negatively impacted trade;

f. Another challenge that had been identified was when the importing Member did not communicate in advance to applicants details on all the necessary documents and the information required for these documents. Repeated requests for additional documents and information could lead to delays in the approval procedure;

g. The need for information exchange and communication between regulators and industry had also been highlighted.

3.11. Participants welcomed the co-stewards' summary and generally agreed with the description of key challenges. Some participants, however, queried whether the summary covered all the relevant issues. In this context, one participant highlighted the importance and role of SPS National Enquiry Points for the purposes of communication and information exchange, as specified in the SPS Agreement. SPS National Enquiry Points should be included in the description of this item.

3.12. Another participant referred to its practice of making relevant information available online, which could be a practical recommendation for Members, including having a functioning website with

available information for example on SPS National Enquiry Points as well as a functional mailbox to facilitate the information exchange on different topics, and using different languages. These could possibly form part of Working Group recommendations. The co-stewards acknowledged that providing comprehensive information online in various languages would be useful to a global audience and could be a cost-saving activity as it could lead to a reduction in the number of *ad hoc* requests for information. Participants however also recognized that there could be possible legitimate limitations as to what was reasonable to expect given resource constraints. Members did not necessarily have the resources to maintain functioning websites. One suggestion made in this respect was that Members could identify priorities and that there could be regional initiatives to develop similar requirements for approval procedures.

3.13. Specific challenges that had been observed with approval procedures in terms of transparency and communication or information exchange were further discussed. One participant referred to unclear information requirements and difficulties in obtaining information pertaining to the requirements for the approval procedures. It was also sometimes unclear whether an approval procedure was in fact required and there could be a lack of clarity and accessible guidance for information requirements in the processes for pre-market approval procedures. There could also be a lack of transparency on the implementation of approval procedures as well as the maintenance of approvals, for example transparency on listing requirements for products and establishments, how these lists were prepared and maintained, and who was responsible for maintaining the lists. The participant added that this could lead to miscommunication and lack of understanding on whom to notify and when. The same participant further referred to a lack of transparency with respect to maintaining approval procedures.

3.14. Addressing challenges relating to communication and information exchanges in relation to listing products and establishments, one participant highlighted that there was significant uncertainty for exporters when there was a lack of timely responses to requests, incomplete responses, or imprecise description of deficiencies in applications. This could cause challenges in communication regarding the required information and lead to multiple requests back-and-forth, burdensome information requirements, and delays in providing the results of approval procedures. Possible solutions to these challenges should be explored.

3.15. One participant took the view that the type of approval procedures posing the greatest challenges to international trade were risk assessment procedures, with undue delays being the main issue. Concerns raised in the SPS Committee often related to undue delays of risk assessment procedures and guidance on this issue was available in WTO panel and Appellate Body reports. The participant, however, considered that the type of approval procedures posing the greatest challenges to international trade needed to be distinguished from the type of approval procedures that the SPS Committee should seek to address. Taking time and resource constraints into account, the Working Group should avoid conducting an analysis more detailed than that of WTO panels and avoid protracted discussions on the legal definition of the term approval procedures. Issues related to transparency of procedures for sampling, testing and certification should be identified as the key challenges that the SPS Committee should seek to address.

3.16. Finally, one participant requested that the issue of obtaining complete information at the beginning of the process be reflected in the work of the Working Group and suggested to work on a recommendation for Members to make their best efforts to give complete information at the beginning of the process. While recognizing Members' autonomy in defining and conducting approval procedures, greater predictability in approval procedures was key. Members needed to provide transparency in the negotiation processes and to have a temporal forecast of the duration of processes. This would allow for greater predictability regarding when processes would end as well as provide a better understanding of what would qualify as undue delay.

3.2 "Justification and discrimination of approval procedures" and "Harmonization with international standards"

3.17. On the topic of **harmonization with international standards**, several participants recalled that Members were encouraged to use international standards, guidelines, and recommendations where these existed in accordance with Article 3.1 of the SPS Agreement. However, several participants reported challenges related to the lack of harmonization of approval procedures with international standards. One participant noted that, in the trade in animals or animal products, while Members at times might reference a standard or guideline developed by WOAH (founded as OIE), in applying a sanitary measure for the trade in animals or animal products, the measure did not always conform to nor seemed to be based on that standard or guideline.

3.18. In addition, many participants highlighted challenges relating to **unjustified approval procedures or measures applied in an unjustified or discriminatory manner**. In this context, the importance of science-based SPS measures was highlighted, and the Working Group was called to discuss the review of the application of unjustified SPS measures in trade, related to export restrictions by Members that were not backed by scientific evidence and affected food exports. One participant noted that it had faced situations where a disease was present in the potential importing country, but the sanitary measure applied to the imported product required that the exporting country be free of the same disease. Another participant referred to situations with certification requirements where information required or import checks seemed to go beyond what was necessary to meet the importing Member's ALOP. In earlier discussions, this participant had noted that import checks could impact trade when there was lack of clarity, transparency, and predictability in these processes; the integrity of the good was affected more than necessary; and when import checks were more frequent than necessary, based on risk. Building on this comment, another participant highlighted the need to check that there was equal treatment.[16]

3.19. To foster Working Group discussions, the co-stewards updated their summary on key challenges.[17] Based on this revised summary, the co-stewards highlighted the following key points that had emerged as they relate to "justification and discrimination" as well as "harmonization with international standards":

a. There were challenges when approval procedures were not justified or based on scientific principles and risk assessments; these approval procedures negatively impacted trade. This could lead to approval procedures that were overly burdensome, more trade restrictive than necessary, did not take into account bilateral circumstances or past performance, and could lead to duplicative requirements;

b. Discriminatory approval procedures were a challenge impacting trade, for example when disease freedom was required for exporting countries even though the disease in question was present in the importing country. As well, there could be discriminatory fees;

c. The lack of harmonization with international standards, guidelines, and recommendations was a challenge, since differing approval procedures created difficulties and uncertainty for trade and decreased predictability;

d. Another challenge was that Members might indicate that an approval procedure aligned with a particular international standard, guideline, or recommendation, but in application the approval procedure did not conform to nor seemed to be based upon the referenced international standard, guideline, or recommendation. This created uncertainty and negatively impacted trade.

3.20. Participants considered the co-stewards' summary to be helpful to advance the discussions. One participant expressed reservation, however, as to whether the summary covered all the issues, discrimination being one of the most difficult issues to identify. Another participant cautioned not to discuss specific SPS measures that might be taken by particular Members, but to approach these issues from an eyes wide-open perspective. There were instances where Members imposed measures without a sound justification or without basing these measures on international standards because of domestic or political considerations. The Working Group was not a forum to discuss those instances where Members might be adopting SPS measures while being fully aware that these were inconsistent with the SPS Agreement. Rather, it would be more productive to focus on how technical capacities and regulatory cooperation could be strengthened, so that Members could have the required resources to comply with the SPS Agreement.

3.21. On the topic of harmonization with international standards, the following challenge was further discussed: standards were not developed quickly enough in light of international developments. The process of agreeing on new standards was a difficult one, and since standards were sometimes outdated, WTO Members needed to adopt other SPS measures. In that context, one possible recommendation that the Working Group could develop would be to encourage the use of e-tools to provide clear and timely information. Encouraging the sharing of information online could help address many of the challenges discussed in the Working Group.

[16] See para. 1.8. *et seq.* above.
[17] See para. 3.10. above.

3.22. On discriminatory treatment, one participant noted that, in certain instances, different exporting Members received different information from the same importing Member regarding its approval procedures: one exporting Member might not have all relevant information, while others might. One participant specifically referred to: (i) receiving basic information on approval procedures, which fitted under the umbrella of transparency obligations in the SPS Agreement but was not always provided; and (ii) receiving complete information on requirements. Regarding the latter, an importing Member might present a list of approval steps and, after a long period, inform the exporting Member of the need for additional information that had not been required in the initial list. Two proposals were submitted to deal with this issue: (i) recommending that all Members should make their best efforts to give complete information in a non-discriminatory manner, which could be easily achieved through accessible information on websites or by providing documents with information on exporting to a certain Member; and (ii) recommending that organizations dealing with cooperation and technical assistance help Members make complete information available to all Members.

3.23. Building on these comments, another participant observed that the themes of transparency, information sharing, and communication, were intertwined with other key challenges and could be possible areas for further reflection and possibly a complementary Working Group outcome. The importance of having information available online and having complete information available to all Members from the outset was acknowledged. In addition, a number of specific trade concerns (STCs) raised in the SPS Committee had highlighted these key challenges of justification, discrimination, and harmonization with international standards. One particular challenging area was approval and listing of establishments, where there could be burdensome information requirements beyond what was necessary, not based on international standards or supported by scientific evidence. This could cause lengthy approval listing processes, including with costly and burdensome audits, questionnaires, and exchange of information processes. There were also challenges with certification processes, where requirements went beyond what was necessary or deviated from international standards, increasing costs and administrative burdens and creating obstacles for trade. As seen in the SPS Committee, these challenges related to different types of approval procedures, such as pre-market approvals.

3.24. With respect to pre-market product approvals, one participant observed that Members needed to adhere to what was established in the international standards; so that these allowed the commercialization without the requirements being excessive, especially for products for which there was already market access. Sometimes, excessively detailed questionnaires were requested and did not take into account justifiable international standards. It would be important that already completed control, inspection, and approval processes be taken into account and recognized for other similar products.

3.25. Finally, the Working Group discussed outreach and capacity building, as well as stakeholder engagement as possible areas where ideas could be shared, including on how Members might overcome human resource limitations. In this connection, the co-stewards reminded that, following the discussions on what the key challenges were that participants faced, the next step would be to discuss possible principles of approval procedures.

3.3 "Timing and undue delays" and "Other challenges"

3.26. Issues related to **timing, undue delay, or synchronization** were raised as cross-cutting issues by many participants. The issue of undue delay was said to be critical and of particular concern. To illustrate this, one participant observed that most STCs in the SPS Committee reflected undue delays.

3.27. One participant observed that when a Member unduly delayed, without due justification, the acceptance into its market of a product from an exporting Member, which was exported to multiple destinations in compliance with the SPS requirements for the product, this created unnecessary and unjustified barriers to trade affecting negatively both exporters and consumers. Recalling that international trade must be facilitated, another participant called on the Working Group to analyze the issue of undue delays in approval procedures to avoid establishing/generating technical barriers to trade, as well as to analyze unjustified delays in the inspection and phytosanitary qualification processes for entry by importing Members.

3.28. In addition, participants shared experiences about delays, for example situations where reports on the progress or outcome of an approval procedure were still awaited, despite several requests. Unjustified delays in SPS admissibility processes by Members that import agricultural and

agro-industrial products were highlighted, with the effect of slowing down formalities, thereby restricting trade flows and access for goods. The lack of timely and objective responses in terms of inspections conducted by health authorities of importing Members to approve producing and exporting establishments in other Members was also raised as a topic for discussion by the Working Group.

3.29. One participant identified the following approval procedures, where undue delays had major impact for international trade of livestock and agriculture products: (i) approval of import for food and feed, plants, animals, plant and animal products; (ii) risk assessment for a particular product, such as pest risk analysis, and import risk analysis; (iii) authorization/approval of processing establishments; and (iv) animal or plant health and food safety control system audits. These approval procedures were usually initiated with a request for market access from the exporting party. Generally, the continuation of the process was conditioned to the finalization or prioritization of other requirements or depended on the administrative burden of the importing party. This, in addition to the fact that approval procedures also implied exchanges of information between competent authorities and could imply physical audits, could take several years. In the participant's experience, the entire process could take between two and ten years, with a great variability among Members and products, making it very difficult to estimate the time that a particular process would take. Furthermore, main difficulties and possible causes of undue delays were identified, e.g. the excessive administrative burden, the lack of transparency of the importing party, the difficulties of communication in the process, and non-science-based/unjustified requirements.

3.30. In the early Working Group discussions, some participants had also zoomed-in on pre-market approval procedures, and the issue of these varying between Members and leading to asynchronous or misaligned approvals.[18] One participant had added that regarding the approval of individual products instead of complete product categories, approval/inspection processes were presented focused on each individual establishment, instead of carrying out comprehensive evaluations focused on the exporting Member's systems. These processes needed to be repeated after a few years, which caused duplication of control, inspection, and approval procedures, in addition to increasing costs and hindering access to markets.

3.31. Some participants suggested that the Working Group draft guidelines, for example with definitive timeframes. One such proposal was for the Working Group to draft recommendations on the proper implementation of paragraphs 1(a) and 1(b) of Annex C to the SPS Agreement. In order to provide useful information that could serve as a basis for future SPS Committee recommendations in this area, the following was suggested: (i) identification and characterization of approval procedures most commonly applied or of greater importance in trade, as well as their respective standard processing periods; and (ii) review and analysis of the predictability of, and Members' compliance with, that period, as set forth in paragraph 1(b) of Annex C of the SPS Agreement. Another suggestion was that each Member outline its approval procedures in detail in the first stage of negotiations with the other party and that the maximum deadline for completing all stages of the approval procedures not exceed 24 months, subject to specific adjustments or the possibility to use alternative procedures in adverse cases (regional or global, such as the COVID-19 pandemic).[19] Finally, the Working Group could discuss approaches to the definition of "reasonable time" required for the approval procedures. Other participants highlighted that in the development of guidelines and specifically relating to timeframes, the Working Group should ensure that no additional burden was placed on Members with limited resources.

3.32. With respect to **other challenges**, the impact of the COVID-19 pandemic on approval procedures and SPS requirements in general for market access of imported products was put forward as a possible topic for the Working Group. One participant cautioned that any alternative procedures, if agreed to in order to meet deadlines in adverse cases such as the COVID-19 pandemic, needed to be used to avoid barriers to trade and unnecessary delays in face of situations of regional and/or global adversities. Another proposal was to discuss collaborative strategies to ensure the implementation of approval procedures by Members, overcoming administrative constraints or even situations like COVID-19, in order to prevent trade from being adversely affected.

3.33. Another frequent challenge when seeking approval for market access was highlighted by a participant who imported a significant proportion of the raw materials used for processing due to its limited agricultural activity. Yet, this production model was not recognized/permitted in certain

[18] See para. 1.8. above.

[19] This proposal and subsequent discussions in the Working Group are detailed in paragraph 4.7. *et seq.* below.

Members' approval procedures. Given the connectedness of global supply chains, the participant noted that similar production models could be adopted by more Members. Allowing Members to leverage the increasingly connected global supply chain created more opportunities for an effective use of resources.

3.34. To foster further discussions, the co-stewards highlighted the following key points on "timing and undue delay" as well as "other challenges, such as COVID-19" from their revised summary of key challenges, which they had based on Working Group discussions thus far and the 2019 Thematic Session on Approval Procedures:

a. Undue delays in approval procedures were noted as a challenge by participants. Undue delays slowed down approvals, which restricted trade and negatively affected exporters and consumers. Undue delays in risk assessment procedures had been highlighted as one of the main challenges with approval procedures;

b. The timing of approval procedures was also noted as a challenge. For instance, pre-market approval procedures could vary between Members, which led to asynchronous or misalignment of approvals. Although typically considered a temporary issue, these delays could result in decreased profit and delayed innovation due to the potential loss of product and product quality;

c. The impact of undue delays in approval procedures initiated by market access requests on trade of livestock and agriculture products was highlighted as a common and critical issue. These approval procedures included the exchange of information between competent authorities and in some cases audits, and their conclusion could depend on the finalization or prioritization of other requirements, or the administrative resources of the importing party;

d. The length of approval procedures could vary based on the Member and products involved, which resulted in unpredictability of the length of approval procedures;

e. Greater predictability and transparency in approval procedures had been emphasized, with a view to predict the duration of approval procedures and establish an understanding of what could be classified as undue delay;

f. Global challenges resulting in administrative constrains, such as the COVID-19 pandemic, could adversely affect international trade and approval procedures;

g. Other challenges included the lack of trust between parties, and a lack of capacity to administer the required approval procedures in the competent authority of the importing Member.

3.35. In the discussions that followed, one participant provided an illustrative list of challenges of approval procedures associated with timing and undue delays. Citing the case of citrus fruit exports, the participant noted that there had been cases of undue delays of up to five years between the initiation of a request and the reception of the proposal for phytosanitary import requirements. Additional examples of undue delays in approval procedures related to the export of sheep meat, beef, poultry, and honey; noting that there had been requests for information, which had been previously submitted, lack of response from counterparts, delays in on-site inspections, and instances where the counterpart had requested to advance simultaneously with the market authorization of its export products as a condition to advance the process. Referring to the impact of these challenges on international trade, one participant highlighted that unjustified and undue delays had restricted market access of agricultural products, which had created disparities with Members where similar sanitary and phytosanitary conditions prevailed and could be considered a disguised barrier to trade. Additional challenges related to the complexity and lack of harmonization of questionnaires requested by importing Members, as well as the request for nonessential information in certain occasions.

3.36. Other examples of issues associated with timing and undue delays were identified in relation to pest risk analysis processes and pre-audit evaluations for live animals. One participant identified instances where additional information had been requested by the importing party in the revision of pest risk analysis questionnaires or pre-audit evaluations, which was technically unjustified or unnecessary for the approval procedure. It would be useful to simplify the questionnaire and the

exchange of pest risk analysis and pre-audit information to reduce documentary stages. Delays resulted from unjustified steps in pest risk analysis processes and from the lack of information at the start of the pest risk analysis process regarding possible additional steps. A reduction or anticipation of such delays would provide more predictability to these processes or evaluations.

3.37. Undue delays were also observed in the context of on-site audits for the renovation of or first-time authorizations for processing plant facilities. Remote audit contingency plans could help address this issue. Alternative approval inspection processes, such as remote or documentary audits, could be implemented in emergency cases such as the COVID-19 pandemic, where on-site evaluations were not possible. Related issues included uncertainty related to timing and undue delays and the problems these created for the private sector, particularly in the context of seasonality in agricultural production.

3.38. One participant distinguished between delays caused by the potential exporter and those caused by the potential importer. The participant highlighted situations in which a workplan had been carried out by the importing and exporting party and technical consultations and work had been completed, but the process had come to a halt. Recalling an earlier suggestion to work on a recommendation for Members to make their best efforts to give complete information at the beginning of the process, this referred to approval procedures where there was a broadly predictable timetable, but once the timetable had been completed the process had nonetheless stopped.

3.39. Understanding that there was no easy definition, one participant considered it would be useful to characterize what was considered an undue delay. At the beginning of the approval process, clear steps and an average time for conclusion of the process should be indicated. This would create predictability to the exporting party and provide a better understanding of what could be considered to be an undue delay.

3.40. Another participant noted that while approval procedures could be resource intensive and required time, they could be completed without undue delays. Delays or asynchrony in the timing of approval procedures between Members could negatively impact trade, creating uncertainty between exporters. The participant referred to delays in the approval of listing of establishments, in providing the results of approvals and publishing the list of approved products and establishments, and in the implementation of import conditions, in particular for restoring and/or providing new market access. Other delays related to the negotiation of export certification, scheduling of audits or issuance of reports. In addition, issues with timing and undue delays were again highlighted for pre-market product approval, such as approval of biotechnology products, which could vary between Members and be misaligned with best practices. While a temporary issue, it was one that frequently impacted trade and could result in delays in the commercialization of new products, or increased costs, prompting Members to implement controls to ensure that products were not exported to Members where they were not approved.

3.41. Finally, another participant highlighted the importance of acknowledging the significance of the market access process. The effects of delays as well as resource constraints faced by Members were acknowledged. The participant considered that there was a perspective component in determining undue delays as Members asking for market access could consider any delay as undue. In relation to previous exchanges in the Working Group regarding efforts to streamline processes, the participant considered it useful to look at approval processes through the lens of resource constraints, and to identify alternatives to streamline the approval process whilst considering the level of protection needed in the domestic market and ensuring the safety of products.

3.42. Concluding the discussions on key challenges, the co-stewards thanked participants for their interventions around the topics of resource constraints, definition of undue delay, and need for alternatives, as well as the reinforcement of issues such as transparency, advance awareness of the process and communication. The co-stewards noted that emphasizing these issues reinforced the importance of the linkages of timing and undue delays and transparency or having a clear understanding of the processes and technical justification for requirements at the outset. The co-stewards highlighted the issue of linking import and export requests, which was not a legitimate consideration when making technical assessments. In addition, the issue of resource constraints and the need to prioritize were highlighted. The co-stewards noted that the discussions led to conversations about possible solutions and recalled the then upcoming Thematic Session on the Use of Remote (Virtual) Audits and Verification in Regulatory Frameworks.

4 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

4.1. The Working Group also discussed the principles of approval procedures that facilitated international trade while meeting the importing Member's ALOP, and the SPS Committee's role in highlighting these principles. The discussions were informed by the Working Group's work on tools and best practices (Section 2) and key challenges of approval procedures (Section 3).

4.2. Participants proposed several principles of approval procedures, largely mirroring the key challenges of approval procedures discussed in the Working Group. One participant referred to ensuring that SPS measures were science-based in line with Articles 3 and 5 of the SPS Agreement; the principle of transparency, where Members make information available via a website or upon request through the SPS National Enquiry Points, in line with Annex B of the SPS Agreement; the principle of non-discrimination whereby Members shall ensure that their SPS measures do not arbitrarily or unjustifiably discriminate between Members, in particular where the SPS situation was similar in the importing and exporting Member, in line with Article 2.3 of the SPS Agreement; and the principle of consistency, whereby an importing Member's treatment of like products should be the same when these products were imported from different Members with the same SPS status.

4.3. Another participant also drew attention to the principles of risk-based approval procedures, timely approval, communication, and transparency. Some of these principles and characteristics could be considered by Members to build into their domestic systems to support approval procedures that met the ALOP while facilitating trade. The participant highlighted the need for approval procedures to be based on scientific principles and an assessment of risk, to be conducted and completed in a timely manner and for the outcomes of the approval procedure to be communicated upon the conclusion of the assessment. The need for approval procedures to include mechanisms for communication, allowing for opportunities for clarification of requirements, was highlighted as a tool to facilitate the provision of the necessary information by the proponent. Open and ongoing communication was a key element for approval procedures to be undertaken in a timely manner. Approval procedures should be transparent, with information on status and requirements, such as guidance documents, made available or provided to the proponent proactively or upon request.

4.4. One participant also proposed the operationality and timely flow of information within stages of approval procedures, including: publication of the processing period; examination of the completeness of the documentation and the communication of deficiencies; transmission of the results of the procedure; processing of applications, even when these had deficiencies; and reporting on the stage of the procedure, with an explanation for any delays.

4.5. Another participant suggested that the Working Group discuss the following as draft principles of approval procedures: simplified procedures, expedited and completed without undue delays; procedures not applied in a manner that would constitute an arbitrary or unjustifiable discrimination against other Members; publication of the standard processing period or communication of the anticipated processing periods of procedures upon request; information requirements limited to the extent necessary for appropriate control, inspection and approval procedures, including for the approval of the use of additives or establishment of tolerances for contaminants in food, beverages, or feedstuffs; and fees imposed for the procedures equitable in relation to fees charges on like domestic products and no higher than the actual cost of the service.

4.6. Further drawing attention to the topics of transparency, necessity, communication, and harmonization with international standards, one participant noted that, as a general rule, the fundamental principles of the SPS Agreement should be implemented and precisely described in documents related to approval procedures. The participant highlighted the need for transparency on the applicable regulation of each approval procedure and who must comply with it. Explanatory documents and the publication of procedures and requirements, including stages and deadlines applicable to both parties, were necessary to avoid undue delays. The participant referred to instances where deadlines were set but often vague. Noting that in some instances the information requested, for example through questionnaires, was difficult to gather, the participant remarked the need to explain the reasons for the importing Member to demand compliance with approval procedures and to justify the documentation required. Lastly, the participant highlighted the need to promote opportunities to consult on the approval procedure, the documentation to be submitted, and the procedure's progress and results. Promoting harmonization of approval procedures with international standards, guidelines, and recommendations to facilitate trade was also highlighted.

4.7. Putting forward a proposal for the review of approval procedures, one participant indicated that its position was directly linked to the issue of undue delays, an issue that was also reflected in most of the STCs presented in recent meetings of the SPS Committee. The participant proposed that Members detail their approval procedures in the first stage of negotiations with the relevant party, including information on the stages of the approval procedures and deadlines for completion, as well as responses or information input from both parties. Regarding the maximum deadline for completion of all stages of the approval procedure, the participant suggested it should not exceed 24 months, with the possibility for adjustments if bilaterally agreed. The participant highlighted that parties should be encouraged to adopt simplification or facilitation procedures, taking into account the recognitions of equivalence between systems. Deadline extensions for each stage of the approval procedure were to be duly justified in order not to exceed the maximum final deadline bilaterally agreed upon to complete the process. The participant also suggested that Members should have pre-stipulated or bilaterally agreed alternative procedures, such as video conference inspections and/or the adoption of simplified and electronic procedures, to meet the deadlines in adverse cases such as those related to the COVID-19 pandemic.

4.8. On this specific proposal, another participant remarked that the Working Group would need to define stages of approval procedures with clear time limitations to finalize the overall process within 24 months as proposed. The participant queried whether the Working Group would have enough time to proceed with the suggestion given the timelines set forth in document G/SPS/W/328/Rev.1. The participant further noted that the suggestions contained details aimed to build up and standardize approval procedures, and that it would be challenging for the Working Group and the SPS Committee to reach consensus. The proponent replied that the proposal consisted in establishing a text to guide Members to commit themselves to establish a timetable that listed the approval procedures and their deadlines for conclusion, thereby making undue delay in approval procedures easier to identify and characterize. To avoid becoming a limitation to Members, possible extensions for the conclusion could be agreed between the parties. Referring to the maximum limit of 24 months for the entire approval procedure, the participant noted that they were open to other suggestions. According to the participant, the proposal respected the regulatory differences among Members and allowed for flexible approval procedures on a bilateral basis. The suggested approach intended to prevent the use of unclear and undefined approval procedure steps to justify undue delays, which unnecessarily prolonged the process and created trade barriers.

4.9. One participant considered that a transparency approach should be part of each Members' approval procedure, with Members clearly determining their approval procedures at the beginning of the negotiation process including steps and deadlines, as well as providing information and justifications for possible postponements. The participant deemed useful to include a maximum time for completion of all approval procedures, including necessary postponements. In relation to another participant's suggestion to base approval procedures on international standards, guidelines, or recommendations "as far as possible", using the standards provisionally until regulatory cooperation between the relevant parties was achieved, one participant took the view that the term "as far as possible" weakened the SPS Agreement and international standards. The parties involved should be encouraged to seek measures in compliance to what was provided in the SPS Agreement and with basis on ISSB guidelines in order to simplify the process and make it more agile.

4.10. Another participant proposed to develop an approval procedure to be agreed by the Working Group and indicated that it was essential to have standardized approval methods to have certainty and transparency in the results, therefore reducing uncertainty to a minimum acceptable to the parties. The participant further noted that approval procedures should be based on scientific principles and risk assessments to increase reliability, and to define the scope of the approval procedure and its cross-border trade implications to facilitate compliance.

4.11. One participant suggested that the Working Group define and clarify key principles that should guide the development and improvement of approval procedures, which would align with proposals to address specific challenges associated with approval procedures. The participant referred to Annex C of the SPS Agreement and indicated that its flexibilities, while necessary to account for the range of regulatory approaches used by Members, could lead to challenges and uncertainty.

4.12. The co-stewards presented a summary of exchanges on principles of approval procedures, based on participants' contributions throughout the discussions in the Working Group and the presentations and discussions during the 2019 Thematic Session on Approval Procedures. The co-stewards highlighted the following points:

a. Basing approval procedures on risk and applying approval procedures only to the extent necessary and in the least trade restrictive manner were items highlighted by participants in the discussions;

b. Conducting approval procedures in a timely manner and without undue delay; the importance of ensuring timely and predictable approvals, completed without undue delays; outlining timeliness of approval procedures; accepting applications at any time of the year; initiating approval procedures once applications were received; and communicating the conclusions of the procedure in a timely manner had been emphasized by participants;

c. The importance of transparency and communication was also highlighted. This included communicating with the proponent through online systems or websites prior to commencing and during the approval procedures, as well as providing updates on the status of the approval procedure to the proponent and communicating the anticipated duration and timelines in advance of commencing an approval procedure;

d. The importance of ensuring that SPS measures did not unjustifiably discriminate between Members had also been raised in the discussions. Participants had emphasized that approval procedures should equally not be applied in a manner that would constitute an arbitrary discrimination against other Members;

e. The need for increased acceptance of international standards, guidelines and recommendations for approval procedures, as well as the importance of promoting the application of international standards, guidelines and recommendations had also been highlighted;

f. Participants had also highlighted that the fees imposed for an approval procedure on imported products should be equitable in relation to fees charged on like domestic products, and no higher than the actual cost of the service.

4.13. Participants welcomed the co-stewards' summary. One participant recalled that it had suggested a pragmatic approach focusing on concrete issues identified by participants and that many of the key challenges related to principles already contained in the SPS Agreement. The participant highlighted the need to avoid discussions on the legal interpretation of the SPS Agreement and to be mindful of the scope of the SPS Agreement and the role of the Working Group. Regarding the structure of the co-stewards' summary, another participant suggested using a template to identify the challenges from an exporting and importing Member's perspective.

4.14. Inviting additional comments from participants, the co-stewards noted that the following main principles of approval procedures had emerged from the exchanges:

a. need for science-based, risk-based SPS measures;
b. timely approval and no undue delay;
c. transparency, communication, and publication;
d. non-discriminatory and consistent treatment of Members with the same SPS status;
e. harmonization with international standards; and
f. equitable fees.

4.15. Participants made some additional remarks regarding these principles. Participants highlighted the need for **science-based, risk-based** approval procedures to enable the predictability and reliability of approval procedures.

4.16. Regarding the principles of **timely approval and no undue delay**, conducting approval procedures in a timely manner, ensuring the timeliness in approval procedures, and the need to conduct and complete approval procedures without undue delays were highlighted by several participants. The need to communicate the outcome of the approval procedure in a timely manner upon the conclusion of the assessment was also noted.

4.17. Turning to the topics of **transparency, communication, and publication**, the role of transparency in improving the predictability of the approval procedure process and addressing undue delays was remarked by participants. Some participants highlighted the need for information on the approval procedure and its requirements, including guidance documents and questionnaires, to be

made available from the outset; the need to share information on the standard processing period in advance; the need to proactively or upon request provide status updates on the approval procedures to the proponent; and the need to have standardized approval methods. For approval procedures to be conducted and completed in a timely manner, some participants highlighted the need to reinforce and maintain an open and ongoing communication, with one participant stressing the need to include mechanisms for communication in approval procedures to allow for opportunities for clarification of the requirements and help the proponent to provide the necessary information. Certain participants also highlighted the need for information requirements to be limited to what was necessary for appropriate control, inspection and approval procedures. Some participants noted that the requirements and standard processing periods of approval procedures, including procedure stages and deadlines applicable to both parties, should be published to avoid undue delays.

4.18. Regarding the principle of **non-discriminatory and consistent treatment of Members with the same SPS status**, certain participants again highlighted the need for Members to ensure that their SPS measures did not arbitrarily or unjustifiably discriminate between Members, especially where similar SPS conditions prevailed between the importing and exporting Member, and for approval procedures not to be applied in a manner which would constitute an arbitrary or unjustifiable discrimination.

4.19. The principles of **harmonization with international standards** and **equitable fees** were also again underlined by participants.

5 ADDITIONAL DISCUSSIONS ON POSSIBLE WORKING GROUP OUTCOMES

5.1. The Working Group discussed possible outcomes of its work and output documents throughout its various rounds of work, as reflected in Sections 2-4 above. For example, in the initial rounds of work, in addition to its collection of available tools and resources, one participant proposed that Members provide their own approval procedures to be collected in the form of a repository.[20] Other suggestions included recommendations on the use of e-tools to provide clear and timely information and SPS Committee guidelines on transparency, information sharing, and communication.

5.2. The Working Group's sixth round of work focused on discussing possible outcomes of the Working Group. One participant considered that the development of a survey open to SPS Committee Members would have a positive impact on the development of guidance as an outcome of the Working Group. The survey could replicate the exchanges of the experiences and concerns on approval procedures in the Working Group, with a view to collect and classify Members' concerns or possible solutions. Based on the co-stewards' summary of key challenges of approval procedures, another participant suggested to include columns reflecting the views of the importing and exporting Members, and possible solutions to streamline the process in relation to the challenges that had been broadly identified in the Working Group. Another participant questioned the efficacy of conducting a survey.

5.3. The Working Group further discussed the possibility of developing guidelines or recommendations. One participant noted that the SPS Committee could develop guidelines on the implementation of Annex C of the SPS Agreement, to allow for concrete examples and recommendations on what would be expected from Members concerning the principles contained in Annex C. The Working Group could draft recommendations focused on the principles of approval procedures that addressed the challenges which had been discussed in the Working Group.

5.4. Another participant reiterated its proposal to develop guidelines on certain principles including those of transparency, information sharing, and communication. The participant took the view that it could be a useful outcome of the Working Group, as these guidelines could enhance the implementation of approval procedures in accordance with the provisions of Annex C of the SPS Agreement and could complement existing SPS Committee guidelines and the standards, guidelines, and recommendations developed by the ISSBs. These guidelines could also help address the challenge of undue delays. If the Working Group were to agree to develop guidelines, another participant suggested that an initial draft be prepared for discussion, noting the lengthiness of the process of developing SPS Committee guidelines. Preparing a compilation of best practices or recommendations based on the Working Group's discussions could be an alternative outcome to the development of SPS Committee guidelines.

[20] See para. 2.17. above.

5.5. The co-stewards suggested a report to the SPS Committee with a factual account of the Working Group's discussions and recommendations/observations. One such observation could be that the challenges and principles that had emerged from the discussions were within the bounds of and addressed by the SPS Agreement. One participant emphasized the importance of predictability, the idea that Members must make their approval procedures public and the importance of notifying approval procedures. This was an area that should be reflected in the report to the SPS Committee. Another participant suggested that the recommendations or observations of the Working Group could be channelled through the sixth review of the operation and implementation of the SPS Agreement. Another participant supported the idea, provided that it worked timing-wise. One participant proposed to refer to the document as a compilation of the Working Group's process, not a "report". There could also be a shorter easier-to-digest summary of the Working Group's work.

5.6. The co-stewards noted that the output documents of the Working Group could consist of: a short document with a high-level account of the work of the Working Group, setting-out the outcomes of the Working Group; a factual process-based summary of the discussions, building on the compilations of participants' contributions that had been circulated by the Secretariat to the Working Group in each round of work; and the collection of available tools and resources. These documents were further discussed in the Working Group's seventh and final round of work and eventually circulated as documents G/SPS/GEN/2099, G/SPS/GEN/2097, G/SPS/GEN/2098.

ANNEX A: OVERVIEW OF SUGGESTED TOPICS FOR THE WORKING GROUP CONSIDERATION

This table provides an overview of the main topics to be explored by the Working Group, as they emerged from initial Working Group discussions. This table does not reflect topics that were subsequently put forward or clarifications subsequently provided.

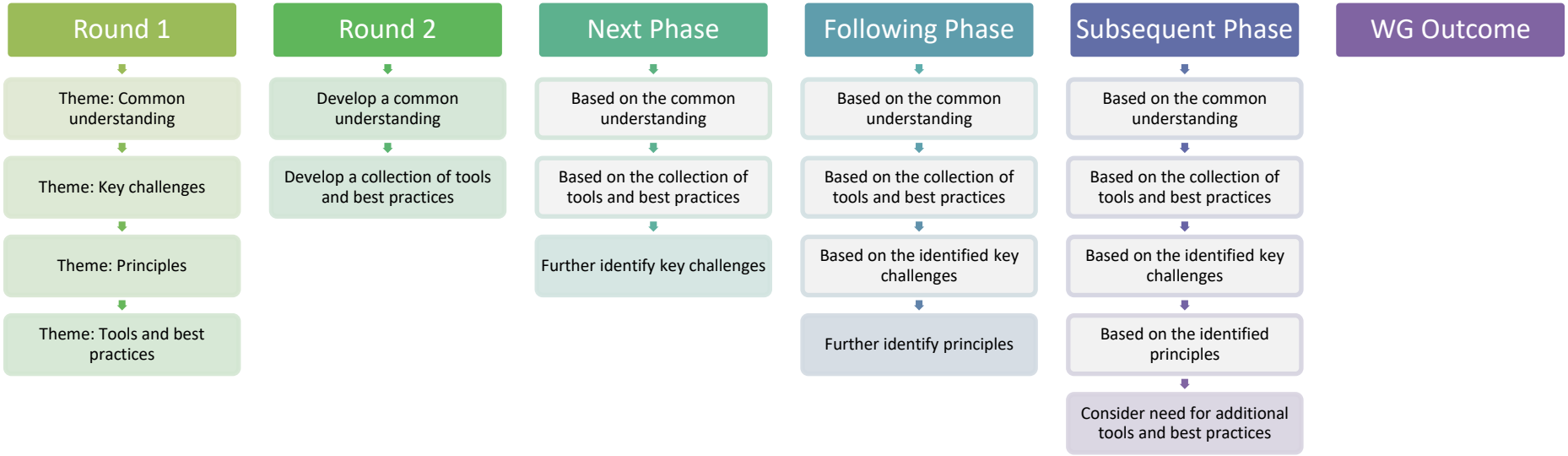
Main theme	Suggested topic	Individual participant's suggestions					
Common understanding of approval procedures	**Types of approval procedures and associated definitions**	Consider types of approval procedures and how to enhance implementation of these various types. Initial consideration: audits, import checks, certification, and pre-market product approvals.	Determine a definition of "approval procedures": "approval procedures" are procedures to check and ensure the fulfilment of SPS measures, but some Members regard them as including procedures for risk assessment.	Glossary of terms / definitions: data portability, common application dossiers, unilateral and mutual recognition, history of safe use, emergency use authorization.			
Key challenges of approval procedures that impact international trade and that the Committee should seek to address	**International Standards**	Members may refer to an OIE standard (now WOAH), but the measure does not conform/is not based on this standard.	Review of recommended conformity assessment procedures applicable to the imported goods in port.				
	Justification and discrimination of approval procedures	Disease-free status required from exporting Member even when the disease is present in importing Member.	Review of the application of unjustified SPS measures, restrictions not backed by science.	Importing side: unjustified requests.			

Main theme	Suggested topic	Individual participant's suggestions					
	Transparency	Lack of clear process (animal and animal products).	Operationality and timely flow of information in relation to stages of approval procedures: publication of the processing period.	Transparency regarding the availability of the rules, unclear procedures, vague timeframes. Importing side: unclear.	Clarification of criteria for examining completeness of documentation. Necessary documents to be announced to applicants in advance.	Transparency of approval procedures in import risk analysis, including regarding regionalization recognition processes. Minimum requirements for information necessary to complete approval procedures.	
	Communication and information exchange	Lack of communication. After repeated requests, reports have not been shared, creating uncertainty. Unclear what may be hindering the completion of the report.	Approval procedures should contain mechanisms for communication, to allow for opportunities to clarify requirements of the approval procedures.	Timely flow of information in relation to stages of approval procedures: completeness of the documentation and the communication of deficiencies; transmission of the results of the procedure; reporting the stage of the procedure, explaining any delays.	Importing side: unclear, lack of data, guarantee.	Informing applicant in a precise and complete manner of deficiencies.	
	Timing/undue delays	Undue delays: a few participants suggested guidelines with timeframes. No additional burdens should be placed on Members with limited resources.	To serve as a basis for Committee recommendation: consideration of approval procedures commonly applied or of great importance, and their standard processing periods; analysis of the predictability of, and Members' compliance with these periods.	Unjustified delays slowing down formalities. Lack of timely and objective responses in inspections to approve producing / exporting establishments. Operationality and timely flow of information.	Interpretation of "undue delay" could be considered.	Procedures to ensure that results are transmitted "as soon as possible ... in a precise and complete manner". Importance of reasons / explanations for implementation without undue delay.	Approaches to the definition of "reasonable time" required for the approval procedures.
	Other challenges	Impact of COVID-19 on approval procedures/SPS requirements.					

Main theme	Suggested topic	Individual participant's suggestions					
Principles of approval procedures that facilitate international trade while meeting the importing Member's ALOP and the Committee's role in highlighting these principles		Key principles: (i) ensuring SPS measures are science-based; (ii) transparency; (iii) non-discrimination; (iv) consistency of treatment for Members with same SPS status.	Principles for initial consideration: (i) risk-based; (ii) timely; (iii) communication; (iv) transparency.	Elements: (i) simplified procedures, without undue delay; (ii) non-discrimination; (iii) publication/ communication of standard/ anticipated processing period; (iv) information requirements limited to what is necessary; (v) equitable fees.			
Tools available and best practices to enhance the implementation of the obligations of the SPS Agreement as they apply to approval procedures		Best Practices on: (i) transparency (compliance with notification obligations with reference to international standards); (ii) functional SPS National Enquiry Points; (iii) accessible established procedures; (iv) national coordination.	Best practices on: (i) international standards; (ii) regulatory cooperation; (iii) setting of import tolerances / thresholds; (iv) consideration of other Members' approvals as part of domestic approval procedure / to respond to a non-compliance.	Measures to manage approval asynchronies between Members that export and import GMOs. Collaborative strategies to ensure implementation of procedures, overcoming administrative constraints or even situations like COVID-19.	After identifying challenges, Working Group can deal with tools and best practices available to address them.	Tools include: (i) decision by WTO Ministerial Conference; (ii) SPS Committee guidelines.	Best practices to address asynchronous approvals

ANNEX B: OVERARCHING PROCESS FOR THE WORKING GROUP

The following reflects a document shared with the participants on 9 December 2021, highlighting the various phases for the Working Group as they were envisaged by the co-stewards following initial identification of the various topics for the Working Group's consideration.



NB: Phases are not related to the "rounds" occurring between the SPS Committee meetings. There may be multiple rounds in each phase depending on the process achieved by the WG. The WG will enter a new phase once the objectives have been achieved.