RESTRICTED

G/TBT/M/82

5 January 2021

(21-0079) Page: 1/123

Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 28-29 OCTOBER 2020

CHAIR: MR LAURENCE SANDRAL

Note by the Secretariat[1]

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/TBT/18.

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Specific Trade Concerns

2.1.1 Withdrawn concerns

2.1. The Chair reported that the following STCs had been withdrawn from the agenda at the request of the concerned Member:

- European Union - Amendments of UN Regulation No.22 (ECE/TRANS/WP.29/2020/60_Protective helmets)
- Thailand - Ministerial Regulations on Standards Marks and Rules/Procedures for Licenses for Industrial Products B.E. 2563 (2020)
- United States - Guidance on Federal Conformity Assessment Activities (IMS ID 625)

[1] This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members or to their rights and obligations under the WTO.

2.1.2 New Specific Trade Concerns

2.1.2.1 China - Provisions for Cosmetics Registration (Draft for Comments), G/TBT/N/CHN/1454 (IMS ID 641[2])

2.2. The representative of Japan provided the following statement. Regarding China's draft of the "Provisions for Cosmetics Registration", we appreciate that China provided the opportunity to comment on the WTO/TBT notification. As we have noted in the comment to the WTO/TBT notification, Japan would like to express the following concerns. First, regarding information disclosure, in the context of protection of intellectual property, Japan requests that confidential corporate information specified by registrants or filers not be disclosed to the public. In case it is necessary to disclose such specified confidential information, registrants or filers should be given the opportunity to consult with the National Medical Products Administration (NMPA) in advance. In particular, Japan would like to request that confidential corporate information be protected in the following cases. Regarding disclosure of summary of evidence for efficacy claim to the public on the websites designated by NMPA, Japan requests that the scope of disclosure be clarified so as to exclude confidential corporate information. In addition, "Provisions for Cosmetics Registration" requires registrants or filers to indicate the source of the ingredients and their quality specification, to provide all manufacturing process information and to configure product standards during registration or filing process. Furthermore, this provision and "Instructions for Cosmetic Registration and Notification Dossiers", which had been out for public comment in August, provide to publish all or part of the submitted information. Since the submitted information includes confidential corporate information, Japan would like to request to China that the scope of submitted information be minimized as much as possible and that confidential corporate information not be subject to disclosure and be kept it secret. Second, the sales certifications proving that the products have been sold on the market in the country of production are imposed only on imported cosmetics. Products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin.

2.3. Third, "Instructions for Cosmetic Registration and Notification Dossiers" provides cases where original registration or filing is cancelled and subsequent re-registration or re-filing is necessary, and cases where only changes of original registration or filing are required. Japan would like to request that it is not necessary to cancel original registration or filing if changes are not related to product safety or related to a product's name. Fourth, regarding testing laboratories, China's regulations do not accept test results obtained by in-house or foreign laboratories. Japan requests a more flexible framework in which test results obtained by in-house or foreign laboratories through internationally recognized practices such as ISO can be accepted. Fifth, as "Cosmetics Supervision and Administration Regulation" and its implementing regulations will cause great change, a reasonable transition period is necessary to ensure business continuity. Japan would like to request that China provide an adequate grace period, at least one year after promulgation of all relevant regulations, in order to allow time for producers to adapt to a new cosmetic regulatory system.

2.4. The representative of the United States provided the following statement. The cosmetics industry is a bright spot in the growth of China's rising bilateral trade with the United States and indeed the world. From 2017 to 2019, Chinese imports of US cosmetics increased by an incredible 69%, showing the value that Chinese consumers place on US products. Likewise, the United States is a significant consumer of Chinese cosmetics and many US cosmetics companies have significant investments in China that serve Chinese consumers and manufacture products for export. Given projections that China's cosmetics market will more than double in the next ten years from USD 50 billion to USD 100 billion, there is significant potential to drive growth via trade for the thousands of foreign and Chinese small and medium enterprises that operate in this industry. In the "Provisions for Cosmetics Registration" (G/TBT/N/CHN/1454) China references vague requirements for companies' quality management systems. In the subsequent "Instructions for Cosmetics Registration and Notification Dossiers", which would implement the "Provisions for Cosmetics Registration", China continues its requirement for animal testing of imported products, if the importer cannot provide a Good Manufacturing Practices (GMP) certification from its national regulator. This requirement brings into question China's commitment to growing bilateral cosmetics trade, as it creates an unnecessary obstacle to international trade.

[2] For previous statements follow the thread under IMS ID 641 (under dates raised and references).

2.5. In the past year, the United States, other WTO Members and industry have all met with Chinese trade and NMPA officials to explain that regulator-issued GMP certificates are not available in some countries, but that third-party certification per the ISO cosmetics GMP standard (22716:2007) is available, if self-certification is insufficient. The continued insistence by China for a regulator-issued certification, when one is not available in some countries and while viable alternatives exist, brings into question China's commitment to its obligations under the TBT Agreement. In addition, while the United States appreciates China's commitment to reduce the time required to receive approvals to market cosmetics products and new ingredients, we are concerned that NMPA's new filing and registration requirements may require more information than necessary to fulfil its objective of managing product safety in China's cosmetics marketplace.

2.6. US companies, in comments submitted to China, have raised concerns that the proposed documentation requirements are so extensive and prescriptive as to discourage innovation, while putting companies' intellectual property and CBI at risk. For example, G/TBT/N/CHN/1454 requires cosmetics companies to submit an enterprise standard, which specifies the step-by-step process and methods by which products are manufactured. The measure also requires, for market access, disclosures to third-party testing and registration agents of CBI and potential trade secrets in filings and registrations for cosmetics and cosmetics ingredients. US cosmetics companies are concerned that these requirements will put their intellectual property at risk of unauthorized disclosure and will fail to protect their legitimate commercial interests. We also question the provision requiring companies to disclose on a public website CBI, including potential trade secrets, about their ingredients, products and the analytical methods used to validate claims. This will not assist consumers in understanding product claims, but will be of interest to potential competitors. Given these concerns, we urge China to evaluate the necessity of requiring such extensive documentation, particularly given its enhanced requirements for company testing of product and ingredient safety and NMPA increased investments in post-market monitoring. As will be expressed in our subsequent intervention on Cosmetics Supervision and Administration Regulation (CSAR), we expect these measures to have a significant effect on trade and therefore ask that China notify all draft implementing measures to the WTO ahead of CSAR's January 2021 implementation.

2.7. The representative of the Republic of Korea provided the following statement. Korea supports China's effort to adopt and reflect global trends in the regulation of the ingredients, mixing, labelling and advertisement of cosmetic products. Starting from the preparation of the "Cosmetic Supervision and Administration Regulation" scheduled to take effect in January 2021, China has made various efforts including the revision and legislation of relevant subordinate regulations. We hope that such efforts come to fruition through the cosmetics regulation currently under the process of legislation and revision. However, Korea would like to share a few trade concerns regarding the draft "Provisions for Cosmetics Registration" notified to the WTO in August 2020. According to Article 36 of the Provision, applicants applying for the approval or registration of cosmetics are required to clarify the source and quality specifications of all ingredients in the application. However, the scope of required documents on ingredients remains unclear. If the scope of the required documents includes the specifications of all ingredients, Korea believes that the Regulation is more trade restrictive than necessary to fulfil a legitimate objective. Applicants have already been submitting data on new or harmful ingredients as part of the safety evaluation report included in the application for approval. Furthermore, the source and quality data of all ingredients are considered as trade secrets. Therefore, Korea would like to request China to consider revising the provision.

2.8. According to Article 43 on the efficacy data of cosmetics, a summary of cosmetic efficacy claims must be disclosed to the public at the dedicated website designated by the NMPA. However, even the minimal requirements to be included in the summary contain a number of trade secrets that are critical to businesses. Thus, Korea calls on China to remove the disclosure provision. Under Article 48 and 59, China requires applicants to withdraw the pre-existing product registration or approval and newly apply for a registration or an approval when there are changes to the product name, applicant information, and the address of the domestic responsible agent. Since these are minor changes that do not have significant implications for the safety and efficacy of the product, Korea kindly asks China to require post-approval or post-registration changes instead of re-registrations or re-authorizations. Such practices would create an unnecessary trade barrier by costing time and imposing administrative burden on the cosmetics industry. Fourth, Korea invites China to share information on the date of entry into force and status of the provision and grant reasonable transition period of at least one year for the industry to prepare to comply with the new requirements according to the TBT Agreement's Article 2.12. Korea would like to recall Article 2.2 of the TBT Agreement,

according to which Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

2.9. The representative of Australia provided the following statement. Australia notes that the primary focus of China's draft Provisions for Cosmetics Registration appears to be cosmetics produced domestically in China. We would be grateful if China could clarify whether these proposed measures will apply to imported cosmetics. These provisions contain a number of references to requirements in other regulations, standards and technical specifications, for example: Article 42 notes that people should follow the requirements of standards, technical specifications and registration inspection regulations; and Article 68 requests compliance with mandatory national standards and technical specifications. Australia requests that China provide further clarity and details on the requirement for filing imported cosmetic products. In particular, we request a copy of the standards, technical specifications, registration inspection regulations and mandatory national standards that are mentioned in this draft. In line with our mutual WTO obligations, Australia requests that China notify the WTO and supply WTO Members with a copy of the mandatory national standards and other national laws, regulations, rules and technical specifications mentioned in this draft. This will provide greater clarity and certainty for businesses and assist all WTO Members to better assess the potential impact of these measures on trade.

2.10. The representative of the European Union provided the following statement. The EU would like to support the delegations of Japan, Korea, the United States, and Australia. The notified draft contains rules for the implementation of the new CSAR. The EU finds this implementing legislation clear and consistent with the CSAR principles. The EU is of the opinion that the clear steps outlined in the implementing rules can lead to a faster and more efficient registration and filing mechanism. In particular, the obligation for reviewers to identify mistakes and applicants to answer questions at once will avoid the current practice of repeated, time-consuming question-answer loops during applications. However, the EU would like to underline that certain requirements go beyond the CSAR principles in a way that they would create problems for the operation of cosmetic companies, including both domestic manufacturers and importers. Since the NMPA new filing and registration requirements are more extensive than what was required previously, the EU is concerned more information may be required than necessary (including disclosure of CBI) to access China's cosmetics marketplace. In addition, some requirements are not entirely clear from the notified text and the EU would appreciate further clarification in particular on the concerns raised by the EU in its comments sent to the WTO on 19 October.

2.11. The representative of New Zealand provided the following statement. New Zealand welcomes China's endeavours to modernize its regulatory system for cosmetics and also welcomes the opportunity to comment on China's proposed cosmetics measures notified under G/TBT/N/CHN/1454. While we welcome the direction to improve safety and quality assurance, New Zealand would like to encourage China to ensure that facilitation of trade is considered in the design of the regulations. New Zealand holds concerns, that we understand are shared by a number of countries, around issues such as having more detailed disclosure of formulas than is required in other markets, including specific sources of each ingredient, and not accepting certification that is accepted in other markets. New Zealand requests that China also provide further clarity on the proposed testing measures and encourages China to clarify in the regulation that test reports can be accepted from accredited laboratories situated outside of China. We would also appreciate further clarification on what standards registered products should comply with. We respectfully remind China of its obligation to accept international standards where appropriate, including aligning its national standards with relevant international standards. New Zealand looks forward to engaging further with China on this matter to better understand the requirements of the proposed measures. This will enable New Zealand and other WTO Members to assess in greater detail the potential impact on trade of these measures.

2.12. In response, the representative of China provided the following statement. According to scientific researches, there are certain differences in skin texture between different people. In practice, Chinese competent authorities have also found significant differences between sunscreen index reports of sunscreen products issued by Chinese laboratories based on Chinese subjects and the ones issued by other Members' laboratories. In order to protect legitimate rights and interests of consumers and ensure the accuracy of inspection results, China has proposed the requirement that the efficacy inspection of special cosmetics should be completed at the cosmetics registration and filing inspection agencies. However, China has not prohibited foreign inspection agencies from being cosmetics registration and filing inspection agencies. At present, many laboratories from

foreign inspection agencies located in China have achieved China Metrology Accreditation (CMA) certification in the field of cosmetics and have undertaken cosmetics registration and filing inspections. Therefore, we hold the opinion that China has not placed discriminatory treatment in cosmetics inspection.

2.1.2.2 China - Administrative Measures on Cosmetic Labelling (IMS ID 642[3])

2.13. The representative of Japan provided the following statement. Regarding China's draft of the "Administrative Measures on Cosmetic Labelling" published on 21 September 2020, Japan appreciates China's consideration of our concerns on "Cosmetics Supervision and Administration Regulation". However, Japan would like to express the following concerns: Article 5 provides that the content of the added Chinese labels, such as information regarding product safety and efficacy, shall be consistent with the original labels. However, the original labels are designed to comply with regulations in the country of production and it is natural that their contents do not always comply with China's regulations. Therefore, Japan would like to request China that such requirement does not apply to labelling contents required by regulations in the country of production, and that the requirement will not be more trade restrictive than necessary to fulfil legitimate objectives.

2.14. Regarding Article 6, in order to avoid confusion for consumers, Japan would like to ask China that the label indicate a single responsible person ("cosmetics registrants or filers" or in the case of imported products, "responsible person in China"), and we consider that the label requirements regarding producers is not necessary. With respect to the rules for labelling of all ingredients in cosmetics, there is an internationally recognized listing practice that ingredients with a compounding amount of 1% or less are allowed to list in no particular order. However, Article 12 provides that only ingredients with a compounding amount of 0.1% or less are allowed to list in no particular order. Japan would like to request to China that the rules for labelling should follow the internationally recognized practice so as not to be more trade restrictive than necessary.

2.15. Article 19 provides that the indications as "evaluated and verified efficacy" could be put on products only if the efficacy is confirmed by the qualified testing laboratory in China. Japan would like to request to China that the requirement be removed, since all efficacy indications have been verified based on scientific evidence regardless of whether they are confirmed by a testing laboratory in China or not. As "Cosmetics Supervision and Administration Regulation" and its implementing regulations will cause great change, reasonable transition time is necessary to ensure business continuity. Japan would like to request that China provide an adequate grace period, at least one year after promulgation of all relevant regulations in order to allow time for producers to adapt to a new cosmetic regulatory system. In addition, Japan would like to request that products on the market could be sold until the expiration date for use even after the grace period.

2.16. The representative of the Republic of Korea provided the following statement. Cosmetics labels play a crucial role in providing consumers with not only instructions and precautions for use but also the list of ingredients, net content and manufacturer or distributor information, among others. Recognizing the importance of managing cosmetic labels, China revised the Administrative Measures on Cosmetic Labelling in September 2020 to set the labelling requirements, and Korea expresses full support for the efforts. However, Korea echoes the comments by Japan and would like to share concerns over a few provisions in the draft revision that may create trade barriers. With respect to imported cosmetics bearing Chinese over-labels, the Regulation requires the information regarding product safety and efficacy claim on the over-labels to be consistent with that on the original label. Each country has its own rules and regulations. The contents of the label required by the regulation of the country of origin could be prohibited under the revised measure for labelling regulation. To address this issue, Korea would like to ask China if it could allow indicating an explanation for the inconsistency on the over-label.

2.17. Regarding Article 12, Korea invites China to maintain its current regulation on the declaration of the ingredient list and colorants in cosmetics on the labels. The requirement under Article 12 seems to be inconsistent with the international practice. The rationale for such revision also remains unclear to Korea. For example, some ingredients may produce a significant effect even at a 0.1% or lower concentration. However, indicating the content of such ingredients as "other ingredients in small amounts" may mislead a consumer to believe that the ingredients have no efficacy. Also, we request that China exempt the declaration of the substances added to a cosmetic during manufacture

[3] For previous statements follow the thread under IMS ID 642 (under dates raised and references).

but present in the finished cosmetic at an insignificant level and not having any technical or functional effect in that cosmetic. Article 14 stipulates that when cosmetics are marketed as multi-unit or multi-component packages, the earliest expiration date of all units or components should be declared on the label of the outer packaging. However, in some cases, expiration dates must be declared on the individual multi-unit or multi-component packages. Thereby, Korea requests China to allow the declaration of expiration date on the packaging of each unit or component. The regulation requires that efficacy claim evaluation reports contain information including the purpose of verification, verification method, results, and conclusion. We call for China to consider that such information include a number of trade secrets and exclude them from the scope of information for disclosure. According to Article 21, China prohibits the use of labelling or efficacy claims using terminology and mechanism that are not widely accepted in the scientific field. We kindly ask China to provide the definition, objective and rationale for the measure. We request that China provide sufficient transition period for stakeholders to comply with the requirements in these regulations. According to our understanding, the regulations are currently under an internal commenting process. Korea urges China to notify them to the WTO at the earliest opportunity to allow the Members to submit comments.

2.18. The representative of Australia provided the following statement. Australia understands that China has recently drafted new Administrative measures on Cosmetics Labelling. In line with our mutual WTO obligations, Australia requests that China notify the WTO and supply WTO Members with a copy of these new administrative measures. Australia also requests that China provide WTO Members with an opportunity to comment on the measures before they are finalized.

2.19. The representative of the United States provided the following statement. The United States would like to support the delegations of Japan, Korea, the European Union, and Australia. The United States similarly requests that China promptly notify the draft Administrative Measures on Cosmetics Labelling to the WTO, allow reasonable time for stakeholders to comment, take such comments into account before the measures are finalized, and provide for a reasonable transition period after adoption.

2.20. The representative of the European Union provided the following statement. The European Union would like to support the delegations of Japan, Korea, the United States, and Australia. The EU welcomes the on-going efforts by the Chinese authorities to draft implementing legislations that will transform the principles of the new CSAR into practical, actionable requirements. The EU understands that China has recently drafted new "Administrative Measures on Cosmetic Labelling". In line with our mutual WTO obligations, the EU requests China to notify the WTO and to provide WTO Members with an opportunity to comment on the notified measures before they are finalized. The EU would like to make already today some general remarks on these draft measures that were subject to a public consultation in China until 20 October 2020.

2.21. The EU welcomes the continued possibility to apply international practice to over-sticker label with a sticker. The proposed draft measures require "consistency" between the safety and efficacy information printed on the original packaging and the sticker added as the Chinese label. The interpretation of "consistency" is, however, not entirely clear and could lead to difficulties in the practical application processes for new products. In particular for product claims, the EU considers important that the actual wording takes into account the cultural and linguistic background of the consumer. Certain product claims may be considered as important in the country of origin, but may not resonate with Chinese consumers. Therefore, "consistency" between the original label and the Chinese sticker should not necessarily equate a "verbatim translation". Obviously, such practice must not be used to circumvent labelling restrictions set under the Chinese legislation.

2.22. It is also important to remind that differences between the original label and the Chinese sticker are sometimes caused by different mandatory labelling requirements between the country of origin and China (e.g. different rules for expressing the results of UV protection tests as "SPF numbers" on the packaging). As regards the proposed requirement on printing of the hygiene permit number on the inner packaging, the EU is of the opinion that this should not be necessary for product identification or traceability. For in-market control purposes and consumer information, it is sufficient that the information is available on the visible outer surface of the product. To our knowledge, no major trade region in the world requires this type of labelling of the inner packaging and such requirement would bring China in a non-compatible situation with the rest of the world. The EU would therefore ask the Chinese authorities to consider removing the requirement to show the registration number and Chinese product name on the inner packaging.

2.23. Finally, yet importantly, the implementation of the new labelling rules will require significant adaptation by companies. In order to ensure a smooth transition and avoid the disruption of supply of safe and efficacious products on the Chinese market, a sufficiently long transition period of 24 months should be considered. A differentiated approach should also be considered for products already on the market or currently undergoing registration or filing, and products newly introduced to the market. Experience from the EU shows that it is beneficial to have a certain period of time during which the old and the new requirements run in parallel and companies can "phase in" their products according to their priorities and resource constraints. The EU would also like to know when the drafting process of this measure will be finalized and when the text of the "Administrative Measures on Cosmetic Labelling" will be notified to the WTO.

2.24. The representative of New Zealand provided the following statement. New Zealand would like to join other Members in raising concerns regarding the notification of this measure. New Zealand respectfully asks that China notify this measure to the WTO TBT Committee, in accordance with WTO transparency obligations. Like others, New Zealand requests that a copy of the draft measures be made available to WTO Members and that a reasonable period of time be provided for Members to submit comments, before the measures are finalized.

2.25. In response, the representative of China provided the following statement. At present, the competent authorities are preparing for notification of the "Administrative Measures on Cosmetic Labelling" according to procedures. Members are welcomed to comment on that notification.

2.1.2.3 Kingdom of Saudi Arabia, Kingdom of Bahrain, State of Kuwait, Oman, Qatar, Yemen, United Arab Emirates - Halal Feedstuff, G/TBT/N/ARE/474, G/TBT/N/BHR/574, G/TBT/N/KWT/532, G/TBT/N/OMN/407, G/TBT/N/QAT/570, G/TBT/N/SAU/1134, G/TBT/N/YEM/176 (IMS ID 643[4])

2.26. The representative of the United States provided the following statement. The United States requests clarification from Gulf Cooperation Council (GCC) members and Yemen on the recent notification of a Halal feed measure. The United States is unaware of any other country establishing technical regulations for Halal animal feed; thus, this regulation would set a precedent if implemented. The proposed regulation requires that Halal feedstuff must either come from vegetative sources or animals slaughtered in accordance with Islamic Sharia law. The United States also notes that, based on analysis of trade data, most countries that supply animal feed to GCC Members are not Muslim countries with the national framework in place to meet these criteria. On 10 July 2020, the United States submitted comments on this measure to notifying WTO Members. We look forward to receiving substantive replies to our comments.

2.27. The United States would like to emphasize the trade-restrictive nature of this notified draft measure on the impact of trade in feedstuffs. The United States requests that the GCC provide additional details on this measure. For instance, would meat and poultry producers be required to feed Halal feedstuff to their livestock? The national standards cited in the proposed regulation are BRUNEI DARUSSALAM STANDARD HALAL FOOD PBD24: 2007 and MALAYSIAN HALAL STANDARD (MS1500:2004.) Can GCC members explain how these standards are relevant to the proposal or how the proposal intends to use these standards to cover feedstuff? We ask that GCC member states provide greater clarity on the intended scope of this measure, as well as the type of oversight envisioned. How would the GCC member states and Yemen conduct oversight and apply control systems imported animal feed to ensure adherence to this draft technical regulation? Can GCC members explain the implementation schedule for this measure? Given the potentially trade-restrictive nature of this measure, the United States encourages officials from the GCC member states and Yemen to set up dedicated technical exchanges with all interested private sector stakeholders and trading partners prior to considering requirements and application of a measure on Halal feedstuffs.

2.28. The representative of the European Union provided the following statement. The European Union would like to thank the GCC countries and Yemen for providing an opportunity to WTO Members to comment on the draft GCC Technical Regulation on Halal Feedstuff and refer to its written comments of 12 June 2020. The European Union would also like to thank to the Kingdom of Saudi Arabia for the recent reply to the EU written comments. The reply seems to confirm that the use of Halal feedstuff would be a condition for imports of animal products certified and labelled as

[4] For previous statements follow the thread under IMS ID 643 (under dates raised and references).

Halal. In this regard, the European Union would like to ask the GCC countries and Yemen to abstain from requiring the use of Halal feedstuff for animals reared in non-GCC countries and Yemen as a condition for the imports into the GCC countries and Yemen of Halal-certified animal products for human consumption. Such condition would require an alteration to the feeding regime for food-producing animals in the EU and would negatively affect EU exports. The European Union appreciates that the Kingdom of Saudi Arabia in its recent written reply provided explanations on the planned oversight and control systems to ensure compliance with the standard and on applicable certification requirements. Following the analysis of the reply, the European Union might ask for further clarifications in this respect.

2.29. In response, the representative of the United Arab Emirates provided the following statement, on behalf of the Kingdom of Saudi Arabia, the Kingdom of Bahrain, the State of Kuwait, Oman, Qatar and Yemen. The Kingdom of Saudi Arabia would like to thank the United States and the European Union for their valuable comments and is pleased to clarify the matter related to these comments. Our response to comments from the United States and the EU has been sent to their respective TBT Enquiry Points. To date, the draft is under review at the level of the GCC Standardization Organization (GSO) technical committee. Your comments will be taken into consideration. Furthermore, Saudi Arabia would like to invite interested Members to discuss this matter bilaterally.

2.1.2.4 China - Commercial Cryptography Administrative Regulations (IMS ID 644[5])

2.30. The representative of the United States provided the following statement. The United States has concerns regarding China's draft Commercial Cryptography Administrative Regulations, issued by the State Cryptography Administration on 20 August 2020 and we submitted comments to China in September 2020. The United States is concerned that this draft measure would impose potentially far-reaching, highly trade-restrictive cryptography-related constraints on foreign information and communication technology (ICT) products. Does China intend to notify this measure to the TBT Committee and allow for additional stakeholder comments? The provisions in the draft measure may raise serious concerns under the WTO agreements, and appear to conflict with globally-accepted practices to assess encryption in commercial ICT applications. We understand that China has received numerous comments on this draft. We hope that China will carefully consider the input from all stakeholders, including the US Government and our industry stakeholders, and make substantial changes and clarifications to the draft measure prior to implementation.

2.31. The draft measure would establish a licensing scheme for all imports and exports of commercial cryptography in instances where "social and public interests" are concerned. Can China explain how it plans to implement this scheme in line with its national treatment commitments? What steps is China taking to ensure the scheme will be not operated as an unnecessary obstacle to trade? Given China's TBT obligations in Article 5, what steps is China taking to ensure its cryptography accreditation, testing and certification system will operate in accordance with Article 5 of the TBT Agreement? Specifically, how will China ensure that the conditions for foreign products are no less favourable than those accorded to domestic products? Although the draft measure ostensibly encourages participation in "the development of international standards for commercial cryptography," Articles 10 to 12 appear to mandate compliance with Chinese standards, which may diverge from international standards. In addition, the draft measure includes a standards-setting process for commercial cryptography that appears to provide a different level of openness to domestic participants as compared to foreign participants. In the United States' view, China should adopt and use relevant international standards and harmonize its practices with relevant international best practices. We would appreciate any update you can provide today on the status of the draft measure, and how China intends to consider the public comments it received.

2.32. The representative of Canada provided the following statement. Canada provided comments on 17 September 2020 to China's State Cryptography Administration, on the draft revised Regulations on the Administration of Commercial Cryptography promulgated on 20 August 2020. We look forward to receiving a response. As indicated in these comments, Canada would appreciate China's consideration of modifying the regulations to provide further clarity, transparency and predictability by: (i) defining what products involving "national economy", "people's livelihood" and "the public interest" are; (ii) clarifying that international standards will be the basis for China's commercial cryptographic technical regulations; (iii) supporting the creation of equitable standards by indicating that all stakeholders can participate in the creation of commercial cryptographic

[5] For previous statements follow the thread under IMS ID 644 (under dates raised and references).

standards; and (iv) indicating whether, along with commercial cryptography, core and ordinary cryptography, as defined in China's Cryptography Law, will also be subject to new regulations. Canada expressed support for the substantive comments made by the US and the EU previously and would further encourage China to notify the measure to the WTO TBT Committee, providing WTO Members and stakeholders the appropriate time to review and comment on the measure.

2.33. The representative of the European Union provided the following statement. The EU is also concerned about this partial implementation measure of the Cryptography Law and sent comments to the State Cryptography Administration of the People's Republic of China (SCA) in September. Specifically, our concerns relate to (i) the scope of the law; (ii) the lack of clarity of concepts and precision of procedures; (iii) the protection of intellectual property; (iv) the imposition of pre-market and export controls; (v) the requirements around testing and certification; (vi) the imposition of additional "national security reviews"; and (vii) the use of domestic standards, along with the lack of meaningful access to pertinent Chinese standards development organizations. The EU urges the SCA to address these concerns in the further development of the draft regulations in order to ensure that legal and regulatory requirements are based on a non-discriminatory basis, do not favour specific technologies, do not limit market access and do not lead to forced transfer of intellectual property. Additionally, the EU encourages the SCA to open up, in practice, the "Cryptography Industry Standardization Technical Committee" (CISTC) to foreign-invested industry based in China. The EU would appreciate its comments being taken into consideration and invites the SCA to notify the draft regulations to the TBT Committee.

2.34. In response, the representative of China provided the following statement. In order to implement the requirements of promoting administration in accordance with the law, and to deepen the reform of "streamline administration and delegate powers" in the field of commercial cryptography, China is revising the Regulations on the Administration of Commercial Cryptography in accordance with the legislative spirit of the Law on Cryptography. The revision of the Regulations follows the principles of law-based, open, transparent and on a scientific basis. Besides, China will solicit opinions widely and ensure the stakeholders' participation in legislative activities through legal means.

2.1.2.5 Mexico - Decree amending, supplementing and repealing various provisions of the Regulations on Sanitary Control of Products and Services and the Implementing Regulations to the General Law on Health with Respect to Advertising, G/TBT/N/MEX/468, G/TBT/N/MEX/468/Add.1, G/TBT/N/MEX/468/Add.1/Corr.1 (IMS ID 645[6])

2.35. The representative of the United States provided the following statement. The United States appreciates Mexico's notification of its amendments to the Regulations on Sanitary Control Products and Services and Implementing Regulations to the General Law on Health with Respect to Advertising, as notified in G/TBT/N/MEX/468. The US Government and several US industry stakeholders provided comments to this notification by the comment deadline. We look forward to hearing responses to some of our questions from Mexico. While we support Mexico's efforts to reduce obesity and diet-related non-communicable diseases (NCDs), we are concerned that Mexico's proposed measure on nutrient fortification and advertising may be more trade restrictive than necessary to meet Mexico's legitimate objective, may not be based on robust scientific evidence, does not appear to consider the relevant international standards, and may limit the availability of fortified food options to meet consumers' dietary needs. Article 161 of the Decree appears to prohibit the voluntary nutrient fortification of "pre-packaged foods and non-alcoholic beverages with the nutrient profiles established for the front-of-pack warning labelling" as defined under NOM-051 (notified as G/TBT/N/MEX/178/Add.13). On 10 September, CONAMER (*Comisión Nacional de Mejora Regulatoria*) published a revised version of this draft regulation that did not include Article 161 fortification restrictions contained in the 3 June draft regulation. Can Mexico confirm that Article 161 fortification restrictions will not be included in the final decree?

2.36. In addition, the proposed measure appears to have the effect of limiting certain types of positive claim labels on products required to carry a warning label under NOM-051. We urge Mexico to consider the potential impact of its proposal to ban these sorts of claims on products that carry a warning label and to clarify whether it intends to limit nutrient content claims or other positive health claims on packages carrying warning labels. The proposed measure also appears to require that

[6] For previous statements follow the thread under IMS ID 645 (under dates raised and references).

advertising of pre-packaged food and non-alcoholic beverages that carry warning labels under NOM-051 shall not include "characters, animations, cartoons, celebrities, athletes or pets, interactive elements, such as visual-special games or digital downloads," that promote their consumption. Trademarks play an important role in commerce by allowing companies to distinguish their products in the market and preventing consumer confusion. The United States notes that industry and a market research firm estimate the requirement of NOM-051 will apply to over 80% of food products on grocery store shelves in Mexico. It is our understanding that a wide variety of foods that the public may consume to reach their recommended daily intake of beneficial nutrients, such as yogurts, cereals, orange juice, bread, and canned beans, may be prohibited from voluntary fortification under this proposed measure. Given the significant implications of this regulation for producers of packaged foods and beverages, and the complexity of each one of these additional restrictions on claims, advertising, and possibly fortification we request that Mexico allow an extended implementation period for proposed changes to its fortification and advertising regulations to allow sufficient time for consultations with stakeholders and to fully consider comments from stakeholders, including trading partners.

2.37. The representative of the European Union provided the following statement. The European Union would like to thank Mexico for the possibility to send written comments on the notification G/TBT/N/MEX/468 and for the useful bilateral exchange. Firstly, the EU appreciates that the draft Article 161 was removed in the revised version of the draft amendment to Regulations on Sanitary Control of Products and Services, submitted to public consultation on 10 September 2020. The removed draft Article 161 prohibited the addition of nutrients to unprocessed or fresh foods, as well as to pre-packed foods and non-alcoholic beverages that meet the nutritional profiles established for the front-of-pack warning labels. The EU would like to ask Mexico to confirm that this provision will not be included in the final amendment. Secondly, with regard to draft Articles 11 bis and 25 Bis 3, the EU would like to ask Mexico to clarify the necessity of including precautionary indication on the label for additives and ingredients that are subject to the pre-market risk assessment and authorization, which should address the risks for consumers' health. In addition, the EU would like to ask Mexico to clarify the process and parameters for the determination of additives, ingredients or substances that would require a precautionary indication.

2.38. The representative of Colombia provided the following statement. Colombia supports and shares Mexico's objective of informing consumers clearly and truthfully of the content of critical nutrients that present health risks if consumed to excess. However, we would like to express our support for the trade concern raised by the United States regarding the "Decree amending, supplementing and repealing various provisions of the Regulations on Sanitary Control of Products and Services and the Implementing Regulations to the General Law on Health with Respect to Advertising". Colombia submitted comments prepared by our industry on the draft measure through the information service. It regrets that no account of the comments made has been taken in the final measure, and we therefore reiterate the following concerns of our industry: The health regulation includes definitions on front-of-pack warning labels, critical nutrients and portion size. The Ministry of Health, in coordination with public and private research and higher education institutions, will establish food and non-alcoholic beverage portion sizes as benchmarks. Pre-packaged food and non-alcoholic beverages should only include front-of-pack warning labels provided for in the corresponding regulation, with no other labelling used. Nutrients may not be added to pre-packaged foods and non-alcoholic beverages that meet the nutritional profiles established for front-of-pack warning labelling except for those where there is a requirement to do so.

2.39. Advertising of products with warning labels: Must include the stamps and wording of NOM-51. May not include children's animated or cartoon characters, such as special visual games or digital downloads, aimed at enticing, promoting or encouraging children to consume, purchase or choose the products concerned. In this regard, Colombia considers that the above restrictions should not be established for the following reasons: The intention is to establish legislative actions, going beyond their purely regulatory purpose. They do not stem from a higher regulation. They grant powers to the health authority that should go to other authorities. They violate the Mexican free competition regime. They infringe the protection of intellectual property rights. The regulations are not a legal instrument from which rights must emanate or restrictions be created. The scope of the regulations is unclear, causing considerable uncertainty for the inspection, surveillance and control process. The authorizations granted by the State concerning components, raw materials, ingredients and additives are unknown. They constitute restrictions on the right of consumers to be well informed. Significantly restricting the fortification of packaged foods could have unintended

consequences for the micronutrient intake of the population. The voluntary fortification of food is internationally recognized by the World Health Organization as an effective contributor to public health.

2.40. They are more trade restrictive than necessary to fulfil the objective of improving public health, in violation of Article 2.2 of the TBT Agreement, which states that: "(…) Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective". In light of the above, Colombia respectfully requests Mexico to undertake a review of the regulation issued and to take into account the comments submitted in the framework of international public consultations and to grant a reasonable period of time in line with industry norms, to enable enterprises to make the adjustments in the production process that are required under the regulation, with a minimum of two years.

2.41. The representative of Chile provided the following statement. Chile thanks Mexico for the information provided in notification G/TBT/N/MEX/468, G/TBT/N/MEX/468/Add.1 and G/TBT/N/MEX/468/Add.1/Corr.1. Also, concerning the publication in the Official Journal of the "Agreement establishing criteria for the implementation, verification, monitoring and conformity assessment of the Amendment to Mexican Official Standard NOM-051-SCFI/SSA1-2010", this establishes that the use of adhesives or stickers should not be prevented, as long as they meet all the commercial and health information requirements stipulated in the Amendment. This applies until 31 March 2021. In other words, during phase one, from 1 October 2020 to 31 March 2021, adhesives or stickers may be temporarily used on product labels. In this regard, I wish to reiterate that the use of adhesives is a matter of ongoing interest, based on Chile's national and international experience, as regards the permanent application of this mechanism, with the single objective of complying, on the one hand, with the legitimate aims of public policy and, on the other, of preventing an unnecessary barrier to trade. Chile reiterates its interest in Mexico considering the permanent use of adhesive stickers and transfers.

2.42. In response, the representative of Mexico provided the following statement. The delegation of Mexico thanks the United States and the European Union for sharing their comments regarding the notification through which the Decree amending, supplementing and repealing various provisions of the Regulations on Sanitary Control of Products and Services and the Implementing Regulations to the General Law on Health with Respect to Advertising was amended, which was notified for public consultation on 6 July 2020 in document G/TBT/N/MEX/468. With respect to the statements shared, I would like to make the following remarks. As regards the concerns relating to Article 161, the delegation of Mexico confirms that the amendment to this Article was removed. The amendment provided for the restriction on the addition of nutrients in those pre-packed food and non-alcoholic beverages that complied with the nutritional profiles established for front-of-pack advisory labelling set out in NOM-051, which only applies to pre-packed food and non-alcoholic beverages with added sugars, fats or sodium. However, it is worth underlining that the restriction on adding nutrients to unprocessed or fresh food has been applicable in Article 161 since such regulations came into force; consequently, regardless of whether Article 161 is not amended as initially notified, the ban on adding nutrients to unprocessed or fresh food still stands.

2.43. Also, with regard to Articles 11*bis* and 25*bis* 3, the inclusion of precautionary and warning messages is stipulated under Article 25 of the regulations in question as part of the mandatory health information that should be included in the labelling of the products subject to those regulations. In this regard, the proposed amendment to Articles 11 and 25*bis* 3 only seeks harmonization with this Article in order to achieve regulatory consistency. Notwithstanding the above, as set out in Article 11 and 25*bis* 3, the corresponding technical regulations are those which would define the wording that must be included, depending on the type of product and on the basis of the ingredients or additives identified that may put at risk the health of consumers, for example: NOM-201-SSA1-2015. Products and services. Water and ice for human consumption, packaged and in bulk. Sanitary specifications; NOM-218-SSA1-2011. Products and services. Non-alcoholic flavoured beverages, whether or not frozen, concentrated products for the preparation thereof, and beverages containing added caffeine. Sanitary specifications and provisions. Test methods; NOM-142-SSA1/SCFI-2014. Alcoholic beverages. Health specifications. Health and commercial labelling; NOM-141-SSA1/SCFI-2012. Labelling of pre-packaged cosmetic products. Health and commercial labelling; NOM-189-SSA1/SCFI-2002. Products and services. Labelling and packaging for hygiene products for household use. Lastly, and regarding the questions on advertising, it is important to clarify that such

provisions are set out in section 4.1.5 of the amendment to NOM-051 published in its final form on 27 March of this year. Although this technical regulation came into force on 1 October 2020, as regards the system of front-of-pack labelling, the other sections, including 4.1.5 (advertising), will enter into force on 1 April 2021, which will provide approximately one year for its compliance.

2.1.2.6 India - Phase II of the Mandatory Testing and Certification of Telecommunications Equipment (MTCTE), implementing the Indian Telegraph Amendment, G/TBT/N/IND/158, G/TBT/N/IND/159, G/TBT/N/IND/160 (IMS ID 646[7])

2.44. The representative of the United States provided the following statement. The United States understands that a 23 June 2020 notification published by India's Ministry of Communications, Department of Telecommunications (DoT) introduced Phase II of the MTCTE regime, effective 1 October 2020. Phase II expands testing and certification to three additional product categories: transmission terminal equipment; passive optical network family of broadband equipment; and feedback devices. Considering the scope of test requirements under the MTCTE; the complexity of the newly included Phase II categories; and factors, including the COVID-19 pandemic, which may impact product testing and certification timelines, the United States respectfully requests that India provide a minimum of one year for in-country testing and certification from the date of any MTCTE phase notification, including Phase II, such that the effective date for Phase II is no earlier than 23 June 2021.

2.45. US industry notes that several products within the scope of Phase II have already been manufactured and placed on the Indian market. The United States requests that India allow the fixture of logo stickers on product packaging of these products to meet MTCTE labelling requirements. US industry also notes that only two laboratories in India have the capability to test the technical requirements outlined in the Indian Telegraph (Amendment) Rules, 2017. To avoid unnecessary delays, the United States urges India to continue issuing provisional certificates; providing a validity period of two years for these certificates; and accepting requests for exemption for the technical requirements until enough laboratories are established. The United States understands that, according to a 24 June 2020 addendum from the DoT, India will not accept test results from laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories beginning 1 October 2020. If this is accurate, please explain the basis of and justification for no longer accepting such test results. The United States requests that DoT allow for the submission of ILAC test results for an initial one-year period from the date of publication of any future phase of MTCTE.

2.46. The representative of Canada provided the following statement. Telecommunications exports to India are an important Canadian interest. Canada appreciates the clarification provided by India, on its MTCTE program, in response to statements made at the May meeting of the Committee. We wish to emphasize the importance of providing adequate notice to suppliers of changes to testing requirements, as they must produce the product for testing, ship it to India and then wait for the product to be tested. Canada notes that, on 23 June 2020, India's Telecommunications Engineering Centre issued a notification[8] that additional products would need to meet its new testing requirements, as of 1 October 2020. We also note that India's WTO notifications (G/TBT/N/IND/158, G/TBT/N/IND/159 and G/TBT/N/IND/160) were issued on 12 August 2020 and on an urgent basis and, consequently, provided no time for comments. We seek India's clarification of why these measures, applicable to products that have been on the market for some time, needed to be implemented with three-months notice on an urgent basis. In addition, Canada wishes to reiterate its concern regarding India's movement away from accepting testing, for telecommunications equipment, in ILAC-accredited labs outside India and the cost of duplicative in-country testing. We note that accepting foreign test results, in appropriately accredited labs, is the least trade-restrictive manner of achieving legitimate safety and security objectives and seek India's agreement to continue this widely-accepted practice.

2.47. In response, the representative of India provided the following statement. Considering the factors like COVID-19, etc., Phase II of MTCTE was launched with only three low-impact products. For these products, test results in respect of technical parameters were acceptable from laboratories accredited by ILAC signatories up to 30 September 2020. Extension of acceptance of test results in respect of technical parameters from laboratories accredited by ILAC signatories beyond 30

[7] For previous statements follow the thread under IMS ID 646 (under dates raised and references).
[8] https://www.tec.gov.in/pdf/MTCTE/MTCTE_Phase2_240620.pdf

September 2020, is under consideration. To ensure that the existing supply chain is not disturbed and business continuity is maintained, the requirement of labelling on MTCTE certified products is exempted as a relaxation for an initial period of six months with effect from the date from which testing and certification for that telecom product is made mandatory in India. Regarding the provision for exemption of few test parameters, due to the inadequacy of testing infrastructure and the issue of a provisional certificate with a validity period of two years, it may be noted; this provision already exists in the MTCTE scheme. The equipment manufacturers are utilizing this provision already. Further, if the testing capability for a particular test parameter does not exist in the country, the exemption for that test parameter is granted, and a provisional certificate with a validity period of two years is issued.

2.48. It may also be noted; the MTCTE scheme provides for acceptance of test results from laboratories accredited by ILAC signatories, by way of relaxation, till the time sufficient test capability is developed in the country. Testing capacity for the requirements outlined in the Indian Telegraph (Amendment) Rules, 2017, is reviewed from time to time. As adequate in-country testing capability exists for EMI/EMC and safety-related test parameters, relaxation for acceptance of test results from laboratories accredited by ILAC signatories in respect of EMI/EMC and safety-related test parameters ceased to exist after 31 March 2020. For technical parameters, acceptance of test results from laboratories accredited by ILAC signatories was available up to 30 September 2020. As testing capability regarding technical parameters is still not considered adequate, relaxation for acceptance of test results from laboratories accredited by ILAC signatories is under consideration for extension beyond 30 September 2020.

2.1.2.7 Zimbabwe - Electricity (Minimum Energy Efficiency Performance of Domestic Electrical Appliances) Regulations, 2020, G/TBT/N/ZWE/2 (IMS ID 647[9])

2.49. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of Zimbabwe to introduce energy efficiency regulations with a view to protect the environment and conserve energy resources. Furthermore, Korean companies are fully committed to comply with the regulations of the Zimbabwe. On 10 July 2020, Korea sent official comments to the Zimbabwe Enquiry Point regarding this regulation, but Korea has not yet received a response from the relevant authority. Therefore, Korea requests Zimbabwe to review the following difficulties. First, according to Schedule I (Appliances Listing) of the regulations describing energy performance testing standards by products, as a result of checking the test standards for household refrigerator and air conditioner, there appears to be a mistake as the corresponding standards are non-existent. Therefore, Korea asks Zimbabwe to consider making changes by reflecting our suggestions proposed in the table below. Also, regarding ZWS 1008:2016, which is the standard for testing induction cook stoves, Korea asks Zimbabwe to confirm whether this standard is present and is harmonized with international standards, and if so, please inform us as to how we may access this standard.

2.50. Second, the regulation specifies only standards for testing methods related to each product, but it does not specify specific requirements by products such as energy efficiency rating requirements, label designs, etc. In addition, due to the lack of information for locally designated testing laboratories, the conformity assessment process and information for complying with Article 7(1) which requires registration to the Zimbabwe Energy Regulatory Authority (ZERA), many Korean companies are facing difficulties when preparing for exports. Therefore, Korea requests Zimbabwe to provide detailed requirements by products, the status of designated testing laboratories, the conformity assessment process and the guidelines for information registration to the ZERA. Third, Zimbabwe has announced that these regulations are scheduled to take effect on 1 February 2021, but this date leaves insufficient time to prepare for exports due to the lack of essential information for regulatory compliance as mentioned above. Therefore, Korea requests Zimbabwe to delay the implementation of the regulations for a period at least six months after correcting the regulations, and providing essential information necessary to comply with the regulations.

2.51. In response, the representative of Zimbabwe provided the following statement. ZERA is still checking on all standards with a view to replacing all non-existent ones. With regard to Standard ZWS 1008:2016 we are reporting that this standard is based on the American standard ASTM F2834. We will also look into the specific requirements by products such as energy efficiency, including their rating requirements, and also label designs. We will submit the conformity regulations SI 124 which provide the due process and also the guidelines. We are also reporting that the regulations will not

[9] For previous statements follow the thread under IMS ID 647 (under dates raised and references).

be effective in February 2021. This is mainly due to the COVID-19 pandemic challenges. We will advise a gazetting date after the pre-implementation phase. We are ready to engage with Korea bilaterally on this issue.

2.1.2.8 Mexico - Various State Measures Restricting Sale of Food and Drink Products to Minors (IMS ID 648[10])

2.52. The representative of the United States provided the following statement. The United States is concerned about new measures in the Mexican States of Oaxaca and Tabasco, which ban the sale of foods and beverages, carrying high-in sugar, fat or calorie nutrition label(s) to children 18 years of age or younger. These state measures prohibit packaged foods and beverages as those products sold with added sugar, saturated fats, trans fats, and sodium exceeding nutrient thresholds, in accordance to the corresponding federal technical regulation, Official Mexican Standard NOM-051 SCFI/SSA1-2010 "Labelling for pre-packaged food and non-alcoholic beverages – Commercial and Health Information, as Mexico notified in G/TBT/N/MEX/178/Add.13. We request Mexico notify these state-level measures to the WTO (and USMCA). We requested notification on 18 August, through the US WTO/USMCA TBT Enquiry Point, at an early and appropriate stage, to allow for Member comments, and to allow state governments to take Member comments into consideration in their final measures.

2.53. State Registers published notice of these measures in Oaxaca and Tabasco in August. We understand the Governor of Oaxaca approved the measure on 8 September, and an implementation plan is under development. We also understand the measure in Tabasco is awaiting the governor's approval. What is the timeline for implementing these measures? Are there other steps these states will take before implementation? Given the number of small retailers and vendors in Mexico, how would these measures be enforced? While the United States continues to support initiatives that advance the goal of promoting healthy dietary choices and lifestyles to children, we urge Mexico to consider whether it can attain its public health goals through the use of less trade-restrictive alternatives. Preliminary industry and market research firms estimate that more than 80% of the pre-packaged foods and non-alcoholic beverages in Mexico will have at least one warning sign, meaning they could not be purchased or provided to minors except by a parent or guardian. We are concerned that these measures restrict anyone under the age of 18 from purchasing common groceries such as cheeses, bread, and some meat products, which lead to possible food security concerns. Can Mexico explain how it proposes to enforce such a broad sales ban?

2.54. We would like to note that sustained, healthy changes to diet behaviour and consumer preferences take time. We understand that 24 of the 31 states in Mexico, plus Mexico City, are considering enacting restrictions. In addition, we learned via communications through our respective Enquiry Points that Mexico does not believe that state-level measures should be notified to the WTO TBT Committee, and therefore does not plan to do so. In the United States' view, these measures form part of a larger package of measures that include federal-level technical regulations, and therefore should be notified to the WTO. Can Mexico explain why it believes the measures should not be notified? Also, we understand that a proposal for a federal-level ban was introduced before Mexico's Senate on 21 September. Can you provide more information on the status of this proposal?

2.55. The representative of Colombia provided the following statement. Colombia wishes to register its interest in this matter and will carry out a detailed review of the related information.

2.56. In response, the representative of Mexico provided the following statement. The delegation of Mexico thanks the delegation of the United States for sharing its comments on the draft regulatory amendments in some States, which seek to prohibit the sale of some food and non-alcoholic beverages to minors. The proposed state-level measures are part of the national strategy aimed at combating public health issues in the country such as obesity and excess weight, both in adults and minors. According to UNICEF[11], overweight and obesity in Mexico are a problem occurring in infancy, that is, between 0 and 5 years of age. At least one in every 20 children under the age of five is obese, which makes them prone to being overweight for the rest of their lives and puts them at risk of suffering from, *inter alia*, circulatory, heart and kidney diseases and diabetes. The proportion of children suffering from overweight or obesity has increased to one out of every three. The main

[10] For previous statements follow the thread under IMS ID 648 (under dates raised and references).

[11] https://www.unicef.org/mexico/sobrepeso-y-obesidad-en-ni%C3 per centB1os-ni%C3 per centB1as-y-adolescentes

nutritional problem suffered by children aged between 6 and 11 years is the presence of both disorders, obesity and overweight. As a consequence, Mexico is one of the countries with the highest rate of childhood obesity in the world. Furthermore, UNICEF states that the main causes of obesity and overweight in children are the consumption of processed food with high levels of sugar, trans fats and salt, as well as sweetened beverages, which are readily available given their wide distribution, low cost and promotion in the mass media.

2.57. As regards the points made by the delegation of the United States, and following an analysis carried out by the relevant authorities of the Government of Mexico, the legislative amendments that have been adopted, to date in two states of the Republic of Mexico (Tabasco and Oaxaca), are not considered to meet the terms that would make them verifiable as a technical regulation under the definition in the WTO Agreement on Technical Barriers to Trade and, therefore, the notification requirements stipulated therein are not applicable. The link between such state measures and NOM-051 on the commercial and health requirements for the labelling of pre-packed food and non-alcoholic beverages only refers to the scope of application, that is, it aims to prohibit the sale to minors of food and non-alcoholic beverages to which the requirements of NOM-051 apply. Also, no secondary legislation has been issued on the implementation of the measures concerned, and consequently there is no information to share in this regard at this time. The Government of Mexico reiterates its commitment to complying with the international commitments set out in the Agreement on Technical Barriers to Trade and those relative to the Free Trade Treaties of which Mexico is a member. However, it also reiterates its commitment to safeguarding the health of the Mexican people.

2.1.2.9 India - Indian standards and import restrictions in the automotive sector (Quality Control Orders): wheel rims, safety glass, helmets, G/TBT/N/IND/118, G/TBT/N/IND/147, G/TBT/N/IND/167 (IMS ID 649[12])

2.58. The representative of the European Union provided the following statement. Recently India adopted a number of measures in the automotive sector that raised important concerns across the EU industry. These recent Indian measures - Quality Control Orders - in the automotive sector regard mandatory markings for wheel rims, new standards for safety glass, and Bureau of Indian Standards (BIS) compulsory certification for helmets for two-wheeler riders. All three notifications from India foresaw only 30 days for comments. The EU takes this opportunity to recall that according to Article 2.9.4 of the TBT Agreement, Members shall, without discrimination, allow reasonable time for other Members to make comments on notified draft technical regulations. Furthermore, in its recommendation G/TBT/9 of 13 November 2000, the TBT Committee agreed that the normal time limit for comments on notifications should be at least 60 days. One month commenting period has proven too short for the EU to react before the final date for comments. The EU would like to underline that all measures in question appear to have protectionist orientation and are sending very worrying signals not only to EU industry, but also to EU investors and EU Member States. Once these measures come into force, they will cause extra burden and economic cost to the EU industry that will have to undergo cumbersome procedures to obtain necessary permissions and/or licences without any added value or scientific evidence that these measures would actually contribute to improved safety beyond the UNECE framework.

2.59. As regards the wheel rims, the draft Quality Control Order (QCO) issued by the Department of Heavy Industries (DHI) would make mandatory Indian Standards Institution (ISI) marking on all automotive wheel rims and would generate additional costs for the European automotive manufacturers. As per Order dated 21 September 2020 issued in Gazette of India, it stated that the Automobile Wheel Rim Component (Quality Control) Order 2020 shall come into force after one year from the date of its publication in the Official Gazette. The European Union welcomes this decision by the Indian Government. The EU would like to ask India to reconsider the introduction of this QCO – to repeal it or to waive its application to EU trustworthy manufacturers. The EU believes that BIS markings should be optional for components which are already in compliance with the current marking requirements as notified by the Ministry of Road Transport and Highways under the Central Motor Vehicle Rules (CMVR), and are either installed on new vehicles in accordance with UN Regulation 142 concerning the approval of motor vehicles with regard to the installation of their tyres or are type approved as replacement wheels according to UN Regulation 124 concerning the approval of wheels for passenger cars and their trailers.

[12] For previous statements follow the thread under IMS ID 649 (under dates raised and references).

2.60. The European Union would like to thank Indian authorities for the decision to postpone the introduction of the mandatory ISI marking for automotive Safety Glasses to April 2021. According to the new QCO, originally scheduled to enter into force on 16 September 2020, automotive glass not mounted in vehicles (loose or spare parts) sold in India would have to obtain a new national licence and marking. Despite the much welcome delay of the entry into force, the European companies still face difficulties and delays in their preparation for the new certification system. Not all rules are clear in the new scheme, and the prohibition to travel from and to India due to the COVID-19 restrictions make this new scheme more difficult to implement, and there are still problems of delays due to the pandemic. While acknowledging the purpose of BIS licensing to guarantee the quality of safety glasses used in transport vehicles, in view of the current situation concerning the outbreak of COVID-19, it would be difficult for EU companies to comply with the new requirements within the deadlines set by the QCO. Furthermore, the new requirements may generate additional costs to EU automotive glass manufacturers, as they would require complex procedures such as audits, tooling changes, etc.

2.61. The European Union would like to ask India to further delay the entry into force of this measure, so that the EU industry may fully comply with the Order. This would allow the EU companies to meet the requirements and to continue supplying customers in India. The QCO on Protective Helmets for Two-Wheeler Riders is set to come into force on 1 March 2021. The EU would like to request India to keep the BIS marking as optional for components, which are type approved according to UN Regulation 22 concerning the approval of protective helmets and of their visors for drivers and passengers of motorcycles and mopeds. The European Union finds these measures to be unproportionate and cause obstacles to trade. The European Union would very much appreciate if India could reconsider the mandatory introduction of QCOs on the wheel rims, automotive safety glass, and helmets.

2.62. The representative of the United States provided the following statement. The United States is aware that India recently adopted a number of QCOs in the automotive sector, which concern mandatory markings for wheel rims, new standards for safety glass, and compulsory certification with the BIS for helmets for two-wheeler riders. The United States supports the request that India provide at least 60 days for interested stakeholders to provide comments on these QCOs, and that India take submitted comments into account before finalizing these QCOs.

2.63. In response, the representative of India provided the following statement. India wishes to inform the Members that the testing and certification system for wheel rims in India is in line with the global regime. Component certification is an essential pre-requisite of Whole Vehicle Type Approval, and the two are complementary. This practice is well established worldwide and quite harmonized under Whole Vehicle Type Approval. In the European Union, wheel rim is not identified as a separate safety-critical component in UNECE. But in India, it is recognized as an individual safety component under CMVR, given the local road infrastructure, a variety of tyres used, and driving behaviour. Because of its crucial role in driving safety, Indian standards are prepared to ensure quality, reliability, and wheel rims consistency. These standards prescribe the general and performance requirements of wheel rims intended for use on two, three, and four-wheeled motor vehicles. The QCO (automotive wheel rims) is non-discriminatory, both at the original fitment level of automobiles and after sales/repair service. It aims to ensure that the supply of only quality products in the Indian market is duly certified and approved by the Indian implementing agency. The QCO also provides market surveillance to check the entry of substandard products into the Indian market. The QCO was issued after due consultation with stakeholders. Further, as desired by the stakeholders, a sufficient lead time of one year from the date of publication of the Gazette Notification of the QCO has been provided for the industry to prepare itself. In reference to safety glass it submitted, the QCO in Safety Glass was issued on 12 March 2020, with 16 September 2020 as the implementation date. On request, this date is now extended to 1 April 2021. Additionally, the order is amended on 18 September 2020, which currently states that safety glass used in the vehicle imported in India by vehicle manufacturer under the provisions of rule 126 of "Central Motor Vehicle Rules, 1989" is not covered under QCO of safety glass. It may also be noted; there is no proposal to further extend the QCO on safety glass beyond 1 April 2021.

2.64. As regards the helmets, India is the largest two-wheeler market in the world. Around 15 million two-wheelers are sold in the country every year. Also, the fatalities due to road accidents, i.e., around 150,000 per year, are the highest in the world, about 11% of the total global road accident fatalities. And further, the deaths involving two-wheelers are a significant number, and deaths without helmets or with helmets of low quality are also very high. The Government and the

Apex Court, i.e., the Supreme Court, focus hard on policies and measures to make people wear proper helmets while riding two-wheelers. In this regard, there was a move to reduce the maximum weight of the helmets so that people should use helmets, and BIS, the Indian certification standard organization, had issued the notification in this regard, which has prescribed the maximum weight of helmets to 1,200 grams from earlier 1,500 grams. But due to the demand from the foreign helmet importers, the cap on weight from 1,200 was extended to 1,500 grams. Now there is a proposal for including the helmet in the compulsory certification regime. This will ensure that the helmets are manufactured or imported only with the BIS standard specifications and would ensure good quality helmets, which would provide adequate protection and cause fewer deaths. The BIS provides a mechanism for foreign manufacturers to obtain BIS certification, enabling them to sell in India. Considering India's road safety scenario above, which is quite different from any European country, certified helmets' requirements are a high priority.

2.1.2.10 Russian Federation - Federal Law n° 468 on wine making and wine growing in the Russian Federation (IMS ID 650[13])

2.65. The representative of the European Union provided the following statement. Russia has adopted a measure "Federal Law Nº 468 of 27.12.2019 on wine making and wine growing in the Russian Federation". This measure has not been notified to the WTO. The Law entered into force on 26 June 2020, only six months after its adoption, despite requests to postpone this date, including a joint letter by the EU, Australia, Switzerland and the US. We understand that the Ministry of Agriculture has very recently been appointed by decree as the supervising authority to oversee the implementation of this law. We are grateful to this Ministry for the technical meeting that took place on 14 October with the EU Delegation in Moscow. We hope that the Ministry will be able to engage actively with foreign stakeholders, who remain very concerned and provide the clarifications they need. The Law is already in force, but amendments to the Law (the so-called Bakharev's proposal) are being discussed by the Duma, which adds new uncertainties for foreign businesses who need to adjust to the new regulatory environment.

2.66. This Federal Law contains several provisions that amount to obstacles for the importation of wine and wine-based products into the Russian Federation territory (i.e. inconsistency with International Organisation of Vine and Wine (OIV) labelling and winemaking rules, inspection of EU facilities by Russian officials, disqualification of wine-based products, use of EU Geographical indication names to define categories of wines in the law, such as Champagne and Cognac, by Russian domestic producers etc). We note the presence of a stock-exhaustion clause which only concerns products already in Russia before 26 June 2020 and wonder why it is linked to cumbersome rules to display products separately in shops. The EU is very concerned that the Law will have a strong impact on import of foreign wines. We also note statements by the Russian Wine Federation that the declared objective is to drastically reduce imports in order to favour the development of the Russian wine sector. In addition to the issues posed by the Federal Law itself, some of its requirements do not coincide, or even contradict, with the technical requirements set out in the EAEU Technical Regulation (TR) on safety of alcohol products, contributing to regulatory uncertainty. For example the Federal Law states that for wine the content of ethyl alcohol must be between 7.5 to 18%, whereas the EAEU TR sets the range between 8.5 to 18%. Our first question relates to the date of the entry into force of the EAEU TR in Russia. We understand from the EU Delegation that the date of implementation of the TR will be postponed by one year; could you please confirm? Secondly, we understand that the Ministry of Finance in cooperation with the Ministry of Agriculture will, over the coming months, work at harmonizing the Russian Law and the EAEU TR; is it correct? How will it work in practice to ensure that the two documents are in line? Will modifications be done only in the TR, only in the law or in both documents? Could this harmonization phase be a good opportunity to correct also divergences with the international standards produced by OIV?

2.67. Discrepancies between the Russian Law and OIV provisions, on-going adoption of an amendment at the Russian Duma, discrepancies between provisions of the Russian Law and of the EAEU TR, postponement of the entry into force of the EAEU TR, work of the Ministries of Finance and Agriculture to remove discrepancies between the Russian Law and the EAEU TR; the dimensions of regulatory uncertainty are many, with significant impact on foreign producers. Lastly, it seems that the Federal Law also contains provisions covered by the Agreement on trade-related aspects of intellectual property rights. The EU would like to invite Russia to notify the measure to the Council for Trade-related Aspects of Intellectual Property (TRIPS). The EU invites Russia to notify the new

[13] For previous statements follow the thread under IMS ID 650 (under dates raised and references).

wine measure, under the TBT Agreement as well as under the TRIPS Agreement. Meanwhile, the European Union would like to ask Russia to postpone further effective implementation of the law pending these clarification exercise, and to take these comments into consideration during the on-going amendment procedure.

2.68. The representative of Australia provided the following statement. Australia understands Russia has adopted "Federal Law Nº 468 of 27.12.2019 on wine making and wine growing in the Russian Federation", which entered into force on 26 June 2020. The Federal Law poses several barriers to the importation of wine into Russia, which coupled with the short timelines for the law's implementation, are of concern to the Australian wine industry. A key concern is the mandatory declaration of vintage and variety required under the new law. This does not reflect OIV practices, of which Russia is a member. Article 18 of Russia's Federal wine law stipulates the start date of the wine ageing process as 1 January of the year following harvest, which puts Australian and other southern hemisphere producers at a distinct disadvantage given that the grape harvest for these regions relies on a different biological growing season and harvest. That is, 1 January in the northern hemisphere is winter, whereas Australian and New World grapes are harvested early in the year, after 1 January. In relation to the ageing process, Article 18 includes a category referred to as "brand" wine, which requires 18 months ageing following 1 January in the year following harvest. If this means wine cannot be given a brand unless it has been aged for 18 months, only Australian wine from 2018 and earlier would be permitted to carry a brand in Russia.

2.69. Article 24 prohibits the addition of water in wine, which poses a significant barrier to trade for New World growers. Australian food regulations permit the addition of water to dilute high sugar musts to aid fermentation. Minimal additions of water aids fermentation during periods of difficult seasonal conditions, including drought. Russia's Federal wine law includes provisions covered by the Agreement on TRIPS, including geographical indications. Australia invites Russia to notify the measure to the Council for TRIPS accordingly. Additionally, Australia notes several obligations within the federal wine law are inconsistent with the Eurasian Economic Union Technical Regulation 047/2018 "On safety of alcohol products", which is expected to enter into force in January 2021. Australia seeks further clarification from Russia on how this regulation and Federal Law Nº 468 will be implemented once entered into force. Australia encourages Russia to take into account these concerns when reconsidering the implementation of the new Federal wine law and we look forward to Russia notifying the WTO accordingly as soon as possible.

2.70. The representative of the United States provided the following statement. The United States supports the request that Russia notify implementing measures to the WTO TBT Committee, provide at least 60 days for interested stakeholders to provide comments on the measure, and that Russia take submitted comments into account before finalizing the regulations.

2.71. The representative of Chile provided the following statement. Chile would like to echo the comments made by the EU, Australia and the United States concerning this new Federal Law on wine. It requests that Russia postpone the entry into force of the Law and that, in this regard, it submit the relevant notification to the WTO TBT Committee, so that comments may be submitted during a period of at least 60 days.

2.72. In response, the representative of the Russian Federation provided the following statement. We took note of the statements made by the EU, Australia, the US and Chile on this agenda item. Statements will be forwarded to the capital for consideration. Federal Law on wine making and wine growing was passed to develop wine making and wine growing industries taking into account obligations of the Russian Federation in the WTO. The requirements of this law are applied equally to both Russian and foreign products. On some of the specific issues raised today we have the following comments. With regards to EU's claims that the Federal Law uses cognac and champagne names to define categories of drinks, we would like to note that the Federal Law doesn't use the term "cognac" in its text. The term "champagne" is used by the Federal Law only in a word collocation "Russian champagne" which denotes a subgroup of Russian wines. The term is applicable only to Russian wines produced in a special way and is not associated to the EU's Geographical Indication (GI) name. As explained on numerous occasions, champagne transformed into generic name in Russia and is not associated with the GI due to a long history of the use of this term in Russia. All wine producers have full range of rights that are not limited by the Federal Law to register their GIs and Appellations of Origins in the Federal Service for Intellectual Property and they are always welcome to do that. With regards to invitations to notify the Federal Law in TRIPS Council, we fail to see grounds set out in Article 63 of the TRIPS Agreement for notification of the Federal Law. On

the claims of inconsistency of the Federal Law provisions with OIV labelling requirements, we note that we commented on some of them over previous TBT Committee meetings under agenda item "Russian Federation - Draft technical regulation on alcohol drinks safety". So, on this we would refer to our statements made during November 2019 and February 2020 Committee meetings.

2.1.2.11 India - Order related to requirement of Non-GM cum GM-free certificate accompanied with imported food consignment, G/TBT/N/IND/168 (IMS ID 651[14])

2.73. The representative of the United States provided the following statement. The United States has serious concerns with India's new measure mandating a "non-GM (genetically modified) origin and GM-free certificate" for certain agricultural imports to India, notified (as final) on 2 September 2020 as G/TBT/N/IND/168, with a proposed entry into force date of 1 January 2021. While we appreciate India's notification of this measure to the TBT Committee, we note that there is a lack of clarity regarding the legitimate objective and scope of the measure, how the measure will be implemented or enforced, and how the measure fulfils the legitimate objective. India appears to be implying that genetically modified foods are less safe than their conventional counterparts. India states in its notification the requirement of GM-free certificates is needed "to ensure that only non-GM foods are imported into India", and India's order explains the need for GM-free certificates in terms of "ensuring the safety and wholesomeness of article of foods imported into India". The United States notes its concern regarding this justification and invites India to clarify these objectives. The certification requirements, contrary to India's claims, do not contribute to "ensuring the safety" of food imported into India. Many foods in global commerce have been evaluated in multiple countries with each country reaching the same conclusion of safety.

2.74. The United States notes that India's measure does not align with science- and risk-based decision making, creates certification requirements with which relevant national authorities may be unable to comply, and does not appear to consider relevant economic factors, such as costs of compliance, or potential trade disruptions. The Government of India's requirements appear to apply to imports of all listed products, regardless of whether GM varieties of those products are in commercial production in the country of export. All Members exporting to India may encounter additional burdens to trade for those crops listed under Annex I of India's order. The Government of India has not clarified in writing whether the order applies only to imports intended for human consumption and whether the order applies only to raw, unprocessed products. The Government of India has also not laid out a process for relevant Indian authorities to make determinations regarding whether imported shipments are subject to the order. Given the substantial uncertainty and the potential for significant disruptions to trade, we request that India withdraw this requirement and consider alternative approaches that are consistent with approaches of other Members to avoid creating unnecessary obstacles to international trade. If India is unable to withdraw this requirement, we request that India explain the justification for the measure and provide any relevant international norms on which this measure is based.

2.75. The representative of Brazil provided the following statement. Brazil strongly supports India's commitment to ensuring high standards of health and safety for its population. Nonetheless, we would like to express concerns related to its recent order setting requirements of non-GM cum GM-free certificates accompanied by imported food consignments, notified as G/TBT/N/IND/168. This regulation applies to 24 crops and requires official certification to attest that imported products are not genetically modified. Besides, certification must be issued for each cargo individually. The text of the regulation presents a template for the certificate to be issued by the competent authority of each country. India has not yet published any regulatory impact assessment, risk analysis, or technical document that presents the link between said regulation and the legitimate objectives it is willing to safeguard. The lack of information regarding the scientific grounds for this regulation raises concerns about transparency in the regulatory process undertaken by Indian authorities. Neither has India explained how this regulation relates to any relevant international standards for food safety and genetically modified organisms (GMOs), differing from obligations set under Article 5.12 of the TBT Agreement. The Indian regulation is expected to be particularly harmful to Brazilian exporters of apples, cowpea beans, tobacco, sugar cane, and corn. Besides, the order establishes overly burdensome requirements for the so-called Competent National Authority, which would have to issue a certificate for every single consignment of the food products listed in the Annex. Despite providing a period for comments, the Indian Government has already set a date for entry into force of the regulation (1 January 2021), which raises concerns about India's compliance with Article 2.9.4. of

[14] For previous statements follow the thread under IMS ID 651 (under dates raised and references).

the TBT Agreement and about its willingness to actually take into account timely submitted comments. In light of the above, Brazil believes that regulation G/TBT/N/IND/168 is more trade restrictive than necessary to fulfil any legitimate objective under the scope of the TBT Agreement. We kindly ask India to reassess this draft measure. Moreover, could India please indicate the studies and the relevant international studies it relied upon in order to draft this regulation?

2.76. The representative of Colombia provided the following statement. Colombia wishes to support the trade concern raised by Brazil and the United States regarding the Order adopted on 12 October 2020 by the Food Safety and Standards Authority of India (FSSAI), which is part of the country's Ministry of Health, which stipulates the requirement for a certificate demonstrating that imports of a list of 24 fresh fruit, vegetable and grain products are free from genetically modified organisms (GMO). The certificate must be issued by the relevant national authority of the exporting country. We consider that the measure could restrict exports of certain fresh fruits, vegetables and grains to that market, as there is no clarity with respect to the legitimate objective pursued, its scope and the new requirements required by India. Furthermore, currently not all analytical techniques to check for genetically modified foods have been developed or certified, meaning that the measure may become an unnecessary obstacle to trade, violating Article 2.2 of the TBT Agreement, which states that: "(…) Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade".

2.77. Moreover, regarding the time limits set out in notification G/TBT/N/IND/168 of 2 September 2020, India stipulates in its regulation that the measure would enter into force on 1 January 2021. In this respect, we wish to recall that, in accordance with Article 2.12 of the TBT Agreement, "Members shall allow a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member". This ensures that both the relevant national authority and the productive sector may increase their technical capacity and make the corresponding documentary adjustments to implement a new procedure for the issuance of GMO-free certificates, which will certainly incur an additional cost for exporters. Such a situation creates uncertainty and possible major disruptions to trade. We support the requests for India to withdraw this requirement and to consider other alternatives to avoid the creation of unnecessary obstacles to international trade. Finally, Colombia thanks India for the opportunity to express its concerns on this issue.

2.78. The representative of Argentina provided the following statement. Argentina would like to express its concern regarding the new Order issued by the Food Safety and Standards Authority of India (FSSAI) requiring imports of food products to have a certificate of Non-GM product origin, which was notified in document G/TBT/N/IND/168. It is important to highlight that, under the WTO Agreements, any standard of this type must be based on scientific principles. In this case, we wish to stress that scientific evidence shows that genetically modified products are as safe as their conventional equivalents, have been marketed safely and harmlessly for decades and have undergone rigorous scientific examination to prove so. In light of the above, there is no justification for discriminating between one or the other. We therefore consider that the standard notified by India is disproportionate and creates unnecessary barriers to international trade. We have already submitted more detailed comments and specific questions through the TBT Focal Point and hope that these will reviewed by the Indian authorities in order to safeguard the normal flow of trade in agri-food products.

2.79. The representative of New Zealand provided the following statement. New Zealand acknowledges and supports measures that focus on legitimate objectives, including the protection of human health and safety. However, New Zealand respectfully requests clarification from India regarding the specific intent and objective of the proposed measures. New Zealand is concerned that India's proposed requirements regarding non-GM certification for specific foods will actually impose further restrictions and costs on existing trade due to the requirement to provide consignment-based non-GM certification. New Zealand would appreciate clarification regarding what consideration India has accorded to less trade-restrictive alternatives for those countries that have not approved the release of any genetically modified crops into the environment. New Zealand notes the measures appear to be implemented under food safety legislation. If the protection of human health is the objective, in whole or in part, can India advise whether they intend to also notify the proposed measures to the SPS Committee, given its relevance to provisions within the SPS Agreement, particularly Codex Alimentarius? Subsequent to India's responses, New Zealand looks forward to

sharing its concerns in greater detail, including by way of written submission on India's notification G/TBT/N/IND/168.

2.80. The representative of Japan provided the following statement. Japan shares the concerns on India's new measure obligating a "non-GM origin and GM-free certificate" for 24 agricultural products imported to India. Japan has been concerned that the India's proposed measures would create unnecessary trade barriers and have negative impacts on agricultural trade between India and WTO Members. There is a lack of clarity regarding the justification for the measure and how the measure will be implemented. Especially Japan would like India to explain the rationale for requiring the GM-free certificate, for which there are no established detection methods on GMO(s) from the GM crop, and how to inspect such products with the non-GM certificate at the border in India. Japan would also like India to clarify the necessity of the non-GM certificate if the production and importation of such GM crops are prohibited in the domestic regulations of exporting countries. Japan would like to ask India to address the concerns raised by Member countries and as long as the proposed regulation has the substantial uncertainty and the potential negative impact on international trade, Japan would kindly ask India to reconsider the implementation of the proposed measures.

2.81. The representative of Canada provided the following statement. Canada recognizes India's sovereign right to implement measures it deems appropriate to fulfil a legitimate objective, such as protecting human health and safety or protecting the environment. However, Canada is concerned that India's non-GM import certification requirement will disproportionately impact the ability of GM-producing countries to export to India and unnecessarily restrict international trade. Countries around the world have developed effective regulatory frameworks to assess the risks of GM food products prior to their approval and commercialization. In Canada, all novel products, including those derived from genetic modification, have undergone rigorous scientific safety assessments according to international guidance and standards, to ensure they are as safe and nutritious as their conventional counterpart. A novel plant product is authorized for commercialization only once it has received appropriate safety approvals.

2.82. India's new requirement will be particularly challenging for countries like Canada where the National Competent Authority assesses the safety of GM products prior to their release on the market and therefore, does not issue any import certification for these products. In an effort to better understand the health and/or safety concerns India's measures is looking to address, we respectfully request that India share the available scientific information and/or justification that would support the rationale behind India's non-GM certification requirement. We also strongly encourage India to delay the imminent implementation of this measure to provide trading partners with sufficient time to engage with India and have concerns taken into account. In fact, Canada has submitted comments through India's TBT Enquiry Point detailing its concerns. We look forward to India's response and remain available to pursue further discussions on this issue in a bilateral setting.

2.83. The representative of Australia provided the following statement. Australia recognizes the right of the Indian Government to take measures necessary to protect public health. Australia wishes to emphasize the importance of compliance with its WTO obligations, in particular the requirements that measures be implemented in a non-discriminatory manner and in a way that is no more trade restrictive than necessary. This is particularly important during COVID-19 as trade facilitates food security around the globe. Australia is considering India's draft amendments to its Food and Safety Order related to "requirement of Non-GM cum GM-free certificate accompanied with imported food consignment" and intend to provide written submission within the TBT notification comment period. Australia welcomes India's consideration of our comments and looks forward to India's response and engagement on the issue.

2.84. The representative of Chile provided the following statement. The Republic of Chile welcomes the opportunity to comment on the "Order related to requirement of Non-GM cum GM free certificate accompanied with imported food consignment", communicated to the World Trade Organization by means of notification G/TBT/N/IND/168 and reported on 2 September 2020. We wish to provide the following comment for your consideration, as regards issuing a certificate for non-transgenic or non-GM products: According to the information provided, this notification will enter into force on 1 January 2021, at which time food consignments listed in Annex 1 of the regulation referred to in this notification must comply with the issue of a certificate (Annex 2) establishing that the exported products are not genetically modified or transgenic. In this regard, we wish to state that under Chilean law (Exempt Resolution N° 1523 of 2001), the use of genetically modified products for domestic food production is not authorized. Their use is only authorized for sowing for trial purposes

or seed multiplication for export purposes. In this respect and to date, Chile has not authorized any fruit species, whether for domestic or export use. In light of the above, it considers that requesting this type of certificate is establishing an unnecessary requirement. Therefore, consignments should only be accompanied by the plant health certificate in the framework of the International Plant Protection Convention (IPPC). Lastly, Chile thanks India for responding to such comments and for adopting measures aimed at strengthening international trade, and hopes to continue to collaborate on safe trading relations between both countries.

2.85. The representative of Paraguay provided the following statement. We will be following the matter closely, as the regulation is still being analysed in our capital. We will be in contact with our colleagues from India, if necessary, once this analysis is complete. Like our colleagues from other delegations that have spoken before us, we would welcome greater clarification on the scope of the measure and its scientific justification.

2.86. In response, the representative of India provided the following statement. In response, India would like to state that the Order dated 21 August 2020 regarding the requirement of Non-GM cum GM-free certificate accompanied by imported food consignments was notified on 2 September 2020 for comments from WTO TBT Member countries. The 60-day time to receive comments ends on 31 October 2020. Food Safety and Standards Authority of India (FSSAI) is accepting comments on the said notification, which will be examined after 31 October 2020.

2.1.2.12 Republic of Korea - Revision of Safety Conformation Criteria for Textile Products for Infants, G/TBT/N/KOR/678 (IMS ID 652[15])

2.87. The representative of the European Union provided the following statement. The EU would like to raise its concerns with regard to Korea's requirements for conformity testing of textile products for infants. In February 2018, Korea introduced new safety requirements for infant clothing, which changed the testing and certification procedures of these products. The EU believes that infant clothing has a very low human risk exposure, unlike infant humidifiers or hand warmers. Therefore, the EU does not have such stringent testing and certification requirements for the safety of infant clothing as we believe that extra testing would be more trade restrictive than necessary to fulfil a legitimate objective, i.e. not in line with Article 2.2 of the TBT Agreement. It is our understanding that other major markets also do not have such stringent regulations on infant clothing. As a result of the measure, the testing and certification costs have increased substantially for European manufacturers. As an example, one manufacturer's average monthly costs more than doubled in 2018 compared to the 2017 monthly average and increased by eight times in 2019 compared to the 2017 monthly average. Additionally, there are reports from EU industry that the testing is not been carried out on an equal basis between domestic and foreign producers, to the detriment of importers. The EU has had multiple meetings with the relevant Korean authorities in order to resolve the situation. The Korean Agency for Technology and Standards (KATS) has recognized that infant clothing is not a hazardous product, and was included in the regulation due to a separate problem with humidifiers. However, they are unwilling to rectify the situation despite not knowing how compliance has changed as a result of the measure. Compliance rates of some EU companies in textiles had already been more than 98.5%. Therefore, the EU would like the Korean authorities to take the necessary steps to remove this trade barrier.

2.88. In response, the representative of the Republic of Korea provided the following statement. Korea appreciates the interest of EU member States in Korea's requirements for textile products for infants. Korea would like to deliver the official response from the regulatory authority. On 27 October 2020, representatives of the EU in Korea and Korean relevant authority held a meeting regarding this STC and discussed the concerns raised by the EU in detail. Today's answer from Korea will be the same as what we explained at the meeting yesterday. The EU has raised concerns regarding specific textile products used by or for infants less than 36 months of age, specifically, that the requirements are too strict given that the EU believes that infant clothing has a very low human risk exposure. However, a risk assessment on textile products for infants in Korea found that such a risk was high in infants, especially due to damages caused by strings, cords, harmful substances, and others. The safety of infant clothing products must be verified through product inspection. Korea also notes that the diversity and complexity of risk assessments may result in differences in the level of risk for infant clothing between Korea and the EU.

[15] For previous statements follow the thread under IMS ID 652 (under dates raised and references).

2.89. Regarding the EU's concerns about a substantial increase in testing and certification costs for European manufacturers in 2018 and 2019 due to amended requirements for textile products for infants, Korea notes that period-specific EU manufacturers had attempted to expand their sales in the Korean market, and the increase in the costs of testing are likely to be on a one-time basis. It is not likely that the increase in the costs of testing can be attributed solely to the amendment of the requirements. EU also claimed that testing has not been carried out on an equal basis between domestic and foreign producers for infant clothing. However, the relevant act, the "Special Act on the Safety of Children's Products", certainly ensures equal treatment between domestic and foreign manufactures with respect to national treatment in the context of goods and manufacturers. Korea also notes that on no occasion have other countries made a similar complaint in this respect. Furthermore, EU manufacturers stated that the compliance rate of infant clothing stands at 98.5%, but Korea has not found any basis for this claim. Korea very much hopes to resolve the EU's concerns at this TBT Committee in a mutually beneficial manner.

2.1.2.13 United States - Appliance Efficiency for Sprinkler Bodies, G/TBT/N/USA/1489 (IMS ID 653[16])

2.90. The representative of China provided the following statement. China appreciates the efforts of the US to improve the performance of sprinkler bodies. However, China still requests the US: (i) to further clarify the application scope of sprinkler products; (ii) to clarify the accuracy requirements of the pressure level test points in 1(c), 3(b) and 3(f) of Appendix B of Water Sense (r) Specification for Spray Sprinkler Bodies. Since the requirements of test methods in ISO 15886-3:2012 5.1 have been accepted and used globally, we suggest the US to be consistent with ISO standard; (iii) to clarify the distance between the needle valve and the outlet pressure sensor in Appendix B, 3(c).

2.91. In response, the representative of the United States provided the following statement. China did not submit comment to the United States through the USA WTO TBT Enquiry Point, and its questions came to us just this week, which is late in terms of our ability to liaise with California to prepare a response. We will take the concerns back with us and engage the State of California, accordingly. If we are able, we will post replies back to the eAgenda by 3 November or reply to China bilaterally after the meeting.

2.1.2.14 Chile - Technical specifications for the design of energy efficiency labels for washing machines, G/TBT/N/CHL/297, G/TBT/N/CHL/325 (IMS ID 654[17])

2.92. The representative of the Republic of Korea provided the following statement. Korea would like to make some comments regarding this regulation as follows. Regarding the regulation on washing machine energy-efficiency label in Chile, Korea received official comments from the Chile TBT Enquiry point in July and October 2020. However, Korea has not yet received a clear response from Chile regarding our requests, so Korea again requests the Chilean authorities to review the following concerns. According to Number 9 of Table A (Resolución Exenta N°70 de fecha 30.12.2014 -Ministerio de Energía), the tolerance of energy consumption is ± 11% and the tolerance of water consumption is ± 4%. If negative tolerance is applied, it might result in failure in follow-up testing even though the product has better energy efficiency. Therefore, in Europe and the majority of countries including Korea and Peru, neighbouring country of Chile, the tolerance of energy consumption and water consumption is less than +10 %. Thus, Korea requests Chile to modify the tolerance of energy consumption and water consumption on the energy efficiency label to less than +10%.

2.93. In response, the representative of Chile provided the following statement. Chile wishes to inform this Committee that these measures were notified in 2015, on 2 February and 2 October, respectively. On both occasions, Chile allowed time for comments in this TBT Committee, pursuant to the provisions on transparency established by the Agreement, and did not receive comments from Korea on either occasion. The information received at this meeting will be submitted to the Ministry of Energy in due course in order to provide the delegation of Korea with a proper reply.

[16] For previous statements follow the thread under IMS ID 653 (under dates raised and references).
[17] For previous statements follow the thread under IMS ID 654 (under dates raised and references).

2.1.2.15 European Union - Information requirements in SCIP Database (IMS ID 655[18])

2.94. The representative of China provided the following statement. The (EU) Directive 2018/851 amending Directive 2008/98/EC was officially published on 14 June 2018, and came into force 20 days later. Article 9(1)(I) of (EU) 2018/851 requires that any supplier of an article shall provide product information as required by Article 33(1) of Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) (EC 1907/2006) before 5 January 2021. Article 9(2) stipulates that European Chemicals Agency (ECHA) shall establish a database by 5 January 2020 to collect relevant information related to Article 33(1) of REACH. This database was defined by ECHA as the SCIP Database. China supports EU's management of waste, but still remains concerned about the SCIP Database, and requests EU to postpone the notified deadline of 5 January 2021 to at least 12 months after the finalization of the database. ECHA has not finalized the database for notification before 5 January 2020 as required by (EU) 2018/851. According to the information from ECHA, the final version of SCIP Database will not be available until the end of October 2020. There are only two months left for the suppliers to develop and test their own systems to adapt to this SCIP Database and prepare all information for notification. Obtaining the required information from international supply chains, and making validation and notification to SCIP system, are quite time consuming for suppliers.

2.95. (EU) 2018/851 stipulates that member States shall bring into force their own laws, regulations and administrative provisions necessary to comply with this Directive by 5 July 2020. However, to date, many EU member States haven't yet transposed this Directive into their national legislation, which would affect the effective and consistent application of the Directive. REACH 33(1) only requires the suppliers to provide the recipient of the article with sufficient information to allow safe use of the article including, as a minimum, the name of that substance. However, the current SCIP Database requires more data to be notified, i.e., among others, Primary Article Identifier, Article category, Production in European Union, Linked Article, and Material category. It is recommended that ECHA assesses the proportionality, necessity and impact of data required other than those specified by REACH 33(1), and launches an industry-wide consultation process for the extra requirements. The notification of the articles containing SVHCs above 0.1% via SCIP Database is a legal obligation defined in (EU) 2018/851, the delayed submission of such information will definitely create compliance risks for the suppliers who provide the products on EU market. China respects the EU's efforts to promote a circular economy but hopes that EU can provide the industry with a sufficient transitional period to better implement these new regulations.

2.96. In response, the representative of the European Union provided the following statement. The SCIP Database is an important step to ensure traceability of Substances of Very High Concern in materials and products. It will bridge the current gap in the information flow to support waste operators to improve their waste separation and recycling techniques and processes. This will benefit both the circular economy and the objective of a toxic-free environment. As provided for in the revised WFD, from 5 January 2021 onwards EU suppliers have the responsibility of fulfilling the obligation of providing information to the ECHA on substances of very high concern in articles and products. EU suppliers include EU producers and assemblers, EU importers, and EU distributors of articles and other actors who place articles on the market. Companies outside of the EU are not subject to this obligation and are not allowed to submit SCIP notifications. However, importers of articles in the EU need to turn to their non-EU suppliers and request information that they need to provide to the SCIP Database.

2.97. The European Union understands the diversity and complexity of supply chains of industries, as well as the challenges that businesses are facing in fulfilling the obligation mandated by Article 9 of the WFD. In this context, the European Union would like to note that certain information should already be communicated to EU suppliers for them to fulfil their obligation under Article 33 of the REACH Regulation. Therefore, the Commission expects that, to a certain extent, suppliers can build on arrangements put in place to comply with the existing obligation under Article 33 of the REACH Regulation to provide information on the presence of substances of very high concern in articles. The support and collaboration of non-EU suppliers is important to ensure the achievement of the objectives of the SCIP Database. The European Union encourages non-EU suppliers to support their EU customers by providing them the necessary information about the presence of Candidate List substances in their supplied articles. The Commission and ECHA have put all efforts to ensure compliance with the legal obligation within the prescribed two years. Over the last 21 months, ECHA

[18] For previous statements follow the thread under IMS ID 655 (under dates raised and references).

has been developing the database in close consultation with the Commission services, the member States and the stakeholders with the objective to meet the legal deadline. ECHA has published the "Detailed information requirements for the SCIP Database"[19] and in its SCIP format[20] already in autumn 2019. ECHA has also provided extensive information for guidance and assistance to duty holders on its dedicated SCIP webpages.[21]

2.98. ECHA made the first version of the SCIP Database available in February 2020, nearly one year in advance of the deadline, to allow industry to get familiar with the technical functions of the database and test it in a "live" situation. ECHA announced that, on 28 October 2020, the SCIP Database will be formally opened up for submitting notifications to comply with the legal obligation, two months in advance of the entry into application date of the legal duty. A new manual on information requirements has been published on 23 October 2020. The manual assists users in complying with their obligations, to identify the duty holders and the articles within the scope of the notification and explains the information required in a SCIP notification. The obligations of the revised WFD need to be transposed into the national law of EU member States and will be enforced by EU member States. The Commission is monitoring the transposition of Directive 2018/851 by EU member States including verification of the conformity of the national transposition measures once notified to the Commission. The European Union remains available to provide replies with regard to the SCIP Database to interested Members.

2.1.2.16 Tajikistan - Additional inspection control of imported food products for palm oil content (IMS ID 656[22])

2.99. The representative of the Russian Federation provided the following statement. Russia expresses its concern regarding Government Resolution of Tajikistan № 260 of 1 May 2020 that introduced a ban on imports of palm oil and instructs Tajikistan's authorities to conduct laboratory inspection control of imported food products to identify if they contain palm oil as an ingredient. We recognize Tajikistan's right to protect public health. However, this protection shall be in line with Tajikistan's international obligations, specifically, WTO provisions. In this regard we would like to highlight the following points. Firstly, the Resolution in question introduced mandatory laboratory inspections. Such requirements represent conformity assessment procedures and should be notified to the WTO under Article 5.6 of the TBT Agreement to allow interested Members to submit comments. Secondly, Tajikistan should have provided the transition period for adaptation to new requirements of not less than six months after publication of new requirements. Unfortunately, neither notification nor reasonable period of time to adapt have been provided by Tajikistan. Thirdly, the Resolution does not contain similar requirements for domestic manufacturers. In this regard, Tajikistan seems to act not in compliance with national treatment obligation of Article 2.1 of the TBT Agreement. Fourthly, the Resolution does not specify schemes and procedures for laboratory inspection control upon importation which creates uncertainties for exporters for all kinds of food products containing edible oil. Russia requests to suspend the Resolution, notify it under the TBT Agreement, consider the comments of the WTO Members and take them into account. We urge Tajikistan to eliminate all discriminatory provisions of the Resolution and bring it in conformity with WTO rules. Russia remains open for bilateral engagement with Tajikistan on this and other issues.

2.100. In response, the representative of Tajikistan provided the following statement. I would like to thank the Russian Federation for their interest and exchange of views well ahead of this meeting. While the issue is being reviewed by the capital I want to share the following updates. According to Item 1 of the Resolution № 260 dated 1 May 2020 the import of all types of palm oil, with the exception of its import as a raw material for industrial processing and production of final products are prohibited into the territory of the Republic of Tajikistan. Accordingly based on Paragraph 2 Item 3 of the Resolution the Committee for Food Security was instructed, together with the ministries of industry and new technologies, health and social protection of population, the Agency for Standardization, Metrology, Certification and Trade Inspection within two months bring normative and technical documentation on food products, in the production of which the use of palm oil is envisaged in compliance with the requirements of this regulation. Based on scientific evidences palm

[19] https://echa.europa.eu/documents/10162/28213971/scip_information_requirements_en.pdf/9715c4b1-d5fb-b2de-bfb0-c216ee6a785d

[20] https://echa.europa.eu/scip-format

[21] https://echa.europa.eu/scip-database

[22] For previous statements follow the thread under IMS ID 656 (under dates raised and references).

oil is a harmful product, the consumption of which increases the level of cholesterol in the human body, causes heart disease, stroke, gastrointestinal tract, diabetes and obesity, as well as adversely affects human genetics, leading to cancer and infertility.

2.101. According to the norms set by the World Health Organization, the daily intake of non-dietary fats, including palm oil, should not exceed 1%. Currently palm oil is widely used in the production of baby food, confectionery and dairy products. In particular, there are cases of adding palm oil to the composition of ice cream, sour cream, cream, butter, confectionery and other foodstuff in the food industry of the country. Unfortunately, most foreign and domestic manufacturers do not provide the necessary information on the use or existence of palm oil in the packaging or label of the product, which contradicts the relevant provisions of the TBT Agreement. Please note that the Resolution is in compliance with WTO rules particularly with Article XX of GATT (General Exceptions) sub-paragraph (b) necessary to protect human, animal or plant life or health. According to available information at present due to harmful effects of palm oil on human health, its import and use is restricted in some countries, and the legislation of some countries including the Russian Federation imposes additional customs duties on its import. Finally, my delegation stands ready to discuss the issue bilaterally.

2.1.2.17 France - New legislative requirements about index of repairability of electrical and electronic equipment (IMS ID 657[23])

2.102. The representative of China provided the following statement. China supports France's efforts to fight against waste and boost the circular economy and looks forward to the consideration of replies to our concerns. With the wide scope of electronic and electrical equipment, the mandatory requirements may have a significant impact on the design, production and sales of electronic and electrical equipment for manufacturers. China requests France to notify the contents relating to article L541-9-2 of France Environmental Code as well as a draft decree in the Council of France relating to the method of calculation and the information signage for consumers of the obligatory reparability index for electrical and electronic products sold in France, so that other WTO Members can comment. It is recommended that France provides a reasonable transition period for the implementation of article L541-9-2 of the France Environmental Code. Article L541-9-2 of the France Environmental Code will take effect on 1 January 2021. However, key elements such as the products that are subject to the new requirements, the testing methods and standards, and the conformity assessment methods necessary for the implementation of the new requirements are not released. The COVID-19 epidemic also added difficulties for the enterprises to adapt to the new requirements. According to Article 2.12 of the TBT Agreement, China requests France to postpone the application of this requirement to at least one year after the publication of the list of relevant equipment, the standards, calculation methods and compliance methods of the index of reparability, or provide different transition periods according to the complexity of the structure of electrical and electronic equipment.

2.103. In response, the representative of the European Union provided the following statement. France has notified this draft decree to the WTO, as well as the related draft orders, on 23 October 2020, the day after the above-mentioned draft texts had completed their intra-EU assessment. These notifications are currently being processed by the WTO Secretariat. French Law n ° 2020-105 of 10 February 2020 relating to the fight against waste and the circular economy provides in Article 130 for the entry into force on 1 January 2021 of the provisions provided for in Article 16 relating to the implementation of a reparability index on electrical and electronic equipment. However, the checks and penalties for failure to make the reparability index available to consumers or for incorrect calculations will only be applicable from 1 January 2022, in accordance with the provisions of the same article 130 of the law. This provision reflects the consideration of the need for economic actors for an adaptation period for the deployment of the measure in the first year of implementation.

2.1.2.18 European Union - Waste Framework Directive (IMS ID 658[24])

2.104. The representative of India provided the following statement. The Republic of India understands and supports the EU's efforts on waste management but is strongly concerned about EU's Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 (Amendment to 2008 WFD) which adversely affects the Indian exporters to the EU. India would

[23] For previous statements follow the thread under IMS ID 657 (under dates raised and references).
[24] For previous statements follow the thread under IMS ID 658 (under dates raised and references).

appreciate if the EU could respond to this concern in writing. *The Scheme*: The revised EU WFD obliges suppliers to provide, starting from 5 January 2021, details of articles placed in the EU, to ECHA. This Directive seeks information on substances of very high concern from the Candidate List that is maintained with REACH which are present in the supplied articles. Furthermore, while this information can be supplied directly by the manufacturers based in Europe, the same is not possible for the manufacturers from outside of the EU, who have to engage an intermediary (i.e. Only Representative) to provide the information.

2.105. *Negative impact*: This measure bears the following effects on the exporters of articles to the EU. It increases the administrative burden on the business operators and the industry. It imposes additional costs. Its negative impact on the Micro, Small and Medium-sized Enterprises (MSMEs) will be detrimental. For non-EU Members, it increases additional barriers. As per the Directive, the responsibility for fulfilling the requirements of ECHA in line with REACH lies with the importers established in the European Union. Since manufacturers or exporters cannot directly provide the information to ECHA, they will be forced to contract a representative established in the European Union to undertake the required registration process. This requirement is applicable to all manufacturers, exporters, and distributors, regardless of the quantity of article placed in the EU. This will add to the increase in costs and also act as a barrier to trade for non-EU countries, particularly because: suppliers who place less than 1-tonne quantity of the article annually are also required to engage a representative, which they were previously not required to do if the article contained SVHCs; distributors, etc., also have to comply with this obligation, which creates duplicity of notification requirements, since the manufacturer may already have provided the relevant information to the ECHA.

2.106. *WTO Agreement Violation*: Under the Transparency and Notification obligations of the TBT Agreement, Members are required to notify all new measures. It is observed that no notification has been made by the EU or the EU member States to the WTO before they transpose and implement this legislation. *Action Sought from EU*: Given the above, India would like to request the EU to: notify this measure to WTO; and defer implementation of this measure until the comments are received from the Members.

2.107. The representative of the United States provided the following statement. We appreciate the opportunity to raise this new concern regarding Directive (EU) 2018/851 of the European Union and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste. Specifically, we are hearing concerns from industry regarding the information reporting requirements associated with the new Substances of Concern In articles as such or in complex Products (SCIP) Database (SCIP) chemicals database being created by ECHA. We appreciate that ECHA has been working with industry over the last two years on the development of the database, including holding several stakeholder workshops. However, there are several remaining concerns. We are aware that there have been several delays in the roll out of the database and now there will be a very short timeframe between when the database is expected to be finalized in October and when companies have to fully comply with the reporting requirements in January 2021. We also understand that the reporting requirements for substances of very high concern (SVHC) have been greatly increased, expanding the number of mandatory elements from two to seven and including additional information elements. Furthermore, we are hearing concerns from industry about the protection of their intellectual property as the database will be public. We understand that these concerns are shared by European, Asian, and North and South American industries and that industry has asked for a one-year delay to work out the remaining implementation issues with the database and to provide time for companies to obtain the information from their suppliers. How do you intend to address these concerns? Are you considering a delay? In your view, is just over two months really enough time for industry to be able to get up to speed on a new system for reporting on additional elements for what is sometimes thousands of product components? What happens if member States have not transposed the requirements into their legislation by January 2021?

2.108. The representative of Canada provided the following statement. Under Article 9.2 of the WFD, the ECHA was under the legal obligation to establish the SCIP Database by 5 January 2020. However, despite a recently announced date for the formal launch of the database of 28 October 2020 – which is today - the legal obligation for importers and suppliers to input data into the database remains unchanged, and legal enforcement will apply from 5 January 2021, which is only two months away. Operators have lost the expected transition period built in the Directive to assess, prepare, and input the information in the SCIP Database. This has caused significant concern among Canadian industry stakeholders, who, despite their best efforts at preparing for this change, now

fear they may lack the time required to have their data recorded in the database. Complex products will require numerous notifications, whose parameters, details and format have only been confirmed and finalized by ECHA in past weeks. The EU borders will be a clear checkpoint for enforcement of the Directive on foreign goods entering the EU, and Canada is concerned that the various degree of independence in member States' enforcement mechanisms will affect the homogenous application and enforcement of the database across the EU as of 5 January 2020. In light of this, Canada respectfully requests that the EU delay the entry into effect of the SCIP Database for at least one year to give operators and member States the time to further comply with the requirements.

2.109. In response, the representative of the European Union provided the following statement. The EU refers to its statement under item 2.1.2.15 .[25] I am aware that this measure causes concern among importers to the EU, so the EU is open to bilateral contact provided they are available to reply bilaterally to Members. I suspect that this point will stay in the Committee for a while so I would ask Members to put everything in one point. I simply note that this is the same issue as STC 17.

2.1.2.19 European Union - Wine labelling requirements – listing of importers for multiple destinations (IMS ID 659[26])

2.110. The representative of Australia provided the following statement. Australia understands that, following the end of the Brexit transition period, the UK intends to roll over existing EU wine laws and regulations. As the EU would be aware, this will mean that from 1 January 2021, wine imported into in the UK, either in bulk or in bottles, and sold in the UK will require the name and address of a UK-based importer on the label. We understand that this will be the same as the requirement that currently applies, and will continue to apply to bottled wine sold in the EU market. Given that wine is regularly exported to the EU through the UK, it would be logical for wine to give details of both EU and UK importers on a single label; and ensure trade can continue uninterrupted and without additional expense to wine producers. Under EU regulation, we understand that an indication of the "importer" is a compulsory indication for wine imported into the EU (under Regulation No. 1308/2013 and Delegated Regulation 2019/33) to identify the natural or legal person or group of persons importing the wine into the EU. We are supportive of the EU's objective of clearly identifying the business food operator, i.e. the person assuming responsibility for bringing the wine into circulation in the EU, and not misleading consumers.

2.111. However, we are requesting that the EU ensure its labelling requirements are no more trade restrictive than necessary to achieve the EU's objectives. We believe that the EU allowing an "optional particular" on labels to cover importers in other third countries would be consistent with the EU's objectives, while still clearly identifying the EU importer and person assuming responsibility, for example: "For the EU, imported by:" and "For the UK, imported by:". Australia is seeking clarity from the EU whether under current EU regulation it is possible to list importers for multiple destinations on the same wine bottle label. Further guidance and clarity are important to provide certainty to traders and ensure no interruptions to trade occur at the end of the Brexit transition period. We look forward to working closely with the EU on this issue in coming weeks to ensure a mutually satisfactory outcome by the end of the Brexit transition period and we are continuing similar discussions with the UK to resolve this issue for wine imported into the UK.

2.112. In response, the representative of the European Union provided the following statement. The EU points out that the indication of the "importer" is a compulsory indication for wine imported into the EU and that the importer is a natural or legal person or a group of such persons established in the EU. Any other indication on the label mentioning the entity that brought the wine into another third country before import into the Union could be only acceptable as an optional particular, provided it does not appear in combination with the words "importer" or "imported by (…)" and is not misleading for consumers as regards the business food operator (i.e. the person assuming responsibility for bringing the wine into circulation in the EU).

[25] European Union - Information requirements in SCIP Database (IMS ID 655).
[26] For previous statements follow the thread under IMS ID 659 (under dates raised and references).

2.1.2.20 India - Phthalic Anhydride (Quality Control) Order, 2019, G/TBT/N/IND/116 (IMS ID 660[27])

2.113. The representative of the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu provided the following statement. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu would like to express our concerns over the Order of India's Ministry of Chemicals and Fertilizers on Phthalic Anhydride, published on 23 April 2020. The draft measure was notified by India to the TBT Committee as G/TBT/N/IND/116 on 25 November 2019. The Order came into force on 23 October 2020. Given this Order is part of a series of 22 orders on chemicals notified by India since 2019, our concerns expressed in item 2.1.3.10 [28] will also apply to this measure except that we would like to focus on three points of concerns here. Firstly, the annual factory visit requirement remains as our major concern over the Order. Implementation of such requirement creates additional costs and extra burden for manufacturers located outside India. The COVID-19 pandemic makes the situation even worse for foreign manufacturers because the access of their products to Indian market is tantamount to a factual denial when arrangement for a factory inspection visit is not possible due to the restrictions of cross-country travel. Moreover, it is hard to be optimistic that the travel restrictions will be lifted at any time soon as the confirmed cases are still rising. This makes it more difficult, if not impossible, for foreign manufacturers to comply with the said requirement even if they are willing to do so. We thank India for giving another 90 days to postpone the effective date of this measure to 17 January 2021, which however in our view is still difficult for our manufacturers to complete the required procedures. To this end, we take this opportunity to recommend that the Indian Government consider a suspension of or a temporary exemption from the on-site factory visit requirements for foreign manufacturers during the period of COVID-19 pandemic.

2.114. If India still considers on-site visit necessary, we suggest that the Indian authorities consider alternative measures temporarily adopted in response to the severe circumstance of pandemic, such as authorizing or commissioning qualified inspection bodies located in the exporting Members (e.g. inspection bodies accredited under the ILAC-MRA framework) to perform on-site factory visits on its behalf at least during the COVID-19 pandemic to mitigate the severe difficulties faced by foreign manufacturers. In this case, the Indian inspection agency can still participate remotely through video conference and/or supplementary document reviews. Similar approaches, i.e. alternative procedures to enable compliance to be checked by remote or electronic means, have also been adopted by some WTO Members as indicated in the document "Standards, Regulations and COVID-19 – What Actions Taken by WTO Members?" prepared by the WTO Secretariat. We would like to urge India to take these alternative procedures into consideration so that the impact of COVID-19 on trade in goods can be reduced. My government adopted temporary measures to assist foreign manufacturers in meeting the requirements for factory visit/inspection in response to the impact of COVID-19 pandemic. The inspection is performed remotely, following the practices stated in IAF MD4:2018 "IAF Mandatory Document for the Use of ICT for Auditing/Assessment Purposes" and supported by document review. An on-site visit/inspection shall be arranged within six months after the travel restriction is lifted. If India is interested in detailed practices of our approach, we will be pleased to share our experiences. We would be grateful if India would take the above-mentioned comments into account and reflect in the implementation of the Order accordingly.

2.115. In response, the representative of India provided the following statement. We thank the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu for their interest in the matter. The concern raised is noted, and the matter is under examination.

2.1.2.21 Viet Nam - Decree No.17/2020/ND-CP, G/TBT/N/VNM/116/Add.2 (IMS ID 661[29])

2.116. The representative of Thailand provided the following statement. Thailand would like to thank Viet Nam for amending Decree 116/2017/ND-CP which has been promulgated in Decree No.17/2020/ND-CP. We are glad to learn that Viet Nam took Thailand's requests and accepted ISO 9001 certificate and IATF 16949 certificate, prescribed in document no. 8753/BGTVT-KHCN dated 4 September 2020, as documents to ensure conformity of production. However, there are some remaining difficulties which our manufacturers and exporters have faced, as a result of Decree

[27] For previous statements follow the thread under IMS ID 660 (under dates raised and references).
[28] India - Quality Control Orders for Chemical and Petrochemical Substances (IMS ID 630).
[29] For previous statements follow the thread under IMS ID 661 (under dates raised and references).

17/2020/ND-CP implementation and some required practices, regarding emission test for type assessment and additional documents required by Viet Nam authorities during COVID-19 epidemic. First, Viet Nam mandates every model in each type of vehicles is subject to the emission test for type assessment which is not in compliance with international practices. We would like to remind Viet Nam that the TBT Agreement requires that technical regulations shall be not more trade restrictive than necessary to fulfil a legitimate objective and not create unnecessary obstacles to international trade. Therefore, we request Viet Nam to test only one vehicle that is the representative of the type with the highest emission level to ensure all other models in that type will meet the emission requirement.

2.117. Secondly, during the COVID-19 pandemic, Viet Nam authority allows importers to submit COP certificate, ECE certificate or UNECE certificate, instead of testing facility. We found that Viet Nam requires Thai importers to submit additional document after submitting COP certificate, ECE certificate such as list of equipment and instrument used in production process including detailed information of its numbers and manufacturing dates. We consider that the additional document requirement may cause difficulties and create unnecessary obstacles to trade between Thailand and Viet Nam. In this regard, we would like to request Viet Nam if Viet Nam could possibly waive the mentioned additional document in order to facilitate trade between us. Lastly, we would be grateful if Viet Nam takes our concerns into consideration and amends the above-mentioned issues which are also found in our written comments.

2.118. The representative of Japan provided the following statement. Japan would like to share concerns regarding Decree No.17/2020 expressed by Thailand. We welcome the amendment of the Degree 116/2018 by the Decree 17/2020. Japan would like to request that Viet Nam ensure that the operation of these revised regulations will not be more trade restrictive than necessary.

2.119. In response, the representative of Viet Nam provided the following statement. Viet Nam would like to thank Thailand and Japan for conveying your concerns on the implementation of Decree 17/2020/ND-CP of Viet Nam. Decree 17/2020/ND-CP was notified to WTO Members on 28 April 2020 in notification G/TBT/N/VNM/116/Add.2, which clearly indicated that the amended and supplemented provisions of Decree 116/2018/ND-CP came into force on 5 February 2020. Decree No. 17/2020/ND-CP also requires COP assessment at the relevant foreign facility to ensure the conformity of production in a non-discriminatory manner. However, on-site COP assessment of a foreign facility is impossible in the COVID-19 pandemic. To avoid disruption of trade, Viet Nam has temporarily postponed the requirement and just accepted ECE, EC, or IATF16949 certificate as evidence of conformity of production. The on-site COP assessment will be resumed onward and retroactively when a respective exporting country declares free from COVID-19. For the purpose of the on-site assessment, an "Information Sheet" is provided for manufacturers to fill in the necessary information. Please note that this form is applicable to both domestic and foreign manufacturers. Since on-site assessment of a foreign facility cannot be made during this COVID-19 pandemic, the importers are only asked to provide general information about the manufacturer and its products. The remainder of the form will need to be filled in after the on-site COP assessments are performed. Having explained that, we would like to emphasize that Viet Nam is open, flexible to facilitate trade and address any concerns. We are ready to provide additional information or explanation to Thailand and Japan if they so wish through bilateral consultations.

2.1.2.22 Panama - Onions and Potatoes Harvest Life and Sprouting Requirements, G/TBT/N/PAN/86, G/TBT/N/PAN/102, G/TBT/N/PAN/102/Add.1 (IMS ID 662[30])

2.120. The representative of the United States provided the following statement. In 2016 and 2019, Panama notified its onion and potato regulations, respectively, to the TBT Committee, establishing a harvest date requirement, a sprouting limit, and temperature and storage criteria. We commented on both measures, and the US Embassy in Panama discussed our concerns with Panamanian officials many times. Our concerns were not addressed. We thank Panama for delaying implementation of the potato regulation until 2 January 2021. We request that Panama postpone the harvest date and sprouting requirements from both regulations and notify the TBT Committee of these regulatory changes. The harvest date requirement and sprouting limit for potatoes and onions are unnecessary and are not commercially viable. Panama has not provided scientific justification for these requirements. For both products, the retailer and the consumer visually inspect the product before

[30] For previous statements follow the thread under IMS ID 662 (under dates raised and references).

purchasing. Quality defects such as sprouting and rot are easy to see, and the consumer has the choice of whether to buy the product.

2.121. Panama has provided no scientific assessment of the adverse health effects from consuming sprouts – most consumers simply cut them off or choose not to buy them. To be clear, we are not asking Panama to remove the restriction on rotten vegetables. The United States is not aware of any shipments of rotten vegetables to Panama. Panama's measures also deviate from the relevant international standard in the Codex Alimentarius. The relevant Codex standard specifically excludes fruits and vegetables from "best by" labelling. What is the justification for Panama's deviation from this standard? US onion exports have already been negatively impacted. In February, Panama detained a number of shipments and destroyed US onions for non-compliance with the harvest date requirement. US onion exports to Panama have dropped 72% compared to last year. US potato shipments will also be unable to comply with the harvest date requirement. We also ask Panama to clarify the purpose of the temperature and storage requirements. If they are for SPS-related reasons, Panama should suspend this part of the regulations until it has notified them to the SPS Committee and considered comments submitted.

2.122. In response, the representative of Panama provided the following statement. We have maintained contact with both the delegation of the United States and our capital so as to address this concern. We will continue such efforts. In the meantime, we take note of the comments made today, which I will forward to my Ministry. We hope that we will soon have some information to share with this Committee.

2.1.2.23 United Kingdom - Wine labelling and documentation requirements at the end of the Brexit transition period (IMS ID 663[31])

2.123. The representative of Australia provided the following statement. Australia would like to seek clarification on the labelling and paperwork requirements that will apply to wine imports into the United Kingdom after the Brexit transition period. Our wine industry is concerned with the current lack of clarity around the requirements despite the Brexit transition period scheduled to finish at the end of year. Australia understands that, following the UK's exit from the European Union, the UK intends to roll over existing EU wine laws and regulations. However, it is still not clear what labelling requirements will apply to agri-food products exported from the UK to the EU, including, for example: Australian bulk wine bottled in, and then re-exported from the UK; as well as bottled wine exported to the UK, some of which may be transhipped to other markets. We are interested in ensuring there is the flexibility to allow the listing of importers for multiple destinations on the label on wine bottles imported into the UK. We believe it is possible to include a UK importer, as well as importers in other third countries and still meet regulatory objectives post-Brexit transition period, for example: "For the UK, imported by:" and "For the EU, imported by:". Our industry is also concerned with the lack of clarity on the documentation requirements for imported wine following the Brexit transition period. It isn't clear whether a VI-1 form, or its equivalent, will be required to import into the UK, and then whether a separate, additional, VI-1 form will then be needed to export from the UK to the EU; and whether similarly an additional VI-1 form is needed if wine is exported to the EU and then exported to the UK. Australia recognizes the United Kingdom's right to regulate, but we would like to seek the UK's assurance that the certification paperwork and labelling requirements required for the UK market will not be overly burdensome and create undue delay and costs. We want the UK to ensure any labelling and paperwork requirements are no more trade restrictive than necessary to achieve their objectives and look forward to working closely with the UK on this issue to ensure a mutually satisfactory outcome by the end of the Brexit transition period.

2.124. The representative of Uruguay provided the following statement. Our delegation has indicated to our peers in the United Kingdom, in various forums, its interest in understanding the regulatory requirements and conditions that will apply to various agricultural exports from Uruguay once the transition period established in the Agreement on the United Kingdom's withdrawal from the European Union has expired. In that regard, since the United Kingdom has been the main destination for Uruguayan wine exports to the European Common Market in recent years, our delegation wishes to express its interest in receiving detailed information on the regulatory requirements and conditions, including for documentation and labelling, that will apply to wine imports to this Member's market as of 1 January 2021.

[31] For previous statements follow the thread under IMS ID 663 (under dates raised and references).

2.125. In response, the representative of the United Kingdom provided the following statement. The United Kingdom would like to thank Australia and Uruguay for their interest in our wine labelling and documentation requirements following the end of the United Kingdom-European Union transition period. We would also like to thank Australia for the constructive engagement we have had on this topic bilaterally. We look forward to reviewing Uruguay's comments in due course. As detailed in the United Kingdom's statement of the 26 February 2020 under Article 15.2 of the TBT Agreement, (contained in document G/TBT/2/Add.128, the United Kingdom ceased to be a member State of the European Union on 31 January 2020. The United Kingdom and the European Union agreed to a transition period, due to end on 31 December 2020, during which the large majority of European Union law continues to apply in the United Kingdom. The European Union Withdrawal Act 2018 preserves and incorporates into our domestic law, those elements of European Union law which will apply in the United Kingdom at the end of that transition period. The United Kingdom Government announced on 14 October 2020 measures setting out requirements for importer details and wine product labels for products to be marketed up until 1 October 2022. Until that date, wine marketed in Great Britain can show either a United Kingdom or a European Union importer on the label. If there are later changes after that date, we will notify interested parties. From the 1 January 2021, the United Kingdom will continue to accept European Union wine import certificates (VI-1). These arrangements are set out in the Common Organization of the Markets in Agricultural Products and Common Agricultural Policy (Miscellaneous Amendments) (EU Exit) Regulations 2019.

2.126. Provisions relating to the operation of United Kingdom VI-1 arrangements, including the pro-forma of the United Kingdom VI-1 form, are contained in the Agricultural Products, Food and Drink (Amendment etc.) (EU Exit) Regulations 2020 and The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 as read in parallel with the appropriate retained European Union law. Further details of the labelling and certification measures being introduced will soon be available on the UK Government website.[32] Arrangements relating to imports, exports and movement of wine will all be subject to simplified procedures as set out in the United Kingdom/Australia Agreement on Trade in Wine upon its entry into force. From the 1 January 2021, wine bottled in the United Kingdom and re-exported to the European Union will continue to be subject to European Union rules. The United Kingdom takes note that Australia has sought assurances that our processes will not be overly burdensome. We will work closely with the industry to ensure a streamlined system is developed, ensuring that any labelling and documentation requirements are no more trade restrictive than necessary to achieve our policy objectives. The United Kingdom welcomes further bilateral engagement with Australia and Uruguay if additional clarification is necessary.

2.1.2.24 United States - Revised Origin Marking Requirement for Goods Produced in Hong Kong (IMS ID 664[33])

2.127. The representative of Hong Kong, China provided the following statement. Hong Kong, China would like to express its strong objection to the revised requirement promulgated by the United States Customs and Border Protection (USCBP) that affects goods produced in Hong Kong and imported into the US. On 11 August 2020, the USCBP published a notice that, after 25 September 2020, goods produced in Hong Kong must be marked to indicate that their origin is "China" for the purposes of the origin marking requirement set forth in Section 304 of the Tariff Act of 1930, 19 U.S.C. § 1304. By a subsequent notice, the USCBP extended the date for compliance with this requirement to 9 November 2020. The US' measure arbitrarily dictates the name to be used on the origin marking without regard to the facts, prevailing commercial practices and relevant WTO rules. It in effect deprives the rights of Hong Kong products being marked "Hong Kong" in their origin markings. The US' measure constitutes a "technical regulation" under the TBT Agreement and such technical regulation is inconsistent with the TBT Agreement as the US does not accord to products imported from Hong Kong treatment no less favourable than the treatment that it accords to like products originating in other countries. In mid-September, Hong Kong, China wrote to request the US to withdraw such measure with immediate effect and sought bilateral discussions with the US with a view to resolving the matter in our mutual interests. We also took the opportunity at the General Council meeting on 13 October and the Committee on Trade Facilitation meeting on 20 October to register our concerns. Regrettably, the US has so far not withdrawn the measure. As a result, earlier today, Hong Kong, China filed a request for consultations with the US in accordance with the rules and procedures of the WTO dispute settlement mechanism and relevant provisions in

[32] https://www.gov.uk/

[33] For previous statements follow the thread under IMS ID 664 (under dates raised and references).

the WTO agreements. We urge, again, the US to honour its commitment under the TBT Agreement, take necessary actions to ensure its compliance with the Agreement as well as other rules under the WTO, and withdraw immediately its revised origin marking requirement on Hong Kong products.

2.128. In response, the representative of the United States provided the following statement. The United States has no comment.

2.1.3 Previously raised concerns

2.1.3.1 China - Requirements for information security products, including, inter alia, the Office of State Commercial Cryptography Administration (OSCCA) 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS) (IMS ID 294[34])

2.129. The representative of Japan provided the following statement. Japan continues to have concerns regarding China's "Regulation on the Administration of Commercial Cipher Codes" and "Cyber Security Multi-Level Protection Scheme". Japan would like to refer to the previous statement which we made at the last TBT Committee in May 2020. With respect to "Regulation on the Administration of Commercial Cipher Codes", we recognize that the public consultation was completed on 19 September 2020. Since Japan provided comments primarily concerning the following points, Japan would like to request that China consider these points and reflect them in the regulation. Japan requests China to clarify the definitions of terms, the concrete requirement for review, and the scope of the regulation. Japan asks China to make certain that foreign companies' market access to China will not be hampered and that confidential technology will not be leaked. Japan requests China to ensure that the development of relevant regulations and procedures be consistent with international standards and practices. Japan would like to request that China provide relevant information regarding the current revision process and that the regulations would be implemented transparently.

2.130. The representative of the European Union provided the following statement. Regarding the MLPS, the EU would like to refer to its comments and points raised in its statement at previous TBT Committee meetings, namely concerns around (i) the further extension in scope of protection Level 3 and above; (ii) the nature of the expert review that the guidelines prescribe; and (iii) a lack of clarity in certain definitions, and subsequent unwarranted and significant market entry restrictions. The EU calls for enhanced proportionality and transparency in the implementation of the Cyber-MLPS, instead of introducing burdensome requirements and broadening the scope of Level 3 networks. The EU also asks China to confirm whether the draft will be notified to the WTO for comments, to allow for adequate participation of interested parties.

2.131. In response, the representative of China provided the following statement. Regarding the Multi-Level Protection Scheme (MLPS), as technology develops, in response to more complicated cybersecurity circumstances, information security MLPS needs to be improved. Based on experience in past years and responding to new development, Cybersecurity Law stipulates that China will carry out the cybersecurity MLPS, which is based on information security MLPS. To fulfil the requirements in Cybersecurity Law, regulations on cybersecurity MLPS is under drafting, which was published for comments in June 2018 and will replace the former administrative measures on information security MLPS.

2.1.3.2 China - Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council), G/TBT/N/CHN/1313 (IMS ID 428[35])

2.132. The representative of the Republic of Korea provided the following statement. Korea thanks China for engaging in-depth discussions and providing replies on the recognition of internationally accredited laboratories through bilateral and the multilateral channels including the WTO Committee meeting. We note China's reply that "qualified laboratories" under the draft revision of the regulation means testing organizations certified by the NMPA. However, we regret that China has not taken the opportunity to respond to our question on whether internationally accredited laboratories would also be recognized as NMPA-certified laboratories in China. Without China's reply to this question, Korea is led to believe that China will not recognize internationally accredited laboratories. Thus, Korea

[34] For previous statements follow the thread under IMS ID 294 (under dates raised and references).
[35] For previous statements follow the thread under IMS ID 428 (under dates raised and references).

urges China to respond specifically and clearly on whether the NMPA will recognize test results from internationally accredited or overseas laboratories. Korea also requests China to share related procedures if it plans to recognize the results from the overseas laboratories. If not, we invite China to consider recognizing results from internationally accredited or overseas laboratories through NMPA certification. This would reduce time and costs needed for the industry to prepare for the registration or authorization in China and help to facilitate trade. Lastly, we kindly ask China to share the information on the date of entry into force of the revised regulations currently under review by the judiciary branch once the timeline becomes finalized.

2.133. In response, the representative of China provided the following statement. At present, the competent authority is revising the "Regulations on the Supervision and Administration of Medical Devices" and will promptly announce to the public when the procedures are over.

2.1.3.3 China - Cyberspace Administration of China – Draft implementing measures for the Cybersecurity Review of Network Products and Services (IMS ID 533[36])

2.134. The representative of Japan provided the following statement. Japan has concerns regarding the Cybersecurity Review Measures and would like to refer to the previous statement which we made at the last TBT Committee in May 2020. At the last TBT Committee, China explained that the Cybersecurity Review of Network Products and Services is not to restrict nor discriminate against foreign products and services, and China welcomes foreign products and services to enter the Chinese market. Japan would like to request that China provide relevant information regarding the current revision process and that the regulations be implemented transparently.

2.135. The representative of the European Union provided the following statement. The EU has raised the Security Review of Network Products and Services, including the Cybersecurity Review Measures, in this Committee on several occasions, stressing our concerns related to these measures. The EU also submitted written comments to the public consultation. We understand that these Review Measures entered into force 1 June 2020. We remain concerned that the measures are quite general and very broad discretionary powers are left to the authorities in charge of the security review, raising concerns for foreign ICT operators. The measures are directed towards the purchasing activity of Critical Information Infrastructure (CII) operators by encouraging operators to apply for reviews in the case that they deem their purchase or procurement might pose a risk to the Chinese national security. Most European companies established in China would become suppliers or sub-suppliers of these operators, and therefore would also be affected by the reviews. The EU urges China to ensure the clarity, transparency and objectiveness of the security review so that the measure does not become a new market access barrier. For its specific comments, the EU refers to its statement at previous TBT Committee meetings and we would appreciate clarifications to our previously raised questions. Can China also please provide an update of this measure?

2.136. The representative of Canada provided the following statement. Canada would like to echo the points made by the European Union and Japan. Canada remains concerned by the absence of the following in the Implementing Measures for the Cybersecurity Review, which we understand were brought into force on 1 June without revision: clarity regarding what constitutes CII; defined criteria operators of CII are to use in assessing a security threat; and a clear commitment to national treatment, MFN treatment and the use of international standards.

2.137. In response, the representative of China provided the following statement. Cybersecurity review is an important system established by all Members. The main purpose is to strengthen supply chain security, to improve the security and controllability of CII, and to protect national security. This is also a common practice by many Members. The "Cybersecurity Review Measures" were implemented on 1 June 2020, and the "Cybersecurity Review of Network Products and Services" was repealed at the same time. This new measure is formulated based on summarization of years of working practices, on the experiences of relevant systems designed in developed Members, and on rounds of solicitation of opinions of all stakeholders. It is not aimed at specific Members or specific enterprises.

[36] For previous statements follow the thread under IMS ID 533 (under dates raised and references).

2.1.3.4 European Union - Amendments to the Directive 2009/28/EC, Renewable Energy Directive (IMS ID 553[37])

2.138. The representative of Colombia provided the following statement. Colombia wishes to reiterate its ongoing concern regarding Directive (EU) 2018/2001 of the European Parliament and of the Council, which establishes that, as from 2021, first generation biofuels shall account for a share of no more than 7% in the transport sector, and that first generation biofuels posing a high risk of indirect land use change (ILUC) shall have their contribution to the renewable energy share gradually reduced to 0% by 2030. In Colombia's view, these provisions are inconsistent with the national treatment and MFN obligations set out in the GATT 1994 and Articles 2.1 and 2.2 of the WTO TBT Agreement. We therefore reaffirm the arguments that have been presented at the TBT Committee meetings concerning this matter, which appear in document G/TBT/W/714 dated 2 March 2020. Colombia once again requests the EU to conduct a thorough review of the delegated act in 2021, in order to adopt an approach that enables sustainable palm oil to contribute to the EU's renewable energy targets. We would be grateful if the EU could share further information on the internal process to review the delegated act. We once again welcome the opportunity to comment on this matter and note that we understand that this matter is being addressed under the WTO dispute settlement procedures.

2.139. The representative of Guatemala provided the following statement. The systemic concern regarding this measure has been noted and will be followed up accordingly.

2.140. The representative of Ecuador provided the following statement. My delegation reiterates its concern regarding this measure. As a signatory to the Paris Agreement, Ecuador commends all efforts to meet climate targets. This involves incentivizing the use of raw materials that are both more efficient and environmentally friendly. We are of the view that palm oil, when obtained in accordance with sustainability criteria, can meet this goal. For this reason, we believe that the draft European Directive may not effectively ensure that the targets for cutting greenhouse gas emissions are met and, in its current form, will have a direct effect on oil palm. Any environmental measure for fulfilling the European climate agenda must be compatible with the multilateral trading system and should not be a means of arbitrary or unjustifiable discrimination, or a disguised restriction on international trade. Moreover, Ecuador continues to have concerns regarding the ILUC methodology and the characterizations based on general criteria used by the EU for the certification of biofuels, bioliquids and biomass fuels. We are concerned that, in terms of trade, the measure favours vegetable oils produced in the EU, which could contravene the principle of national treatment. For this reason, we would like to know on the basis of which criteria Annex V has been established. We are particularly concerned that the methodology in question may have a restrictive or even discriminatory effect.

2.141. Lastly, I would like to stress that Ecuador has made significant progress in meeting its national targets and commitments for mitigating and adapting to climate change. It is currently a world leader in the implementation of policies, measures and actions to reduce emissions from deforestation and forest degradation. This national commitment has also been taken on by the Ecuadorian palm-growing sector, which signed an agreement aimed at moving towards sustainable, deforestation-free oil palm production, with a roadmap setting out concrete actions to achieve zero-deforestation. Ecuador is the second country in the world to have met the requirements established by the United Nations Framework Convention on Climate Change to gain access to performance-based payments for reducing emissions from deforestation and forest degradation. Furthermore, this measure could have a negative socio-economic impact on the Ecuadorian palm-growing sector, which produced approximately 455,000 tonnes of crude palm oil in 2019. Crude palm oil accounts for 3.5% of the country's agricultural GDP, representing over USD 194.34 million. There are approximately 6,568 palm oil producers, of whom 88% are small producers with less than 50 hectares under production and 51% are small producers in small-scale family farming with less than 10 hectares under production. The importance of this sector lies in its socio-economic contribution to the country, with foreign exchange earnings from exports of around USD 216 million per year, according to the figures for 2019. The sector accounts for some 120,000 direct and indirect jobs throughout the production chain.

2.142. In response, the representative of the European Union provided the following statement. As indicated in many previous meetings, this issue of amendments to the EU Renewable Energy

[37] For previous statements follow the thread under IMS ID 553 (under dates raised and references).

Directive is now subject to WTO dispute settlement proceedings, notably under DS593 (EU – Certain measures concerning palm oil and oil palm-based biofuels). In order to preserve the integrity of such proceedings, the European Union will defer all discussions to that forum and accordingly refrain from discussing this matter in this Committee.

2.1.3.5 India - Air Conditioner and its related Parts (Quality Control) Order, 2019, G/TBT/N/IND/110 (IMS ID 598[38])

2.143. The representative of the United States provided the following statement. The United States remains concerned with the exclusive use of Indian standards for air conditioner (A/C) energy efficiency, application of separate energy efficiency requirements to component parts, and certification requirements by the BIS set forth in India's Air Conditioner and its related Parts, Hermetic Compressor and Temperature Sensing Control (Quality Control) Order, 2019 (Air Conditioners QCO). Many US companies use relevant international standards developed by the Air-Conditioning, Heating and Refrigeration Institute (AHRI) to verify the energy efficiency of their products, which are accepted in foreign markets and used extensively by the heating and cooling industry. The United States suggests that, to expedite availability of A/C equipment with documented verification testing records, BIS should also recognize, without further testing, equipment for which AHRI's Product Performance Certification Program has verified energy efficiency.

2.144. The United States notes that AHRI standards can provide greater specificity in energy efficiency evaluation than the comparable ISO standards for energy efficiency calculations. For example, AHRI standards define a specific testing approach related to test set-up and execution. By comparison, the ISO standards testing approach is less specific, which can cause testing results to vary widely due to variations in test set-up. The United States also notes that applying separate energy efficiency requirements to A/C component parts, including temperature sensors and hermetic compressors, does not accurately measure the energy efficiency of A/C systems. Fully-assembled A/Cs are designed to work as integrated systems to achieve energy efficiency targets, with the performance of each component impacting the performance of the other components, as well as the energy efficiency of the overall system. Thus, the stand-alone energy efficiency rating is not an accurate indicator of a component's energy efficiency when part of the overall A/C system. The United States understands that the choice of components in finished products is already a major consideration for manufacturers when designing products to meet energy efficiency requirements. Further, according to US industry, no other markets or relevant international standards apply separate energy efficiency requirements to component parts as a method of energy efficiency evaluation. Additionally, if India continues to apply separate requirements to component parts, the United States requests that India provide an additional one-year grace period to extend the implementation date for compliance with the requirements for component parts to 1 January 2022.

2.145. The representative of the Republic of Korea provided the following statement. Korea is grateful for suspending implementation of the regulations for seven months and accepting Korea's comments. However, due to corporate difficulties regarding this regulation, Korea would like to request the following from India. Korean companies have their manufacturing facilities not only in India but also in other countries to sell air conditioners to India. The factory inspection within India of BIS certification appears to be gradually resumed. However, the factory inspection within other countries from BIS was not conducted during the grace period, so the factories within other countries of Korean companies have faced difficulties in compliance with India regulations. Therefore, Korea would like to request for India to provide an additional six-month grace period or an exemption from factory inspection within other countries for BIS certification until BIS certification bodies could perform normal duties.

2.146. In response, the representative of India provided the following statement. India wishes to inform the Members that this STC was raised in the last three meetings. A detailed reply to the points raised was given in the earlier response in May. However, we would like to add that the request to provide a grace period was already agreed. A seven-month grace period was extended. The said QCO, Air Conditioner, and its related Parts (Quality Control) Order, 2018, now comes into force from 1 January 2021. There is no plan for further extension.

[38] For previous statements follow the thread under IMS ID 598 (under dates raised and references).

2.1.3.6 Kingdom of Saudi Arabia - Electrical Clothes Dryers Energy Performance Requirements and Labelling, G/TBT/N/SAU/987 (IMS ID 605[39])

2.147. The representative of the Republic of Korea provided the following statement. Korea is thankful for your responses to positive reviews of our comments in the May 2020 WTO TBT Committee Meeting that electrical clothes dryer energy efficiency standard (Saudi Standards, Metrology and Quality Organization (SASO) 2883) will be revised by the end of 2020. However, since that meeting, it has not been confirmed whether or not the standard has been revised. Korea would like to ask Saudi Arabia to share the timeline of the amendment process.

2.148. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia thanks Korea for raising this concern and we would like to point out that the SASO 2883:2017/AMD2:2020 "Electrical Clothes Dryers - Energy Performance Requirements and Labelling" has been revised and approved by SASO board on 9 July 2020. This amendment was published in the Official Gazette on 4 September 2020 and reflected on the Energy Efficiency Registration system (SLS).

2.1.3.7 China - Draft Administrative Measures for Registration of Overseas Producers of Imported Foods (IMS ID 611[40])

2.149. The representative of the United States provided the following statement. The United States remains concerned with China's draft "Administrative Measures for Registration of Overseas Producers of Imported Foods" (Administrative Measures) and urges China to reconsider putting in place such a restrictive and burdensome regulation. The measure appears to affect all food products, regardless of risk or whether foods are already subject to additional import certification requirements, such as seafood and dairy products exported to China. Furthermore, the draft measure requires foreign competent authorities to confirm that exporting manufacturers are in continuous compliance with China's laws, regulations, and standards. Such requirements would impose additional burdens on foreign competent authorities without regard to exporting country's regulatory resources and legal authority. We anticipate that the draft measure, if implemented, would likely create major trade disruptions for every country that exports food and agricultural products to China, including for developing countries whose competent authorities may have limited capacity to meet China's proposed requirements. During the May TBT Committee meeting, China indicated that it was still drafting this measure. Can China provide any updates to its timeline for completing the draft and notifying the measure to the WTO?

2.150. The representative of Brazil provided the following statement. On top of complexifying the registration and supervision of high-risk food products exported to China, the draft measure also expands the scope of products subject to registration procedures. If adopted, all Brazilian food producers who intend to export to China would need to provide pre-export registration following stricter requirements. The measure also creates new burdensome requirements related to food labelling. Our private sector estimates that, if applied as presented in the initial draft, the regulation could affect exports of meat, fish, milk, soy, sugar, animal and vegetable oil, coffee, fruits, vegetables, cereals, and cocoa, with the potential to also impact beverages. As far as we can ascertain, China has not published any regulatory impact assessment, risk analysis or technical document that presents the link between said regulation and the legitimate objectives it is willing to safeguard. The lack of information regarding the scientific grounds for this regulation raises concerns about transparency in the regulatory process undertaken by Chinese authorities. On top of that, by refraining from notifying the draft measure, China did not abide by its transparency obligations under either TBT or the SPS Agreements.

2.151. The Draft Administrative Measures for Registration of Overseas Producers of Imported Foods seems to grant discriminatory treatment towards imported food products in relation to those produced in China, which are not subject to the rules of such an onerous registration process. These procedures are more trade restrictive than necessary and they pose a great burden on producers and on the competent authorities of the exporting countries, without clearly demonstrating the gains in terms of food safety and health promotion. We kindly urge China to consider less trade-restrictive alternatives that could properly address its legitimate concerns. The proposed measure also departs from a relevant international standard, notably the Codex CAC / GL 38-2001 standard "Guidelines

[39] For previous statements follow the thread under IMS ID 605 (under dates raised and references).
[40] For previous statements follow the thread under IMS ID 611 (under dates raised and references).

for Design, Production, Issuance, and Use of Generic Official Certificates", by adopting a different registration model that is more costly than that contained in said standard. Therefore, we respectfully ask China to provide further details regarding how it plans to implement new burdensome requirements such as annual reports and inspections. We also urge China to consider defining reasonable transitional periods for producers and exporters to adapt to the regulation. We would deeply appreciate if China could present the scientific studies and risk analyses that supported the development of the draft measure, as well as the reasons and the technical basis for outsourcing inspection responsibility to the competent national authorities. For a greater certainty, we also ask China to present the exact coverage of the measure, elucidating to which products the measure shall apply. Finally, could China also commit to notify to the TBT Committee all of the next steps in the development of this regulation? Would China be able to provide time frames for the publication of the final regulation and its entry into force?

2.152. The representative of the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu provided the following statement. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu would like to thank China for updating the status of the proposed administrative measures at the previous meeting. We share the same concerns expressed by other Members. As the proposed measure would create impacts on a very broad scope of food products and enormous burden on foreign competent authorities, we would like to request China to provide further information on progress of the draft and the timeline for notifying it to the WTO TBT and SPS Committees.

2.153. The representative of the Republic of Korea provided the following statement. Korea supports concerns raised by other Members on the draft administrative measure. The revised administrative measure requires the registration of overseas producers of all imported food products. Such requirements would impose an enormous administrative burden and incur excessive time and cost on importing and exporting parties. Although Korea supports China's legitimate purpose, "food safety", applying the measure on all imported foods without scientific evidence or clear stipulation of processes would be more trade restrictive than necessary. Therefore, Korea believes that the measure should be carefully reviewed. During the last TBT Committee meeting, China mentioned its plan to notify the measure following the finalization of the revision to the TBT Committee. Thereby, Korea requests China to share the information on current revision status and the timeline for its notification.

2.154. The representative of the European Union provided the following statement. The EU is also very concerned about this measure as this will have a serious impact on importers into China. The delegation of the EU in China submitted extensive comments informally on the proposal and we would expect a revised version to be notified through WTO channels for formal consultation with trade partners before China undertakes any steps towards the adoption of such a far-reaching measure. As presented, the measure would bring substantial additional administrative burden for companies and competent authorities, including China Customs. The already long and time-consuming registration process will be further extended. The EU shares China's concerns as regards food safety. Nevertheless, measures have to avoid unnecessary constraints. They should conform to WTO agreements and Codex Alimentarius guidelines.[41]

2.155. Accordingly, inspection systems should be applied to particular commodities and processing methods, in proportion with the associated risks. The measure covers all food and beverages imported into China. This suggests that the rules proposed are applicable regardless of the risk associated with the products concerned. It will thus have a serious impact on the transaction costs of our trade, and very little impact, if any, on its safety. In other words, this measure appears highly disproportionate for products that are currently traded under a self-registration regime. The EU kindly requests that China explains the objective of this proposal and stands willing to discuss any legitimate concerns in order to find consensual solutions.

2.156. The representative of Mexico provided the following statement. The delegation of Mexico refers to the Draft Administrative Measures for Registration of Overseas Producers of Imported Foods, published by the General Administration of Customs of China (GACC) on 26 November 2019. These draft measures seek to replace Decree No. 145 on "administrative measures for registration of overseas producers of imported foods", issued by China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). Mexico submitted its concerns through the written procedure of the WTO TBT Committee in May 2020, which in general refer to the following: The

[41] i.e. CAC/GL 20-1995 on principles for food import and export inspection and certification

scope of the draft measures is unclear. The measures do not establish any categories or include a list of the products covered. The draft measures also include labelling requirements for a "minimum sales package", but do not specify the scope of the products covered or explain the meaning of this reference (minimum sales package). The draft measures require the competent authorities in the country of origin to follow an additional certification procedure in order to ensure compliance with the regulations of the Government of China. This would represent an additional procedure for the Mexican authorities and for exporters, who would have to certify their products twice. The first procedure would involve ensuring compliance with the export requirements contained in domestic regulations, while the second would involve ensuring compliance with requirements for exports to China. This procedure would impose burdensome workloads on exporters and the Mexican authorities and may therefore contravene the principle of proportionality provided for in Article 2.2 of the WTO TBT Agreement.

2.157. The draft measures require that a specific risk assessment be carried out for the product before importers may be registered, but include no information on the scientific or technical basis for the determination of the proposed assessment. China also needs to identify whether the required risk assessment is based on an international standard. The draft measures were not notified to the members of the WTO TBT Committee, which contravenes the transparency requirements set out in Article 2.9 of the TBT Agreement by not allowing TBT Committee Members to submit comments and take part in the process of developing the draft measures. During the written procedure of May 2020 of the TBT Committee, the delegation of China indicated that the measure was at the development stage and would be notified once it was ready. In light of the above, the delegation of Mexico kindly requests the delegation of China to: Provide information on the current status of the measure, as well as on a possible date for its entry into force, the next steps to be taken or any update thereof. Clarify the scope of the draft measures, as well as the labelling requirements set out therein. If alcoholic beverages are included in the products covered by these regulations, Mexico would be interested in engaging in bilateral talks with the Chinese authorities to discuss a less restrictive procedure with respect to imports of certain products, such as tequila, and would like to propose the acceptance of a certificate of authenticity for export. Explain how the proposed measures are effective and proportionate in terms of meeting China's legitimate food safety objective. Share the technical and scientific information and international standards on which the development of these draft measures is based. More specifically, we would like to know the justification for requesting risk assessments for the products covered. Comply with the transparency commitments of the TBT Agreement and allow for a period of public consultation for submitting comments on the draft measures. The delegation of Mexico thanks the delegation of China for giving its consideration to this statement and to the requests made therein.

2.158. The representative of Japan provided the following statement. Japan also shares the concerns on China's draft administrative measures for registration of overseas producers. Japan has been seriously concerned that China's proposed measures would create unnecessary trade barriers and have negative impacts on food trade between China and WTO Members. The measures would impose an obligation on foreign competent authorities to inspect and supervise manufacturing companies in accordance with Chinese laws and regulations, and to confirm them to the Chinese Government. In addition, the measures would cover all food products imported in China. However, it is not clearly explained by China yet that the scope of the measures is set on a scientific assessment of the risks of each food product. The measures could be overly trade restrictive without scientific evidence. Japan would like to request China to submit the notification in timely manner, provide relevant information on this matter as appropriate, and properly address the concerns of the WTO Members.

2.159. The representative of Switzerland provided the following statement. Switzerland maintains its concerns regarding the proposed registration of overseas manufacturers of imported food and would like to thank the United States, Brazil and Chinese Taipei for keeping this item on the agenda. We refer to previous statements for more detailed comments and call on China to consider other ways and means to ensure the importation of safe food products. We stand ready to engage with China on this matter and look forward to receiving detailed answers to our questions and comments submitted previously.

2.160. In response, the representative of China provided the following statement. We would like to thank the relevant WTO Members for their attention to China's revision of the "Administrative Measures for Registration of Overseas Producers of Imported Foods". The implementation of registration of overseas producers of imported food is based on the requirement of the Food Safety

Law of the People's Republic of China. With China's further opening up, both the trade volume of imported food and the number of foreign food production enterprises registered are growing significantly, the former registration administrative measures can no longer meet the requirement of the current situation. Therefore, China is revising the "Administrative Measures for Registration of Overseas Producers of Imported Foods", with the aim of effectively implementing the legal provisions and improving the management system. The core of revision is to further optimize the registration procedures, clarify the responsibilities of all relevant parties and facilitate the registration and trade. Without repeating our statement at last meeting, I would like to refer to the feedback given during that meeting. I just want to highlight one point: At present, the revision of the "Administrative Measures for Registration of Overseas Producers of Imported Foods" is still at the drafting stage. Once the drafting is completed, China will make notification to WTO according to the relevant notification procedures and will welcome comments and suggestions from all Members.

2.1.3.8 Colombia - Food Prioritized for its Sodium Content, Certification Requirements, G/TBT/N/COL/238, G/TBT/N/COL/238/Add.1 (IMS ID 609[42])

2.161. The representative of Costa Rica provided the following statement. Costa Rica appreciates the opportunity to express concern regarding the proposed Colombian Technical Regulation establishing the maximum sodium content for a prioritized list of a broad range of foods, such as tuna, chicken sausages, chorizo, salted biscuits, ham, peanuts, butter, mayonnaise, breads, pastas, wheat flour products, cream cheese, soups, sauces and sausages. Costa Rica agrees with Colombia's reasoning that it is necessary to implement strategies aimed at protecting public health through the reduction of arterial hypertension and related non-communicable diseases. However, it is concerning that the proposed maximum sodium levels for the selected products are neither substantiated by scientific evidence nor based on the international reference standards established under the Codex Alimentarius. We call on Colombia to share with Costa Rica the scientific basis and risk assessment supporting the sodium levels established for each product, so as to facilitate our analysis of the legislation. Ultimately, we are seeking compliance with the main pillar of the TBT Agreement, which is based on the prevention of unjustified barriers to trade. This is particularly relevant at a time when our countries' economic and social recovery hinges on a guaranteed and uninterrupted flow of safe and affordable food.

2.162. The representative of the United States provided the following statement. The United States appreciates Colombia's continued engagement with the United States on their new sodium level requirements for various agriculture products, notified to the TBT Committee as G/TBT/N/COL/238. The United States continues to support Colombia's efforts to reduce hypertension and related NCDs. However, we are concerned that the implementation of the sodium regulations appears imminent despite the numerous concerns raised by both WTO Members and industry stakeholders. The United States respectfully requests that Colombia consider ways to incorporate our comments into the draft regulation. We also request that Colombia publish revision for domestic and international consultations prior to implementation. Studies indicate that the reformulation and product development cycles generally take three years ahead of market readiness and required reductions may take two or more development cycles to maintain functionality, lifespan, and enable adaptation of consumer taste. Under the timelines in the currently proposed regulation, some US processed foods would likely be unable to meet the requirements to be sold on the Colombian market. Despite Colombia's responses from previous WTO TBT Committee meetings and responses to US Government comments, the United States still seeks clarification on how Colombia will apply sanctions for processed foods that do not comply with the mandatory sodium reduction levels.

2.163. Another key concern for our stakeholders is the addition of the Certificate of Conformity to demonstrate compliance with the food label statement requirements in Colombia's technical regulations. Can Colombia elaborate on its response to the United States' comments in August 2020 and provide more information on the two different certificate schemes it referenced for companies to demonstrate conformity at the port of entry? The United States is concerned that provision of lot-by-lot certificates of conformity is burdensome and costly for importers. Specifically, there are two areas of concern both in the duplicative nature of requiring both registration and certification, and that the new certificate requires certification lot-by-lot. The United States again requests details on the frequency with which these certificates will need to be issued and information on the inspection and confirmation process for these certificates. We reiterate our interest in having an open dialogue with your Ministry of Health, where we can learn and share information regarding ways to develop

[42] For previous statements follow the thread under IMS ID 609 (under dates raised and references).

evidence-based programs to address Colombia's public health objectives while minimizing negative economic impact.

2.164. The representative of the European Union provided the following statement. The European Union would like to thank Colombia for its reply of March 2020 to the EU written comments of November 2019 and would appreciate any updated information on the status of the draft regulation. The European Union would like to note that it fully supports and shares the objective pursued by Colombia to reduce overall sodium intake in an attempt to contribute to the reduction of high blood pressure and other associated diseases. In the last TBT Committee meeting, Colombia replied, with regard to EU questions on certificate of conformity for nutritional declarations, that time frames for issuance, inspection and confirmation for these certificates are not provided for in the draft regulation and will be established by the certification body. The EU notes that this information is essential for importers who need to be aware well in advance of the means to comply with the regulation. Therefore, the EU would like to ask Colombia again for information on the period of validity and the verification process for the certificate. The European Union would also like to ask Colombia whether and under which conditions certificates issued by foreign conformity assessment bodies and test results for sodium content issued by foreign laboratories would be accepted. Furthermore, the EU would welcome clarifications as to the type of sanctions that would be imposed to non-compliant products following the date of entry into force of the regulation.

2.165. The representative of Guatemala provided the following statement. The technical regulation seeks to establish the maximum sodium content for the food prioritized under the National Strategy for the Reduction of Sodium Consumption, with the aim of contributing to the reduction of arterial hypertension and related non-communicable diseases, and with the legitimate objective of protecting the health of the Colombian population. Guatemala wishes to thank Costa Rica, the United States and the European Union for including this item on the agenda. We recognize the legitimate objective of the Colombian authorities to ensure human health, and the efforts made to reduce hypertension. The notified technical regulations establish a maximum sodium content for certain processed foods. Guatemala remains concerned about the conformity assessment proposed in the draft regulation. The pre-packaged food industry, whether products are domestic or imported, complies with a significant number of technical regulations and is constantly monitored by the Colombian Government, including in respect of the sanitary registration and distribution of products. Certificates can only be issued by certification bodies, and sodium content can only be determined through a laboratory analysis. This "third-party conformity certificate" requirement is considered to be a barrier to international trade. Furthermore, the tolerance established in the draft technical regulation is very low, and Guatemala therefore hopes that the limits for various foods will be reconsidered.

2.166. Guatemala is also concerned about the lack of harmonization of the limits with other public policy instruments, such as the nutritional information that must be displayed on the labels of pre-packaged foods. The maximum sodium content must be consistent with front-of-package advisory labelling thresholds. At the TBT Committee meeting in May this year, Colombia once again made it clear that the sale of products exceeding the established maximum sodium content was not banned, since the companies responsible for such non-compliance would be punished. However, if the measure is analysed, it can, in practice, be considered a sales ban, as companies will not want to receive a penalty every time non-compliance is reported. We wish to reiterate that this is a matter of concern for economies such as Guatemala's. The lack of harmonization of the trade regulations issued by Colombia, together with the lack of clarity regarding the country's international trade facilitation measures, limits the ability of small and medium-sized Guatemalan producers to access its market.

2.167. In response, the representative of Colombia provided the following statement. Our authorities have received various comments and observations from several trading partners, which are being reviewed. We have also been in close contact and shared information with a number of delegations and industry representatives. We can report that the draft regulation on maximum sodium content in processed foods has not yet entered into force and the content of the standard is still being assessed in capital by the various competent authorities.

2.1.3.9 Russian Federation - Law No. 425 - on Amending Article 4 of Russian Federation Law "On Protecting Consumer Rights" (IMS ID 612[43])

2.168. The representative of the United States provided the following statement. We are again raising our concerns about the recently adopted amendment to Russia's "Law on Protection of Consumer Rights", which requires pre-installation of Russian software on "technically complex goods" (TCGs) sold in Russia. While we recognize that Russia has postponed the implementation deadline until 1 January 2021, due in large part to the coronavirus pandemic, many concerns and questions remain. We presented some of these questions to Russia in writing in March, but have not yet received a response. When we raised this issue in the February meeting, Russia asserted that the measure is not a technical regulation. However, the TBT Agreement provides that a technical regulation is any document "which lays down product characteristics and production methods, including the applicable administrative provisions, with which compliance is mandatory". The measure mandates product characteristics and production methods for TCGs sold in Russia – namely that these devices must contain certain software which must be pre-installed. Law No. 425-FZ therefore appears to meet the definition of a technical regulation. If Russia does not agree, please explain why the requirement is not a technical regulation.

2.169. In addition, it remains unclear what legitimate objective Russia is trying to achieve with these requirements. An Explanatory Note issued by Russia's Federal Antimonopoly Service (FAS) stated the need to ensure non-discriminatory access of Russian software developers to electronic devices. Many of the TCGs targeted by this technical regulation already feature software from Russian developers and include app platforms which encourage participation by Russian companies. Does Russia have evidence that Russian developers are being denied access to develop software for TCGs? We ask Russia to explain how the requirement is not more trade restrictive than necessary and does not create unnecessary obstacles to trade. We also ask Russia to explain how this measure does not discriminate against foreign software products. As we have stated before, we urge Russia to notify these implementing regulations to the TBT Committee, to allow reasonable time for stakeholders to make comments in writing, to discuss these comments upon request, and to take these written comments and the results of the discussions into account before finalization and implementation. Finally, we request that Russia provide a reasonable period of at least six months between publication of the final regulation and its entry into force. Even the extension of the implementation deadline until 1 January 2021 may not give industry a reasonable interval to adapt to the new requirements.

2.170. The representative of the European Union provided the following statement. The European Union has concerns on amending article 4 of the Russian Federation Law "On Protecting Consumer Rights". These concern mainly certain discriminatory aspects as well as the proportionality of the measure. We call on Russia to comply with its WTO obligations and notify the measure to the TBT Committee. We are also looking forward to receiving the answers to the questions raised by the US delegation.

2.171. The representative of Japan provided the following statement. Japan would like to share concerns regarding this measure expressed by the US. This proposed measure includes unclear articles regarding definitions of terms, concrete requirements for review and evaluation, and the scope of regulations including covered software list. Japan's concern is that the measures may hamper market access for foreign companies in Russia, depending on the concrete details of rules governing its implementation. Therefore, Japan would like to ask Russia to implement this measure in a non-discriminatory manner and not to make it more trade restrictive than necessary in line with the TBT Agreement. Japan would like to request that Russia notify this measure and the relevant regulations to the TBT Committee to ensure transparency of the procedure.

2.172. In response, the representative of the Russian Federation provided the following statement. Russia reiterates its statements made during the previous meetings of the Committee on TBT. We do not consider this measure to be a technical regulation as it does not comply with the definition provided in the Annex 1 of the TBT Agreement. The measure does not set any prohibitions or restrictions for installation of foreign software, nor does it impart or establish any requirements on de-installation of any pre-established software, whether Russian or foreign, and applies equally to both Russian and foreign TCGs.

[43] For previous statements follow the thread under IMS ID 612 (under dates raised and references).

2.1.3.10 India - Quality Control Orders for Chemical and Petrochemical Substances, G/TBT/N/IND/116, G/TBT/N/IND/121, G/TBT/N/IND/122, G/TBT/N/IND/123, G/TBT/N/IND/124, G/TBT/N/IND/125, G/TBT/N/IND/126, G/TBT/N/IND/127, G/TBT/N/IND/128, G/TBT/N/IND/129, G/TBT/N/IND/130, G/TBT/N/IND/132, G/TBT/N/IND/133, G/TBT/N/IND/134, G/TBT/N/IND/135, G/TBT/N/IND/136, G/TBT/N/IND/137, G/TBT/N/IND/138, G/TBT/N/IND/139, G/TBT/N/IND/140, G/TBT/N/IND/141, G/TBT/N/IND/142, G/TBT/N/IND/144, G/TBT/N/IND/150, G/TBT/N/IND/151, G/TBT/N/IND/152, G/TBT/N/IND/153, G/TBT/N/IND/154 (IMS ID 630[44])

2.173. The representative of the United States provided the following statement. We understand that on 22 October 2019, the Ministry of Chemicals and Fertilizers (MoCF), Department of Chemicals and Petrochemicals circulated a notice that invited industry stakeholders to discuss with MoCF its proposed plan to make BIS standards mandatory for 72 identified chemicals and petrochemicals. We are also aware that, beginning in November 2019, India's MoCF has notified 27 QCOs in 27 separate notifications to the WTO TBT Committee. We greatly appreciate India's notification of these 27 QCOs to the WTO TBT Committee, and we thank India for providing stakeholders with the opportunity to submit comments in response to these QCOs. We are aware that each QCO appears to identify substances that correspond to or fall under one of the 72 substances identified in the October 2019 meeting notice, and that each QCO proposes to mandate compliance to BIS standards for the identified substance. We kindly request that India provide links to how WTO Members can access these BIS standards identified in the 27 notified QCOs.

2.174. We also request that India include links to standards as posted to the BIS site identified in any future QCO that India plans to notify as part of its efforts to mandate conformity to BIS standards for chemicals and petrochemicals. Because the notified QCOs do not currently include text or links to available BIS standards that they propose to mandate, interested parties, including industry stakeholders, have no consistent way to access and are unable to become fully acquainted with the QCOs. Furthermore, the referenced standards are not often posted to the BIS website. We encourage India to notify and provide opportunities for public comment for any future QCO that India plans to notify as part of its efforts to mandate BIS standards for chemicals and petrochemicals. We encourage India to provide an update on how it intends to use Government orders to mandate conformity with the BIS standards as part of India's standards and conformity assessment regime. We request that India explain how it will engage with international stakeholders in developing its mandatory technical requirements as part of its conformity assessment regime. We encourage India to consider existing international standards when revising BIS standards and to recognize relevant international standards, where they exist, as a basis for meeting Indian requirements. Are any of the QCOs notified now final? We encourage India not to adopt final measures until it has notified any revisions to the draft measures to the WTO TBT Committee and taken into account comments from interested parties.

2.175. The representative of the European Union provided the following statement. The European Union would like express its concern over the visible trend towards mandatory domestic standards in India that deviate from international ones in a growing number of sectors. In this case, they pertain to a whole range of chemical products under the HS chapters 28 and 29. Within less than a year (i.e., between April 2019 and July 2020), India has made to the WTO 29 notifications concerning chemical products. Of these, 20 are covering petrochemicals (Combined Nomenclature (CN) chapter 29), including such important mass products like methanol, toluene, styrene, ethylene glycol, acetic acid, terephtalic acid, acetone and melamine, and another nine deal with inorganic chemicals (CN chapter 28). The EU would like to remind the authorities of India that in accordance with the TBT Agreement, standards are considered voluntary, whereas mandatory standards are considered as technical regulations. The EU notes that for practically all the chemicals concerned by these notifications, there are neither international standards, nor technical regulations imposed in other countries. Furthermore, the Indian standards which are being rendered mandatory had already been in place for long periods (sometimes even for decades), which makes it difficult to understand the reason for changing their status, all at once, within such a short period of time. The EU fears that it will be easier to enforce the requirements on imports than on local manufactured products and thus the measure could potentially be discriminatory in nature.

[44] For previous statements follow the thread under IMS ID 630 (under dates raised and references).

2.176. The EU would like to recall Article 2.2 of the TBT Agreement, according to which Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. The EU would like to encourage India to align the BIS standards with international approaches. The Indian Government is already a leader in promoting harmonized application of the United Nationals Globally Harmonized System of Chemical Classification and Labelling (GHS). Best practices could be leveraged in working with key trading partner countries, to coordinate an inclusive and efficient development of new chemical management rules. It is also of critical importance to ensure the mutual recognition of data generated under different regulatory schemes in other jurisdictions and avoid unnecessary animal testing. This is in alignment with the OECD MAD (Mutual Acceptance of Data) Agreement, to which India is a signatory, which states that there should be no requirements for test laboratories to be certified by a government agency nor for laboratories to perform tests in the country of registration.

2.177. The representative of Canada provided the following statement. Canada reiterates the concerns it raised at the May 2020 Committee meeting concerning all "QCOs" on chemical and petrochemical substances notified by India since November 2019. These prospective measures would make mandatory the use of Indian Standards on the notified substances. Acknowledging the offer made by India in this Committee to discuss, bilaterally, any other issue Members may have on this measure, Canada reached out to India's Enquiry Point to seek to advance discussions on this STC. To date, its request for clarification remains unanswered. Nevertheless, on account of the nature of its concerns with India's proposed measures, Canada thinks that open and transparent discussions on this STC at the TBT Committee would better serve the interests of interested WTO Members and stakeholders. The approach followed by India in notifying the measures generates significant concerns vis-à-vis the obligations of the TBT Agreement, notably Articles 2.2 and 2.5, as they avoid providing interested parties and stakeholders a genuine consultation period to review the measures and provide comments. The notifications lacked any attempts to explain the new measures, except for the statement that "the Central Government […] is of the opinion that it is necessary or expedient so to do in the public interest". As per Article 2.5 of the TBT Agreement, can India explain to WTO Members the justification behind this "opinion […] in the public interest" and its link to the new measures?

2.178. The notifications also lacked supporting documentation that would explain the stated objectives of the proposals, i.e., to ensure "health, safety and environment for prevention of deceptive practices and national safety". As per Articles 2.2 and 2.5 of the TBT Agreement, can India explain to WTO Members: (i) how its previous regulatory environment was lacking with regard to health, safety, environment, and – specifically – "national safety"; (ii) how the proposed measures will meet the above-mentioned objectives; and (iii) how India's proposed approach is not more trade restrictive than necessary to achieve these objectives, including the risk of non-fulfilment? Declarations of the new mandatory nature of the Indian Standards were made without facilitating stakeholders' access to any related information on them, including direction on where one could find the latest official version of the Standards, some of which are decades old. Has India conducted a comprehensive review of those standards prior to ensure they reflect current methods of production before seeking to make them mandatory? Canadian stakeholders are concerned that these new measures and the lack of clarity surrounding them could seriously undermine the ability of foreign chemical manufacturers to access the Indian market. The new permit requirements will add a significant level of bureaucracy for both industry and Indian regulators, and could reasonably be expected to result in significant delays in the import process. India previously confirmed that the "certification period [of 1 year] has been prescribed in the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 and would not be feasible to change." Canada, again, requests additional clarification on the steps India has taken to ensure the capacity of its administrative authorities to effectively implement and enforce the new measures, as well as deliver the new permits in a timely manner.

2.179. Canada has serious concerns with the opaque method of notification followed by India, which has been repeated a number of times in all "QCOs" notified since November 2019. Canada recognizes and strongly supports Members' right to regulate. However, Members must ensure that such actions do not create unnecessary obstacles to international trade, and follow internationally agreed-upon rules and processes to ensure a level playing field and the viability of the international trading system. The lack of transparency, justification, and overall clarity displayed here goes against this international regime.

2.180. The representative of the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu provided the following statement. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu would like to thank India for responding positively to our concerns at the previous meeting on the draft orders regarding the mandatory requirements for a number of chemical and petrochemical substances, which basically involve the bearing of the Standard Mark under a license from the BIS. Among the notified measures, we are particularly concerned about the one for Terephthalic Acid (notified in G/TBT/N/IND/124 on 31 March 2020). We would like to seek elaboration and clarification from India on issues that are still of our concern, which mainly involve the obligations stated in Articles 5.1.1 and 5.1.2 of the TBT Agreement that conformity assessment procedures shall be non-discriminatory and shall not be more strict or be applied more strictly than is necessary. As the new mandatory certification unavoidably increases trade cost and uncertainty, we are still concerned about the necessity of this draft order. India indicated in its notification (G/TBT/N/IND/124) and response that the objective of the new Order is to "keeping in view the health, safety and environment for prevention of deceptive practices and national safety." We would like to ask India to elaborate on the reasons for changing the voluntary certification to mandatory, in particular information on the risk assessment that supported such a change.

2.181. The likely discrimination against imported products and/or foreign manufacturers of this draft Order is of concern to us. According to Scheme-I of Schedule-II of India's BIS Conformity Assessment Regulations 2018, some of the requirements will significantly increase the burden and costs for foreign products vis-à-vis their domestic Indian counterparts. Firstly, the certification requires product testing and annual factory visit. The certification/licence is valid only for one year for initial application, and one to five years for renewals. We are concerned over the very short validity of the certification that will make it more difficult, if not impossible, for foreign manufacturers to apply for a renewal only 12 months after the issuance date. We seek India's clarification of the rationale behind this design and how this requirement can be applied to both domestic and foreign applicants on a non-discriminatory basis taking into account the practical difficulties faced exclusively by foreign manufacturers. Secondly, according to India's response, BIS does not recognize nor accept third-party testing reports from laboratories outside India. As this creates a significantly higher burden for manufacturers located outside India, we seek India's reasons for this non-recognition/non-acceptance. To this end, we once again call for India to consider providing opportunities for testing laboratories and relevant inspection bodies from other WTO Members to participate in the intended conformity assessment process with the view of reducing the impact.

2.182. Thirdly, we are highly concerned with the requirement for annual "on-site" factory visit/inspection, a costly requirement to fulfil especially for manufacturers located outside India. As the BIS Conformity Assessment Regulations 2018 stipulates that "the need for carrying out the inspection shall be decided keeping in view the risk associated with", we seek further information from India on the risk assessment underpinning the new Order's decision that there is a need to carry out annual factory visit/inspection no matter whether it applies to initial application or renewal proceedings. In particular, we call for India to share with Members the risk factors and other reasons that prevent India from adopting less trade-restrictive alternative approaches. Another point we would like to bring to India's attention is the impact of COVID-19 on the implementation of the BIS Conformity Assessment Regulations 2018 especially for the requirement of factory visit or on-site inspection. As more countries are expected to impose travel bans or restrictions to control the spread of COVID-19, this pandemic will amplify the challenges for foreign producers to comply with the said Regulations. We would like to suggest that the Indian authorities consider temporary measures to authorize qualified inspection bodies located in the exporting Members (e.g. inspection bodies accredited under ILAC-MRA framework) to facilitate factory inspections in lieu of Indian delegation to mitigate the problem. The India inspecting agency can still participate remotely through video conference and/or supplementary document reviews. In summary, we urge India to inform other Members how the non-discrimination principle is observed and the necessity of this requirement in accordance of Articles 5.1.1 and 5.1.2 of the TBT Agreement. In particular, we call for India to share with Members the risk factors and other reasons that prevent India from adopting less trade-restrictive alternative approaches. We would be grateful if the above-mentioned comments could be taken into account and replied to before adoption of the notified draft.

2.183. The representative of the Republic of Korea provided the following statement. Korea would like to make some comments regarding this regulation as follows. First of all, Korea thanks India for the six-month suspension of the Acetone QCO, which resolved the difficulties of Korean enterprises. In addition, Korea is pleased to hear the announcement from India regarding the document to be

uploaded to the official website soon in response to item 2.1.2.20 [45] regarding Phthalic Anhydride QCO. However, Korea would like to make requests as Korean companies have the following difficulty with regard to the enforcement date of Potassium Carbonate QCO, 2020 of India. Although the enforcement date of Potassium Carbonate QCO is scheduled to take effect in December 2020, Korean companies have completed the application for certification, but the acquisition of certification including factory inspection has been delayed because COVID-19 has made it difficult for BIS to perform their duties normally. Therefore, Korea requests India to postpone the implementation of Potassium Carbonate QCO for more than three months in consideration of the delay in certification process due to COVID-19.

2.184. The representative of Singapore provided the following statement. Singapore would like to register its concerns over India's notified QCOs relating to chemical and petrochemical substances. The QCOs would make mandatory the conformity of a series of chemicals and petrochemicals to Indian Standards. Singapore is concerned that some of the QCOs appears to be more trade restrictive than necessary and could undermine foreign chemical manufacturers' access to the Indian market. There are technical specifications and testing requirements that appear to be unique to India. Singapore encourages India to consider referencing available international standards in its requirements. Singapore also notes that on-site factory visits and inspections are required as part of the certification process. Given the on-going COVID-19 pandemic, there would be limitations in arranging for on-site visits, particularly for factories that are located outside of India. In light of the above, Singapore seeks India's reconsideration on the application of mandatory certification to BIS' standards for chemicals and petrochemicals. If that is not possible, Singapore would like to request for India to delay the entry into force of the QCOs, to allow for an appropriate transitional period and to avoid unnecessary impacts to trade. Singapore looks forward to having a bilateral discussion on the matter.

2.185. The representative of Japan provided the following statement. Japan shares the concerns regarding "QCOs for Chemical and Petrochemical Substances" expressed by the US, EU, Canada, Chinese Taipei and Republic of Korea. Japan understands that India will make 72 chemicals and petrochemicals standards into technical regulations by introducing a permit system. Japan would like to request that India ensure that these technical regulations are to be introduced in a manner consistent with the TBT Agreement, especially in terms of not being more trade restrictive than necessary to fulfil its legitimate objectives.

2.186. In response, the representative of India provided the following statement. India issuing 29 QCOs for chemicals and petrochemicals of HS chapters 28 and 29 is not a deviation from international practices. As per Article 2.2 of the TBT Agreement, Members are allowed to formulate Technical Regulations. The standards are made mandatory for products of mass consumption, including the downstream industries, to fulfil legitimate objectives of: national security requirements, prevention of deceptive practices, protection of human health and safety protection of animal and plant life and preservation of the environment. As per the laid down procedure, the draft QCO has been displayed on the WTO TBT website, giving enough and open opportunity to the Members to share their objections within 60 days. It is pertinent to note that even if other countries have not formulated TR's for such chemicals, the number of TRs of chemicals and petrochemicals in India is less than in other nations. For a long time, the Indian standards of chemicals and petrochemicals were voluntary. The trade of chemicals and petrochemicals usually occurs as per the specifications settled between the manufacturer and buyer irrespective of the specifications stipulated in the BIS standard, which sometimes resulted in dumping inferior quality chemicals into India. Many chemicals are toxic and hazardous. The impurities such as heavy metals, cyanides, isocyanates, halides, etc. enter the human and plant chain, thereby harming human and animal life. Under mandatory standards regime, safe, reliable, and quality chemicals will be available.

2.187. TRs for chemicals and petrochemicals are formulated not to create unnecessary obstacles to international trade. It is pertinent to mention that the TBT Agreement permits making the standards mandatory, and other countries are also following this practice. Both domestic and foreign manufacturers should comply with the provisions of the BIS Act, 2016. To align with the international standards, the BIS studied the available international standards before finalizing the Standards under discussion. The aspect of unnecessary animal testing and the element of Mutual Acceptance of Data is being looked into under India's current Chemicals (Management and Safety) Rules formulation process. The request for postponement of the enforcement date of QCO of Phthalic

[45]India - Phthalic Anhydride (Quality Control) Order, 2019 (IMS ID 660).

Anhydride, and Potassium Carbonate is under examination. India is keen to keep transparency in the matters relating to the issuance of QCOs. India has notified 22 QCOs on WTO TBT site. It is possible that India may make more standards of chemicals and petrochemicals mandatory. However, it is not possible to provide an indicative list of chemicals and petrochemicals proposed to be covered under mandatory standards in the future.

2.188. India has formulated an individual standard of specific chemical indicating discreet and separate numbers under the BIS Act, giving technical characteristics and details of testing methods. Since each chemical has a different BIS standard number, possesses other characteristics and other testing methods, India has not preferred to file a single comprehensive mandatory notification. Standards are made mandatory after having a consultation with manufacturers, consumers of chemicals, and petrochemicals. WTO Members are informed through the display of notification on the TBT site. The Department of Chemicals and Petrochemicals (DCPC) has notified the draft QCOs on chemicals and petrochemicals under the provisions of the BIS Act 2016 and Rules and Regulations framed thereunder, which envisages conformity assessment Scheme-1 of BIS (Conformity Assessment) Regulation 2018. As per draft QCOs, the product specified therein shall conform to the corresponding Indian Standard and shall bear the standard mark under the BIS's licence as per Scheme-1, mentioned above. This QCO is equally applicable to domestic and foreign manufacturers who intend to export their products in India. Under the provisions of the BIS Act 2016, no person shall manufacture, import, distribute, sell, hire, lease, store, or exhibit for sale chemicals and petrochemicals notified in the QCO without a standard mark, except for a valid licence. For persons selling these chemicals without a requisite certificate (licence), penal provisions of the BIS Act 2016 shall be applicable. The violators shall be prosecuted as per the Act and are punishable with fine or with imprisonment also. The requirement for the use of Standard Mark as per Scheme -1 is given in BIS (Conformity Assessment) Regulations 2018. A copy of the same is available on the BIS website (www.bis.gov.in).

2.189. The BIS is already providing its services under Foreign Manufacturers Certification Scheme, and more than 1,000 licences have been granted, which are operative in 50 countries. Under the provisions of Scheme -1 of BIS (Conformity Assessment) Regulation 2018, the licence can be granted for a period of minimum one but up to two years and subsequently can be renewed for a period of minimum one but up to five years. Under the provisions of Scheme-1 of BIS (Conformity Assessment) Regulation 2018, BIS grants a manufacturer a licence based on a successful assessment of a manufacturer's manufacturing infrastructure, production process, quality control, and testing capabilities via a visit to its manufacturing premises. The conformity of the product to the relevant standard is also established through third-party laboratory testing located in India or testing in the manufacturing premises or a combination of both. There is no provision under Scheme-1 of BIS (Conformity Assessment) Regulation 2018, to accept quality control assessments conducted by foreign firms and laboratories. As per QCOs on chemicals and petrochemicals, every product shall conform to corresponding Indian standards specified there and shall bear the standard mark under BIS's licence as per Scheme-1 of BIS (Conformity Assessment) Regulation, 2018. The BIS reviewed the standards of chemicals and petrochemicals which were notified by DCPC, and due consideration was given to international standards like ISO/ASTM, where available.

2.1.3.11 India - Draft Chemicals (Management and Safety) Rules, 2020 (IMS ID 622[46])

2.190. The representative of the United States provided the following statement. The United States appreciates India's efforts to engage with both the US Government and US industry on the Draft Chemicals (Management and Safety) Rules ("Draft Rules"). We thank India for its 26 December 2019 response letter in which the MoCF committed to notify the Draft Rules, provide stakeholders at least 60 days to submit comments, and to take comments into account before finalizing the measure. The United States respectfully requests that India provide an update clarifying when the Draft Rules will be notified to the WTO TBT Committee. We ask that India also notify any subsequent versions of the Draft Rules that contain substantive changes, as well as any related implementing measures, including those pertaining to the process for public consultation and appeals of substance classifications. We strongly encourage India to evaluate risk-based approaches to identify and prioritize chemicals for regulatory action, and we echo industry's concerns about the Draft Rules' inclusion of 750 chemicals, classified as Priority Substances, without public consultation on either the inclusion of these substances or the methodology used to identify them.

[46] For previous statements follow the thread under IMS ID 622 (under dates raised and references).

2.191. We welcome India to consult with our agency of competency, the US Environmental Protection Agency (EPA), on matters of interest (for example, the matters highlighted by US industry stakeholders in their comments). We note that the broad criteria used by the proposed risk management system could affect many products, such as cosmetics, pharmaceuticals, toys and agricultural pesticides, which are already regulated in India under other relevant regulations. For example, the safety of cosmetics and their ingredients is regulated by the Central Drug Standards Control Organization, in coordination with the Bureau of Indian Standards. Can India confirm that current approvals/registrations (for products including cosmetics, pharmaceuticals, toys, and agricultural pesticides) under existing Indian regulatory frameworks will remain valid? Can India clarify how the Draft Rules' notification requirements apply to downstream users and whether exemption of certain sectors or products from the Draft Rules would apply to all the requirements (registration, notification, authorization, labelling, etc.)? The Draft Rules appear to exempt substances in articles which are produced at levels below a certain number of tonnes per annum, but do not specify this *de minimis* threshold (described in Section 3(4)(a) as "[tons per annum"). Can India provide the number of tonnes per annum below which exemptions will be granted? How is this threshold calculated?

2.192. The representative of Canada provided the following statement. Canada understands that the Draft Chemicals Rules are now in their fourth and "final" iteration, and have only been shared with a select group of stakeholders and business associations so far. This situation creates a major asymmetry between those who have had access to the Draft Chemicals Rules and were able to influence their development, and those who will discover the extent of the Draft Chemicals Rules only once they are published. Canada urges India to notify the draft rules as soon as possible in order to ensure that all interested parties are given sufficient time to review and provide comments, and ensure that sufficient time is allowed after the consultation period for Indian authorities to give due consideration and responses to those comments. Is India in a position to share with the Committee a timeline for the publication and consultation period of the Draft Chemicals Rules?

2.193. Due to the novelty and complexity of the Draft Chemicals Rules, and their potential to disrupt trade, Canada also supports a long transition period to give stakeholders the time they need to prepare. This will be essential, considering that some stakeholders have been given an advantage by being consulted on four iterations of the Draft Chemicals Rules, while the intricacies of the new rules remain unknown to the rest of the world. Stakeholders will need time, resources and capacity to implement the new rules appropriately, and a phased implementation period could help ease the transition. Canada urges India to make its regulatory process more open, transparent and collaborative, and to take the necessary time to work with all stakeholders and all WTO Members to assist them in understanding the full impact of the Draft Chemicals Rules.

2.194. In response, the representative of India provided the following statement. India would like to thank the US and Canada for its interest in the matter. India would like to inform the Members that the Draft Chemicals (Management and Safety) Rules 2020 is still under circulation among the industry associations for extensive stakeholders consultation, which is entirely internal. Once the draft gets finalized, it will be notified to WTO TBT Committee for circulation to Members, providing them the opportunity to comment within a reasonable time.

2.1.3.12 European Union - Draft Commission Regulation amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives, G/TBT/N/EU/702 (IMS ID 628[47])

2.195. The representative of Mexico provided the following statement. The delegation of Mexico refers to the concern regarding the Draft Commission Regulation amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanicals species containing hydroxyanthracene derivatives, which was notified to TBT Committee Members in document G/TBT/N/EU/702. The delegation of Mexico thanks the European Union for the comments received in reply to the observations submitted in the public consultation process. Notwithstanding the replies received, the delegation of Mexico reiterates the concerns it has raised in this forum regarding the proportionality of the measure and its potential impacts on the trade of products containing or derived from aloe or aloin. The draft regulations proposed by the EU might prove to be a measure more restrictive than necessary in view of the legitimate objective pursued,

[47] For previous statements follow the thread under IMS ID 628 (under dates raised and references).

considering that it would involve an absolute ban on the use of aloe and its extracts in food and beverage formulas. The implementation of this measure would adversely impact the Mexican industry that produces and exports to the European Union a variety of products for human consumption containing aloin, a component naturally found in aloe vera. In addition to reiterating our concern, we request that the European Union reconsider the need to implement such a measure, until such time as it is supported by sufficient scientific evidence. The delegation of Mexico thanks the delegation of the European Union for giving its consideration to this statement and to the requests made therein.

2.196. The representative of the Dominican Republic provided the following statement. The European Union has submitted draft legislation amending Annex III to Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives (HADs), a substance that occurs naturally in aloe vera. This draft legislation could have a negative impact on exports of aloe vera by-products or industrialized products containing aloe vera exported by the Dominican Republic to the European market. The Dominican Republic wishes to take this opportunity to voice its concern that the European Union has failed to notify the draft in question to the WTO Committee on Sanitary and Phytosanitary Measures. It was, however, notified to the Committee on Technical Barriers to Trade in document G/TBT/N/EU/702. Article VII of the Agreement on Sanitary and Phytosanitary Measures requires Members to notify their provisions in order to ensure transparency. There are two major aloe vera producing firms, Sábila SRL and Universal Aloe SAS (Forever Living), operating in the Dominican Republic under the free zone regime. In 2019, the total value of their exports reached USD 8,805,431, while this figure was USD 4,851,466 for the period from January to August 2020. The two firms' cumulative investment stood at USD 9,226,800 in 2019. Furthermore, according to trade statistics from firms in the country's free zone, 83% of aloe vera products that are exported go to the European market.

2.197. The US firm Universal Aloe SAS (Forever Living) is considered to be the global market leader. For over 30 years, it has owned approximately 3,000 hectares of land, with over 20 million aloe vera plants, located within the Dominican Republic's border area. The firm has been the economic backbone of a marginalized and deprived area of the country. It has created 550 direct and some 3,000 indirect jobs, thereby having a positive impact on more than 800 families. The firm exports aloe vera gel to the United States for processing and re-export to 150 countries. Fourteen containers are currently exported each week for an approximate value of USD 12 million per year. The European Union is the main market for the parent company, Forever Living. The legislation amending Annex III to Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives states that: "In its Scientific Opinion of 9 October 2013 on the scientific substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function, the European Food Safety Authority (EFSA) concluded that hydroxyanthracene derivatives in food can improve bowel function, but advised against long-term use and consumption at high doses due to potential safety concerns such as the danger of electrolyte imbalance, impaired function of the intestine and dependence on laxatives. Plants containing hydroxyanthracene derivatives […] are widely used in food supplements and herbal medicinal products for their laxative effect."

2.198. Based on the information provided, the Dominican Republic requests that the following factors be taken into consideration: Parts of the plant containing HADs: Aloe vera leaves are composed of three layers: (i) a thick, green outer rind; (ii) a thin layer of yellow latex containing HADs; and (iii) an inner layer of clear, thick, and moist gel containing nutrients. Therefore, the part of the plant with the lowest concentration of the substance under investigation by the EFSA is the aloe vera gel, which is the part used by the firm Universal Aloe. The HADs are found in the yellow latex, which is used to produce laxatives. Production processes: Some companies use the yellow latex to produce laxative medicines or food supplements, while others, such as Forever Living, use only the inner gel for its juice. In other words, it is possible to adopt production processes that involve removing the outer green rind and the yellow latex, thereby reducing the HAD content to a level even lower than that found in common vegetables such as cabbage and rhubarb. A cheaper alternative process also exists, which involves grinding and then filtering the entire aloe vera plant. While filtering is necessary because the entire plant, including the parts containing HADs, is crushed, the process does result in a reduction in nutrient content. Annex III to Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins, minerals and certain other substances to food comprises three parts: Part A: Prohibited Substances; Part B: Restricted substances; and Part C: Substances under community scrutiny.

2.199. Given that certain parts of the plant contain minimal HAD levels, which are even lower than those found in some vegetables, and that it is possible to use only part of the plant in the production process, we are of the view that the ban is a disproportionate measure. This is especially the case, since EFSA studies show that scientific uncertainty persists. In other words, there is no evidence of scientific value to support or justify the ban that the European Union is seeking to impose. For this reason, the amendment to the Regulation is more restrictive than necessary and constitutes a barrier to trade. The Dominican Republic considers that, in the absence of risk-based scientific studies from the European health authorities, a thorough analysis of hydroxyanthracene tolerances in aloe vera gel is needed. Moreover, a scientific investigation should be conducted to test for and confirm any harmful impact on DNA and potential carcinogenic effects. Furthermore, it is necessary to define and make a distinction between the terms "extract" and "juice". Certification should be available for juices that meet international standards. A longer transition period of at least three years is also required so that national productive sectors can adjust and adapt. As aloe vera and its by-products form part of our country's exportable supply and these products enter the European market with tariff preferences granted under the Economic Partnership Agreement between the European Union and CARIFORUM, the implementation of this ban would have significant adverse effects, which would not be limited to reducing the Dominican Republic's exports to the European market.

2.200. The Dominican Government is of the view that, given the international COVID-19 pandemic, it is not the right time to change market dynamics and requirements. The pandemic has had a severe negative impact on industries, which are operating with fewer staff and at reduced capacity, resulting in a fall in sales and revenue. The Dominican Republic recognizes the European Union's right to apply measures to protect human health. However, we recommend considering equally effective alternative provisions, such as inspections of production sources, with a view to confirming the existence of products developed without hydroxyanthracene derivatives and establishing maximum levels for this substance in the development of aloe vera based products. Lastly, the measures that the European Union is seeking to implement constitute provisions subject to the Agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS). They would thus run counter to a number of provisions under these Agreements, specifically Articles 5.1.2, 2.1 and 2.2 of the TBT Agreement and Article VII of the SPS Agreement, among others.

2.201. In response, the representative of the European Union provided the following statement. As explained in detail at the TBT Committee meeting in May, the proposed draft measure is based on the scientific advice of the European Food Safety Authority (EFSA) and on extensive consultations with member States and all interested parties. The measure is in accordance with the procedure under Article 8 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to food. Besides the TBT notification, the draft measure was published for a seven-week consultation period. The EU has carefully analyzed all the comments received. The measure has been revised to clarify that it is possible during manufacturing to remove HADs from the botanical extracts, but impurities of these substances may still be present. In this context, the EU Reference Laboratory on mycotoxins and plant toxins (EURL) was asked for assistance in establishing a validated analytical method and its limits of quantification for HADs in different botanical preparations, including Aloe preparations. On the basis of the report of the EU Reference Laboratory, the European Commission held a technical discussion with member States on 28 September 2020. The Commission presented the results of that discussion and of a targeted stakeholder consultation to member States at the last meeting of the Standing Committee on Plants, Animals, Food and Feed. The Committee agreed on harmonized limits of quantification for HADs, including aloins, to address industry concerns regarding impurities and ensure a harmonized enforcement of the future rules.

2.1.3.13 European Union - Organic production and labelling - Maté (erva-mate), G/TBT/N/EU/738 (IMS ID 524[48])

2.202. The representative of Brazil provided the following statement. Brazil regrets having to raise STC 524 again. Brazil had raised this STC for the last time in the TBT Committee meeting of November 2019, in which the European Union stressed that erva-mate was not within the scope of the current organic Regulation (Regulation (EC) 834/2007) and there was no possibility to modify this. However, the EU noted that, as proposed by the European Commission, the new Regulation (EU) 2018/848 on organic production and labelling adopted on 30 May 2018 by the European Parliament and the Council included Maté under its scope. The new regulation would enter into force

[48] For previous statements follow the thread under IMS ID 524 (under dates raised and references).

on 1 January 2021. In September 2020, the EU notified a proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2018/848 on organic production as regards its date of application and certain other dates (G/TBT/N/EU/738). Following its adoption, instead of entering into application on 1 January 2021, Regulation (EU) 2018/848 will enter into application on 1 January 2022. The postponement of the entry into force of Regulation (EU) 2018/848 shows the EU's disregard towards the matters presented by Brazil under this long-standing STC. As we have stated in previous meetings, not including erva-mate in the organic product list without any technical or scientific justification was discriminatory and more trade restrictive than necessary, and thus inconsistent with the TBT Agreement. Until January 2022, provided that no further postponements will be enacted, Brazilian producers will be denied access to EU markets on an equitable basis, and their losses are not expected to meet any sort of compensation.

2.203. In response, the representative of the European Union provided the following statement. The European Union notes that it has replied to Brazil on this issue in previous TBT Committee meetings, as well as bilaterally. As previously explained, Erva-Mate is not within the scope of the current EU Regulation on organics (Regulation (EC) 834/2007) and there is no possibility to modify this. However, as proposed by the European Commission, the new Regulation (EU) 2018/848 on organic production and labelling adopted on 30 May 2018 by the European Parliament and the Council includes Erva-Mate under its scope. The new organics Regulation was due to enter into application on 1 January 2021. Nevertheless, following the on-going COVID-19 crisis, the organic sector needed additional time to adapt to the new rules on production, controls and trade. For this reason, the EU recently notified to the TBT Committee a draft Regulation, for adoption and publication before the end of 2021, postponing the entry into application of the organics Regulation by one year (G/TBT/N/EU/738). The European Union acknowledges Brazil's written comments on this TBT notification. The new organic rules will enter into application on 1 January 2022.

2.1.3.14 European Union - Hazard-based approach to plant protection products and setting of import tolerances, G/TBT/N/EU/383, G/TBT/N/EU/384, G/SPS/N/EU/166, G/SPS/N/EU/166/Add.2 (IMS ID 393[49])

2.204. The representative of Costa Rica provided the following statement. As on previous occasions, Costa Rica would again like to reiterate its support for the trade concern raised by the United States, Canada and Australia. As we have stated on numerous occasions at this Committee's previous meetings, we are concerned about the hazard-based approach adopted by the European Union (EU). In our view, under the obligations of the multilateral system, all technical requirements must be based on the relevant international reference standard or a risk assessment providing the scientific evidence to support the measure. We once again urge the EU to ensure that the implementation of its regulations is based on the use of risk assessments through the application of criteria supported by sufficient scientific evidence, in line with the commitments established in the TBT Agreement.

2.205. The representative of the United States provided the following statement. The United States takes the floor to reiterate concerns on endocrine disruptors, which many WTO Members have expressed at previous TBT Committee meetings without any satisfactory response from the EU. The EU has stated that it will conduct risk assessments for maximum residue levels (MRLs) and import tolerances for substances triggering its hazard criteria; however, this does not appear to be the case. The EFSA does not set risk endpoints even for substances for which other authorities, including Codex, have successfully completed risk assessments and set MRLs. The EU's hazard criteria, including its endocrine disruptor criteria, have been in place since November 2018. Since that time the EU has not renewed approval of active substances without completing a consumer dietary risk assessment, pointing to the potential of the substance to fit in its hazard criteria. As we conveyed previously, we have serious concerns about the scientific underpinnings, non-discrimination, transparency, and predictability in application of the EU's process. We are troubled that these concerns have gone so long unaddressed and ask the EU when it will respond to our questions, with clarity and specificity.

2.206. The representative of Canada provided the following statement. Today more than ever, safe and sustainable agricultural practices, including the use of plant protection products, must not be overlooked as an effective way to achieve food security. Ensuring access to safe and nutritious food, especially during these uncertain times, is paramount. As stated during past TBT Committees, Canada is concerned with the EU's approach to decision making for plant protection products, and

[49] For previous statements follow the thread under IMS ID 393 (under dates raised and references).

particularly the impact of these decisions on trade of agricultural commodities and setting of import tolerances. Canada is keen to understand how decisions by the European Commission to cancel the authorization of a plant protection product, that is deemed to meet the hazard-based cut-off criteria, will affect import tolerance (IT) requests made in accordance with the procedures laid down in Regulation (EC) No. 396/2005. It also remains unclear how the EU will take into consideration risk assessment techniques developed by relevant international organizations when a plant protection product has already been determined to meet the hazard-based criteria for the purpose of ITs. We welcome the EU's commitment to host seminars with third countries and stakeholders. We recognize that timelines to hold these sessions may have been temporarily disrupted due to the current global pandemic, but we look forward to participating in this information exchange when circumstances permit. We trust that these events will provide sufficient detailed information to clarify and address our concerns.

2.207. In the meantime, Canada would welcome any additional information that will help ensure predictability of trade, as non-renewal decisions are currently in the process of being implemented by the EU. Until a clear and predictable process for setting import tolerances is implemented, maximum residue limits for active substances which are not re-authorized in the EU should be maintained at existing levels to allow trade to continue. We look forward to continuing our engagement with the EU and hope that regulatory changes arising from any new policy will be implemented in a coherent and transparent way that will minimize unnecessary barriers to trade and provide sufficient time to allow producers and exporters to make timely business decisions.

2.208. The representative of Australia provided the following statement. Australia reiterates its position from previous meetings about the importance of adopting a science and risk-based approach for regulating plant protection products rather than considering only the potential for harm (hazard) due to the intrinsic properties of a chemical. Australia thanks the EU for its comments at the previous TBT meeting and would welcome any updates on the procedures for handling requests for import tolerances for active substances falling under the "cut-off" criteria in Regulation (EC) No 1107/2009.

2.209. The representative of Brazil provided the following statement. Brazil would like to refer to its previous statements regarding STC 393. As many WTO Members have pointed out, the EU has systematically refused to take into account concerns raised by many WTO Members regarding notifications G/TBT/N/EU/383 and G/TBT/N/EU/384. We emphasize that regulations on endocrine disruptors should be established according to sound scientific principles, taking all available data into consideration. Serious evaluations must be able to separate chemicals that have the potential to cause harm due to their endocrine mode of action from those substances that do not pose a threat to human health. The European approach to limit the use of pesticides is more trade restrictive than necessary to fulfil its legitimate objectives under the TBT Agreement. It also disregards risk analyses in the setting of regulatory measures that may have serious impact on trade.

2.210. The representative of Colombia provided the following statement. Colombia once again shares the concern raised regarding the approach taken by the EU for identifying substances with endocrine-disrupting or carcinogenic properties. As we have stated across different items on various occasions in this Committee, we reiterate the need to use risk analysis and scientific evidence as methodical tools for making decisions under the three components of assessment, management and communication. The EU's action shows that risk assessment is losing ground, with its decisions to accept or allow the use of substances being taken using a hazard-based approach, disregarding the conditions of use that can define risk scenarios and lead to scientifically based decisions. In light of the above, Colombia considers that the EU proposal must take into account scientific evidence, production processes and methods, the international recommendations of the Codex Alimentarius, and the relevant ecological and environmental conditions in countries that may be affected by the implementation of the measure, in order to avoid creating an unnecessary technical barrier to trade. Given that this specific trade concern has been raised repeatedly on numerous occasions in this Committee, we would respectfully like to ask how these observations are being taken into account, and would appreciate receiving further information from the EU on how decisions on the approval of the use of plant protection substances are taken and how maximum residue limits for products are defined.

2.211. The representative of Guatemala provided the following statement. Guatemala reiterates its concern regarding the matter of endocrine disruptors and the hazard-based approach. The importance of the general risk analysis framework needs to be recognized (this includes risk assessment, risk management and risk communication). The precautionary principle is justified

when potentially negative effects are identified, available scientific data is assessed and there is growing scientific uncertainty. We would like to reiterate the importance of using risk analysis for import tolerances, particularly for tropical developing countries, where climatic conditions differ from those in the EU, in that we do not have a harsh winter to help control pests. We urge the European Union to establish measures that do not unnecessarily restrict trade.

2.212. The representative of Ecuador provided the following statement. We thank Australia, Canada, Costa Rica and the United States for once again including this specific trade concern on the Committee's agenda. We echo their concerns and refer to our previous statements on this matter. We wish to once again reiterate our trade and systemic concern relating to the EU's use of a hazard-based approach, instead of risk assessments with criteria supported by sufficient scientific evidence, in line with the commitments set forth in the TBT Agreement.

2.213. The representative of Uruguay provided the following statement. We wish to support the comments made by the preceding Members and reiterate our trade and systemic concern relating to the European Union's use of a hazard-based approach, instead of an approach based on full scientific risk assessments, when making regulatory decisions concerning the authorization of active substances used in plant protection products and when setting import tolerance levels for substances that meet the cut-off criteria in its corresponding regulations. We firmly believe that regulatory decisions should be based on evidence from an assessment of the actual risks associated with plant protection products, taking into account their exposure. Otherwise, such products may be withdrawn despite their safe use and significant role in pest management systems. An approach based on hazard rather than on actual risk could have a negative and disproportionate impact on sustainable agricultural production, food security and international trade in food products, contributing little or nothing to the cited aim of protecting public health. In this regard, we concur with Canada that now more than ever we should ensure and facilitate people's access to safe and nutritious food, produced in accordance with good agricultural practices.

2.214. Uruguay continues to support any multilateral work undertaken by the Codex Alimentarius to develop a harmonized, risk-based approach for substances with endocrine-disrupting properties that ensures the protection of health while facilitating international trade in food products. In the meantime, we once again urge the European Union to give due consideration to the concerns expressed and to reconsider its regulatory approach, with a view to preventing the unjustified proliferation of barriers to international trade in agricultural products and the serious socio-economic consequences of such an approach for other Members, in particular developing and least developed countries, for whom the European Union is an important market. Like other Members, we are still waiting for the European Union to announce that it will hold the seminars and information sessions that it has promised, at an appropriate time and in an appropriate format given the current situation, to continue exchanging information on this matter.

2.215. The representative of Paraguay provided the following statement. In the interest of time, this statement will cover five trade concerns, which we consider to be linked: No. 40 – EU: Precautionary principle; No. 43 - EU: Transitional periods[50]; No. 44 – EU: chlorothalonil[51]; No. 47 - EU: mancozeb[52]; and No. 58 - EU: Picoxystrobin[53]. The hazard-based approach adopted by the European Union (EU) is the source of these concerns, which we will address jointly here in a single statement. The lack of risk assessment continues to increasingly limit the use of plant protection products and reduce MRLs to trade-restrictive levels, the argument being that it is impossible to determine whether the use of many substances is safe due to a lack of conclusive scientific evidence, even in cases where the Codex Alimentarius has identified certain substances as being safe. At the same time, there is still a lack of clarity over the import tolerance procedure, even though the EU has indicated on many occasions that the procedure will be conducted on a case-by-case basis and that "other legitimate factors", which have yet to be defined by the EU, will be taken into consideration. Moreover, the EU has announced in its Farm to Fork Strategy that environmental factors will be taken into account when considering such tolerances, yet when faced

[50] European Union - Transitional periods for MRLs and international consultations (IMS ID 580)
[51] European Union - chlorothalonil (pesticide active substance) (IMS ID 579)
[52] European Union - Non-renewal of the approval of the active substance mancozeb (IMS ID 627)
[53] European Union - Regulation (EC) No 1107/2009 - non-renewal of approval of the active substance picoxystrobin (IMS ID 535)

with requests for information on how this will be done, it has failed to provide the necessary information.

2.216. In addition, the EU's transitional period does not allow enough time for the adaptation of entire production systems and, in practice, allows more time for EU producers than for producers in the EU's trading partners. We have heard the EU turn down repeated requests to extend the transitional periods, claiming that this would compromise its level of protection and the health of its consumers. However, since the implementation of these regulations began, emergency authorizations allowing European producers to continue using these substances in spite of the ban have increased exponentially, according to the EU's own data. We wonder how to reconcile these concerns, which, on the one hand, do not allow a few more months to be provided to foreign producers, yet, on the other, do allow already banned products to continue being used, for up to three months for each emergency approval, with no cap on the number of times that such approvals may be renewed. With regard to the specific substances on various items of today's agenda, we would like to reiterate the following: As we stated in the written procedure that was carried out at the end of May, mancozeb is an active substance that has been in use for over 50 years and continues to be considered an important tool in controlling certain types of fungi throughout the world. Mancozeb is used on more than 70 types of crops and for controlling over 400 diseases. Producers in my country use it to control soybean rust, which affects soybeans. Withdrawing this product from circulation, given the lack of substitutes with the same properties, we run the risk of not only increasing the use of other fungicides during productive cycles, but also of reducing their efficacy. This would negatively impact production yields in my country, which, unlike other countries, does not subsidize farming or have the resources to compensate farmers for their losses.

2.217. We recall that the most common substitute for mancozeb is chlorothalonil, a low-risk substance sold freely in Paraguay. It is used on various exports, as part of the rotation of substances to avoid pest resistance, and has suffered the same fate as mancozeb, despite both substances not posing any risks to human health or the environment if used in accordance with good agricultural practices. Picoxystrobin, which is also used on various export crops, is another tool used in the rotation of plant protection products that we will also have to withdraw due to further implementation of decisions that do not take into account the risk factor. In total, out of the approximately 350 substances that have been or are currently being reviewed, 116 are used as the main or complementary tool in fighting pests in Paraguay, a country whose climatic conditions, and therefore pest-pressure levels, are very different to those of the EU. Although we share the objectives that the EU seeks to achieve with these policies, we do not agree with the method used to achieve them, as it is not based on scientific evidence.

2.218. Consequently, we deeply regret the EU's lack of openness to dialogue, as shown by the following: (i) The continued inclusion of such trade concerns on the agenda and the proliferation of new concerns in response to the pursuance of such policies; (ii) The refusal to delay the amendment and revision of MRLs for plant protection products, contained in communication G/TBT/GEN/296/Rev.4; (iii) The avoidance of concrete answers to direct questions raised in the SPS and Agriculture Committees and during trade policy reviews; (iv) The response that we received from the Permanent Representation of the European Union to our request to establish broad and comprehensive dialogue to address these and other trade concerns in various WTO Committees; and lastly, (v) The fact that the EU submitted all its answers to these concerns yesterday, without first listening to Members' statements today. The pursuance of such policies will cause significant trade damage to the economies of developing countries and jeopardize their ability to achieve sustainable development goals, including those related to food security. We urge the EU to reassess its approach in these exchanges; base its decisions on conclusive scientific evidence and real risk weights, in accordance with the relevant international principles and standards; ensure import tolerances and, where necessary, provide adequate transitional periods.

2.219. In response, the representative of the European Union provided the following statement. The European Union thanks the WTO Members for their interest in the on-going work in the EU on identifying endocrine disruptors for plant protection products. As informed in previous TBT Committee meetings, the scientific criteria to identify endocrine disruptors for plant protection products based on the World Health Organization (WHO) definition are applicable since 10 November 2018 onwards and included in Regulation (EU) No 2018/605. The European Union is aware of general concerns on the EU policy on plant protection products for the definition of scientific criteria to identify endocrine disruptors. We are also aware of concerns on the establishment of import tolerances for substances that are not authorized in the EU, due to the so-called "cut-off" criteria in

Regulation (EC) No 1107/2009. As previously explained, the European Union decided to follow the procedures of Regulation (EC) No 396/2005 for the management of import tolerance requests concerning active substances falling under these cut-off criteria. These procedures include a risk assessment by an Evaluating EU member State and a scientific opinion by the EFSA. The granting of the import tolerance will then be considered in line with risk analysis principles on a case-by-case basis and taking into account all relevant factors. The EU reiterates its commitment to act in full transparency) and will keep Members duly informed about further developments.

2.1.3.15 Indonesia - Halal Product Assurance Law No. 33 of 2014, G/TBT/N/IDN/123 (IMS ID 502[54])

2.220. The representative of the United States provided the following statement. The United States recognizes the importance for Indonesian consumers to know whether products are halal. We want to work with you to ensure that the law achieves your objective without creating any unnecessary barriers to trade. We thank Indonesia for its response to the US Government and US industry comments on the Ministry of Religious Affairs (MORA) Regulation on Implementation of Halal Product Assurance, which it notified to this Committee in G/TBT/N/IDN/123. We understand, however, that in May 2019 Indonesia finalized and issued Government Regulation 31 of 2019 on "Implementation Provisions of Law 33/2014 regarding Halal Product Assurance" related to the Halal Law, which Indonesia has not notified to this Committee. We understand that the MORA has also issued Decree no. 464, a positive list for products requiring halal certification. In October 2020, the United States sent a request to Indonesia's Enquiry Point requesting that Decree no. 464 be notified to this Committee as an addendum to G/TBT/N/IDN/123. We ask that Indonesia respond to that request and reiterate our previous request that Indonesia notify all implementing measures related to the Halal Produce Assurance legislation to the Committee.

2.221. Furthermore, we understand that the Halal Product Assurance Agency is starting to develop implementing measures and guidance for specific product categories. Can you confirm the following list of products are in the scope and the envisioned timeline for the requirements to enter into force? October 2024 for "food and beverage products"; October 2026 for "traditional medicine and health supplements", "cosmetics, chemical product and genetically engineered products", "clothing, headgear and accessories", "household appliances, Muslim worship equipment, stationery and office equipment", and "goods for medical devices risk class A"; October 2029 for "over-the-counter (non-prescription) medicines" and "goods for medical devices risk class B"; October 2034 for "prescription medicines, excluding psychotropic" and "goods for medical devices risk class C"; and there is currently no date specified for biological vaccines and goods for medical devices risk class D. We also await clarification about the status of proposed legislation connected with the following category: "Medicinal product, biological product and medical equipment made from non-halal raw material or non-halal processing," as listed in the notification to this Committee. We ask that Indonesia specify what is the envisioned process and timeline for notifying and soliciting public comment on the implementing measures regarding the certification, packaging, and labelling requirements for each of these product categories.

2.222. We understand that on 5 October, Indonesia finalized an Omnibus Job Creation Bill that modifies the original Halal Law. Will there be further implementing guidance forthcoming based on these changes? We request further information regarding Indonesia's response to US Government comments regarding required labelling for non-halal products. Can you refer us to the applicable regulations for food and cosmetics from Indonesia's National Agency of Drug and Food Control (BPOM/NADFC) that are referenced in Indonesia's response? We also ask that the aforementioned BPOM/NADFC regulations for cosmetics be notified and opened up for comment, if they will result in new labelling requirements not currently in force for US cosmetics imported into Indonesia. In developing these requirements, we ask that Indonesia consider the industry and US Government comments previously submitted expressing concerns as to the feasibility and necessity of requiring that all categories of covered products have separate manufacturing, processing, storage, packaging, distribution, and sale facilities for Halal versus non-Halal products. We remain concerned by Indonesia's explanation at the February 2020 TBT Committee meeting that "naturally Halal" food and beverage products considered exempt from the new Halal Law did not include fresh fruits and vegetables that had been frozen. Can Indonesia explain why the process of freezing would require a Halal certification? Further, we continue to seek clarity on the status of bulk shipments.

[54] For previous statements follow the thread under IMS ID 502 (under dates raised and references).

2.223. We request that Indonesia provide sufficient transition time for stakeholders to understand and comply with the requirements in these regulations. We understand that the MORA implementing regulation will allow for phased implementation of mandatory Halal certification requirements between 2024 and 2034 and that Indonesia will continue to allow the sale of non-certified products until the deadline for each category is reached. Can Indonesia confirm our understanding? We would like to thank Indonesia for previously extending the recognition of foreign Halal certification bodies so that Halal-certified agricultural products can continue to enter Indonesia uninterrupted during this transition time. However, while all five US-based Halal certifiers have started the application process to renew recognition of their Halal certifications, they have received only minimal feedback on their applications. Meanwhile, recognition of one of the five certifiers expired on 5 June 2020. To ensure the continuation of trade, we request that Indonesia again extend recognition of all five US-based Halal certifiers for another two years to prevent trade disruptions for Indonesian industry while the Halal Product Assurance Agency (BPJPH) streamlines its recognition application process. We understand there is also an online registration requirement for each product certified by a foreign Halal certification body, including a requirement that the certificate registration numbers be included on the product label. We request that Indonesia remove or modify this requirement to reflect the fact that Indonesia's Halal Product Assurance Agency ("BPJPH") already conducts verification audits of those foreign Halal certification bodies.

2.224. As written, the registration requirement for importers is also cumbersome and duplicative. Could this online registration be done by foreign Halal certification bodies instead of by importers? Would you confirm that products that received their Halal certification inside of Indonesia would already be registered as part of the domestic Halal certification process and therefore would not need to use the online registration system? We ask that Indonesia provide greater specificity as to which medical devices will be subject to the Halal Law's implementing regulations. We also ask Indonesia to clarify their response to the US medical device industry request to exclude from the scope of the Halal Law in-vitro diagnostic products made of animal material which are used to test human blood, saliva and tissue samples that are not subsequently returned to the human body. We are encouraged by Indonesia's notification of the MORA regulation and urge Indonesia to notify all previous and forthcoming implementing regulations in their draft form prior to their finalization and again request transparency as these rules are developed to provide adequate transition time, and an opportunity for stakeholder comments. Would you confirm that haram (non-Halal) vaccines will be permitted as long as there is no equivalent Halal vaccine available for the same medical condition with comparable safety, efficacy and quality profiles? What will the process be to ensure this?

2.225. The representative of the European Union provided the following statement. The European Union would like to reiterate its serious concerns on the Indonesian Halal Product Guarantee Law No 33 of September 2014 and its implementing provisions, which require mandatory Halal certification and labelling for a very wide range of products to be placed on the Indonesian market. The EU regrets that, contrary to Article 2.9 of the TBT Agreement, Indonesia failed to notify the Halal Law and Implementing Regulation No 31/2019 to the TBT Committee. The EU acknowledges the TBT notification of Implementing Regulation 26/2019 on the Facilitation of Halal Product Assurance and Regulation 31/2018 on Processed Food Labelling and invites Indonesia to reply to the comments submitted, respectively, on 27 April and 12 May 2020. The EU is aware that Indonesia is in the process of adopting the Omnibus Bill on Job Creation, including provisions on the Halal certification process and invites Indonesia to notify the Bill to the WTO. The EU refers to its statements in previous TBT Committees stressing the excessive restrictive impact on trade of the proposed Halal measures and firmly calls upon Indonesia to reconsider its approach and keep Halal certification and labelling voluntary, limiting its effects to the legitimate objective of ensuring reliable information.

2.226. In particular, the requested "non-Halal" information for non-Halal products, the extension of Halal requirements to products other than food and beverages or the need for a cooperation agreement between foreign Halal certification bodies and the Indonesian Halal Products Assurance Agency (BPJPH) as a pre-condition for recognition of Halal certificates represent an excessive burden for economic operators. The additional registration requirement for Halal certifications issued by foreign bodies appears to be duplicative and time consuming. The EU insists that Indonesia accepts test reports from EU laboratories accredited by a body member of the international arrangements for mutual recognition of the ILAC and the International Accreditation Forum (IAF). The EU calls Indonesia to consider less-restrictive measures and to inform Members on the status of Halal implementing provisions.

2.227. The representative of Canada provided the following statement. Canada would like to thank Indonesia for its engagement on this issue. However, we would like to reiterate that Canadian exporters still require additional information on how the Halal Product Assurance Law will be implemented in order to successfully comply with its requirements. Canada looks forward to receiving additional clarification from Indonesia on what the term "toxic" means vis-à-vis grains, fruits and vegetables that must be certified Halal if they are "toxic". Canada appreciates Indonesia's assurances that the Halal law will not ban the sale of non-Halal products in Indonesia nor require non-Halal products to be certified. In our view, it would be beneficial for importers to have this specification made clear in the implementing regulations for the Halal Product Assurance Law. We remain concerned with the mandatory requirement for providing information of non-Halal ingredients on product packages. In our view this could be difficult for manufacturers to implement. Canada would appreciate if Indonesia could clarify the type of information that will be required on non-Halal food packages. If a food does not display a mark for Halal it should be assumed to be non-Halal. Canada has yet to receive the requested clarification of how this law will apply to frozen food. It is our understanding that fresh seafood is exempt from the Halal certification and labelling requirements but that frozen plant products and seafood are considered "processed" under the regulation and will therefore require Halal certification and labelling.

2.228. This requirement could disadvantage imported products that must be frozen in order to maintain freshness during transport and cause confusion among consumers. Canada exported close to CDA$43 million worth of frozen crabs and other frozen seafood to Indonesia in 2019. Can Indonesia explain how the freezing process makes a crab or blueberry non-Halal, based on its certification standards? Is there any form of freezing that can be undertaken that keeps a crab or blueberry Halal, and if so, could Indonesia explain what modifications to the process or other requirements are necessary? While we note that Indonesia remains open to international cooperation with foreign Halal institutions or authorities, the product accreditation process for foreign Halal certifying organizations remains unclear. Does Indonesia intend to publish further guidance on the Halal certification process certifying organizations must follow before the Halal Product Assurance Law and implementing regulations are fully in force? Will further guidance be notified to the TBT Enquiry Point and, if so, will a public comment period be provided?

2.229. Canada encourages Indonesia to provide timely information as further implementing regulations are developed to provide trading partners with sufficient time to comment and seek clarifications as needed. We understand that the outstanding application of a Canadian certification body that we raised during the last Committee meeting is being processed. Canada would like to thank Indonesia for moving ahead with the review of this application. However, this process reinforces a concern that Canada has previously raised – how will Indonesia engage with countries, such as Canada, that rely on successful non-governmental accreditation organizations to oversee Halal certification? The Regulation of the Minister of Religious Affairs of the Republic of Indonesia concerning the Operation of the Halal Product Guarantee Article 24 states that it is possible for accreditation institutions in other countries that have gained recognition in regional or international accreditation organizations to accredit a Canadian certification body. What is the acceptable alternative to a proof of accreditation from a local standards agency?

2.230. The representative of Brazil provided the following statement. Brazil would like to thank Indonesia for the clarifications provided in its statement regarding STC 502 in the previous TBT meeting. Brazil attaches great importance to the regulatory process aiming to implement Halal Product Assurance Law 33 (2014). We will continue to support this STC so as to keep track of any upcoming regulatory progress on the subject.

2.231. The representative of Australia provided the following statement. Australia welcomes on-going discussions on the Indonesian Halal Product Assurance Law no.33 of 2014 (Halal Law), and continues to seek for the law to be implemented transparently and in close communication with businesses and trading partners. We encourage Indonesia to continue to facilitate an open dialogue with trading partners to allow foreign businesses and their valued Indonesian importers to remain adequately informed of Halal Law implementation regulations. Australia welcomes further dialogue on the Halal Law to ensure its implementation is no more trade restrictive than necessary.

2.232. The representative of New Zealand provided the following statement. New Zealand would like to thank Indonesia for its on-going engagement to date regarding this matter. In reference to Article 29 paragraph (2), New Zealand continues to seek further guidance on the timeframe for release of the ministerial decree that will stipulate the type of products that must be Halal certified.

We ask for some clarity on the status of Halal Certification Organizations whose certification will soon expire or has already expired with Majelis Ulama Indonesia (MUI), and whether there are any transitory arrangements in place for them to continue to certify before the conclusion of Mutual Recognition Arrangements or other agreements. We appreciate any further information from Indonesia as to whether there are any other regulations relating to Halal under development, in addition to the Minister of Religious Affairs' regulation noted in your response. We understand that the Halal certification fees will need to be set in a Ministry of Finance regulation, and welcome any further clarification on this. We understand that the Omnibus Bill will require regulatory amendments under Halal Law 33/2014. Can Indonesia provide any further guidance on what these proposed changes may include and how they will affect the proposed Halal Assurance system.

2.233. In response, the representative of Indonesia provided the following statement. Indonesia would like to reiterate its previous statement that the implementation of Halal certification is effective in accordance with the article 33 of the Draft of MORA as notified previously in this Committee. In preparing the implementation of the Halal certification, which will take effect in 2024 for the first stage, implementing provisions are currently being developed and reviewed, taking into account comments and inputs from stakeholders. In addition, the Draft of MORA that has been notified through G/TBT/N/IDN/123 as one of the implementing provisions of Halal Law is yet to be enforced as the draft also undertakes review process at this time. Another implementing provision of the Halal Assurance Law is the Decree of MORA 464 which regulates all type of products that are mandatory to be halal certified. This Decree is also currently under review to consider comments and inputs from stakeholders. Hence, this regulation is also yet to come into effect.

2.234. In accordance with Law No 33 of 2014 Chapter III on Halal Product Materials and Processes, materials used in halal process consist of raw materials, processed materials, additives, and auxiliary materials. The aforementioned materials may come from animals, plants, microbes; or materials produced through chemical processes, biological processes, or genetic engineering processes. Materials derived from animals are basically Halal, except those that are prohibited according to the Islamic Sharia Law. Based on this, the materials used for Halal products must be free from haram contaminants in accordance with Islamic Sharia law and should not cause harm to human health. Indonesia reaffirms its openness to international cooperation with foreign Halal institutions or authorities. Cooperation with foreign Halal institutions will prioritize the principle of mutual recognition and mutual acceptance in accordance with international regulations and practices. Product registration is a common procedure applied in many countries for almost all products. This procedure aims to ensure traceability and facilitate supervision of the circulation of Halal products. For more detailed concerns and enquiries, we invite Members of this committee to make all necessary communications through Indonesia's WTO TBT Enquiry Point.

2.1.3.16 China - Draft revised Encryption Law of the People's Republic of China by the Office of State Commercial Cryptography Administration (OSCCA) (IMS ID 534[55])

2.235. The representative of Japan provided the following statement. Japan continues to have concerns regarding China's "Encryption Law" that entered into force on 1 January 2020 and would like to refer to the previous statement which we made at the last TBT Committee in May 2020. Japan would like to request that China's regulation not hamper foreign companies' activities or market access to China.

2.236. The representative of the European Union provided the following statement. The EU would like to reiterate its concern on the Cryptography Law that came into force on 1 January 2020. The EU remains concerned about the wide scope of the law, in conjunction with the lack of clarity of a number of foundational concepts as well as administrative procedures described in the text. Both of these factors will negatively impact business confidence. The EU notes with concern that the new law does not recognize China's previous commitment made in 2000 that the cryptography-related regulation would only apply to products whose core function is that of providing encryption – the so-called "Year 2000 Clarification" by the SCA. The EU calls on China to ensure that legal and regulatory requirements are based on a non-discriminatory basis, do not favour specific technologies, do not limit market access and do not lead to a forced transfer of intellectual property. Regulatory procedures related to products containing cryptographic components should be transparent, predictable and consistent with international practices. The EU urges China to guarantee the possibility for foreign invested enterprises (FIEs) to participate on an equal footing with domestic

[55] For previous statements follow the thread under IMS ID 534 (under dates raised and references).

companies in the production, research, development and sale of cryptography products on its market.

2.237. The representative of the United States provided the following statement. The United States supports the other Members raising this STC, and we refer to our previous statements on this measure. We continue to be concerned about the implementing regulations on Encryption Law for China and we hope that China will notify any implementing measures.

2.238. The representative of Canada provided the following statement. Canada would like to refer to its statement made at the November 2019 TBT Committee meeting, as recorded in paragraph 2.95 of document G/TBT/M/79.

2.239. In response, the representative of China provided the following statement. The Law on Cryptography of China took effect on 1 January 2020. The Law clearly stipulates that the governments at all levels and relevant departments shall follow the principle of non-discrimination, and treat all the organizations equally, including foreign-invested enterprises that engage in commercial cryptography research, production, sales, service, importation and exportation, etc. The State encourages commercial cryptography technical cooperation based on voluntary principle and commercial rules in the process of foreign investment. Administrative agencies and their staff are prohibited to force any transfer of commercial cryptography technology by means of administrative measures.

2.1.3.17 European Union - Transitional periods for MRLs and international consultations (IMS ID 580[56])

2.240. The representative of Costa Rica provided the following statement. As in previous meetings, Costa Rica associates itself with the concern raised by the United States, Colombia and Indonesia, as well as with the request for extension of the period for compliance with the new tolerances that are being established for various substances, in view of the serious impact that they have on the agricultural production of our countries. The EU's review of the tolerances for various substances used in agricultural production is a source of huge concern for Costa Rica. As previously stated, it is impossible for agricultural production to adjust to new requirements or tolerances within six months, when the registration of new molecules alone must undergo a complex assessment process lasting much longer than that period. Furthermore, in the current historical context in which the international community finds itself due to the COVID-19 crisis, the implementation of more restrictive measures or additional burdens on international trade in agricultural products constitutes a challenge that is hampering worldwide economic recovery efforts, especially in developing countries. In this regard, we would like to remind the EU of the request made in documents G/SPS/GEN/1778 and G/TBT/GEN/296 - Request for the suspension of the processes and entry into force of reductions of maximum residue levels (MRLs) for plant protection products in light of the COVID-19 pandemic.

2.241. The representative of the United States provided the following statement. We share the concern that the EU transition measures do not provide adequate time for producers to modify their pest management programmes to clear the channels of trade. We recall previously raised concerns that trading partners do not know with certainty the impact of the non-renewal decision on future MRLs, nor can foreign growers make informed decisions on their food production practices in the present. Foreign growers who comply with existing EU MRL standards at the time of production continue to face possible rejection at EU borders — a damaging prospect that EU growers do not face under the current regulatory provisions. Once again, the United States reiterates its request that the EU conduct full risk assessments prior to setting new MRLs, and we ask that the EU extend its MRL transitional measures to account for realistic production and processing times for food and agricultural products.

2.242. The representative of Colombia provided the following statement. Colombia wishes to reiterate its grave concern regarding international consultation processes adopted and the transition periods granted by the European Union prior to the entry into force of provisions under which the EU no longer approves the marketing of certain plant protection substances and amends maximum residue limits (MRLs). These concerns are being reiterated because, to date, there is no alternative that would help resolve the problems that short transition periods cause for fruit and vegetable

[56] For previous statements follow the thread under IMS ID 580 (under dates raised and references).

producers in Latin American countries. In this context, we reaffirm the arguments put forward and compiled in document G/TBT/W/695 of 13 November 2019. The uncertainty faced by agricultural producers related to short transition periods raises concern. These measures create additional burdens for agricultural producers, who need to make decisions on the use of crop protection products a year or more before the final product arrives on the European market. This is particularly complex for products with long production and harvest cycles as, while complying with European standards at the time of sowing, they may face regulatory changes that prevent exports at the time of harvest and distribution of the product. The same challenges arise in processed and frozen foods. For such products, short transition periods can create situations in which imported products are discriminated against in favour of domestic products, as goods produced in accordance with the EU standards in force at the time of production may no longer be eligible to enter the EU by the future date on which they arrive at the border.

2.243. Moreover, the situation that has arisen as a result of the COVID-19 global health emergency has forced the health and scientific authorities of all countries, including Colombia, to focus attention on that crisis. By the same token, key sectors such as food producers, organizations and associations are having to make significant efforts to ensure biosecurity controls in the fruit and vegetable supply chain. This is reducing their ability to analyse draft regulatory measures and adjust production methods accordingly, creating additional burdens on international trade in food products, which is hampering worldwide economy recovery efforts, especially in developing countries. In line with the statements made in communication G/TBT/GEN/296/Rev.3, currently supported by 39 Members, we request the EU to temporarily suspend review processes of market approvals for plant protection substances, the processes currently under way to establish new MRLs, and the entry into force of regulations in these areas, planned for 2020. Furthermore, Colombia maintains that notification of transition periods or MRLs to the WTO should not be conducted as a simple formality within the regulatory process, but should provide a real forum for Members to submit substantive observations and comments for genuine consideration by the Committee that could lead to changes or adjustments to proposed regulations.

2.244. Therefore, within the framework of this Committee, it cannot be acceptable for the European Union to state that, as soon as the EFSA recommendation and PAFF Committee opinion are known, countries should be able to "make the relevant adjustments", given that this information has not been notified to the WTO and therefore the public consultation period has not expired. In accordance with the provisions of Articles 2.5 and 2.12 of the TBT Agreement, Colombia considers that there should be further technical discussions, taking into consideration the arguments and technical, scientific and economic evidence submitted by the Members concerned, to review the time periods for bringing into force the regulatory changes to MRLs, in order to prevent them from becoming unnecessary barriers to trade. Colombia once again welcomes the opportunity to express its concerns on this issue and looks forward to a response from the European Union.

2.245. The representative of Indonesia provided the following statement. Indonesia thanks Costa Rica, the United States, Colombia, Brazil, Guatemala, Uruguay, Ecuador, El Salvador, Panama, and Paraguay for raising this issue and shares the same concern regarding EU regulation on Transitional Periods for MRLs and International Consultations. However, Indonesia is of the view that this measure is more stringent than necessary and has the potential to disrupt trade, specifically for developing countries who export horticulture and other agriculture products to the EU. Indonesia regrets the application of this measure and, therefore, urges the EU to ensure that this measure is not less restrictive than necessary. Furthermore, Indonesia urges EU to align with the existing internationally accepted risk assessment approach as stated in Article 2.4 of TBT Agreement in order to remove the obstacles to trade. Indonesia as a developing country establishes the standards and regulations based on Codex MRLs for pesticides that has been approved by all the member countries. Indonesia would also like to request the EU to provide a sufficient transition period especially for developing countries to adapt to the EU policy on MRLs of pesticides.

2.246. The representative of Brazil provided the following statement. Brazil supports the concerns raised by the US, Costa Rica, Colombia and Indonesia, and we would like to refer to our previous statements regarding STC 580. We respectfully bring to the attention of the EU its obligations under Article 2.12 of the TBT Agreement, which relate to the establishment of a reasonable interval between the publication of technical regulations and their entry into force, except in cases of urgent problems of safety, health, environmental protection or national security. It is of utmost importance to guarantee an adequate transitional period, especially for those cases in which the scientific opinions of the EFSA on the toxicity of substances are "inconclusive" or only indicate a "suspected

risk". In 2019, for instance, the EU defined a grace period of three months for accepting the presence of MRLs for chlorpyrifos in the EU, following on TBT notification G/TBT/N/EU/682. Such period is incompatible with the production period of an orange crop, when plants have already been sprayed with chlorpyrifos. It is also incompatible with the production process, given that a significant part of the juice is exported frozen. This issue is even more worrisome to small farmers which had already used chlorpyrifos early in their production process.

2.247. The representative of Guatemala provided the following statement. Guatemala wishes to reiterate the importance of the European Union granting transition periods that closely follow the stages of crop production, in particular for crops grown in tropical countries. The productive sectors require more time to adapt and, in particular, find alternative substances, which in some cases means having to wait for suitable production cycles to commence application and testing. We are concerned that our ideas for discussions on finding solutions have not been heard and accepted. The trade concern regarding this issue focuses on safeguarding agricultural producers and exporters exporting to the European Union, who will be affected by the European Union's change in conditions. We would be grateful if the European Union could: (i) establish genuine dialogue to discuss this issue; (ii) extend the transition period, with a view to ensuring that trade is not obstructed any more than is necessary and giving time for tropical developing countries to adapt; and (iii) provide clarification on how our comments on this process in the WTO are taken into account within the regulations.

2.248. The representative of Uruguay provided the following statement. Our delegation welcomes the information provided by the European Union at the Committee's previous meetings, including in May of this year, at which time it indicated, *inter alia,* that the effective application of the reduced maximum residue levels (MRLs) is usually deferred by six months following the entry into force of such changes. However, in view of harvesting periods, the stages at which plant protection products are applied, and the time required to develop and register alternative substances, in practice, the transitional periods granted by the European Union in the provisions amending MRLs for active substances do not provide enough time to make the necessary adjustments to production and ensure that agricultural products, especially processed or frozen products, comply with the new, lower MRLs. Uruguay once again calls on the European Union to adopt regulatory decisions based on internationally accepted standards or to provide conclusive scientific evidence when it is strictly necessary to depart from these standards in order to meet its legitimate objectives, as provided for in the relevant WTO Agreements. Even in cases where the European Union decides, based on a full risk assessment, that it is necessary to reduce the MRLs for active substances used in the agricultural production of other Members, we encourage it to take into consideration the concerns expressed by various delegations regarding the insufficient length of the transitional periods that are usually granted to make the relevant adjustments.

2.249. The representative of Ecuador provided the following statement. Ecuador shares the concerns raised by Colombia, Costa Rica, Indonesia and the United States. We echo our previous statements on this specific trade concern. Ecuador once again reiterates its concern regarding the transitional periods granted by the EU for implementing its measures relating to the non-renewal of the use of substances and the reduction of MRLs. These periods fail to provide sufficient time for producers to adapt so as to prevent their access to the European market from being unnecessarily affected. We therefore urge the European Union to provide a period of at least 36 months, which is the time needed to develop a new phytosanitary pest control product. Ecuadorian farmers are, even against the backdrop of COVID-19, making every effort to comply with the EU's requirements. However, it is impossible to do so in such a short period of time. A period of at least 36 months would be more appropriate for making the necessary adjustments in production and would enable producers to ensure compliance with the conditions laid down in the European regulations.

2.250. The representative of El Salvador provided the following statement. El Salvador shares the views expressed by other delegations regarding the various European Union draft technical regulations on maximum residue levels. We urge the EU to ensure that these are based on technical evidence and do not result in unjustified restrictions on trade. Furthermore we would like to refer to the communication circulated in G/TBT/GEN/296 and its revisions, by Costa Rica, Guatemala, the Dominican Republic, Colombia, Argentina, Panama, Ecuador, Paraguay, Peru, Nicaragua, Honduras, El Salvador and others, in which the EU is requested to suspend for 12 months the review processes of MRLs as well as the entry into force of all regulations in this area planned for 2020.

2.251. The representative of Panama provided the following statement. Like other delegations, Panama still has concerns regarding the potential EU regulations. These concerns have been expressed at previous meetings. Therefore, in order to be brief, and given that we have an extensive list of specific trade concerns, I wish to refer to previous statements we have made on the subject.

2.252. The representative of Paraguay provided the following statement. Paraguay refers to its statement under *European Union - Hazard-based approach to plant protection products and setting of import tolerances (IMS ID 393),* para. 2.215.

2.253. The representative of Chile provided the following statement. The delegation of Chile echoes the trade concern raised by the United States and supported by Costa Rica, Colombia, Indonesia, Brazil and the other delegations that took the floor before me concerning the new maximum residue levels for various agricultural products set out by the European Union.

2.254. The representative of Canada provided the following statement. Canada would like to reiterate its concern with the EU's transition periods for maximum residue limits. Currently, transition periods do not apply to third countries, making it very difficult for exporters to adapt to the new requirements. The current approach does not acknowledge the reality of agricultural supply chains such as multi-year inventory and extensive shelf life, including in foreign countries. At a time when ensuring food security is paramount, the EU must consider transition periods for MRLs taking into account the need for exporters to adapt to new requirements, as it has done for its domestic producers.

2.255. In response, the representative of the European Union provided the following statement. As clarified in previous TBT Committees, as a matter of principle, the EU considers that concerns on the setting of MRLs for pesticides – and any details regarding their implementation – should be an issue for discussion at the SPS Committee, rather than at the TBT Committee. Further to requests by some Members, and in the interest of transparency, the EU decided to notify all draft measures on pesticide active substances that are relevant for the TBT Committee additionally also to the SPS Committee. In practice, future draft acts on the non-approval or restriction of approval of an active substance will be notified to both Committees. However, in the interest of efficient proceedings in both Committees and in line with the respective Agreements, the EU considers that matters on approvals of active substances should be discussed exclusively in the TBT Committee, and matters on the setting of MRLs for pesticides should be discussed exclusively in the SPS Committee. The EU provided detailed information to Members as regards possible transitional periods when MRLs are lowered at the previous TBT Committee meeting last May.

2.1.3.18 European Union - chlorothalonil (pesticide active substance), G/TBT/N/EU/625, G/SPS/N/EU/394 (IMS ID 579[57])

2.256. The representative of Costa Rica provided the following statement. Costa Rica fully supports the comments made by Colombia and reiterates its concern regarding the measure notified by the European Union in document G/TBT/N/EU/625 relating to the non-renewal of the approval of the active substance chlorothalonil. Costa Rica has repeatedly raised its concern over the lack of conclusive scientific evidence and the application of a precautionary approach in the processes to renew the marketing permits, which then affect the establishment of MRLs. This is the case for chlorothalonil, with the Regulation relating to this substance entering into effect in May 2020 despite the many concerns raised in various WTO bodies at both the bilateral and regional level, at an extremely difficult time for tropical agricultural exporting countries such as Costa Rica, which continue to feel the adverse effects of the pandemic. In this respect, we support the call made by Costa Rica, Colombia and 37 other WTO Members in document G/TBT/GEN/296/Rev.3 for the EU to temporarily suspend all review processes of market approvals for plant protection substances, as well as the entry into force of regulations in this area planned for 2020, including the non-renewal of the active substance chlorothalonil.

2.257. The representative of Indonesia provided the following statement. Indonesia shares the concern of Costa Rica, Colombia, Brazil, Guatemala, El Salvador and Ecuador regarding EU regulation on chlorothalonil. Indonesia has great interest in this matter as we are exporting agriculture products such as fruits, onion, peanut, and chili to the EU region. In addition, in ensuring Maximum Residue Limits of chlorothalonil, Indonesia refers to the international standard of Codex MRLs for Pesticides

[57] For previous statements follow the thread under IMS ID 579 (under dates raised and references).

as reflected in Ministry of Agriculture Regulation No.55 of 2016 regarding Food Safety Supervision Against Importation of Plant-Originated Fresh Food. Indonesia is of the view that the EU's measure on chlorothalonil is more stringent than necessary and has the potential to disrupt trade, specifically for developing countries which export horticulture and other agriculture products to the EU. In this regard, Indonesia would like to request the EU to use an internationally accepted risk assessment approach, based on realistic appropriate data and scientific study as stated in Codex MRLs for Pesticides which permitted the use of this substance in various plant products. Indonesia would also like to remind the EU that Article 2.4 of the TBT Agreement requests Members to use existing international standards, or the relevant parts of them, as a basis for their technical regulations. We are of the view that trade disruption could not be avoided if Members arbitrarily start to disregard any international standards in their technical regulations.

2.258. The representative of Colombia provided the following statement. Colombia reiterates its concern regarding the measure notified by the European Union in document G/TBT/N/EU/625 relating to the non-renewal of the approval of the active substance chlorothalonil. Despite the many comments and requests for a longer transition period to adapt production processes, which in the agricultural sector are particularly complex, this regulation entered into force in May, without the EU taking into account the concerns raised by various members in this Organization and in other settings. This substance is key to pest control for a wide variety of crops, particularly bananas, as it is used for the control of Black Sigatoka, a fungus that devastates banana crops. Beyond this particular case, the EU has been adopting measures under which approval for the use or marketing of plant protection products is not being renewed, which has an impact on the exports of its trading partners. Subsequently added to these measures was the reduction of the MRLs to the minimum detection level, further hindering sales of certain agricultural products. These measures have been taken without any sound scientific evidence and without any proof that they effectively constitute less trade-restrictive measures to ensure an appropriate level of protection for consumers.

2.259. In Colombia, the use of plant protection substances – such as chlorothalonil – is essential in agricultural production for the protection of crops against pests and diseases, and for maintaining the quality and safety of products during storage, transport and distribution, before they reach consumers in the European market. It is important to note that, regarding the review of substances, EFSA has published, as it has done more and more frequently, reasoned opinions stating that, owing to insufficient information, the risk assessment for active ingredients is inconclusive. We consider that the European Commission (DG SANTE) has wrongly interpreted these opinions and thus, as a precaution, has not renewed the marketing permits for the substances. Contrary to the provisions of the WTO TBT Agreement, the EU's decisions are not provisional and do not demonstrate any effort to obtain the further information necessary to conduct a more objective risk assessment. The foregoing constitutes a violation of Article 2.2 of the TBT Agreement, which stipulates that technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective. As indicated, there is insufficient information to establish criteria for acceptance or rejection of the chlorothalonil compound, given that, from a scientific point of view, its effect on health has not been clearly determined.

2.260. We reiterate that it is essential for the EU to use a risk-assessment approach in decision-making to determine marketing approvals for active substances, as the EU has stated in a similar context, given that there is insufficient scientific evidence to identify the various toxicological aspects that may affect human health, or the environment in the case of chlorothalonil. Any measures adopted must be based on scientific evidence and international standards and take account of the biodiverse agriculture of tropical countries such as Colombia. Moreover, the situation that has arisen as a result of the COVID-19 global health emergency has forced the health and scientific authorities of all countries, including Colombia, to focus attention on that crisis. By the same token, key sectors such as food producers, organizations and associations are having to make significant efforts to ensure biosecurity controls in the fruit and vegetable supply chain. This is reducing their ability to analyse draft regulatory measures and adjust production methods accordingly, creating additional burdens on international trade in food products, which is hampering worldwide economy recovery efforts, especially in developing countries. In line with the statements made in document G/TBT/GEN/296/Rev.3, signed by 39 Members, we request the EU to temporarily suspend review processes of market approvals for plant protection substances, and the entry into force of regulations in this area, planned for 2020, including the non-renewal of the active substance chlorothalonil.

2.261. The representative of Brazil provided the following statement. Brazil supports STC 579 and refers to its previous statements on the matter. We respectfully differ from the EU's decision to base measures on a hazard-based approach, without an adequate risk analysis and with no compliance with long-standing scientific principles. The non-renewal of approval for chlorothalonil by the EU did not duly consider that it is currently authorized in more than 100 countries, and that the MRLs allowed by Codex could reach up to 70 mg/kg. We stress our systemic concern with the fact that some hazard-based analyses conducted by the EFSA led to the non-renewal of approvals of some substances and subsequently to the reduction of their MRLs. The Brazilian National Health Agency has set MRLs for chlorothalonil applied to more than 30 crops. The case of chlorothalonil affects Brazil's exports of banana, coffee, citrus fruits, papaya, watermelon, among others.

2.262. The representative of Guatemala provided the following statement. Guatemala shares the concern regarding the entry into force of this regulation last month, especially because we still have no information on scientific evidence of the damage to human health caused by consuming fruits and vegetables, particularly those produced in Latin America. This is why it is important to request a risk analysis. Chlorothalonil is used in the production of bananas, snow peas, sugar snap peas, French beans and coffee. It is a compound used as a broad-spectrum and fast-acting contact fungicide. No other molecule on the market is currently as effective for controlling the Ascochyta fungus, above all in vegetables. Guatemala's climatic conditions provide this fungus with the ideal environment to reproduce, affecting crops and seriously harming Guatemalan producers and exporters and the economy. Substances such as mancozeb, azoxystrobin, pyraclostrobin, sulphur and difenoconazole can be used to substitute chlorothalonil. The registration of four of these alternative substances was not renewed for marketing in the European Union, and, as a result, maximum residue levels have been reduced to almost zero tolerance, leaving Guatemalan agricultural production with no options that can effectively combat diseases of fungal origin.

2.263. Guatemala is geographically located in the tropics, where, unlike Europe, there are only two seasons, one rainy and one dry. This provides an ideal climate for pests and diseases to spread throughout the year and stimulates the growth of fungi, which can damage crops. The country is one of the world's leading producers of non-traditional vegetables and produced 70 million pounds of peas and 65 million pounds of green beans in 2019, making it one of the main exporters of these crops to the European Union. In Guatemala, the dynamics and growth of the sector have helped improve the quality of life of more than 60,000 families in some 200 rural communities that make up the sector's production base, generating around 20,000 jobs. Guatemala's banana exports accounted for 30% of total exports of traditional products in 2018 and 11.2% of total exports from the customs territory. The banana is the world's most consumed and exported fruit. Banana production has directly and indirectly created over 280,000 jobs, and any changes to the production cycle resulting from an increase in disease due to a lack of alternative substances would affect over 1,120,000 Guatemalans (Independent Banana Producers' Association, APIB, 2019).

2.264. We would therefore be grateful if the European Union would consider the particular circumstances of tropical countries when implementing the measures, until it has conclusive studies and has aligned itself with the provisions of the Codex. Accordingly, we request it to: (a) consider the risk assessment approach and scientific evidence; (b) set maximum residue levels (MRLs) that also correspond to the reality of tropical countries. These countries cannot be expected to have the same climatic conditions as European countries; this is just not feasible. We therefore request that the MRLs for chlorothalonil be reviewed, taking into account that no chemical substance on the market can replace chlorothalonil and effectively control the Ascochyta fungus; and (c) provide scientifically-based information showing that vegetables and fruit exported from Guatemala or third countries are harmful to the health of European consumers.

2.265. The representative of El Salvador provided the following statement. Our delegation is concerned about the negative impact that this measure will have on exports of Salvadorian agricultural products and those of many developing countries to the European market.

2.266. The representative of Ecuador provided the following statement. Ecuador wishes to reiterate its concern in relation to notification G/TBT/N/EU/625 on the non-renewal of the use of the active substance chlorothalonil and document SANTE/10186/2018 Rev 1, through which the EU confirms the non-renewal of the use of the substance. Chlorothalonil is the main tool for controlling Black Sigatoka in bananas due to its effectiveness, low cost and multisite mode of action, meaning that the risk of resistance is low. It is available in a wide range of products, through many suppliers, and is widely available in the country. Our concern stems from the fact that the non-renewal of the use

of chlorothalonil has resulted in the notification of document G/SPS/N/EU/394 on 15 June 2020 concerning the draft Regulation on the existing MRLs for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine. This proposes reducing the MRL for chlorothalonil in bananas from 15 ppm to 0.01 ppm. Changing the MRL to the default level will affect our country's banana production.

2.267. Ecuador is a major banana-producing country, meaning that any negative impact on this sector will have significant repercussions for social development and especially for the economy of small, medium and large producers in the country. No substitute or similar phytosanitary products with the same environmental or toxicological profile are available, since similar questions have been raised about the environmental and health effects of the alternatives to chlorothalonil (mancozeb, metiram, folpet, propineb). The productive banana sector provides jobs for 2.5 million people. Every year, 300 million boxes of bananas leave Ecuador to be consumed around the world. These exports generate 2.1 billion in revenue for the country, accounting for 2% of GDP and 35% of agricultural GDP. Farms manage the use of agrochemicals in banana crops very well and maintain a culture of prevention in their operations and on the farm itself. Ecuador is requesting that, before a final decision is taken on implementing this measure and modifying MRLs, the European Commission consider all existing data, with due regard for consumer health and the potential effects on the food producing sector. Ecuador urges the EU to take into consideration the existing scientific information from international specialized agencies recognized by the WTO, such as the Codex Alimentarius, which has relevant on this substance and establishes an MRL of 15 ppm specifically for bananas.

2.268. The representative of Paraguay provided the following statement. Paraguay refers to its statement under *European Union - Hazard-based approach to plant protection products and setting of import tolerances (IMS ID 393),* para. 2.215.

2.269. In response, the representative of the European Union provided the following statement. As explained at previous TBT Committee meetings, the EU proposed not to renew the approval of chlorothalonil through Implementing Regulation (EU) No 2019/677[58], adopted on 29 April 2019. The draft Regulation was notified via the TBT procedure. Chlorothalonil was evaluated in accordance with Regulation (EC) No 1107/2009 on the placing of plant protection products on the market.[59] The conclusion[60] by the EFSA on this substance, following assessment by the "rapporteur" member State and an extensive peer review process, was published in January 2018. During the peer review process, the approval criteria provided for in Article 4 of the Regulation were not satisfied with respect to one or more representative uses of at least one plant protection product. Following the non-approval decision, the EU prepared a draft Regulation lowering the MRLs for chlorothalonil, which was notified to the WTO/SPS Committee (G/SPS/N/EU/394). In view of the concerns identified by EFSA, the EU intends to lower all MRLs for chlorothalonil at the relevant limits of quantification. The new values will apply as of August 2021 with no further transitional measures for products that were produced before the Regulation becomes applicable. Import tolerance requests remain possible and will be assessed on a case-by-case basis by the "rapporteur" member State and the EFSA. Such requests would have to be supported by substantial new data addressing the concerns.

2.1.3.19 European Union - Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR), G/TBT/N/EU/71/Add.1; G/TBT/N/EU/72; G/TBT/N/EU/72/Add.1 (IMS ID 594[61])

2.270. The representative of Japan provided the following statement. Japan would like to express its support for the development of medical device regulations that enhances the quality and safety of medical devices in the EU. Japan additionally welcomes that the EU postponed the date of application of MDR by one year in response to the COVID-19 crisis. However, Japan would like to request the following points in order for manufacturers exporting medical devices to Europe to obtain MDR certification by this application date. First, Japan would like to ask the EU to ensure that Notified Bodies (NBs) have sufficient capacity to issue certifications in a timely manner, including commencement of evaluation by NB branch offices in Japan. Second, Japan requests that the EU regularly update "the on-going Medical Device Coordination Group (MDCG) guidance development

[58] OJ L 114, 30.4.2019, p. 15.
[59] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1489747880535&uri=CELEX:32009R1107
[60] EFSA 2018 Conclusion on the peer review of the pesticide risk assessment of the active substance chlorothalonil. EFSA Journal 2018;16(1):5126, http://www.efsa.europa.eu/en/efsajournal/pub/5126
[61] For previous statements follow the thread under IMS ID 594 (under dates raised and references).

plan", since the publication dates for some MDCG guidance documents have not been determined, and also ask the EU to issue all MDCG guidance documents, which are necessary to comply with MDR, as soon as possible. Especially, guidance documents categorized as "Post-Market Surveillance and Vigilance (PMSV)", "New Technology", "EUDAMED" and "Unique Device Identifier (UDI)" are essential information for manufacturers.

2.271. The representative of the United States provided the following statement. Thank you for your detailed update on the status of MDR and IVDR implementation during our bilateral meeting last week. The United States supports the development and enforcement of a well-defined medical device regulatory system that assures the safety and performance of medical devices, especially now given the global health crisis we are facing. The one-year delay in implementation of the MDR provided some necessary relief. However, several issues remain regarding implementation of both the MDR and IVDR, and US industry remains concerned about its continued access to the EU's USD 125 billion medical device market, USD 20 billion of which is supplied by US products. Given pandemic-related travel restrictions are making in-person audits difficult we urge additional consideration be given to allow virtual audits for both the MDR and IVDR. We are concerned that the lack of audits will become a serious bottleneck. While we note that 17 NBs have been approved to assess conformity to the MDR, it is still significantly less than the number of Notified Bodies that were approved under the Medical Device Directive (MDD). We ask for continued attention to the approval process to ensure Notified Body applications continue to move through the review process. We also note that there are currently only four NBs approved to assess conformity to the IVDR. If practical solutions cannot be found to address these looming bottlenecks, we recommend serious consideration also be given to a significant extension in implementation of MDR and IVDR.

2.272. We are also concerned about the status of standards that companies can use to demonstrate compliance with the essential requirements. We understand that many of the standards in the Commission's standardization mandate are not based on the latest international standard. A presumption of conformity is important to support market access in practical terms. We note that in preparation of the implementation of MDR, the Commission selected the Classificazione nazionale e internazionali (CND), a UDI system that is not harmonized with the well-established UDI system that utilizes the Global Medical Device Nomenclature (GMDN). GMDN was developed with the support of the International Organization Standardization and the International Medical Device Regulators Forum, and is widely adopted by the medical device industry and is used by over 70 national medical device regulators to support their activity. We are concerned about the EU's selection of CND, because this selection will undermine the interoperability of the two UDI systems for tracking and reporting purposes, and will pose several significant obstacles to the medical device and healthcare community. Furthermore, the Commission has not made any progress on mapping CND to GMDN and has not addressed interoperability concerns. An additional consequence of the Commission's adoption of CND is that it could encourage other regulators and entities, like the World Health Organization, to adopt CND, creating duplicative requirements for the medical device industry.

2.273. The representative of China provided the following statement. I would not like to repeat what we have said at a previous meeting. Here I would like to refer to our statement on IVDR in the May TBT Committee meeting[62] and China thanks EU for their detailed replies via bilateral channel and we appreciate that very much but here I would like to highlight one point regarding the transition deadline of IVDR because of COVID-19 epidemic impact on the implementation of IVDR. We would like the EU to consider postponing the deadline of transition period of IVDR from May 2022 to May 2024.

2.274. The representative of the Republic of Korea provided the following statement. Korea supports EU's efforts to enhance the safety and quality of medical devices in the EU market through the comprehensive revision of the regulation. In particular, we thank the EU for postponing the implementation of the MDR for a year to allow the Members, health institutions and economic operators to focus on responding to the COVID-19 pandemic. Korea also appreciates that the EU has significantly expanded the number of NBs from 12 to 21 as of September 2020. Nevertheless, we would like to highlight the challenges faced by the Korean industry in entering the EU market due to the lack of information needed to comply with the MDR and the IVDR. Given this concern, we request the EU to swiftly issue the MDCG guidance and also update other regulatory information and guidance documents to help the industry prepare for the implementation of the new regulation. Also,

[62] G/TBT/M/81, paras. 1.465-1.467.

we were informed that a total of 52 applications are pending for designation as NBs. We anticipate that the EU will designate a sufficient number of NBs for CE certification as soon as practicable.

2.275. The representative of Canada provided the following statement. Canada again wishes to echo the points raised by other Members regarding the implementation of this measure, which affects an important export market for Canadian medical device manufacturers. We remain concerned that the number of NBs still appears to be insufficient to carry out the certification and approval activities provided for in the regulations. We are also worried that the creation of a European Medical Device Nomenclature System under the new EU MDR would be in conflict with the existing global device nomenclature system (GMDN) that was created by regulators for regulators and has been implemented in various regulatory jurisdictions. This new system being created in Europe is considered by industry to be a technical barrier to trade as yet another nomenclature system is being introduced. Will this be reconsidered or will there be an exercise of mapping the new European codes to the current GMDN codes?

2.276. The representative of Singapore provided the following statement. Singapore supports the EU's objective of ensuring the enhanced safety and performance of medical devices. We appreciate the European Commission's postponement of the date of application of the MDR till 26 May 2021 to allow relevant stakeholders to prioritize responding to the on-going COVID-19 pandemic. However, Singapore would like to register our concerns regarding the insufficient number of designated NBs under the MDR. We understand that as of 27 October 2020, only 17 NBs have been designated under the MDR. We are concerned that this could lead to backlogs and bottlenecks in the certification process for medical devices. Singapore notes the grace mechanism that has been put in place to smoothen the MDR's transition period, and the EU's consideration of contingencies in response to this issue. We look forward to further developments that will facilitate certification under the MDR and allow for continued access to the EU's medical device market.

2.277. In response, the representative of the European Union provided the following statement. The new legislation on medical devices was adopted by the Council and the European Parliament in April 2017. This new framework sets high standards of quality and safety for medical devices and aims at ensuring the smooth functioning of the internal market. The new provisions were scheduled to apply from 26 May 2020 for medical devices and 26 May 2022 for in-vitro diagnostic medical devices. In view of the exceptional current circumstances of the COVID-19 crisis and, with patient health and safety as a guiding principle, the date of application of the MDR was postponed until 26 May 2021. The IVDR's[63] corresponding date of application remains the same (May 2022). The Commission continues to monitor the impact of the COVID-19 crisis with regard to this application date. The Commission and member States are continuing the work on implementing acts and guidelines under the current circumstances. To date, there have been 60 published guidance documents including several key guidances on clinical requirements. In addition, the date for the launch of expert panels, as well as the registration module of the EUDAMED database, have been adapted to the new application date and will be in place during this quarter. The other parts of the EUDAMED database will be made gradually available. The legislation provides, in the meantime, for alternatives to the EUDAMED use.

2.278. To date, there have been 21 designations of NBs under the two new regulations, 17 under the MDR and four under the IVDR. Additional designations will follow in the next few weeks. NBs designated under the MDR reportedly hold a significant share of the market. The Commission is also expecting a significant increase in the course of this year. Additionally, the grace mechanism to smoothen the transition will remain in place. As a final resort (in duly justified cases and in the interest of public health or patient health or safety), national competent authorities may authorize within their territory the placing on the market of specific devices which have not fulfilled the conformity assessment requirements. In exceptional cases, the Commission may decide to extend those national measures to the territory of the Union for a limited duration. The EU is fully committed to ensure that the new system provides a higher level of patient protection.

[63] Regulation (EU) No 2017/746 of the European Parliament and of the Council of 5 April 2017 on in-vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

2.1.3.20 Peru - Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA, G/TBT/N/PER/97, G/TBT/N/PER/97/Add.1, G/TBT/N/PER/97/Add.2 (IMS ID 618[64])

2.279. The representative of Costa Rica provided the following statement. Costa Rica wishes to thank Peru for keeping us informed of the progress of the process to implement the draft Regulation established under Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA. As we have mentioned, under the proposed amendment to the Manual of Advertising Warnings, the use of stickers or adhesive labels to meet the Manual's labelling requirements will no longer be permitted in Peru as of June 2020. Peru recently informed us that the entry into force of this Regulation had been postponed until 30 June 2021. Although this postponement offers some respite for our exporters, we wish to nonetheless reiterate our concern and respectfully request that the Peruvian authorities consider permitting the use of adhesive labels on a reciprocal basis, given that these labels may be used on Peruvian food products to be marketed in Central America. The food industry has informed us of the negative repercussions on trade that a potential discontinuation of the use of adhesive labels would entail. It should be noted that the use of adhesive labels is widely recognized internationally, as such labels achieve the same public health protection and consumer information purposes achieved by permanent labels. At the CODEX level, for example, Articles 8.1.1 and 8.2.1 of CODEX-STAN 1-1985, General Standard for the Labelling of Prepackaged Foods, permit the use of supplementary or adhesive labels, as long as it is guaranteed that they will not become separated from the container, taking into account cases where the language on the original label is not acceptable to the consumer for whom it is intended.

2.280. Furthermore, we note that countries with labelling schemes requiring the use of high fat, sodium or sugar content warnings, similar to Peru's, have considered supplementary labelling using stickers, which not only provides the required level of protection, but also makes it easier for exporters to comply with non-harmonized international requirements. Peruvian food products sent to the Costa Rican market are able to comply with domestic labelling requirements through the use of supplementary adhesive labels, instead of having to affix permanent labels in the country of origin, exclusively for the Costa Rican market. This undoubtedly fosters trade and is proportionate to the level of protection sought. We therefore ask for reciprocity of treatment. Moreover, we note that other Peruvian instruments, such as Supreme Decree No. 007-98-SA adopting the regulations on sanitary surveillance and control of food and beverages, permit the use of stickers to meet labelling requirements, given that this is an appropriate means for the fulfilment of the proposed legitimate objectives. The fact that Peruvian legislation, in other instruments, permits the use of an adhesive or additional label no doubt shows that there are less trade-restrictive measures through which it is possible to fulfil the proposed legitimate objectives, in accordance with the obligations regarding technical barriers to trade established in the relevant World Trade Organization Agreement and in the existing Agreement between our countries.

2.281. With regard to the commitments made by Peru under the Agreement on Technical Barriers to Trade, we note that the measure giving rise to this trade concern does not appear to have been notified. We therefore ask the Peruvian delegation to confirm whether the notification was made in accordance with the provisions of this Agreement. We are also of the view that, in light of the foregoing, the measure in question may be incompatible with the obligations assumed by Peru under Articles 2.2, 2.4 and 2.9 of the TBT Agreement. Lastly, Costa Rica would like to emphasize once again, as it has already done before this Committee, that in light of the current situation faced by the world as a result of COVID-19, international cooperation in all areas is crucial for tackling the crisis and laying the groundwork for a swift economic recovery post-pandemic, through the promotion of trade-facilitating measures, as opposed to measures that might create technical barriers to trade and hinder economic recovery. For all of the reasons above, we respectfully request that the Peruvian authorities amend the provisions of the Manual of Advertising Warnings to allow the use of adhesive labels with no time-limit.

2.282. The representative of the European Union provided the following statement. The EU would like to thank Peru for extending by one year, until 30 June 2021, the possibility to use stickers for compliance with labelling requirements for processed foods (Resolución Ministerial N°379-2020-

[64] For previous statements follow the thread under IMS ID 618 (under dates raised and references).

Minsa). While this extension is appreciated, the EU would like to ask Peru to provide for a permanent possibility to use stickers. We are committed to working with Peru bilaterally on this issue.

2.283. The representative of Brazil provided the following statement. Brazil shares Peru's endeavour to ensure the highest health standards through technical regulations that help better inform consumers. Brazil regrets having to once again manifest its concerns regarding labelling requirements expressed in the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA (G/TBT/N/PER/97/Add.1) and amended by Supreme Decree No 015-2019-AS (unnotified). As stated by other delegations in previous TBT meetings, the use of adhesive labels is a widespread practice internationally, and it does not affect the provision of reliable information to consumers. Codex standard CODEX-STAN 1-1985 for pre-packaged goods, Articles 8.1.1 and 8.2.1, explicitly allows for the possibility of using additional or adhesive labels, as long as they are attached to the packaging and if the language of the original label is not necessarily that of the consumer for whom it is intended. Since the Peruvian regulation was first brought to our attention, we sought to solve our concerns bilaterally. We acknowledge Peruvian concerns with deceptive practices that could be related to adhesive labelling. Yet, advances in labelling technologies allow for safe affixation of labels. Brazil would be willing to share with Peru its regulatory experience related to such labelling requirements. In our bilateral meetings, Peru failed to provide a time frame for possible amendments to the regulation, which creates greater uncertainty for our private sector to take on informed market decisions. Brazil would like to respectfully ask Peru to permanently align its labelling requirements with current international standards established under the Codex and withdraw the prohibition of adhesive labelling for products under the scope of the Manual of Advertising Warnings. We acknowledge that, according to Decreto Supremo Nº 021-2020-SA, the entry into force of the prohibition on adhesive labels was delayed until 30 June 2021. Brazil considers such postponement a provisional solution and will continue to raise this STC until Peru permanently removes its burdensome requirements for food labelling.

2.284. The representative of Colombia provided the following statement. First of all, Colombia wishes to thank the delegation of Peru for its willingness to engage in dialogue and for the various discussion forums open to our country to voice its concerns. However, we reiterate our concern regarding the Manual of Advertising Warnings prepared in accordance with the implementing regulations to Law No. 30021 on the promotion of healthy eating among children and adolescents, which was issued through Supreme Decree No. 021-2020-MINSA of 12 June 2020 and notified in document G/TBT/N/PER/97/Add.2. In accordance with the above-mentioned regulations, the deadline was extended to 30 June 2021 for the use of adhesive advertising warning labels that was provided for in paragraph 8.3 of section 8 of Supreme Decree No. 012-2018-SA, the Supreme Decree approving the Manual of Advertising Warnings. As a result, from 1 July 2021 processed foods will no longer be able to enter the Peruvian market by using stickers to comply with labelling requirements. In this regard, Colombia considers that allowing the use of stickers does not distort the purpose of Law No. 30021 on healthy eating, its implementing regulations (Supreme Decree No. 017-2017-SA) or the Manual of Advertising Warnings (Supreme Decree No. 012-2018-SA), as the warnings, whether included on stickers or printed directly on the packaging of products, will continue to be clear, legible, prominent and comprehensible, as required by the regulations. Colombia therefore considers that this provision is more restrictive than necessary and may become an unnecessary obstacle to trade, violating Article 2.2 of the Agreement on Technical Barriers to Trade TBT/WTO ("TBT Agreement"), which states that: "(…) Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create (…)".

2.285. A technical measure on labelling that is so specific to a particular country, which must be implemented in the country of origin and does not allow the use of stickers with the required information, is a technical barrier to trade, and constitutes a major barrier to access for importing companies in Peru and producers in countries such as Colombia, especially for enterprises whose current and projected sales volumes in Peru cannot justify the expense of making a "factory" label designed specifically to comply with the regulation. Peru engages in international trade with many trading partners and enterprises with different economies of scale; the enterprises whose economies of scale and volumes of trade do not warrant the increased expense of developing special packaging for trade with a country that imposes an unnecessary barrier of this nature will be most affected. Furthermore, imposing this type of unnecessary trade-restrictive measure runs counter to international labelling practice and the Codex Alimentarius, such as Article 8 on Presentation of

Mandatory Information of CODEX-STAN 1-1985 (Revised in 2018), General Standard for the Labelling of Pre-packaged Foods. It also runs counter to Article 2.4 of the TBT Agreement, which refers to the preparation, adoption and application of technical regulations and reads: "(…) 2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems". In light of the above, Colombia once again requests that Peru look into the feasibility of allowing the use of stickers with warning icons and messages on food packaging to avoid creating an unnecessary technical barrier to trade such as the one envisaged in the Supreme Decree.

2.286. The representative of Guatemala provided the following statement. Article 2 of Supreme Decree No. 015-2019-SA amends paragraph 8 of the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA by establishing that all food and beverages must display advertising warnings, where appropriate, and that the use of stickers featuring advertising warnings is permitted for one year from the entry into force of the Manual. The food and beverages covered by the Manual's second deadline may use stickers displaying advertising warnings for a period of six months after the entry into force of the respective parameter. Micro and small enterprises are permitted to use stickers featuring relevant advertising warnings until 31 March 2022. The measure was not notified to the TBT Committee. Guatemala thanks Costa Rica, the European Union, Brazil and Colombia for including this item on the agenda of the present meeting and recognizes Peru's legitimate objective of protecting human health and providing consumer information. Peru's notification in document G/TBT/N/PER/97, and the addendum G/TBT/N/PER/97/Add.2 of 29 June 2020, which extends, until 30 June 2021, the deadline for the use of adhesive advertising warning labels that was provided for in the Supreme Decree approving the Manual of Advertising Warnings (Manual on Health Warnings) – Supreme Decree No. 021-2020-MINSA, imply that as of that date, pre-packaged food must be labelled, in accordance with the regulations' requirements, in the country of origin.

2.287. Section 8.2 of Codex Standard CXS 1-1985, General Standard for the Labelling of Prepackaged Foods, as revised in 2018, states that a supplementary label containing the mandatory information in the required language may be used and shall fully and accurately reflect the information in the original label. We believe that the measure in question is more restrictive than necessary, since the use of adhesive labels is widely recognized internationally, as such labels fulfil the same public health protection and consumer information purposes as permanent labels, including when affixed in the country from which the products are imported. We therefore insist that Codex provisions be taken into consideration, in particular the General Standard for the Labelling of Prepackaged Foods, which allows supplementary labels to be used, as other trading partners have done, thereby facilitating trade. This is particularly relevant to regulations like the one in question, which are becoming increasingly disharmonized. Guatemala reiterates its concern over the lack of harmonization of front-of-package labelling worldwide and of associated nutrient profiles. For small and medium-sized enterprises trying to internationalize their operations, these are complex measures that restrict trade.

2.288. The representative of Chile provided the following statement. Chile echoes what various countries have said, and I will not repeat what has been about the details of the regulation. Firstly, we thank Peru for extending the period granted, but urge it to make the use of stickers labelled with "High in" on foodstuffs, where required, feasible on a permanent basis. Chile has experience in this area. When implementing Chilean Law No. 20.606 on front-of-pack nutritional labelling, it permitted the use of adhesive stickers on a permanent basis, thereby complying with the legitimate objective pursued under the public policy, without creating an unnecessary additional requirement to achieve this. In view of the above, Peru is invited to reconsider accepting the use of stickers on a permanent basis, and not just until mid-2021.

2.289. In response, the representative of Peru provided the following statement. The delegation of Peru would like to begin by thanking the delegations of Costa Rica, the European Union, Brazil, Colombia, Guatemala and Chile for their statements and comments, in particular to Brazil and Chile for sharing their experiences on this issue. Peru wishes to reiterate that it is committed to fulfilling the legitimate objective of protecting the public health of its citizens, particularly the health of its most vulnerable groups, such as children and adolescents, in accordance with its international trade commitments in this domain. As a result, and in light of the concerns raised by Members and trading

partners within this Organization, the Peruvian authorities have been conducting a comprehensive reassessment of the information mechanisms most suitable for achieving these objectives.

2.290. In order to continue these assessments, Peru, by means of Supreme Decree No. 021-2020-SA, has extended the period during which the use of adhesive advertising warning labels, provided for in paragraph 8.3 of section 8 of Supreme Decree No. 012-2018-SA approving the Manual of Advertising Warnings under Law No. 30021, is permitted until 30 June 2021. As we have stated on previous occasions, Peru is seeking to ensure that the information regulated by the Manual of Advertising Warnings reaches consumers clearly and effectively and cannot be unduly removed, so that they can make informed choices. Lastly, we would like to emphasize once again that Peru wishes to honour its WTO commitments and therefore reaffirms its commitment to not preparing, adopting or applying technical regulations that may create unnecessary barriers to international trade, as established in the Agreement on TBT.

2.1.3.21 European Union - Non-renewal of the approval of the active substance mancozeb, G/TBT/N/EU/712, G/SPS/N/EU/384 (IMS ID 627[65])

2.291. The representative of Costa Rica provided the following statement. Costa Rica wishes to express its support for the concern raised by the United States, Paraguay, Brazil, Australia, Indonesia and Colombia in relation to the draft Implementing Regulation notified by the European Union, under which approval for the use of mancozeb would not be renewed. Costa Rica recognizes that Members have the right to determine the appropriate level of sanitary or phytosanitary protection needed to protect human, animal or plant life or health, and to establish measures to that end. In turn, may we remind Members that these measures must be science-based and should not create unnecessary barriers to trade, especially at a time when the pandemic continues to affect the economic recovery of the international markets. Mancozeb is essential for agricultural production in Costa Rica. The substance is currently used for more than 20 crops that are grown for export and domestic consumption, and is therefore vital for ensuring the supply of food. It is also used to combat pests of economic importance, particularly in banana production.

2.292. Costa Rica is the world's second largest exporter of bananas, and the first country to have obtained a geographical indication for this product. Foreign exchange revenue from banana exports totalled approximately USD 1 billion, representing around 2% of GDP and 38.6% of agricultural GDP. The banana sector also generates 40,000 direct and around 100,000 indirect jobs. The main destination for exports is the European Union, to which over 50% of the fruit produced in Costa Rica is sent. In Costa Rica, there are currently no authorized plant protection products that could be used as substitutes for, or are similar to, mancozeb. This illustrates the impact that would be generated by the ban on the use of mancozeb and the subsequent reduction in MRLs for this substance in bananas. Despite our many reservations about the reasoning behind EU regulations, which will be raised next week in the SPS Committee, our banana sector continues to seek alternatives to mancozeb. However, time will be needed to complete the relevant tests and approval procedures for any alternatives found. Costa Rica therefore requests that the EU postpone the non-renewal process and subsequent reduction of MRLs for mancozeb, so as to give the national sanitary and phytosanitary authorities a reasonable period of time to respond to the numerous challenges posed by the COVID-19 pandemic and find an alternative substance so that Costa Rican farmers can continue to grow bananas and export the volumes required to meet the EU market demand.

2.293. The representative of the United States provided the following statement. The United States notes that the EU has not yet finalized its April 2020 Draft Commission Implementing Regulation concerning the non-renewal of the approval of mancozeb, however, at the October 23 meeting of the Standing Committee on Plants, Animals, Food and Feed, experts from the EU member States supported the Commission's proposal not to renew the authorization of mancozeb. The United States is disappointed that the EU once again has ignored internationally accepted standards for assessing risk and is unnecessarily disrupting trade without demonstrating a benefit to protecting human health. Can the EU fully explain the risk of non-fulfilment to justify its non-renewal of substances? In response to the interventions at the May TBT Committee meeting, the EU simply repeated its assertion that mancozeb meets the EU's hazard cut-off criteria for endocrine disruption and reprotoxicity alongside a concern for non-dietary exposure. The EU neither explained the level of protection it seeks to obtain nor addressed the fact that many countries and Codex have also reviewed this substance and established safe protective MRLs. For example, the United States has

[65] For previous statements follow the thread under IMS ID 627 (under dates raised and references).

completed a rigorous risk assessment and established MRLs for mancozeb following its registration renewal in 2005. The US EPA continues to re-evaluate mancozeb under its Registration Review process.

2.294. Codex has also established MRLs for mancozeb on many food crops based on risk assessment principles and review of good agricultural practices. These MRLs facilitate trade while protecting consumer health. The proposed non-renewal of approval of mancozeb provides yet another example of the negative impact and great uncertainty resulting from the EU's hazard-based cut-off criteria for possible endocrine disruptors. The EU regularly suspends risk assessments of active ingredients following any indication that they might meet its hazard criteria, including the presence of data gaps. As an example, the EU did not finalize the consumer dietary risk assessment of mancozeb in its June 2019 peer review. In August 2020, the EFSA published a reasoned opinion for requested modifications to MRLs for mancozeb for garlic, broccoli, cauliflower, and leeks. EFSA used the residue definitions and reference doses that existed in the EU for mancozeb at the time of the review and found the data sufficient to establish the requested increases to MRLs. However, instead of recommending MRLs it suggested that "further risk management considerations are required" because the 2019 risk assessment was never finalized. Mancozeb is used to protect many fruit, vegetable, nut and field crops against a wide spectrum of diseases, including potato blight, leaf spot, scab, and rust. It is also used for seed treatment for cotton, potatoes, corn, safflower, sorghum, peanuts, tomatoes, flax, and cereal grains. Producers of these crops require regulatory certainty to make effective and responsible crop protection decisions. Routinely failing to complete risk assessments on critical plant protection technologies significantly increases economic risks to producers.

2.295. This draft regulation further highlights our concerns with the EU's MRL transitional arrangements because it allows only a six-month grace period before the MRLs enter into force. Following the six-month period, the remaining time before enforcement of reduced MRLs is completely unknown. Even when MRLs are valid at the time crops are harvested, there is great concern that a more restrictive MRL may be in place before the final product reaches the EU. The United States exported more than USD 3.3 billion in fruits, vegetables, and tree nuts to the EU in 2019. The trade loss resulting from the removal of a single MRL is difficult to measure. However, there is little doubt that the EU's unjustified removal of MRLs for critical crop protection tools unnecessarily increases the cost of food to consumers and creates commercial uncertainty for growers and traders with little known benefit to human health and environmental safety. The United States asks how the EU is meeting its obligation to minimize negative trade effects. The United States asks again the level of protection that the EU seeks to achieve with its non-renewals of approval of active substances, especially when these decisions feed into MRL decisions made in the absence of a scientific assessment of risk? Given the broad acceptance globally of MRLs for substances such as mancozeb, will the EU explain how it is making regulatory decisions that take into account necessary scientific evidence and minimize negative trade effects?

2.296. The representative of Paraguay provided the following statement. Paraguay refers to its statement under *European Union - Hazard-based approach to plant protection products and setting of import tolerances (IMS ID 393),* para. 2.215.

2.297. The representative of Brazil provided the following statement. Brazil would like to once again raise STC 627 regarding the non-renewal of the approval of the active substance mancozeb, according to notification G/TBT/N/EU/712. As stated in our comments submitted to the EU TBT Focal Point, mancozeb is a substance whose use is approved for many different crops by the Brazilian Health Regulatory Agency, including soy. MRLs for soybeans in Brazil are set in 0,3 mg/kg. Around 11% of the soy produced in Brazil is exported to the EU. Therefore, restrictions on mancozeb would significantly impact the income of Brazilian farmers. We have warned European delegates about the relevance we attach to this regulatory process in previous bilateral meetings and we tried to receive more information regarding the review process. However, the EU informed that before the notification publication no comments would be taken into consideration. We look forward to receiving the EU's response to our timely submitted comments on notification G/TBT/N/EU/712. The availability of an alternative to mancozeb in the short to medium term is also limited by the fact that other substances of similar use have already been banned in the European market, such as chlorothalonil.

2.298. Mancozeb is an important tool for the management of fungicide resistance to control soybean rust, one of the most devastating diseases for this crop. It is used as a crop protection additive,

intended to increase the effectiveness of other fungicides, minimizing resistance and prolonging the life cycle of other molecules, which would otherwise have an extremely short life cycle. Also, such crops cannot have their treatments changed in time for exportation to the EU market before late 2020. We also urge European authorities to consider establishing transition periods that are adequate to the production cycle of the affected crops. The implementation of regulations with serious impacts on trade prior to a thorough risk analysis raises concerns about discrimination, transparency, and due scientific evaluation. The Brazilian delegation was informed that the EU used as a basis for the non-renewal of mancozeb a study from 1980 and, considering that more recent studies are available, we would like to hear from the EU delegation if that information is accurate and up to date. Once again, Brazil respectfully asks the EU to respond to the following questions, which were not addressed in the European intervention of the last TBT meeting: (i) what are the most recent studies and assessments used for the re-evaluation of mancozeb; (ii) does the EU consider that the notification was made at an early stage in order to take other Members' views into consideration; (iii) what other less trade-restrictive alternatives were considered in the development of said draft regulation?

2.299. The representative of Australia provided the following statement. Australia recognizes the EU's right to regulate the manufacture and use of plant protection products in agriculture to address risks unique to its settings. However, Australia is concerned about the proposed non-renewal of mancozeb given the potential impact on MRLs and effects this may have on trade, including wine exports to the EU. Australia seeks clarification on the risks to consumers from mancozeb residues on produce, especially wine, and how these will be taken into consideration in the revision of MRLs. Australia notes that the EU has recently made several plant protection products non-renewal decisions and subsequent changes to relevant MRLs which are impacting Australia's trade with Europe. Australia also notes that its competent domestic authority (Australian Pesticides and Veterinary Medicines Authority) and Codex have determined MRLs for dithiocarbamates that ensure the continued protection of human, animal and environmental health while allowing trade to continue.

2.300. The representative of Indonesia provided the following statement. Indonesia thanks Costa Rica, the United States, Paraguay, Brazil, Australia, Colombia and Guatemala for raising this issue and shares the same concern regarding EU regulation on Non-renewal of the approval of the active substance mancozeb. We place great interest on this issue given our agriculture exports to the EU region. In ensuring our standard, Indonesia is referring to the international standard of Codex pesticide MRLs for mancozeb that is still allowed to be used in various plants such as fruits, onion, chili, pepper, pepper chili, and mango. This is reflected in Indonesia Ministry of Agriculture regulation No.55 of 2016 regarding Food Safety Supervision Against Importation of Plant-Originated Fresh Food. Indonesia reiterates its concern on the EU's Non-renewal of the approval of the active substance mancozeb. Indonesia is of the view that this measure is more stringent than necessary and has the potential to disrupt trade, specifically for developing countries who export horticulture and other agriculture products to the EU. Indonesia regrets the application of this measure and, therefore, urges the EU to ensure that this measure is not more restrictive than necessary. We note that the EU refers to the safety and health aspect of environmental whilst developing the Draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance mancozeb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

2.301. However, Indonesia would like to emphasize that the internationally accepted standard provides a balance between safety and health with improving efficiency of production and facilitating the conduct of international trade as recognized by the TBT Agreement. Ensuring the use of recognized international standards is also vital for developing countries in ensuring the enjoyment of transfer of technology as enshrined in the TBT Agreement. In this regard, we urge the EU to use a risk assessment approach that is internationally accepted based on appropriate data and scientific study, particularly in accordance to Codex Pesticides MRLs, which permitted the use of this substance in plant products. Indonesia would also like to remind the EU that the Article 2.4 of the TBT Agreement requests Members to use existing international standards, or the relevant parts of them, as a basis for their technical regulations. We are of the view that the trade disruption could not be avoided if Members arbitrarily start to disregard any international standards in their technical regulations.

2.302. The representative of Colombia provided the following statement. Colombia reiterates its concern regarding the measure notified by the European Union in document G/TBT/N/EU/712 of 17 April 2020 relating to the non-renewal of the approval of the active substance mancozeb, given that this substance is vital to pest control for a wide variety of crops. The EU has been adopting measures resulting in the non-approval of the use of plant protection products, which is affecting the exports of its trading partners. Measures on the suspension or non-approval of the marketing of numerous active substances and the subsequent reduction of their MRLs to the minimum detection limit are being taken without any sound scientific evidence and without proof that such measures are the least trade-restrictive means of achieving an appropriate level of protection. Mancozeb is a fungicide used in more than 70 fruit and vegetable crops across the world to control over 400 phytopathogenic fungi that attack the crops. However, the main use of mancozeb is to prevent the fungi from developing resistance to curative fungicides (by using it in combination with them), helping to ensure that these fungicides remain effective. In Colombia, the use of the active substance mancozeb is essential in agricultural production for protecting banana crops against pests and diseases, such as Black Sigatoka, a devastating disease that attacks the foliar system and is caused by the fungus *Mycosphaerella fijiensis*. This fungus is extremely dangerous and is classed as very high risk by the scientific authorities (Fungicide Resistance Action Committee - FRAC) due to its ability to adapt rapidly to climatic changes and, above all, its inherent capacity to develop resistance to various chemical groups of fungicides.

2.303. This fungus currently shows resistance to three different chemical groups of fungicides used, which is severely limiting the control of the disease. This is why the use of mancozeb is of such importance in banana-producing countries. Recently, the EU also banned the marketing of chlorothalonil, which is the main tool for controlling Black Sigatoka. Banning mancozeb would leave banana-producing countries without any phytosanitary tools to control this disease, resulting in significant economic losses in Latin American countries, which would have highly regrettable consequences for the environment and the economic sustainability of banana crops, with their respective social implications, bearing in mind that in Colombia, for example, over 35,000 people directly and some 120,000 people indirectly depend on the production of bananas for export to the EU for their livelihoods. Such measures would be in disregard of Article 2.2 of the TBT Agreement, which provides that technical regulations shall not be more trade-restrictive than necessary to fulfil a country's legitimate objective. In this case, there is no known method for producing bananas that is more effective than the method involving the use of the above-mentioned active substances.

2.304. As indicated in the comments submitted on EU regulations, there is insufficient scientific justification for changing regulations on active substances, and the decision on the non-renewal of the approval of mancozeb has been taken using a hazard-based approach and applying the precautionary principle. This means that the lack of information and conclusive scientific studies required to make a risk- and science-based decision has been overlooked, contrary to the provisions of the WTO TBT Agreement. The foregoing also constitutes a violation of Article 2.2 of the TBT Agreement, since, as has been indicated, there is insufficient information to establish criteria for the acceptance or rejection of mancozeb. This is because, from a scientific point of view, its effect on health and the environment has not been clearly determined. Furthermore, it should be noted that there are scientific opinions at the European level that indicate that mancozeb is not an endocrine disruptor. On that basis, a scientifically sound evaluation would only be possible if sufficient time is granted to generate information from countries, in order to conduct a risk assessment of all scientific studies available that include the corresponding levels of exposure for determining the safety thresholds for mancozeb.

2.305. In light of the above, Colombia considers that the draft technical regulation amending EU Regulation No. 1107/2009 (non-renewal of the approval of mancozeb) must take into account the scientific evidence and banana production processes and methods in countries that may be affected by the implementation of the regulation, in order to avoid creating an unnecessary technical barrier to trade. Moreover, with regard to the deadlines established in notification G/TBT/N/EU/712 of 12 May 2020, we would be grateful if the EU could provide greater clarity regarding the time frame for the adoption of the measures. In this respect, we wish to recall that, in accordance with Article 2.12 of the TBT Agreement, Members shall allow a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member. In addition to the above, the situation that has arisen as a result of the COVID-19 global health emergency has forced the health and scientific authorities of all countries, including Colombia, to focus attention on that crisis. By the

same token, key sectors such as food producers, organizations and associations are having to make significant efforts to ensure biosecurity controls in the fruit and vegetable supply chain. This is reducing their ability to analyse draft regulatory measures and adjust production methods accordingly, creating additional burdens on international trade in food products, which is hampering worldwide economy recovery efforts, especially in developing countries. In light of the arguments presented, Colombia requests the EU to renew the approval of mancozeb and maintain its maximum residue limits (MRLs) as a risk management measure to guarantee the health of consumers in the EU and facilitate trade for its partners.

2.306. The representative of Guatemala provided the following statement. Guatemala shares this concern given the lack of information on scientific evidence of mancozeb's detrimental effects on human health. Moreover, the European Union (EU) has not presented any scientific evidence of the supposed danger and harmful nature of mancozeb in relation to the consumption of fruit and vegetables exported by third countries to the European market. The EU has previously mentioned that it has identified potentially negative health effects allegedly caused by mancozeb. However, it has failed to provide the countries affected with information on the contamination of products that have been assessed. We note the outcome of the meeting of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) of 23 October this year. Despite the requests of various Member States to continue the discussion on exploring the possibility of renewal, the Commission decided to proceed with a vote on mancozeb, which resulted in a decision not to renew its approval. A grace period of six months has been established for sale and distribution plus six subsequent months. We understand that the EU Mancozeb Task Force will research alternative ways to keep this vital tool available with a view to breaking down European farmers' resistance. However, this type of measure not only affects European farmers who receive economic support from their governments; it also significantly affects agricultural producers in countries that export to the European market, such as tropical developing countries. We note with concern that the European Union has not considered these factors in its assessment.

2.307. For the time being, mancozeb MRLs remain unchanged, but we are concerned that this latest decision will bring about the revision of those MRLs. The EU's practice since the non-renewal has been to revise MRLs and, according to this new trend, they are always revised downwards, without taking into account the climatic conditions in tropical countries and the distances involved in shipping products to the European market. Mancozeb is vital for controlling pests in the production of a number of strategic agricultural crops exported to the EU, including fruit (such as bananas and plantains) and vegetables. Guatemalan producers would therefore be affected. Mancozeb, as a multi-site fungicide, attacks different parts of the fungus and creates no resistance. Very few of the alternative fungicides available on the market have these multi-site properties. In the specific case of plantains and bananas, mancozeb is essential given the absence of alternatives offering the same level of effectiveness. Black Sigatoka, for instance, is caused by the fungus *Mycosphaerella fijiensis*, which invades and necrotizes the leaf tissue, causing leaf death. It is one of the diseases with the greatest economic impact on banana and plantain crops worldwide, and in tropical regions can only be successfully controlled with mancozeb, which is why the ban on the use of mancozeb will have a social and economic impact on Guatemala.

2.308. Plantain and banana crops are a significant source of job creation and foreign exchange, and are also beneficial in terms of rural development and food security in rural communities. The crops provide over 280,000 direct and indirect jobs, thereby affecting more than 1,120,000 Guatemalans. Banana exports accounted for 30% of Guatemala's total exports of traditional products in 2018 and 11.2% of total exports from the customs territory. The banana is the world's most consumed and exported fruit and, as a result, there has been a significant rise in the foreign exchange generated by this crop. Such earnings have been on the increase since 2018, ranging from USD 800 million to USD 1 billion. In light of the above, we request the EU to ensure that these measures do not affect mancozeb MRLs and to maintain its current levels, so as to avoid affecting the production and exports of Guatemala and other Latin American countries. In view of the economic and social impact that this type of measure will have on developing countries, we reiterate the request set out in documents G/SPS/GEN/1778 and G/TBT/GEN/296, especially given the current COVID-19 situation and the second wave of critical cases that now exceed the number recorded in Europe in February and March, while Latin American countries are still coming out of the first wave of the pandemic.

2.309. The representative of Argentina provided the following statement. We maintain our general concern regarding the hazard-based approach used by the EU as regards regulating pesticides, without identification of risk, which is an unnecessary technical barrier to trade. In the case of

mancozeb, this is a broad-spectrum fungicide used for growing fruits, vegetables and field crops. Although Argentina shares the EU's concern over strengthening the protection of human health and the environment, we would once again like to underline the importance of complying with Articles 2.2 and 2.4 of the TBT Agreement, which stipulate that "technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective". We are particularly concerned by the number of substances banned by the EU Commission, which have been increasing with each passing day. As indicated in documents G/SPS/GEN/1778/Rev.4 and G/TBT/GEN/296/Rev.4 (Request for the suspension of the processes and entry into force of reductions of MRLs for plant protection products), this situation may have serious consequences for various WTO Members, particularly developing countries, whose populations and economies are highly dependent on agricultural exports. It is therefore crucial for the EU to use a risk assessment approach in the analysis of these regulatory changes and to have conclusive scientific studies to determine the various aspects that may affect human health and the environment.

2.310. The representative of Chile provided the following statement. The delegation of Chile echoes the trade concern raised against the European Union for not renewing the authorization of the active substance mancozeb, a concern that was raised by Costa Rica, the United States, Brazil, Paraguay, Australia, Colombia and Indonesia, and supported by the delegations that took the floor before me. The delegation of Chile will be following up on this topic.

2.311. The representative of Ecuador provided the following statement. We echo their concerns, as well as those raised by other Members. Mancozeb is a fungicide used worldwide on many crops including bananas, cocoa, broccoli, pineapples, pitahayas, mangoes and cape gooseberries. This substance is crucial for the management of pests and resistance in agricultural production, since the tropical climate in countries such as ours means that the behavioural patterns of pests and diseases are very different to those in countries with four seasons. It is vital that studies assessing the renewal of active substances are based on scientific evidence and conclusive data rather than the precautionary principle. Ecuador therefore urges the EU to take into consideration the relevant scientific information emanating from international specialized agencies recognized by the WTO, such as the Codex Alimentarius, which has relevant information on this substance. Ecuador requests the EU to renew the approval of mancozeb. In the absence of alternatives, the ban on the use of mancozeb would leave Black Sigatoka control and management programmes without any phytosanitary tools. This would have very unfortunate consequences for the environment and the economic sustainability of banana crops, which, in turn, would lead to social consequences, given that this sector creates a significant number of jobs. Lastly, we echo the questions posed by Brazil to the EU concerning the re-evaluation of mancozeb, the timeliness of the notification of this draft Regulation, and what other less trade-restrictive alternatives were considered in the development of this draft Regulation.

2.312. In response, the representative of the European Union provided the following statement. As explained in the last TBT Committee meeting, on 17 April 2020, the European Union notified to the TBT Committee a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance mancozeb, in accordance with Regulation (EC) No 1107/2009 on the placing of plant protection products on the market. The non-renewal of the approval is based on a scientific assessment conducted under Regulation (EC) No 1107/2009 by experts from the member States of the European Union and the EFSA. EFSA concluded that mancozeb does not meet the approval criteria as outlined in Article 4 of Regulation (EC) No 1107/2009. The approval of mancozeb can therefore not be renewed. EU member States must withdraw existing authorizations for plant protection products containing mancozeb at the latest by three months from the date of entry into force of the Commission Implementing Regulation. The grace period, in line with Article 46 of Regulation 1107/2009, shall expire, at the latest, after six months from the entry into force of the Implementing Regulation. Following non-approval and the expiry of all grace periods for stocks of products containing this substance, separate action will likely be taken on MRLs and a separate notification will be made in accordance with SPS procedures.

2.1.3.22 Bangladesh - Hazardous Waste (E-waste) Management Rules, 2019, G/TBT/N/BGD/3, G/TBT/N/BGD/3/Add.1 (IMS ID 620[66])

2.313. The representative of the Russian Federation provided the following statement. The Russian Federation thanks the delegation of Bangladesh for bilateral engagement on this issue. However,

[66] For previous statements follow the thread under IMS ID 620 (under dates raised and references).

our concern with the inclusion of nickel into the list of hazardous wastes under the draft E-Waste Management Rules stands. In this regard Russia reiterates its statement made in May 2020. We consider this measure to be more trade restrictive than necessary. If adopted in the notified version, E-Waste Management Rules will distort international trade in nickel and nickel-containing products as well as global value added chains. We kindly ask Bangladesh to postpone the date of entry into force of this draft legal act and reopen discussions on this issue with the WTO Members and other stakeholders. Additionally, we would welcome an update from Bangladesh on the current state of play in the drafting of the measure.

2.314. The representative of the Republic of Korea provided the following statement. Korea highly regards the efforts of the Bangladesh and competent authorities to introduce Hazardous Waste (E-waste) management rules for protecting the environment and managing recycling resources. Furthermore, Korean companies are committed to fully comply with the rules of Bangladesh. Korea sent an official letter to the Bangladesh Enquiry Point on 28 April 2020 on companies' difficulties related to the regulation; as far as we know, Bangladesh has been collecting additional opinions through the WTO TBT. Nevertheless, Korea still has the following difficulties regarding Bangladesh's E-waste Management Rules, and Korea would like to ask for a review of the regulation and for further information. First, no specific enforcement date has been provided for these proposed rules. Although their entry into effect has been stipulated within 2020, compliance with these rules may be difficult if they suddenly enter into force without any prior notice. Therefore, Korea would like to ask Bangladesh to provide us an interval of more than six months between the publication of regulations and their entry into force, and we ask you to advise if there is any information regarding the specific date of enforcement. Second, In Schedule-3 of the regulation, nine non-replaceable chemicals, such as Polyvinyl Chloride (PVC) and Liquid Crystals, etc. have been designated as harmful substances. Designation of these materials is not a common international case. Therefore, Korea would like to ask Bangladesh to provide scientific evidence for this matter and to consider the withdrawal of the designation of these materials. Third, the standards of content limits for some compound hazardous substances included in Schedule-3 are ambiguous. Korea would like to request Bangladesh to provide us with clear information as to whether the standards of content limits are applied to each individual substance or the total amount of the hazardous substances.

2.315. The representative of Canada provided the following statement. Canada welcomes this opportunity to continue discussions on G/TBT/N/BGD/3, Hazardous Waste (E-Waste) Management Rules, 2019, which Bangladesh notified to WTO Members on 20 February 2020. Canada raised this STC at the May 2020 TBT Committee Meeting seeking further clarity on specific aspects of the Management Rules, notably regarding the method and rationale Bangladesh has followed to elaborate groupings in Schedule 3. This includes, for example, the rational for the broad group of "Mineral Wool", the joint entry for "Nickel and Cadmium/Cadmium oxide/ Cadmium Sulphide", and the specifics behind the inclusion of a flame retardant substance like Tetrabromobisphenol-A. The full extent of Canada's questions and concerns can be found in its previous intervention,[67] as well as in its comments submitted to Bangladesh's Enquiry Point on 16 April 2020 and for which Canada looks forward to receiving an official reply from Bangladesh. At the previous Committee meeting, Bangladesh confirmed that its competent authorities were reviewing the concerns raised by WTO Members, and would revert once they had more detailed replies to share. Canada would like to know if Bangladesh is now in a position to share new information and additional supportive documentation on the Management Rules, including timelines for consultations on the full regulatory text. Canada encourages Bangladesh to ensure a high level of transparency on the Management Rules, including by notifying the full text of the new Management Rules as soon as possible and providing the minimum 60-day period, so that all affected parties may assess the potential impacts of the measure and provide substantial comments for Bangladesh's consideration. This would support the shared endeavour of Members to ensure that unnecessary impacts on trade be avoided.

2.316. The representative of the European Union provided the following statement. The European Union has concerns on the hazardous waste management rules. We sent written comments to Bangladesh in April 2020 and are looking forward to receiving written replies before the adoption of the notified drafts. Our main point is that the notified draft restricts use of substances that are not restricted by any existing international legislation and thus creates more restrictions to trade than necessary. The EU would be grateful if the above-mentioned comments could be taken into account and replied to before adoption of the notified draft.

[67] G/TBT/M/81, item 1.2.1.

2.317. The representative of the United States provided the following statement. The United States supports the other Members raising this STC, and we refer to our previous statements on this measure.

2.318. In response, the representative of Bangladesh provided the following statement. Bangladesh thanks Canada, the European Union, the Republic of Korea and the Russian Federation for their interest in the proposed E-Waste Management Rule 2019 and the concerns raised, which are still being reviewed by our competent authorities in capital. Bangladesh also expresses willingness to engage with Members bilaterally about their concerns. We will revert back once we have more detailed replies of specific concerns such as specific dates of enforcement, restriction of chemicals mentioned in Schedule-3, standard of contents in the same schedule, and others.

2.1.3.23 Russian Federation - Draft Technical Regulation on Alcohol Drinks Safety (published on 24 October 2011), G/TBT/N/RUS/2 (IMS ID 332[68])

2.319. The representative of the European Union provided the following statement. In 2012, the Russian Federation notified a draft technical regulation on alcohol products safety. An updated version was adopted in December 2018 and supposed to enter into force on 9 January 2021. In light of transparency and considering the trade implications of this regulation, we would like to ask Russia to fulfil its obligations and notify the revised text to the TBT Committee. The technical regulation also contains provisions covered by the Agreement on TRIPS. The EU would like to invite Russia to also notify the regulation to the Council for TRIPS, as some of these provisions, in particular impacting EU geographical indications, raise serious concerns for the EU. The European Union would like to express the following concerns with the new version of the measure: physical and chemical requirements laid down in the technical regulation in some cases contain more stringent limits than those set in the recommendations of the International Organisation of Vine and Wine (OIV), which Russia is a member of. The application of these diverging requirements would represent a serious obstacle for the importation of these products.

2.320. The EU is concerned by the mandatory labelling requirements, which are not in line with international practice. The EU would like to ask Russia to refer to Codex standards as regards the indication of date markings and storage conditions, which are strictly linked to each other. Could Russia confirm that the use of stickers is allowed, according to CODEX-STAN 1-1985? As already mentioned in a separate STC earlier, the articulation with the "Federal law on wine making and wine growing in the Russian Federation" is problematic on several points. This has to be clarified. In view of these inconsistencies, the EU understands that the Russian authorities have requested to postpone the entry into force of this measure (planned for January 2021) by one year, and grant a transitional period to further discuss the standards and explore whether business operators can progressively adapt them. Can the Russian authorities confirm this and inform when the final decision will be taken and formalised? The European Union would like to ask Russia to take these comments into consideration and to re-notify the new version of the measure, under the TBT agreement as well as under the TRIPS agreement.

2.321. The representative of Ukraine provided the following statement. Ukraine thanks the EU for keeping this issue on the agenda and echoes the concerns raised with regard to the draft TR on Alcohol Drink Safety. Ukraine continues to have strong concerns on the Russian Federation certification requirements for alcohol drinks and we would like to refer to our statements made in the course of the previous TBT Committee meetings for further detail. Today we would like to draw attention to the issue of the cost of conformity assessment procedures for producers from WTO Members other than member states of the Eurasian Economic Union. In particular, this includes additional costs associated with the registration of legal entities on the territory of the Eurasian Economic Union or contracting with existing legal entities registered on the territory of the Union as per established requirements. As a result, the cost of required conformity assessment is higher for other WTO Members compared to the cost for manufacturers based in the Eurasian Economic Union. Ukraine is of the view that such a regime, if not amended, would amount to a violation of Article 5 of the TBT Agreement. Ukraine would like to reiterate its request to the Russian Federation to provide a practical update on the draft TR on alcohol with the aim to remove unjustified technical barriers to trade and comply with the transparency requirements embodied in the TBT Agreement.

[68] For previous statements follow the thread under IMS ID 332 (under dates raised and references).

2.322. In response, the representative of the Russian Federation provided the following statement. The Technical Regulation of the Eurasian Economic Union on safety of alcohol products was adopted in December 2018 and is supposed to enter into force in January of 2021. As was rightly mentioned by our EU counterpart, the draft decision of the Eurasian Economic Commission Council delaying for one year the date of entry into force of the Technical Regulation has been prepared and is now in the process of approval. The draft Technical Regulation was notified in 2012 as per requirements of WTO transparency provisions. Currently, there are no plans to re-notify the adopted text of the Technical Regulation in the TBT Committee. Additionally, we fail to see grounds set out in Article 63 of the TRIPS Agreement for notification of the Technical Regulation in the TRIPS Council. As for physical and chemical requirements, we note that in most cases these requirements are already incorporated in the Russian national legislation and therefore would not represent something new for market players of the Russian alcohol market. The core aim of such requirements is to provide a safe product to Russian consumers. Date of bottling and storage conditions labelling requirements are also not new requirements. They were introduced many years ago to avoid alcohol intoxication and fatal casualties among consumers. As stated previously, we confirm that the use of stickers is allowed as there is no prohibitive provision in the Technical Regulation.

2.1.3.24 European Union - Draft Implementing Regulations amending Regulation (EC) No. 607/2009 laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products, G/TBT/N/EU/44, G/TBT/N/EU/264, G/TBT/N/EU/264/Add.1, G/TBT/N/EU/570, G/TBT/N/EU/571 (IMS ID 345[69])

2.323. The representative of the United States provided the following statement. It is very disappointing that the United States must again raise its concerns with the EU revisions to its draft regulation on geographical indications and traditional terms for wine; and specifically, our industry's pending applications for traditional terms. The EU's persistent failure to provide any information leaves us no choice. Since the June 2018 TBT Committee meeting, the EU has been saying that the pending applications for traditional terms were still under consideration, but that it could not provide a precise timeline for approval. Why is the EU still unable to provide any estimate or tell us where in the process these applications are after over two years? As we indicated at the November 2019, February 2020, and May 2020 TBT Committee meetings, it would be helpful if the EU could provide some transparency about the status of other applications so that we can see how our applications compare. As requested during the February and May 2020 TBT Committee meetings, please tell us the following: how many applications for traditional terms have been lodged over the last ten years; how many of those applications have been approved, rejected, or remain pending; what is the average time between application and a final decision; for pending applications, how long have they been waiting; and how many of the applications have come from member States.

2.324. We also remain concerned about the EU's efforts to restrict the ability of our producers to use common descriptive tools for labelling and marketing their products, such as restricting the use of the term "barrel aged" and certain bottle shapes, to wines with geographical indications. Now that the EU has adopted the regulations, the United States once again requests the EU to move expeditiously to approve our industry's applications so that we can remove this long-standing item from this Committee's agenda, as well as the agenda of the WTO Council on Trade in Goods. Lastly, can the EU confirm how the processing of these applications has changed, if at all, over the last year following the adoption of Implementing Regulation 2019/34? The United States asked for clarification on this point during the November 2019 and February and May 2020 TBT Committee meetings but did not receive clarification from the EU.

2.325. The representative of Brazil provided the following statement. Brazil would like to support the concerns raised by the US and Argentina and refer to our past statements on this STC. We kindly ask the EU to share any updated information related to the use of regulated terms for wines exported to the EU in Regulation (EC) No. 607/2009 and Council Regulation (EC) No 479/2008.

2.326. The representative of Argentina provided the following statement. Argentina reiterates the concerns expressed at previous meetings of this Committee regarding the discrimination suffered by national wines, which are prevented from using the traditional terms "*Reserva*" and "*Gran Reserva*" on their labels, even though our country completed the substantive procedure to approve

[69] For previous statements follow the thread under IMS ID 345 (under dates raised and references).

such terms in March 2012 under EU law. We once again urge the EU to activate all applications for the registration of traditional terms submitted by third countries such as Argentina, which have come to a standstill without any legal justification, thereby constituting a technical barrier to trade.

2.327. The representative of New Zealand provided the following statement. New Zealand recognizes that Members have the right to protect their consumers from deceptive practices in line with their WTO obligations. New Zealand asks that the European Union takes into consideration concerns raised by Members relating to the scope and application of the system of traditional terms, as well as transparency, process, and timelines relating to applications by third countries who wish to use traditional terms in the European Union.

2.328. In response, the representative of the European Union provided the following statement. The EU understands the continued interest of the United States and other Members in this issue. The EU has completed the revision of its internal legislation on traditional terms discussed in previous TBT Committees leading to the adoption of Commission Delegated Regulation (EU) 2019/33 and Commission Implementing Regulation (EU) 2019/34. The EU believes that its internal legislation offers a meaningful and transparent system of protection to traditional terms used on wine products from the EU, as well as on products from third countries. The EU has demonstrated its ability to address specific Members' concerns in this area either via its internal legislation or via bilateral agreements.

2.1.3.25 India - Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012, G/TBT/N/IDN/44, G/TBT/N/IDN/44/Add.1, G/TBT/N/IDN/44/Add.2, G/TBT/N/IDN/44/Add.3, G/TBT/N/IDN/44/Add.4, G/TBT/N/IDN/44/Add.5, G/TBT/N/IDN/44/Add.6, G/TBT/N/IDN/44/Add.7, G/TBT/N/IND/44/Add.8, G/TBT/N/IDN/47, G/TBT/N/IDN/47/Add.1, G/TBT/N/IDN/47/Add.1/Corr.1, G/TBT/N/IDN/47/Add.2, G/TBT/N/IDN/47/Add.3, G/TBT/N/IDN/58 (IMS ID 367[70])

2.329. The representative of the United States provided the following statement. We appreciate India's Ministry of Electronics and Information Technology (MeitY) April 2020 notification to the TBT Committee of the Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order (CRO) Phase IV scope expansion, to include 12 new product categories, including keyboards, USB type external hard disk drives, USB type external solid-state storage devices, and stand-alone switch mode power supplies. We also greatly appreciate MeitY's 16 September 2020 notice in the Indian Gazette, which extended the CRO implementation timeline by six months to 1 April 2021 for the product categories included in the Phase IV scope. US industry is concerned about recent holds BIS has placed on processing the applications of foreign manufacturers, which disrupt US exports to India of 33 ICT products, including notebooks, tablets, and servers. These holds, which do not appear to apply to in-country applicants, delay BIS certification of US products, disrupting trade and generating uncertainty for both exporters and consumers by impacting delivery timelines. These holds are of particular concern when they occur ahead of major sales seasons, as they prevent full commercial participation by US manufacturers. More broadly, India's CRO requirements continue to raise concerns, including the requirement that product testing is performed exclusively by Bureau of Indian Standards-accredited labs located within India; and the failure to recognize test results from ISO/IEC 17025 accredited laboratories.

2.330. The representative of Canada provided the following statement. Canada recognizes and appreciates India's 9 October 2020 WTO TBT notification G/TBT/N/IND/44/Add.8 and its Gazette of India notification, of 16 September 2020, alerting suppliers to the delay, from 1 October 2020 to 1 April 2021, of the expansion of the Compulsory Registration Order (CRO) to cover 12 additional products. Canada would like to highlight the time it takes for firms to adapt to having their products tested in India and to make any adjustments to their products needed to meet Indian, instead of international, technical regulations. At considerable expense to the supplier, goods must be produced, shipped to India and testing conducted before compliance can be achieved. Canada continues to be concerned that the CRO does not allow for the use of international standards or recognize testing conducted in appropriately accredited foreign conformity assessment bodies. Canada would support a further delay in the implementation of the CRO until India adopts IEC standards and removes the high cost of complying with duplicative national standards.

[70] For previous statements follow the thread under IMS ID 367 (under dates raised and references).

2.331. In response, the representative of India provided the following statement. We thank the United States for their interest in the Indian IT sector. As requested by the United States in the last TBT meeting, the date of implementation of the Order is extended until 1 April 2021 via Gazette Notification dated 16 September 2020. We note that the US has mentioned about BIS hold on 33 information and technology products. But as per our record, there is no hold up in the processing of applications under CRS. The US may share the list of such applications for our examination and response.

2.1.3.26 China - Registration Fees for Drugs and Medical Device Products (IMS ID 466[71])

2.332. The representative of the Republic of Korea provided the following statement. Korea has continuously raised concerns on registration fees for drugs and medical device products in China through bilateral and multilateral channels and thanks China for kindly responding to Korea's enquiries. Nevertheless, we urge China to provide substantive replies to our questions and concerns. During the Trade Policy Review in 2016, China stated that the registration fees will be re-evaluated every five years for proper adjustment. Hence, we would like to ask China information about the exact timeline for the registration fee adjustment. In addition, Korea calls for China once again to inform when the notification on Charging Standards for Drug and Medical Device Registration from 2015 will be revised. We also request China to consider determining the registration fee of Chinese and foreign products in an equitable manner to provide equal treatment for domestic and foreign products. In the previous meetings, China explained that the differences between the registration fees of imported and domestic products were due to the fee for foreign inspection according to the quality management system. Korea would like to ask China to consider the possibility of charging the inspection fees as an additional cost and exclude them from the registration fee.

2.333. The representative of Australia provided the following statement. As previously noted in this Committee, Australia maintains an on-going interest in key developments in China's regulation of drugs and medical devices, including with regards to registration fees and processes for pharmaceuticals, complementary medicines and medical devices. These aspects remain of importance to Australian industry. Australia therefore continues to welcome constructive bilateral discussions with China on a range of health technology topics of interest to both sides, and to further cooperation and information exchanges to enhance mutual understanding. In particular, the Australian Government welcomes the opportunity to explore opportunities for relationship building with the NMPA and the Pharmaceuticals Division of the Chinese Ministry of Industry and Information Technology (MIIT).

2.334. In response, the representative of China provided the following statement. The registration fees for drugs and medical devices were common international practice. For example, in 2013 the new medicine registration fees of Members were mostly around 1 million Yuan, some Members even above 10 million Yuan, while it was only 35,000 Yuan in China. Afterwards, it is adjusted to 0.624 million Yuan, which is still much lower than the average level internationally. The fees are mainly determined by the cost of the conformity assessment works. The difference of the registration fees is due to different workload and price level.

2.1.3.27 India - Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulations, 2015, G/TBT/N/IND/51, G/TBT/N/IND/104 (IMS ID 494[72])

2.335. The representative of the European Union provided the following statement. The EU would like to reiterate again its concerns regarding this measure. We welcomed the publication of the regulation on additives for alcoholic beverages in August 2017. The regulation covering standards for alcoholic beverages was published in April 2018, and is being implemented since April 2019, with the exception of the parameter for yeast in various categories of beer and the modification of certain specific provisions, for which an extension of six months had been announced. The EU also welcomes the notification to WTO in July 2019 of a number of amendments to the standards (G/TBT/N/IND/104). The EU sent comments on 26 November 2019 and would welcome a reply. We notably request Indian authorities to consider alignment with OIV standards. In particular, we would appreciate if India could take into account the following: The lack of stock-exhaustion clause and transition period. The presence of some technical specifications that may not be in line with international standards or with international widely-accepted practices. Some labelling requirements

[71] For previous statements follow the thread under IMS ID 466 (under dates raised and references).
[72] For previous statements follow the thread under IMS ID 494 (under dates raised and references).

are excessive and will potentially trigger additional technical controls that might result in unjustified barriers to trade. The Regulation also includes the need to satisfy excessive analytical parameters that would result in additional technical controls. The EU welcomes the publication of the draft regulation related to non-alcoholic beer and certain food additives/colorants used for Campari and Aperol (dated 22 June 2020). We expect that the EU (and other third countries) will still have the possibility to comment on the draft legal proposal. We would like to learn about the timeline for its final approval and publication in the Gazette. We hope that we can continue our discussion and find an acceptable solution to the outstanding issues.

2.336. The representative of Australia provided the following statement. Australia recognizes the right of the Indian Government to take measures necessary to protect public health. Australia wishes to emphasize the importance of compliance with WTO obligations, in particular the requirements that measures be implemented in a non-discriminatory manner and in a way that is no more trade restrictive than necessary. Australia thanks India for revising its draft regulations to allow the addition of water to 70 ml/kg for certain technical purposes. These revised draft regulations go some way to addressing Australia's concerns, however, the revised draft regulations expressly prohibit adding water to dilute high sugar musts to limit the occurrence of "stuck" fermentation. This prohibition would restrict the ability of winemakers to adapt to warming climates, both in Australia and India. In Australia, wine producers are permitted under the Australia New Zealand Food Standards Code to add water to dilute high sugar musts to aid in fermentation. The addition of water is done in minimal circumstances, for technical necessity, in small volumes to aid fermentation during periods of difficult seasonal conditions. Australia requests that India allow the addition of water to dilute high sugar musts to aid in fermentation and revise the draft regulations accordingly.

2.337. The representative of Chile provided the following statement. Regarding the trade concern raised by the European Union and Australia about India's notification G/TBT/N/IND/51 of 2015, the delegation of Chile agrees with the comments made at this meeting by the delegations that have already taken the floor.

2.338. In response, the representative of India provided the following statement. India would like to inform Members that the Food Authority in India has approved the Commonwealth of Australia's request, and the draft regulations have been revised since. They are under the process of final notification.

2.1.3.28 Russian Federation - Rules of cement certification, G/TBT/N/RUS/48, G/TBT/N/RUS/49 (IMS ID 497[73])

2.339. The representative of the European Union provided the following statement. The EU would like to refer to its previous statements in the TBT Committee on this issue. The EU would also like to thank Russia for the very good bilateral held on this issue earlier today. The EU would like to recall that its comments on both Russian notifications G/TBT/N/RUS/48 and G/TBT/N/RUS/49 sent to the Russian Federation in May and June 2016 were never replied to, despite our numerous reminders. The EU deeply regrets that Russia continues to adopt restricting measures in the area of cement certification that are disproportionate, unjustified and not notified to the WTO before their entry into force. Since the introduction of the mandatory certification for cement, EU exports of cement to the Russian Federation are practically blocked, with the exception of white cement, necessary for Russian industry. This situation remains unchanged since the entry into force of these measures. In light of the above, the EU welcomed the 2019 announcement of the Russian authorities declaring that the standards on cement certification would be revised and a new standard eliminating additional inspection procedures would be notified to the WTO at a draft stage, in line with the rules set out by the TBT Agreement. Given the lack of the notification to this day, the EU would like to ask the Russian Federation to inform about the state of play regarding the preparation of this new standard and to share the updated timing for its TBT notification.

2.340. The representative of Ukraine provided the following statement. Ukraine would like to share the concern raised by the EU and reiterate its statements made in the course of the previous TBT Committee meetings with regard to the clearly-identified overly trade-restrictive certification requirements for cement. Access to the Russian Federation market for cement depends on meeting the requirements established within the Eurasian Economic Union. These certification rules require conformity assessment of products. In particular, to be eligible for the conformity assessment the

[73] For previous statements follow the thread under IMS ID 497 (under dates raised and references).

applicant must be a legal entity or individual proprietor, or producer or seller, or agent of a foreign producer. This business relationship must be demonstrated via a written contract with the foreign producer, which must also be registered pursuant to the legislation of the Eurasian Economic Union member state on its territory. Requirements established for the applicants related to their mandatory registration on the territory of member states of the Eurasian Economic Union create an additional burden for other WTO Members compared to producers in the Eurasian Economic Union and may contravene Article 5 of the TBT Agreement. We welcome yet another announcement by the Russian authorities regarding possible amendments to the current regime and would like to encourage the Russian Federation to provide basic information requested by the WTO Members and comply with the fundamental WTO transparency commitment essential for predictable and non-discriminatory trade. Ukraine calls on the Russian Federation to restore conditions which will enable the flow of trade in cement again.

2.341. In response, the representative of the Russian Federation provided the following statement. The measure at issue is aimed at fighting the illicit trade in cement and building materials and ensuring the strength of building materials which is of paramount importance for the durability of buildings. Currently, the amendments to GOST–R "Rules of cement certification" are being discussed internally among the relevant Russian authorities. However, no precise timeline for the outcome of the discussion can be provided now.

2.1.3.29 Egypt - Manufacturer Registration System (Decree No. 43/2016 and Decree No. 992/2015), G/TBT/N/EGY/114, G/TBT/N/EGY/115 (IMS ID 505[74])

2.342. The representative of the Russian Federation provided the following statement. Russia would like to thank Egypt's representative for the bilateral engagement on the registration process. However, we remain concerned by the procedure of registration since it is untransparent and lacks clear deadlines for the processing of applications which provides opportunities for arbitrary decisions regarding market access for particular companies and for protection of domestic industries from import.

2.343. The representative of the European Union provided the following statement. The EU would like to reiterate its concerns with regard to the registration of companies exporting to Egypt under Decree 43/2016. Most of the pending registration cases known to the EU have still not been successfully processed due to expired quality certificates. Such certificates have a validity of one year, therefore they expired because the General Organization of Export and Import Control (GOEIC) failed to register the companies within reasonable time limits. As a result, the European companies are now confronted with additional costs and administrative burden of updating their registration applications. The EU finds it also very worrisome that around half of the non-registered companies are active in the sector of ceramic tiles. The EU ceramics sector has been disproportionately affected by the discretionary application of Decree 43/2016, with practically no registrations taking place since the introduction of the Decree in 2016. Moreover, the EU was informed about an announcement published on GOEIC's website requesting a number of companies, including EU operators, to update their quality certificates by 31 May 2020, otherwise they would need to restart their application process. A similar announcement was published also in early October 2020 with a deadline of 15 October 2020. These announcements were in Arabic only and the companies concerned were not informed about their publication. The EU would appreciate a confirmation from Egypt that all companies, which will submit updated quality control system certificates and complete in this way their application documents, will be registered without any further delay and without the need of restarting the entire application process. Structural problems related to the Decree 43/2016, like the lack of transparency of the registration process, lack of clear deadlines for processing the requests and lack of a clear appeal procedure, still persist. The EU would therefore like to repeat its invitation to Egypt to suspend or further substantially improve the registration process with the objective to remove unnecessary obstacles to trade and to refer for details to the statements of the past TBT Committees.

2.344. The representative of Turkey provided the following statement. Turkey would like to thank Egypt for continuing bilateral discussions on this issue in a constructive way. However, Turkey remains concerned on Egypt's Decrees on manufacturer registration system, since it is still unclear how the applications are evaluated and whether the completion of the process is subject to any time limits. In addition, no notification is made to companies on the status of their application, and

[74] For previous statements follow the thread under IMS ID 505 (under dates raised and references).

whether it is approved or not. Expectedly, companies are facing long delays and bear additional costs in the registration process. Turkey would therefore like to once again ask Egypt to review this measure considering the principles and obligations in the WTO Agreements and ensure its implementation in full transparency.

2.345. In response, the representative of Egypt provided the following statement. We thank the delegations that maintained interest in this issue, we are also thankful for the bilateral exchanges on this matter in Geneva and in capitals. We would like hereby to refer to our previous statements on the positive steps undertaken by the government of Egypt to facilitate the registration process, address the specific problems of some individual companies and to enhance the transparency of the registration process. Egypt reiterates, once again, that the purpose of the registration system is solely to pursue the legitimate objectives of enhancing market surveillance and preventing deceptive practices, and in this spirit the Decree hasn't set the registration to be time bound, instead, the registration is valid as long as the documents presented by companies are valid. And for that we urge both registered companies and those in the process of registration to regularly update the documents presented to ensure that the registration goes more smoothly. And while we are cognizant of the fact that a limited number of applications has been pending for some time, we would like to highlight that reforming the implementation of the system is a work in progress, and that some of the efforts to address this issue have been effectively hindered by the COVID-19 pandemic and the measures adopted by the government to limit its spread, which reflected negatively on the pace of work and on the coordination between different governmental entities involved in the process. Finally, we encourage our partners with specific problems with the system's implementation to continue reaching out to us and to the capital in this respect, and from our side we will continue our follow up with Cairo and with the concerned delegations in Geneva.

2.1.3.30 China - Cybersecurity Law (IMS ID 526[75])

2.346. The representative of Japan provided the following statement. Japan continues to have concerns regarding China's "Cybersecurity Law" and would like to refer to the previous statement which we made at the last TBT Committee in May 2020. Japan is also concerned with related enforcement regulation. Japan would like to request that China provide notification of the enforcement regulations to the TBT Committee and consider comments from stakeholders. In addition, Japan would like to request that China provide adequate lead time from completion of these regulations until their enforcement, and to implement these measures in a transparent manner.

2.347. The representative of the United States provided the following statement. The United States remains very concerned about China's suite of cybersecurity and cryptography measures. As we have said in prior TBT Committee meetings, this is a major concern for US companies, given China's intertwined requirements for conformity assessment systems for security testing, technical regulations, and a multi-level classification scheme laying out requirements including mandatory standards and testing for the purchase of ICT goods across a wide range of commercial sectors. China's Cybersecurity Law entered into force on 1 June 2017, in spite of serious and long-standing concerns from the United States and many other international stakeholders. Since then, China has continued to develop, and in certain cases, finalize related implementing measures that are sometimes general in scope, and sometimes sector-specific. We have many concerns regarding China's Cybersecurity Law and related measures, which impose far-reaching, highly trade-restrictive conditions on foreign ICT products through "secure and controllable" requirements, enforced by cybersecurity review regime checks. Such requirements are largely based on a planned update and expansion of the Ministry of Public Security's MLPS.

2.348. As one example, China's 25 January 2018 draft measure, "Information Security Technology – Guidelines for Grading of Classified Cybersecurity Protection", appears to repeat and elaborate upon China's MLPS. Numerous other concerns have been laid out in prior interventions by the United States and other Members at prior Committee meetings. Additionally, the United States reiterates its serious concerns regarding China's Cryptography Law, which went into effect on 1 January 2020. The United States is concerned that this law codifies potentially far-reaching, highly trade-restrictive cryptography-related constraints on foreign ICT products. Because these issues are technically complex and China's approach appears to be both novel and would have a potentially widespread impact in the commercial sector, the United States requests that China undertake in-depth consultations with the US Government, other WTO Members, and global stakeholders. We also

[75] For previous statements follow the thread under IMS ID 526 (under dates raised and references).

request that China afford subsequent opportunities for interested parties to submit comments on revised iterations of draft standards and all other implementing measures related to the Cybersecurity Law. Given the broad potential impact of these standards and measures and the serious concerns they have raised, it is critical that China act deliberately to collaborate with all interested parties, and take their comments into account before adopting the drafts as written. We will continue to carefully monitor China's implementation of the Cybersecurity Law and related measures, as well as the Cryptography Law. We look forward to continuing this important dialogue with you.

2.349. The representative of the European Union provided the following statement. The EU would like to refer to the statement it has made in previous TBT Committees with regard to the Cybersecurity Law, namely that the scope of the requirements is unclear as key terms have still not been specified in sufficient detail. The EU would like to request more clarity regarding several of the implementing measures following China's Cybersecurity Law. For example, the Cyberspace Administration of China's Cross-Border Data Transfer Measures continue to raise concerns about the broad scope of these regulations, regarding what is considered as CII and which kinds of cross-border data transfers are affected. A definition of critical information appears to cover many commercial activities and whole sectors that have no bearing on national security. Moreover, the list of what is considered important data is open-ended, which has not been further clarified by the released draft for the Data Security Law in July 2020. As a result of the data localization and security assessment requirements, foreign companies operating in China could find themselves in a less competitive situation compared to domestic operators. The EU calls on China to implement the provisions in a non-discriminatory manner, respecting the principles of proportionality, necessity and technology neutrality, and ensuring adequate protection of intellectual property (IP). Moreover, the EU would like to repeat its previous requests for clarifications on the relationship with existing Multi-Level Protection Schemes and the expected implementation timeline. The EU requests that China notifies draft measures concerning any sectoral implementation to the TBT Committee in order to give adequate opportunity for WTO Members and their stakeholders to comment on any subsequent developments.

2.350. The representative of Canada provided the following statement. China's Cybersecurity Law, which came into force on 1 June 2017, forms the overarching framework for China's extensive cybersecurity requirements. Many of the subsequent implementing measures, that build upon and interact with the law, are still in draft form and lack the clarity and precision needed to ensure secure and predictable access to the Chinese market. For example, the definition of CII is an open-ended, imprecise list of broad sectors, which does not permit companies to assess adequately whether their infrastructure is classified as CII. In addition, there is no clear commitment to the use of the international standards that exporters, from all countries, depend upon to construct the supply chains that underpin international trade. Canada seeks China's agreement to achieve the needed clarity and adoption of international standards by either modifying the law, or providing, in its implementing measures, the clear definitions and commitment to international standards required. In the interim, Canada also seeks clarity on how China will implement the law in the absence of a complete set of promulgated implementing measures.

2.351. The representative of Australia provided the following statement. Australia appreciates China's efforts to consult with interested parties on its measures relating to cybersecurity, including China's recent public consultation on its draft Data Security Law, on which Australia made a submission in August 2020. Australia reiterates our previous position regarding China's Cybersecurity Law and related laws, including the Provisions on Internet Security Supervision and Inspection by Public Security Organs. Australia respectfully reiterates our concerns that many details of these laws remain unclear. Australia notes that, consistent with the TBT Agreement, the measures should be implemented in a non-discriminatory manner and in a way that is no more trade restrictive than necessary. Australia urges China to consider less trade-restrictive alternative measures that are reasonably available to achieve its objectives.

2.352. In response, the representative of China provided the following statement. The purpose of Cybersecurity Law is to safeguard national sovereignty in cyber space, as well as national security and public interests, to protect rights and interests of citizens, legal persons and other organizations in China. There are three aspects in the definition of "secure and trustworthy": firstly, the product or service providers shall not use their product or service to illegally obtain users' data, impairing users' disposition of data. Secondly, product or services providers shall not illegally control and operate users' equipment, impairing controllability of the equipment owned or operated by users.

Thirdly, product or service providers shall not seek illegal interest by making use of users' reliance on the product or service, or operate monopoly, including stop providing reasonable safety technical support or force users to upgrade.

2.1.3.31 European Union - Regulation (EC) No 1272/2008 (CLP Regulation) (IMS ID 539[76])

2.353. The representative of the Russian Federation provided the following statement. The Russian Federation remains concerned with cobalt classification approved under the 14th Adaptation to Technical Progress to the Classification, Labelling and Packaging (CLP) Regulation and reiterates its statement made during the previous meetings of the Committee on TBT and the Council for Trade in Goods. The measure was adopted without any scientific justification and assessments of socio-economic impact. As for direct consequences of this measure, while the CLP Regulation sets labelling and packaging requirements, it is clear that the Commission will go further and develop both industrial and product specific as well as technical regulation on the basis of this classification decision, which will set unjustified restrictions or prohibition for the cobalt use. Moreover, even without further restrictions, cobalt and cobalt-containing products consumption will unduly suffer due to their deselection as a result of stigmatization when manufacturing the final products, such as electric vehicles' batteries, energy storage units and similar equipment critical to fight climate change and achieve green sustainability. However, we welcome the Commission's efforts and the progress achieved in the international approval of gastric bioelution at the level of the EU and the OECD. Could the EU inform the Members of the WTO on the state of work on approval of bioelution under the CLP Regulation? We also welcome recent information by the Commission stating that gastric bioelution can now be applied when classifying alloys and compounds. We ask the EU to confirm this understanding. Finally, we request yet again the EU to share the scientific data that the EU used to classify cobalt as carcinogen for the oral route of exposure.

2.354. The representative of Brazil provided the following statement. Brazil supports STC 539 regarding Regulation (EC) No 1272/2008. As previously stated, in the 14th review of adaptation to technical progress (ATP) for Regulation (EC) No 1272/2008, the reclassification of cobalt as a carcinogenic level 1B was approved. The classification of cobalt as a carcinogenic product generates a great potential negative impact on nickel production in Brazil, since cobalt is also found in trace amounts within nickel production. Restrictions on cobalt trade would therefore negatively impact nickel production in Brazil. Brazil is the primary nickel producing country in South America, exporting around 70 thousand tonnes of nickel, according to 2017 figures. According to industry estimates for the same year, the total value of nickel production reaches USD 12,350 million. Around 56% of the nickel mine production in Brazil is at risk with limitations on the trade of cobalt. In light of this concern, we kindly ask the EU to consider revising restrictions on the use of cobalt, while relying on sound scientific analyses to support its technical regulations with significant impact on trade.

2.355. The representative of Australia provided the following statement. Australia would like to support this STC. As previously noted in this Committee, Australia recognizes the European Union's right to regulate for public and occupational health and safety. We also recognize that appropriate classification and labelling for hazardous substances and mixtures can address legitimate public and occupational health concerns. However, Australia and other WTO Members have raised concerns on multiple occasions in this and other forums that these measures are more trade restrictive than necessary. Our concerns have focused on the potential of these regulations to create unnecessary obstacles to international trade in products containing titanium dioxide and cobalt, as well as the related raw materials. Noting that this regulation has been adopted, and will apply from October 2021, we urge the EU to ensure that the implementation of the regulation, including associated labelling and packaging requirements, is no more trade restrictive than necessary. We also urge the EU to ensure that the implementation of these measures has the least possible impact on downstream products containing titanium dioxide and cobalt, including but not limited to: stainless steel products, which may contain trace amounts of cobalt in concentrations greater than the generic limit of 0.1% applied in the regulation; as well as related raw materials, for example, cobalt is increasingly used in battery technology.

2.356. The Australian chemical, cosmetic, medicament, paint and resources sectors remain concerned about implementation of this measures. The EU has provided some information on the downstream consequences for titanium dioxide. We would welcome a further response to our

[76] For previous statements follow the thread under IMS ID 539 (under dates raised and references).

concerns regarding products containing trace amounts of cobalt, noting that the adopted regulation retained the classification of cobalt as a carcinogen through all routes of exposure, rather than limiting the classification to inhalation only. We welcomed the final EU classification being limited to mixtures containing titanium dioxide that are placed on the market in powder form with a diameter smaller than 10 micrometre. Nonetheless, there remains some confusion from Australian industry around the requirements for products that contain titanium dioxide in a non-powdered form, for example in paint, complementary medicines, and sunscreens. For liquid mixture products, there is still an obligation to update labels with a warning that could have detrimental reputational and trade impacts.

2.357. In response, the representative of the European Union provided the following statement. We would like to thank the Russian Federation for a very fruitful bilateral we held on this issue earlier today. The Commission Delegated Regulation amending the CLP Regulation was published in the Official Journal of the EU in the beginning of 2020 and the classification of cobalt will become applicable as of 1 October 2021. The classification of cobalt is based on the independent scientific opinion of ECHA's Risk Assessment Committee (RAC), which takes into account all scientific information available, including the information available in the dossier submitted by an EU member State (The Netherlands) and from the public consultation that is part of the process to arrive at an EU-wide harmonized classification. In addition, all comments sent to the TBT Committee by WTO Members were distributed to member States and they were duly taken into account by the Commission and the member States in the decision-making process. Moreover, it should be taken into account that the Commission considered that the method used to determine the Specific Concentration Limit of 0.01% should be assessed in order to discuss if the method is relevant for inorganic compounds like cobalt. For this reason, the entry in Annex VI to CLP for cobalt is without such specific limit and the generic limit of 0.1% will therefore be applied.

2.358. The EU would like to reiterate that, in line with the UN GHS (UN Globally Harmonized System of Classification and Labelling of Chemicals), the classification of any substance is based on a hazard assessment and not on risk assessment. It should be noted that classification under CLP is based only on the scientific assessment of the hazards derived from the intrinsic properties of a substance and not on its uses, while potential downstream legal or socio-economic considerations are not part of the principles for hazard classification. Nevertheless, the classification under the CLP Regulation does not in itself restrict the placing on the market of cobalt or cobalt-containing products. When a substance is subject to harmonized classification, only labelling and packaging obligations are triggered for that substance and any mixture containing it, but not for articles (e.g. cutlery or other stainless steel articles). As also mentioned in reply of 23 September 2020 to the letter sent by the Russian Minister for Economic Development, Mr Reshetnikov, to Mr. Sinkevičius, the EU Commissioner for the Environment, the EU made progress in the development of a harmonized approach at international level on the use of the bioelution method. Recently, the EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) Scientific Advisory Committee (ESAC) gave a positive opinion on the scientific validity of a bioelution test method, developed by the metals industry to assess the relative in-vitro bioaccessibility of metals and metalloids in inorganic metal compounds and metal (metalloids)-containing materials using a simulated gastric fluid.[77]

2.359. On the basis of this positive opinion, the method was proposed by the European Commission in November 2019 at OECD level for acceptance as a technical guideline. In May 2020 the OECD Working Group of the National Coordinators of the Test Guidelines Programme accepted the Commission's proposal and an OECD subgroup should be set up to work on the technical guideline. Relevant industries are already using the results of the experimental bioelution test to classify their alloys in accordance with article 12(b) of the CLP Regulation. No legal amendment of this article is required to use this method. The classification of alloys is not subject to harmonized classification but it is under the sole responsibility of the industry. Most probably, the companies producing metal alloys and compounds containing cobalt traces are using such bioelution data for classifying their alloys. However, in order to further examine this approach and to ensure a proper use of the experimental data obtained from the bioelution method, a European expert group has been created with the participation of experts of member States and metal industries. The first meeting of this group took place in September 2020, and further meetings of the group will take place to achieve the goals described above.

[77] https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/esac-opinion-scientific-validity-bioelution-test-method

2.360. With regard to the classification of cobalt as carcinogen for all routes of exposure, including the oral route, the EU would like to reiterate that the approach taken is in line with both the UN GHS and the CLP Regulation. In particular, the UN GHS stipulates the following in Table 3.6.2: Label elements for carcinogenicity: "state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard". In the case of cobalt, such evidence was not available, i.e. the scientific data available were not sufficient to conclusively exclude that the oral route of exposure causes the hazard. A potential re-examination of the classification as regards routes of exposure can only be considered if new and relevant data from scientific studies, conclusively demonstrating the absence of carcinogenic effects from oral or dermal routes of exposure, become available. In view of the time needed for such test results to become available, there was no scientific and legal justification to exclude the oral route. In case new scientific information becomes available in the future, an amendment could only be envisaged following a revised RAC opinion.

2.1.3.32 European Union - Regulation (EC) No 1107/2009 - non-renewal of approval of the active substance picoxystrobin, G/TBT/N/EU/437 (IMS ID 535[78])

2.361. The representative of Brazil provided the following statement. Brazil would like to express its concerns regarding the EU's non-renewal of picoxystrobin registries and to refer to our previous interventions on the matter. In January 2017, the EU notified to the TBT Committee that the approval of picoxystrobin was not renewed, according to its TBT notification G/TBT/N/EU/437. In January 2019, the EU decided to establish very restrictive MRLs for seven substances, including picoxystrobin and buprofezin, which are important for Brazil's exports of agricultural commodities. We consider that the transitional period provided for producers to adapt to the new MRLs was unreasonable, given that studies conducted by EFSA were inconclusive, not based in due risk analysis and inconsistent with Codex guidelines. Council Directive 91/414/EEC of the European Commission declared that picoxystrobin was not toxic, the report of the EFSA claimed that it was not possible to deliver final conclusions on the genotoxic potential of picoxystrobin based on the available data. The Food and Agriculture Organization and the World Health Organization specialists had also concluded that the substance was not genotoxic. This substance is used in more than 65 countries and has been approved by many bodies, such as the US EPA, the Canadian Management Regulatory Agency, the Japanese Agency and the Brazilian Health Regulatory Agency. Our delegation considers that the MRLs for picoxystrobin was already very low, for instance, for soybeans the default was set on 0.01mg/kg. In light of the above, we respectfully ask the EU to consider aligning its decision on renewal of approval of active substances with scientific consensus regarding the safety of substances and their use to protect crops.

2.362. The representative of Colombia provided the following statement. The delegation of Colombia wishes to express its systemic interest in this matter, given that this EU measure is related to other specific trade concerns placed on the agenda of this Committee, and on which it has already made statements.

2.363. The representative of Paraguay provided the following statement. Paraguay refers to its statement under *European Union - Hazard-based approach to plant protection products and setting of import tolerances (IMS ID 393),* para. 2.215.

2.364. In response, the representative of the European Union provided the following statement. As explained in detail at several TBT Committees, the European Commission decided not to renew the approval of picoxystrobin through Commission Implementing Regulation (EU) 2017/1455. Authorizations for plant protection products containing picoxystrobin in the EU were to be withdrawn by 30 November 2017. Member States could allow a grace period until 30 November 2018, at the latest. The European Union notified third countries of the draft Regulation via the TBT procedure. The measure did not lead to immediate disruptions in trade, as the measure itself did not amend the MRLs and provided for a grace period for use of products containing picoxystrobin. Given the issues identified by the EFSA, in January 2019, the Commission lowered the existing MRLs to the limit of quantification (LOQ). The European Union notified third countries of the draft Regulation lowering the MRLs via the SPS Committee and they are applicable since 13 August 2019. Import tolerance requests remain possible and will be assessed on a case-by-case basis by EFSA. Such requests would have to be supported by substantial new data addressing relevant concerns.

[78] For previous statements follow the thread under IMS ID 535 (under dates raised and references).

2.1.3.33 China - Catalogue of Solid Wastes Forbidden to Import into China, G/TBT/N/CHN/1211 (IMS ID 545[79])

2.365. The representative of New Zealand provided the following statement. New Zealand acknowledges and supports the right of all WTO members to regulate to achieve legitimate domestic health and environmental objectives. New Zealand applauds China's stated proactive policy objectives in relation to sustainable development, and encourages valid actions to limit harmful environmental impacts from contaminated waste inside its borders. New Zealand in no way seeks to question China's right to regulate to protect its environment. However, New Zealand remains concerned that vanadium slag is included in China's catalogue of banned imports under this measure. We reiterate our view that vanadium slag is a purposefully produced co-product with a purposeful end use in production of specific forms of steel. It is not a waste product, and so should not fall under measures for solid waste. New Zealand recalls that China itself is the largest global producer of vanadium slag, with approximately 500,000 tonnes annual production generated as a co-product from steel mills. New Zealand would appreciate clarification on how China has ensured that the rules that apply to foreign products are no less favourable than those accorded to domestic products. We would be interested also to hear a further explanation from China on how it has ensured that the import ban on vanadium slag is not more trade restrictive than necessary to achieve China's environmental and health protection objectives. New Zealand thanks China for the recent discussion on this issue, and looks forward to further constructive engagement on this topic to better understand China's approach to distinguishing between waste and non-waste materials.

2.366. The representative of Canada provided the following statement. Canada wishes to reiterate past comments and concerns that we have shared on this STC since it was first put on the agenda of the Committee in March 2018, most recently in May 2020.[80]

2.367. In response, the representative of China provided the following statement. China has been pushing for ecological progress, pro-actively practising the values of "sustainable development" and "green development" in order to meet the Chinese people's ever-growing need for a beautiful eco-environment and aiming to solve significant outstanding environmental problems. Advancing the reform of the solid wastes import administration regime is one of the most important steps that the Chinese government has taken to implement the New Development Ideas and to safeguard the eco-environment safety and people's health. In accordance with internationally recognized principles, each Member has the obligation to handle and dispose of the wastes it has generated on its own. China, as a developing Member with the largest population, must make the inevitable choice of restricting and prohibiting imports of solid wastes while improving its own domestic solid wastes treatment and disposal. Current scientific studies indicate that the residues resulting from the recycling and disposal of solid wastes and their carried wastes may pose various risks to human, animal, and plant life and health, as well as to the environment. Since solid wastes have already significantly increased the burden on China's eco-environment and had huge negative impacts on human, animal, and plant life and health, China considers that merely reforming the domestic regulation of solid wastes would not be sufficient for achieving our purpose of safeguarding the ecological safety and population health to the maximum extent possible.

2.368. In the process of adjusting the solid wastes imports policies, Chinese government has adequately taken into account voices at home and abroad, and adjusted the Import Waste Management Catalogue in different batches. China has also set a sufficient transition period for the relevant industries, and has fulfilled transparency obligations under the WTO rules. Meanwhile, China allows solid wastes processed into raw materials that meet the relevant national quality standards to enter China by trade. Over the past decades, enterprises from other WTO Members have exported large quantities of solid wastes to China and derived huge financial gains. China earnestly hopes that these Members could also actively fulfil their international social responsibility and make contributions to the global environmental protection. It has been noticed internationally that cross-border transfers of plastic, electronic and other wastes to developing Members brings serious environmental pollution and international society are actively taking measures. In May of 2019, the 14th session of the Conference of the Parties to the Basel Convention, more than 180 parties agreed on the plastic waste amendments, to strengthen the control of plastic waste cross-border transfers, and to establish the partnership of plastic waste, driving the common action globally in response to plastic pollution. The convention has set up an expert working group to strengthen controls on cross-

[79] For previous statements follow the thread under IMS ID 545 (under dates raised and references).
[80] G/TBT/M/81, para. 1.419.

border movement of e-waste. At present, not only China, but also every Member should follow the fundamental principle of disposal and absorbing the wastes it has generated on its own. Only on the basis of this principle can we reach a better consensus on managing solid waste pollution and search for a solution to this problem. At the same time, abiding by this principle will also contribute to the promotion of the global green low-carbon circular development, and the creation of a clean and beautiful world.

2.1.3.34 Viet Nam - Cybersecurity Measures (IMS ID 544[81])

2.369. The representative of the United States provided the following statement. The United States remains concerned about Viet Nam's proposed data localization measures in its draft cybersecurity decree. We look forward to Viet Nam amending this draft measure in a transparent manner to address concerns that we and other WTO Members have raised, in order to ensure that the Cybersecurity Law is implemented in the least trade-restrictive manner possible. Does Viet Nam have any updates to share on the status of the draft decree?

2.370. The representative of Canada provided the following statement. Canada wishes to reiterate its statement from the May 2020 meeting.[82] Canada continues to seek an update from Viet Nam on its implementation of the Cybersecurity Law, including the status of the draft decree implementing it and planned future actions.

2.371. The representative of Australia provided the following statement. We share other Members' concerns with a number of concepts in Viet Nam's Cybersecurity Law. Australia and other Members have provided feedback on Viet Nam's draft decree implementing the new law, noting our interest in seeing a law that: maintains Viet Nam's entrepreneurialism and embrace of digital platforms; supports increased participation in global e-commerce; and enhances the business environment in Viet Nam, including by being transparent, clear and compliant with international trade commitments and regional trade agreements. We share the view that safeguarding cybersecurity is a legitimate policy objective of governments. But we continue to question whether requirements in the law and draft implementing decree are necessary to meet Viet Nam's cybersecurity objectives. The current laws do not represent the least trade-restrictive manner to achieve those objectives. This may affect Viet Nam's reputation as an open economy and impact its ability to benefit from the digital economy and Industry 4.0. We look forward to continuing to work with Viet Nam on the implementation of the Cybersecurity Law and thank Viet Nam for its engagement on this matter.

2.372. The representative of the European Union provided the following statement. The European Union shares the Member's concerns on the Vietnamese Cybersecurity law as regards its potential economic impact and its compatibility with Viet Nam's commitments under the WTO. The European Union would like to have an update on the draft Implementing Decree on Cybersecurity and invites the Vietnamese government to seriously consider EU concerns and continue the dialogue to ensure alignment to international best practices. We would also appreciate indications as regards further implementing measures and on the plans for taking into consideration comments from interested parties, including industry and stakeholders. The European Union kindly requests that Viet Nam notifies the Cybersecurity law, the draft Implementing Decree and any other planned implementing measures to the TBT Committee, in accordance with Article 2.9 of the TBT Agreement. The European Union encourages Viet Nam to develop and implement Cybersecurity measures in full respect of WTO principles, such as non-discrimination and proportionality and to take into consideration available international standards and practices.

2.373. In response, the representative of Viet Nam provided the following statement. We thank the United States, the European Union, Australia, and Canada for their continued interest in our legislative drafting process for the Decree to implement certain articles of the Cybersecurity Law. Viet Nam would like to reiterate that our process has been transparent with an open mind. All stakeholders' comments have been reviewed for continuing internal consideration.

[81] For previous statements follow the thread under IMS ID 544 (under dates raised and references).
[82] G/TBT/M/81, para. 1.425.

2.1.3.35 Brazil - Technical Regulation 14, 8 February 2018, to set the additional official identity, quality standards for wine and derivatives of grape and wine products as well as the requirements to be acquainted and Technical Regulation No. 48, 31 August 2018 published in the Official Gazette on 10 September 2018, G/TBT/N/BRA/613 G/TBT/N/BRA/956 (IMS ID 568[83])

2.374. The representative of the European Union provided the following statement. The European Union would like to refer to the points raised in the previous TBT Committees. The European Union notes that Brazil is in the lead of several working groups in OIV that work on issues relevant to our bilateral trade, such as categories of sparkling wines related to sugar content, import documentary evidence and list of analytical parameters for imports. The European Union appreciates the efforts of Brazil to seek international consensus within the OIV framework. In this context, the European Union would like to reiterate the invitation to Brazil to make use to the maximum extent possible of the recommendations of the OIV when revising the relevant technical regulations and to remove the current requirements that are not in line with the OIV standards on identity and quality of wine and on maximum content limits. In addition, the European Union would also like to stress that the certification obligation on methyl alcohol and the systematic counter-analysis of certification parameters at border continue creating difficulties for EU wine exporters. The European Union is prepared to work bilaterally with Brazil in this respect.

2.375. In response, the representative of Brazil provided the following statement. Regarding OIV standards, it is important to stress that Brazil indeed leads several OIV working groups and we aim to align our regulations with the organization's standards. Furthermore, Brazil wants to highlight that there is no OIV standard setting out a list of parameters to be used as a guidance for the international trade of wine. Technical Regulation 75, which came into force on 2 January 2020, defines the criteria and analytical parameters to be used in the inspection and control of national and imported wine and derivatives of grape and wine products. Brazil considers that technical regulations (TRs 14, 48, and 75) are necessary to guarantee the quality of wines consumed in national territory, included the obligation analysis on methyl alcohol and the certification parameters at the border. In this context, it is important to remember that Technical Regulations 14 and 48 defined, for both domestic and foreign producers, physical-chemical analytical parameters for wine and derivatives of grape and wine products. With subsequent Technical Regulation 67, notified as G/TBT/N/BRA/853, the models of certificates and related documents required for certification for the export and import of drinks, acetic fermented wines and grape and wine derivatives were approved. Among other elements, Technical Regulation 67 requires the presentation of analysis results for the parameters defined in Technical Regulations 14 and 48. It is important to highlight, with regard to these Technical Regulations, that Brazil provided a grace period of 365 days for countries to adapt to the new requirements.

2.376. Technical Regulation 75, on the other hand, establishes the analytical parameters that must be included in the laboratory reports used in the inspection and control of imported and national beverages. These analytical parameters are set out in Operational Standard No. 1, of 24 January 2020. Therefore, the number of parameters is reduced to seven, in comparison with the 15 parameters contained in the provisions of Technical Regulations 14 and 48. TR 75 does not pose new requirements. The practical effect of such measures, by decreasing the ratio of physical-chemical parameters required by Technical Regulations 14 and 48, is to make the technical criteria for imported wine less trade restrictive. It is our understanding that Technical Regulation 75 is a trade-facilitating measure when compared to past regulations. Brazil is a growing wine consumer and producer, a condition that entails regulatory action for the sector. When developing new regulations on wine, Brazil will continue to abide by WTO rules.

2.1.3.36 Russian Federation - Federal law No 487-FZ, providing a framework for comprehensive use of special labelling and traceability of goods and Decision No. 792-r specifying the goods to which labelling will apply and the dates of introduction of the mandatory labelling (IMS ID 567[84])

2.377. The representative of the European Union provided the following statement. On 28 April 2018 the Russian Government adopted decision № 792-R, listing goods which will be subject to mandatory marking, along with the dates of introduction of these labelling requirements for each

[83] For previous statements follow the thread under IMS ID 568 (under dates raised and references).
[84] For previous statements follow the thread under IMS ID 567 (under dates raised and references).

product category. The EU has very serious concerns on the proportionality of the measure: individual labelling and registration creates significant burden and cost, well beyond the cost of the individual labels. This may be justified for some products of high value and with a high record of counterfeit or tax evasion, such as tobacco products or furs. Therefore the EU requests that Russia reviews the scope of products covered by the measure so that this focuses on high-value products for which there is evidence of a high level of counterfeit and/or tax avoidance. Though we commend the Russian government in its efforts to tackle counterfeiting, this measure includes technical regulations and will have a significant impact on imports from the EU and from other WTO Members to Russia. According to the Decision of 1995 of the TBT Committee, "Members are obliged to notify all mandatory labelling requirements that are not based substantially on a relevant international standard and that may have a significant effect on the trade of other Members". Therefore, this measure should have been notified under the TBT Agreement before its adoption. The EU would like to request the Russian Federation authorities to prepare a comprehensive guideline providing exhaustive information on technical details such as: timetable of goods to be labelled until 2024, deadlines, references to legislation, information contact points, Q&A part where the most frequent issues would be explained, etc. Such a guideline would significantly facilitate situation for a majority of economic operators, both foreign and Russian. The Russian government adopted Resolution No 515 on 26 April 2019 on the "marking of goods subject to mandatory labelling by means of identification". Of course, this measure also falls within the scope of the TBT Agreement and needs to be notified to the WTO. In accordance with the TBT Agreement, sufficient time shall be provided to industry to adapt to the requirements necessary for placing products on the market of the Russian Federation, which is in general six months.

2.378. Some deadlines for labelling of individual product groups have been postponed, but an unclear situation remains on the ground. These postponements for different categories seem to be largely linked to the system not yet being operational. Operators, both Russian and foreign, need additional time to ensure that all products to be placed on the market of the Russian Federation can comply. Introducing changes in the production cycle ahead of the implementation date is difficult, as crucial information on the exact requirements is still lacking. Moreover, the manufacturers have recently been considerably affected by the outbreak of the COVID-19 and all corresponding consequences, such as lockdowns, availability of employees, transport disruptions, etc. Therefore, an extension of transition period is necessary, during which import and/or sale of non-labelled production to Russia would be allowed. This transition period should last at least until the end of 2021 and should cover all products for which labelling started in 2020 and those planned for 2021. Current deadlines seem to be the following: Footwear – started on 1 July 2020; Medicines - started on 1 July 2020; perfumes and eau de toilette - started on 1 October 2020; photo cameras – started on 1 October 2020; tyres - 1 November 2020; textiles - 1 January 2021; dairy- 20 January 2021 and 1 October 2021.

2.379. Additionally, pilot projects for labelling of bottled water is on-going and for beer is supposed to start soon. According to public statements of the Minister for Industry and Trade, Mr. Manturov, labelling of these products is supposed to start in the first half of 2021. Producers of both types of products have already announced that the share of counterfeited products in these two segments is close to zero and obligatory labelling would considerably raise final prices for consumers. Therefore we would like to invite Russian authorities to publish a corresponding analysis providing an overview of counterfeit in segments of bottled water and beer. We ask the Russian Federation to take into consideration the European Union's comments, to ensure that the implementation of this measure is not unecessarily trade restrictive, in accordance with the WTO TBT Agreement.

2.380. In response, the representative of the Russian Federation provided the following statement. The Russian Federation reiterates its statements made during the previous meetings of the Committee on TBT and sticks to the position that the measure at issue cannot be considered as the technical regulation due to the fact that the system does not meet the requirements stipulated in the Agreement on TBT for technical regulations. The labelling requirements in technical regulations refer to fulfilling the technical requirements indicated in technical regulations. We emphasize that the track and trace system is not aimed at securing fulfilling the requirements stipulated in the relevant technical regulations. Besides, the labelling requirements under the technical regulations should contain the information about the product characteristics in a form of inscriptions or the uniform labels as «EAC» or «CE». Track and trace does not apply to the product characteristics or their related processes and production methods. The legislation and comprehensive guidelines regulating the track and trace, whether effective or drafts, are publicly available in the information system of "Chestiyznak" as well as the information about planned pilots and the volume of issued

data-matrix code in respect of each type of products covered by the regulation. The system is transparent and information on it is available for all stakeholders in the Russian and English languages.

2.381. We do not consider the system as disproportionate or burdensome as the concept in respect of each type of products has been elaborated in collaboration with the companies involved in manufacturing, supplying and importing the products covered. In addition, the price of one data-matrix code is approximately half of a ruble that is less than one US cent. In addition, according to the statistics made by the Operator of the System approximately 15 billion codes have been issued for tobacco products, 2 billion codes for shoes, 4 billion for pharmaceuticals, about 36 million codes for textiles. These figures show that market participants adapted to the system, its functioning is stable, and all the negative forecasts in respect of disruption of traditional trade flows due to the Track and Trace System are not confirmed. We note hereby that the guidelines for each type are available on "Chestniy Znak". As for challenges faced by small enterprises, we note that importers ensure appliance Track and Trace in respect of products either at any stage of supply chain from production to imports or at the customs warehouse when products are placed under the customs procedures. In this regard, importers and exporters of products to the territory of Russia determine the mechanism of application of the system.

2.1.3.37 China - Cosmetics Supervision and Administration Regulation and Regulation for Notification of Non-special Cosmetics, G/TBT/N/CHN/1310, G/TBT/N/CHN/1311, G/TBT/N/CHN/1331, G/TBT/N/CHN/1453, G/TBT/N/CHN/1454, G/TBT/N/CHN/1459, G/TBT/N/CHN/1460 (IMS ID 576[85])

2.382. The representative of Japan provided the following statement. As for "Cosmetics Supervision and Administration Regulation", we would like to reiterate the following points. In terms of provisions related to disclosure of new ingredients and efficacy testing materials, Japan requests that the scope of disclosure be clarified so as to exclude confidential corporate information. The regulation provides that "cosmetics registrants or filers" are the persons responsible for quality, safety and efficacy of cosmetic products. However, the regulation and "Administrative Measures on Cosmetic Labelling" provides that the label should indicate "cosmetics registrants or filers" and "cosmetics producers or its contract producers". In order to avoid confusion, Japan requests that the label should indicate only "cosmetics registrants or filers" who are a single responsible person. Furthermore, Japan still has concerns related to the "Management Rules for Testing required for Cosmetic Product Registration and Notification", which was enforced on 12 September 2019. We would like to reiterate the following three points. Regarding testing laboratories, Japan requests a more flexible framework in which test results obtained by in-house or foreign laboratories through internationally recognized practices such as ISO can be accepted. As for the efficacy evaluation, China has not provided detailed information regarding test methods required for whitening products. Since whitening tests take a long time to complete, Japan requests that test results obtained by in-house or foreign laboratories be accepted and the grace period be adequately extended. As we mentioned at the last TBT meeting, in terms of requirements for animal testing, there are conflicting descriptions between "Management Rules for Testing required for Cosmetic Product Registration and Notification" and "Regulation for Notification of Non-special Cosmetics". Japan requests that China ensure consistency between those regulations.

2.383. Moreover, regarding "Interim Measures on the Administration of Overseas Inspections of Cosmetics", Japan would like to continue to express concerns on the following three points. Japan would like to request that China clarify which laws and regulations authorities are to use to determine conformity and specific purposes for conducting overseas inspections. Japan also asks that China ensure that inspections will not be more trade restrictive than necessary, ensuring that the legitimate objectives under the TBT Agreement are fulfilled. The coverage of the inspection including product research and development stage is broader than necessary, and it causes unnecessary burdens for companies. The main purpose of the inspection seems to be to ensure product safety. Information related to research and development is not necessarily essential for product safety assurance, while it is the most confidential corporate information. Therefore, R&D departments of companies should be excluded from the coverage of overseas inspections. Furthermore, inspections for domestic Chinese companies are only conducted on production sites. Japan would like to request that China provide equal treatment to both domestic and overseas companies. Japan requests that China ensure that confidential information will not be disclosed to anyone other than those who are

[85] For previous statements follow the thread under IMS ID 576 (under dates raised and references).

necessary for the legitimate purpose of the inspection, since production sites also contain confidential corporate information. Finally, we would appreciate it if China could provide the detailed timeline for these revision processes. Japan would like to request that China provide an adequate grace period, at least one year after promulgation of all relevant regulations in order to allow time for producers to adapt to new cosmetic regulatory system.

2.384. The representative of the United States provided the following statement. The United States is supportive of China's objective via CSAR to modernize and streamline its system of cosmetics regulation to the benefit of Chinese and US consumers. We note that China is conducting domestic consultations on several important draft measures to implement CSAR. Because such measures are expected to have a significant effect on trade, we request that China notify the WTO of all CSAR implementing measure and standards; provide a minimum of 60 days for WTO Members and industry to comment; consider the comments submitted by WTO Members and industry; and, then re-notify to the WTO any measures for which significant comments are made, before final versions are adopted. We ask that China clarify what is considered a relevant GMP certification so as to exempt importers from having to submit animal toxicological testing for market access. Because the United States Food and Drug Administration, by law, cannot issue GMP certifications for general cosmetics products, please confirm that China will accept a certification from a national trade association and/or a third-party certifier aligned with ISO 22716 Cosmetics – GMP – Guidelines on GMP. If not, we ask that China explain why importers are required to submit the results of animal toxicological tests, while companies manufacturing in China are not subject to such requirement.

2.385. While we appreciate China's commitment to streamline its procedures for approving new cosmetics products and ingredients, we are concerned that NMPA new filing and registration requirements, which are more extensive than what was required previously, may be requiring more information than necessary to fulfil its objective of managing product safety in China's cosmetics marketplace. NMPA's requirement that companies disclose their CBI including product formulations, manufacturing processes, ingredient specifications, and suppliers to local testing and responsible agents increases the risk of unauthorized disclosure of companies' CBI and trade secrets to competitors. NMPA should not require companies to disclose CBI and trade secrets to local testing and registration agents as a condition to access the Chinese market. NMPA should also consider if the required disclosures are necessary for the legitimate exercise of its regulatory authority, as cosmetics generally are lower risk compared to medical products. NMPA can access this information via post-market inspections if concerns with the safety or claims made for specific product or ingredients are identified.

2.386. When disclosures of CBI and potential trade secrets are necessary, NMPA should develop systems to identify and to safeguard cosmetics rights holders' IP and legitimate commercial interests, consistent with TBT and other relevant WTO IP commitments. We also ask that NMPA work with industry to develop a system for public disclosures of claims that supports consumer interest in innovative products while also safeguarding companies' investments in technology and testing in the least trade-restrictive manner. US FDA employs cosmetic product category codes to indicate a product's intended use. In developing its cosmetics classification system, NMPA should be wary of prescriptive classifications, or product standards that emphasize certain manufacturing processes or specific formulations to create a product. Cosmetics companies should be encouraged to develop innovative new products and ingredients, so long as they can also address the safety of their formulations for the anticipated users and uses. The success of China's cosmetics and personal care industry is important to the United States given both the number of Chinese products used daily by American consumers, as well as the economic opportunity China represents to US companies seeking to serve China's growing consumer base. The industry represents an example of the potential for expanding our bilateral trade.

2.387. The representative of the Republic of Korea provided the following statement. Korea supports China's objectives of assuring the quality and safety of cosmetics through the comprehensive revision of this measure. However, Korea remains concerned that some of the provisions within the regulations being drafted could create unnecessary obstacles to trade. The concerns from our industry are as follows. First, under the Regulation, China requires the disclosure of the summary of scientific evidence that support cosmetic efficacy claims, which contain trade secrets. Also, China's labelling requirements differ from the international practice. With regard to these issues, Korea reiterates the concerns it raised regarding the previous STCs on the "Provisions for Cosmetic

Registration" and the "Administrative Measures on Cosmetic Labelling".[86] Above all, the revision of the "Cosmetics Supervision and Administration Regulation" is needed as the matters prescribed in the regulation are reflected in its subordinate provisions and measures. Thereby, Korea urges China to consider the comments from Korea and other Members into revision. Second, the regulation stipulates that test results required for the registration of cosmetic products must be issued by testing laboratories that have obtained CMA in compliance with the regulation. However, only laboratories in China are known to have obtained CMA. Thus, Korea would like to request China to offer flexibility to foreign laboratories in granting CMA and to recognize test results issued by foreign laboratories or internationally recognized laboratories, including test reports submitted for the registration of cosmetic products.

2.388. Third, under the draft of "Cosmetics Supervision and Administration Regulation," the licence for special-use cosmetics has validity periods. The licence issued by most of the countries including Korea, the US, and European states does not have a determined validity period. To harmonize cosmetics regulations, Korea requests that China reconsider setting the validity periods of the licence for special-use cosmetics. During the last TBT Committee meeting, China replied that it will take full consideration of the comments from the Members. However, the finalized draft of the Cosmetics Supervision and Administration Regulation does not seem to be reflecting them. Hence, we request China to take into account our comments and look forward to receiving a response from China.

2.389. The representative of Australia provided the following statement. Australia welcomes efforts by China to modernize and simplify its regulatory system for cosmetics. We hope China will provide commercially viable alternative to testing on animals. We also welcome the progress made by China in clarifying how its new CSAR will be implemented, including notification to the WTO of new draft provisions, guidelines and rules (G/TBT/N/CHN/1453, G/TBT/N/CHN/1454, G/TBT/N/CHN/1459, G/TBT/N/CHN/1460). Australia would also welcome details from China on any further cosmetics measures to implement the CSAR, including intended content and timelines. We encourage China to notify all cosmetics measures and to provide WTO Members with an opportunity to comment. To comply with Chinese requirements, businesses exporting cosmetics to China will also need a clear understanding of China's regulatory framework and any applicable measures. Australia requests that China base technical requirements for cosmetics on relevant international standards in line with the WTO TBT Agreement. Australia also urges China to ensure that its regulations, including ingredient-based safety assessment standards and risk-based categorization are aligned with international practices to ensure that risks to human health are managed in a way that minimizes the impact on trade. We strongly encourage China to provide equal treatment for Chinese and foreign cosmetics. Like other WTO Members have also indicated, Australia encourages China to limit administrative and documentation requirements to those that are strictly necessary, including in relation to disclosures of commercially sensitive information. Australia would welcome the opportunity to engage bilaterally in discussion on cosmetics regulation to promote mutual understanding of our respective regulatory systems for cosmetics.

2.390. The representative of the European Union provided the following statement. The EU would like to support the delegations of Japan, Korea, the United States, and Australia. The EU welcomes the new CSAR that has the potential to create an equal treatment of domestic and imported non-special cosmetic products. It can move China significantly further towards a modern cosmetics legislation based on industry responsibility and safety assessment. Such higher international compatibility of Chinese cosmetics regulation will benefit Chinese consumers, the development progress of the Chinese cosmetics industry and multilateral trade in cosmetics. To achieve fully the objective of equivalent treatment of domestic and imported products, the EU is of the opinion that some requirements could be clarified to better acknowledge and accommodate differences in manufacturing between China and its international trading partners in the administrative management of cosmetic. The proposed draft Regulation for Notification of Non-special Cosmetics (G/TBT/N/CHN/1331) enables importing companies to confirm completely the safety of the product based on safety assessment, granting an exemption from toxicological tests carried out on animals. This exemption is conditional to submission of a certificate of the production quality management system by a regulatory body. The EU understands and welcomes that this aims at creating an equivalent requirement to the pre-market manufacturing licensing requirements applicable to domestic manufacturers.

[86] China – Provisions for Cosmetics Registration (Draft for Comments) (IMS ID 641) and China – Administrative Measures on Cosmetic Labelling (IMS ID 642).

2.391. However, in many countries or regions, including the EU, the administrative management of cosmetics manufacturing is not based on a pre-market licensing approach but on in-market control. Therefore, in most EU member States, the respective authorities may not have a legal basis for issuing such certificates. In most countries, including the EU, companies manufacturing cosmetic products are obliged to follow GMP and attest this in the mandatory product information file. Authorities have the obligation to carry out in-market controls, including control of compliance with the GMP requirement at an appropriate scale at a random basis but also in case of suspicion of quality issues. The EU is of the opinion that in principle, company-issued GMP certificates from manufacturing sites in countries with a functioning in-market control system should therefore be considered as sufficient, especially when done in conjunction with overseas inspections by Chinese authorities in case of suspicion. Therefore, in order to acknowledge and accommodate the administrative differences across the world, the EU would like to kindly propose to Chinese authorities a range of options for consideration as equivalent and valid with regard to the type of document and the organization issuing it such as manufacturing licence, Quality management/GMP certificate or inspection/audit conclusions. Such documents can be issued by state regulatory authorities, local authorities (e.g. provincial or municipal) or industry associations recognized by authorities to issue such a document. This range of options will allow companies to obtain a relevant statement and comply with the proposed requirement, adapted to the legal and administrative management system of the country of manufacture. The EU would appreciate knowing to what extent the EU comments of 24 July 2019 on the draft Regulation for Notification of Non-special Cosmetics (G/TBT/N/CHN/1331) have been or will be taken into account, and whether the notified measure is still at a draft stage.

2.392. In response, the representative of China provided the following statement. Thanks to Japan, the US, Korea, Australia and the EU for raising this concern and for your positive experience sharing and suggestions. We would like to clarify following points regarding the protection of trade secrets in the registration and filing materials. As health-related products, materials as product formula and production process of cosmetics are an important basis for product safety technical review. Registrants and recorders are required to submit safety-related materials, which are also the general rules of many Members to review the safety of health-related products. The product safety information submitted by enterprises is not the content of government information disclosure. According to Chinese government information disclosure regulations, administrative agencies should not make public government information containing commercial secrets, personal privacy or other elements which may cause damage to legitimate rights and interests of third parties after disclosure. Therefore, no situation as leak of trade secrets mentioned by Members exists in the cosmetics registration and filing process. As the issue of alternatives to animal testing, the notified draft placed exactly the same requirements in setting up alternative plans for animal testing for safety evaluation of imported and domestic cosmetics. Regarding the requirements for cosmetics registration and filing materials, the contents requested to be submitted for imported and domestic products are exactly the same. Based on the principle of equal treatment between import and domestic productions, regarding the issue of exemption from animal experiments, both kinds of ordinary products are required to hold production licences or documents related with good manufacturing practice issued by government supervision departments. This is not only measures on ensuring product quality and safety, but also a concrete embodiment of the principle of non-discrimination.

2.1.3.38 European Union - Draft Commission Regulation laying down eco-design requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EC) 642/2009 (and its accompanying annexes), G/TBT/N/EU/609 (IMS ID 575[87])

2.393. The representative of China provided the following statement. China thanks EU for former replies, but after a careful study of the Impact Assessment, China believes that the legal basis of restricting halogenated flame retardants (HFRs) is still insufficient, and requests EU to apply the restriction of HFRs in D4 Annex II of (EU) 2019/2021 in line with Stockholm Convention on Persistent Organic Pollutants (POPs). Firstly, the EU lists the regulations on the use of brominated flame retardants (BFRs) in the "legal background" of Impact Assessment Annex 15, including REACH, RoHS (Restriction of Hazardous Substances), WEEE (Waste Electrical and Electronic Equipment) and the WFD (Waste Framework Directive) legislation. It should be noted in particular that the scope of the above legislation for BFRs is within the Stockholm Convention, and does not extend to the prohibition

[87] For previous statements follow the thread under IMS ID 575 (under dates raised and references).

of all HFRs. In fact, there are over 70 BFRs and only five have persistent, bioaccumulative and toxic (PBT) property and are listed in Stockholm Convention as POPs. Therefore, we consider that the legal basis and scientific basis for the provision of restricting all HFRs in (EU) 2019/2021 is insufficient. Secondly, according to the EU's reply at the 82nd TBT meeting, the EU is drafting the guidelines based on RoHS thresholds, it is recommended that the EU provide the specific names of the restricted HFRs, following the practice of RoHS.

2.394. The representative of Brazil provided the following statement. Brazil supports the concerns raised by China with regard to this STC. Our private sector will be particularly affected by the ban on the use of HFRs in the enclosure and stand of electronic displays, according to The New Version Annex II D, related to "materials efficiency". Such prohibition is not in line with the REACH Regulation and the Restriction of Hazardous Substances Directive. The potentially conflicting regulatory requirements between those measures and the Eco-design Directive raise questions about transparency in regulating these products. We acknowledge the EU concerns with the fact that HFRs in enclosures and stands of electronic displays could hinder recycling of WEEE plastics. However, the recycling of brominated flame retardants, for instance, is being well managed by innovative plastics and polymer recyclers. Therefore, Brazil respectfully asks the European Union to consider withdrawing such burdensome and trade-restrictive requirements.

2.395. In response, the representative of the European Union provided the following statement. Firstly, the legal basis for this amending act is provided by Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009, establishing a framework for the setting of eco-design requirements for energy-related products. This empowers the European Commission to set eco-design requirements for energy-related products, which account for significant volumes of sales and trade in the Union, and which have a significant environmental impact and present significant potential for improvement through design in terms of their environmental impact, without entailing excessive costs. Unless otherwise specified, the requirements of the Stockholm Convention are "*de minimis*" provisions, allowing parties to adopt own measures with a higher level of environmental ambition. Secondly, the proposed text of the amendments is available for public feedback under 3 November.[88] The specific names of the substances in question are laid down in Article 4 of "ANNEX IV – Amendments to the Annexes to Commission Regulation (EU) No 2019/2021". Finally, the proposed Eco-design requirement restricting the use of HFRs does not undermine but complements the objectives and requirements of the REACH, RoHS, and WEEE Directives. A wide range of supporting facts and figures on the recycling of plastics from televisions and other electronic displays can be found in the detailed Impact Assessment carried out prior to the adoption of the initial regulatory act.[89]

2.1.3.39 European Union - Concerns on regulations with regard to eco-design requirements for various products in EU, G/TBT/N/EU/606, G/TBT/N/EU/607, G/TBT/N/EU/615 (IMS ID 592[90])

2.396. The representative of China provided the following statement. China appreciates EU's efforts on environmental protection, and I wish to thank the EU for their feedback to our questions, however we would still suggest that: firstly, EU clarifies whether washing machines without heating function are included in this regulation. The draft regulation requires that the washing process of household washing machines should provide an "ECO 40-60" washing cycle function, but washing machines without heating function are designed without the function of "ECO 40-60", which means it cannot be tested according to the standard. Secondly, China suggests that EU cancels the requirements for spare parts delivery time. China believes that the delivery time for spare parts is a business practice and should not be promulgated and implemented in a regulation, moreover, under the situation of the COVID-19 pandemic, it is not feasible.

2.397. In response, the representative of the European Union provided the following statement. The Eco-design regulation on washing machines and washer dryers (2019/2023) also applies to machines without a heating function (see Articles 1 and 2). The definition of the "eco 40-60" programme does not require the washing machine to have a heating function and is therefore applicable to this type of machine. See Article 2: "eco 40-60" means the name of the programme

[88] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12471-Energy-efficiency-updated-EU-rules-on-ecodesign-and-energy-labelling

[89] https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52019SC0354

[90] For previous statements follow the thread under IMS ID 592 (under dates raised and references).

declared by the manufacturer, importer or authorized representative as able to clean normally soiled cotton laundry declared to be washable at 40 °C or 60 °C, together in the same washing cycle, and to which the eco-design requirements on energy efficiency, washing efficiency, rinsing effectiveness, programme duration and water consumption relate". It should be noted therefore that household washing machines without a heating function shall be tested as described in the Eco-design regulation on washing machines and washer dryers (2019/2023) and shall comply with all requirements of Article 3 of this Regulation. Requirements for spare parts delivery time are essential to encourage customers to have their appliances repaired. As indicated in Annex II to the Eco-design regulation on washing machines and washer dryers (2019/2023), these requirements are applicable as of 1 March 2021. Reparability is an essential element of the circular economy, as recently underlined in the Circular Economy Action Plan, a Communication from the European Commission released on 11 March 2020. So far, we do not have enough elements at our disposal to analyse a potential disruption of the availability of spare parts after 1 March 2021 that might be linked to the COVID-19 crisis.

2.1.3.40 Republic of Korea - Package Recycle Classification Regulation, G/TBT/N/KOR/843, G/TBT/N/KOR/844, G/TBT/N/KOR/857 G/TBT/N/KOR/857/Add.1, (IMS ID 588[91])

2.398. The representative of Canada provided the following statement. As stated in previous Committee meetings[92], Canada remains concerned with the Republic of Korea's Package Recycle Classification Regulation, notified under G/TBT/N/KOR/843, G/TBT/N/KOR/844 and G/TBT/N/KOR/857. Canada recognizes and supports Korea's efforts and actions to protect the environment, particularly with respect to the management of waste and recyclable materials. However, Canada stresses that Korea has yet to provide a response to its letter of comments sent on 22 November 2019 despite its multiple requests to Korea's Enquiry Point and at the TBT Committee. Under Article 2.9.4 of the TBT Agreement, Korea should have "[…] discuss these comments upon request, […]", yet Canada's requests remain unanswered. Korea's response would have helped Canadian stakeholders to better prepare for the entry into force of the Regulation earlier this year. In its statements of February and May 2020, Korea ensured Members that it would "soon" share the final version of this regulation, including the Package Recycling Classification Regulation. To date, Canada has yet to receive notification of these documents, and we are seeking an estimate of when Korea will be sharing the final version of these regulations. Our understanding is that this regulation contains many different pieces of legislation: from the Act on the Promotion of Saving and Recycling of Resources itself, to side regulations and notifications defining a series of exemption (e.g., fruit wines, whisky), methods of determination, and standards of packing material. Some of these pieces of legislation may not have been communicated to WTO Members, and Canada is of the view that interested Parties would benefit from Korea notifying all relevant pieces of legislation under the Act on the Promotion of Saving and Recycling of Resources under a single, consolidated notification. Canada looks forward to Korea's further engagement on this issue.

2.399. The representative of Australia provided the following statement. Australia recognizes the Republic of Korea's right to implement regulations that promote the reduction of waste and the production of easily recyclable packaging materials. Australia thanks Korea for providing an exclusion from displaying recyclability evaluation results on wine bottles ("labelling exemption"). Australia seeks clarification on whether an exemption similar to the labelling exemption will be provided to wine bottles for the environmental fee attached to products categorized as "difficult" to recycle.

2.400. The representative of the European Union provided the following statement. The EU strongly supports actions taken for the protection of the environment and acknowledges the efforts made by the Republic of Korea to facilitate the recycling procedure by encouraging producers to place recycle-friendly products on the market, but the EU remains concerned about the negative impact that the notified measure would have on trade. The EU welcomes the exemption given to glass bottles of wine and whisky products from the labelling requirement. However, the EU continues to be concerned about the requirements for olive oil bottles. These too require opaque packaging in order to avoid sunlight deterioration and preserve the product integrity. Justification documents for the exemption were provided to the Korean Ministry of Environment in June 2020 however no reply has, as yet, been received. The EU would appreciate a positive review of this request and an exemption for olive oil bottles, regardless of the material used, from its labelling requirements without further

[91] For previous statements follow the thread under IMS ID 588 (under dates raised and references).
[92] G/TBT/M/79, item 2.2.4.23; G/TBT/M/80, item 2.2.3.44; G/TBT/M/81, item 1.3.51.

delay. The EU understands that the exemption of a product from the labelling requirement does not entail an exemption from the fee and would like the Republic of Korea to confirm this point and explain the criteria used for the two processes. Additionally, the EU is concerned that the process for the distribution of the environmental fee to companies that produce "easy to recycle" products could provide an unfair advantage to local producers over importers and thus be discriminatory. The EU kindly invites Korea to provide further information on the subject.

2.401. The representative of Mexico provided the following statement. Mexico refers to the Sub Act on the Promotion of Saving and Recycling of Resources, notified by the Republic of Korea in various documents: G/TBT/N/KOR/843, G/TBT/N/KOR/844, G/TBT/N/KOR/857 and G/TBT/N/KOR/857/Add.1. In addition, in September 2020, two further notifications were published in documents G/TBT/N/KOR/918 and G/TBT/N/KOR/919, both of which had the same title and were notified on 22 and 23 September, respectively. The Republic of Korea has stated that only those products graded the "lowest" as "difficult to recycle" were obliged to indicate the recyclability class on their labels and has exempted certain products from this requirement. The delegation of Mexico has stated that its concern is based on the fact that the bottles containing tequila that are exported to the Republic of Korea are made from various materials, not all of which could be classed as "difficult to recycle". This complicates determining whether the measure would apply to the bottles of tequila.

2.402. Furthermore, there is some confusion over the last two documents notified in September and how they are related to the Sub Act, as they also refer to the "Draft Partial Amendment to the Regulation on the Promotion of Saving and Recycling of Resources". In view of the above, the delegation of Mexico requests the delegation of the Republic of Korea to: Provide clarification on the criteria used to determine which bottles would be subject to indication of the wording "difficult to recycle" and which would be exempt. If possible, confirm whether bottles of tequila would be covered by this regulation, or whether they might be excluded from the labelling obligation, as in the case of wine and whisky; Clarify the relationship between the above six notifications and their implications. Or, failing that, clarify if they concern different draft regulations; and Share the English version of the documents notified on September 2020 in order to facilitate their review and the submission of comments during the public consultation period ending on 22 and 23 November 2020, respectively. Also, clarify the differences between each of them. The delegation of Mexico thanks the delegation of the Republic of Korea for giving its consideration to this statement and to the requests made therein.

2.403. The representative of New Zealand provided the following statement. New Zealand supports measures that focus on legitimate objectives, including those that produce positive environmental outcomes, such as encouraging recycling and reducing waste. However, as an exporter of food and beverage products, New Zealand remains interested in understanding how Korea's proposed measures are no more trade restrictive than necessary. We encourage Korea to consider how their measures will impact a wide range of products, including consideration of potential exemptions and flexibility in the scheme. We respectfully request that Korea ensures that transparent and clear guidelines are published on how exporters can comply with these measures. In particular, we ask that such guidelines set out what is and is not classified as "recycle friendly" and the consequences of such classification, to ensure traders can easily comply with the regime and not incur unnecessary barriers or costs to trade.

2.404. In response, the representative of the Republic of Korea provided the following statement. Korea appreciates the interest of the Members in Korea's regulation on packaging materials. Korea would like to deliver the official response from the regulatory authority. Exemption from the labelling obligation is finalized after review by the "Packaging Materials Review Committee" composed of experts in accordance with the "Quality and Structural Standards of Packaging Materials". Therefore, if an olive oil manufacturer or importer requests an exemption from labelling of its products, the "Packing Materials Review Committee" will decide whether to exempt them by reviewing alternative materials and fairness among items. For your information, until now, olive oil manufacturers or importers have not officially requested an exemption from the labelling obligation to the "Packaging Materials Review Committee" by submitting the specific request form. Also, from 2021, the EPR (Extended Producer Responsibility) contributions will be differentiated according to the recycling grade of packaging materials. Those who produce or import "difficult to recycle" grade packaging materials will be charged an additional 20% of their EPR contribution.

2.405. On the other hand, those who produce or import "easy to recycle" grade packing materials will receive subsidies equal to 50% of their EPR contributions. Differentialization of EPR contributions is planned to be applied from items exempted from the duty of labelling (wine, whisky, etc.) and PET bottles from 2021, gradually expanding the applied items. On the other hand, these measures were discussed and decided by importers, producers, and recyclers participating in EPR, so it is difficult to regard them as particularly beneficial to producers in Korea. Korea will continue to consult with stakeholders regarding this regulation and share the final version of the Package Recycle Classification Regulation. After this committee meeting, Korea will consult with the relevant authorities so that we can reply to concerns raised by Canada and other Members which are not included in this response.

2.1.3.41 Qatar - Ministry of Public Health Circular regarding shelf life for cheese (IMS ID 602[93])

2.406. The representative of the United States provided the following statement. The United States remains concerned over the trade disruptions caused by Qatar's dairy product regulation, published by the Ministry of Public Health in May 2019, which, among other effects, restricts the reconstitution of milk and shelf life of cheeses. Qatar adopted this measure without notifying it to the WTO, or providing trading partners the opportunity to comment, or providing a reasonable implementation period. This measure, in fact, appears to have been issued as a final measure, given that no comments were taken into account, and the measure has caused significant disruptions to trade since its implementation on 1 June 2019. Despite many bilateral discussions the United States has had with Qatar, US exporters continue to be blocked due to the enforcement of this measure, and businesses in Qatar have faced shortages of supplies needed for production. Therefore, we request Qatar to terminate this measure and revise it so that trade may continue.

2.407. The representative of the European Union provided the following statement. The European Union would like to recall its concerns with regard to the Qatar Ministry of Public Health Circular of 30 May 2019 establishing new import requirements for UHT milk and white cheese that entered into force the following day, on 1 June 2019. The EU regrets that Qatar did not notify these requirements to the WTO under neither the TBT nor the SPS Agreements. The implementation of these rules is causing serious disruptions to EU exporters as compliance with these requirements is not feasible for certain cheeses and milk products. As consequence, EU products covered by the measure cannot be exported to Qatar anymore. The EU is particularly concerned about the stringent restrictions on the shelf life that disadvantage imported products in comparison to local products, but also about certain product characteristics for UHT milk and white cheeses, in particular obligatory addition of vitamins to milk and low-fat-only requirement for certain white cheeses. These requirements are not in line with Codex Alimentarius relevant international standards, are not science-based and do not guarantee the safety of imported products. The measures therefore appear to be more restrictive than necessary to fulfil the legitimate objective of public health protection. In this context, the EU would like to refer to Articles 2.1, 2.2 and 2.4 of the TBT Agreement. The EU would like to invite Qatar to suspend the application of the measure without further delay, align it to the WTO rules and comply with its notification obligations. The EU would like to thank Qatar for bilateral exchanges during the past months, which unfortunately have not yet resulted in an effective solution. The EU is prepared to continue to work constructively with Qatar to resolve this important issue.

2.408. The representative of Canada provided the following statement. Canada would like to reiterate its concerns with Qatar's new shelf-life requirements for identified milk and cheese products established by the Ministry of Public Health on 30 May 2019. As stated in previous TBT Committee Meetings, Canadian exporters of paneer cheese are unable to fulfil contracts with Qatar importers due to the overly restrictive shelf-life requirements for paneer cheese. The 50-55 day ocean transit from Canada to Qatar effectively makes it impossible to comply with the new 45-day shelf-life requirements. We remain concerned that these stringent shelf-life requirements effectively encourage the domestic or close proximity sourcing of these products which potentially leads to the discriminatory treatment of imported products. Canada once again encourages Qatar to notify this measure to the WTO, pursuant to the WTO's transparency obligations, in order to provide trading partners with the opportunity to comment. Until then, we respectfully request that Qatar suspend its implementation.

[93] For previous statements follow the thread under IMS ID 602 (under dates raised and references).

2.409. Subsequent to the TBT Committee held in February 2020, Canada submitted detailed questions through Qatar's Enquiry Point on 26 March 2020 to obtain additional clarifications on the measure and to highlight specific concerns. At the last TBT Committee meeting in May 2020, Canada reiterated its request for answers. To date, Canada has not received a response. Canada's specific questions are as follows: We understand that paneer cheese would meet the definition of "white cheese" according to this circular. Is this correct? Could Qatar provide details on how the shelf-life requirements were determined? We note that certain cheeses can only be presented in low-fat form and that the addition of vitamins to milk is obligatory. Could Qatar please provide details on how these requirements were determined? We would also appreciate clarifications on the requirements to add vitamins to milk and the low-fat only requirement for certain white cheeses. Could Qatar explain how these requirements were determined and share any relevant information. While we recognize that some processes may have been temporarily disrupted due to the current global pandemic, we would appreciate if Qatar could acknowledge receipt of our questions and inform when a response can be expected. In the meantime, Canada will continue to follow these discussions closely, and looks forward to further engagement with Qatar.

2.410. In response, the representative of Qatar provided the following statement. Qatar has taken note of the continued concern of the United States, the European Union, and Canada regarding Qatar's Ministry of Public health circular on shelf life for cheese and thanks them for their interest. We are still following this matter with the competent authorities in Doha, despite the lockdown imposed by the COVID-19 pandemic. We would like to take this opportunity to reconfirm that these measures have been adopted to ensure the quality of products available in Qatar, and that the protection of consumers is of primary importance to the Government of the State of Qatar with its international obligations under the WTO Agreements, including the TBT Agreement. Also, we would like to assure Members that the relevant measures apply equally to domestic and imported products and are therefore non-discriminatory in nature. Furthermore, any impact that such regulations may have on trade will not be more than necessary to contribute to the fulfilment of the legitimate objective of protecting consumers. In this respect, we would like to emphasize that product-specific requirements applied in the State of Qatar do not prevent the importation and sale of any products that meet quality standards and thus do not have a significant effect on trade. This being said, we will share the concerns expressed today with our capital and will provide replies to the questions we have received as soon as possible. Also, we remain available to continue our constructive discussion with the interested Members to provide additional explanation where necessary.

2.1.3.42 Republic of Korea - Ballast Water Management Act (IMS ID 606[94])

2.411. The representative of the European Union provided the following statement. The EU would like to recall its concerns raised in previous Committees concerning the Republic of Korea's requirements on the certification of ballast water treatment systems (BWTS) manufactured by EU companies for vessels registered under the Korean flag, specifically regarding the time needed to review tests that were already performed. The EU would like to thank the Republic of Korea for facilitating a reduction in the fee request but would also like to underline the importance of a prompt issuance of the certificates for European companies, which are currently under review.

2.412. In response, the representative of the Republic of Korea provided the following statement. Korea appreciates the interest of EU member States in Korea's Ballast Water Management Act. Korea would like to deliver the official response from the regulatory authority. As explained to the last WTO and FTA, Korea's Ballast Water Management Act has already stipulated that foreign systems may be equal to Korean products in the conditions for type approval. So, Korea would like to also explain that Korea has no technical and institutional barriers to foreign system in the procedure of type approval of Ballast Water Management System. Furthermore, Korea has reasonably improved the cost and time required for type approval in March this year so that domestic and foreign companies can obtain type approval more quickly. However, in the case of a European company that is undergoing the type approval process in Korea, the process is considered to be pending because the documents required for the type approval review are not supplemented. Korea would like to inform the EU once again that Korea is providing equal treatment to domestic and foreign companies without any technical or institutional barriers on the type approval of Ballast Water Management System. In addition, any comments or enquiry will be received by Ministry of Oceans and Fisheries, the competent authority of Korea.

[94] For previous statements follow the thread under IMS ID 606 (under dates raised and references).

2.1.3.43 Mexico - Draft Amendment to Mexican Official Standard NOM-051-SCFI/SSA1-2010: General specifications for the labelling of pre-packed food and non-alcoholic beverages, G/TBT/N/MEX/178/Add.9, G/TBT/N/MEX/178/Add.10, G/TBT/N/MEX/178/Add.11, G/TBT/N/MEX/178/Add.13, G/TBT/N/MEX/178/Add.9, G/TBT/N/MEX/468, G/TBT/GEN/302 (IMS ID 608[95])

2.413. The representative of Costa Rica provided the following statement. Costa Rica wishes to support the trade concern raised by the European Union and the United States regarding Mexico's proposed front-of-pack nutrition labelling for food products. In recent years, Costa Rica has very much believed in, and defended, the importance of the work carried out within the Codex Alimentarius framework, and has given equal importance to scientific justification for the measures adopted by each country, whether they be based on the Codex itself or on other technical or scientific evidence, as required by the Agreement on Technical Barriers to Trade. Given that the Codex Alimentarius is currently developing working materials on front-of-pack nutrition labelling, Costa Rica wishes to request once again that the Mexican delegation clarify its position regarding the work carried out in the Codex in this area. With regard to the content of the measure, and bearing in mind that the classification parameters according to which a product is considered to contain excessive calories, sugar, saturated fats, trans fats or sodium are not Codex-based, we reiterate the request made to the Mexican delegation at this Committee's previous meeting, to indicate the scientific basis or international reference standard used to define the key parameters for Mexico's classification and to provide relevant justification for the use of the front-of-pack warning sign as supplementary nutrition information.

2.414. Turning to the consumption by children of products containing added caffeine or sugar substitutes, Costa Rica requests the delegation of Mexico to refer to either the international reference standard used or the risk analysis establishing the risk posed to children by the consumption of products containing these ingredients. Costa Rica believes that the measure adopted by Mexico could generate inconsistencies with TBT Agreement obligations, in particular those established in Articles 2.2 and 2.4. It is Costa Rica's view that as things currently stand worldwide in light of the COVID-19 pandemic, the implementation of certain sanitary and phytosanitary measures that create additional restrictions or burdens, without prejudice to the power that Members have to adopt them if considered necessary, constitutes a challenge that hampers global economic recovery efforts, especially in developing countries that are reliant on international trade, such as Costa Rica. In light of the foregoing, we would be grateful if the Mexican delegation could inform us about the progress of this draft amendment.

2.415. The representative of the United States provided the following statement. The United States supports Mexico's public health objective of reducing diet-related NCDs and appreciates Mexico's notification of NOM-051, "General Labelling Specifications for Pre-Packaged Foods and Non-Alcoholic Drinks – Commercial and Health Information." The United States continues to be concerned that the revised regulation, intended to address public health, may be more trade restrictive than necessary to meet Mexico's legitimate health objectives, may not be based on robust scientific evidence, go beyond international standards and may contribute to consumer confusion. Unfortunately, the concerns we raised about the short time allowed for compliance with these requirements, only six months after the final regulation was published, have now materialized. Delays are growing with trucks backed up along the border due to the significant number of products that unexpectedly must be relabelled and verified. On 1 October, the Government of Mexico published changes to the General Rule for Foreign Trade regarding compliance with technical regulations (NOMs) requiring product labelling. The resolution went into effect on the same day. The Mexican customs authority SAT is enforcing the resolution to require that raw materials, bulk products and, in general, products for use in further industrial or services activities, including food service products, are no longer exempt from the labelling requirements of 14 NOMs. This includes enforcement of the new front-of-packaging labelling included in NOM-051 that entered into force the same day. The US Government and US exporters did not expect food service products would need to comply with NOM-051's labelling requirements intended for the final consumer.

2.416. Inclusion of food service products impacts more than USD 1 billion worth of US exports that were not understood to be in the scope of NOM-051. The dairy industry has estimated that up to USD 750,000 worth of bulk cheese are requiring relabelling every day, while our potato industry estimated costs at USD 500,000 for relabelling in the first five days the measure was in effect. We

[95] For previous statements follow the thread under IMS ID 608 (under dates raised and references).

urge Mexico to clarify that food service products are exempt from compliance with NOM-051 and request that it immediately honour the enforcement delay until 1 December 2020, a grace period already notified to the WTO while trading partners work through clarifications on compliance for food service and other products. While Mexico has stated that a clarification is in process, and that the scope of NOM-051 has not changed with food service products outside the scope of the measure, its clarification has yet to be published. As already mentioned, US industries already hard hit by the complications of the COVID-19 pandemic are bearing additional daily costs that can be avoided. We thank Mexico for the productive discussions so far and its willingness to work with the United States to resolve concerns, however, we urge immediate action. Can Mexico confirm when it will issue the clarification related to enforcement of its technical regulations? The US said: We have received some information from Mexico that could alleviate some of our concerns, but we are not completely done translating and analysing the documents.

2.417. The representative of the European Union provided the following statement. The European Union would like to thank Mexico for the opportunity to send written comments on the notification G/TBT/N/MEX/178/Add.9 Draft Amendment to Mexican Official Standard NOM-051-SCFI/SSA1-2010: General specifications for the labelling of pre-packed food and non-alcoholic beverages and for the reply to these comments. First, the European Union would like to underline that it supports and shares the objective of Mexico to inform the consumers clearly and truthfully of the content of critical nutrients presenting health risks in excessive consumption. At the same time, the EU notes that it is necessary to guarantee an efficient implementation of the new rules to prevent them becoming an obstacle to trade. The phase one of implementation of the NOM-051 started on 1 October 2020. Unfortunately, the worries of the EU food producers that the very short transitional period provided for in NOM-051 would not be sufficient to adapt their labelling practices to the new requirements have now materialized. The EU is receiving numerous complaints from EU importers to Mexico concerning very serious difficulties with implementation of the revised labelling obligations in NOM-051, resulting in blockages of EU containers in customs.

2.418. To minimize negative impact on trade, the European Union invites Mexico to take urgent steps to guarantee efficient custom clearance of the blocked containers. In parallel, the competent Mexican authorities are invited to provide the custom officials and importers with clear guidance on implementation of the new labelling rules. The European Union would like to ask in particular the following questions: The new labelling obligations are already being enforced before custom clearance, despite the two-months grace period given by "Acuerdo Interinstitucional" of July 2020 (ending 30 November 2020). Can Mexico explain why the two-months grace period is not being respected for imported products? The EU appreciates that stickers can be used for compliance with the labelling obligations, however this is only temporary (until 31 March 2020). We would like to invite Mexico to provide for a permanent possibility to use adhesive labels to comply with all the relevant obligations on food labelling. The EU would like to ask for a clarification with regard to the "labelling compliance certificates", which must be obtained from an Authorized Verification Unit (AVU) and must be presented to customs upon arrival of the goods, if the importer does not select neither one of the other two options available to prove labelling compliance. So far, companies report experiencing unusual delays in obtaining those certificates. Could Mexico explain how will efficient issuance of these certificates be guaranteed to avoid delays in customs?

2.419. The European Union would like to thank Mexico for information about the document "Criterios de aplicacion de normas oficiales Mexicanas – insumos no destinados al consumidor final", issued on 26 October 2020, which provides for exemptions from labelling obligations under NOM-051 for food products not destined for final consumer. The European Union appreciates this exemption, will analyse the document and revert to Mexico with further questions, if needed. Finally, the European Union would like to thank Mexico for the useful bilateral discussion and appreciates that some clarifications for importers were provided on the website Servicio Nacional de Información de Comercio Exterior (SNICE). Mexico informed that its competent authorities are working on a guidance documents regarding implementation of the new labelling requirements under NOM-051. Can Mexico specify whether there will be any further guidance documents apart from those already published? The EU said: We are in a similar position to the United States because we recently received some useful information from Mexico.

2.420. The representative of Guatemala provided the following statement. The new Mexican Official Standard (NOM) on the labelling of pre-packaged food and non-alcoholic beverages (NOM-051-SCFI/SSA1-2010), which entered into force on 1 October 2020, seeks to establish the commercial and health information that must be displayed on the labels of pre-packaged domestic

or foreign products marketed in national territory, determine the characteristics of such information and establish a system of front-of-package labelling for the general population, in order to provide consumers with clear and accurate information on the presence of critical nutrients that pose a health risk if consumed in excess. We reiterate our appreciation of Mexico's efforts to protect people's health and provide consumer information and thank Mexico for keeping Members informed at each stage of the notification process for NOM-051-SCFI/SSA1-2010.

2.421. Regarding NOM-051-SCFI/SSA1-2010: General specifications for the labelling of pre-packaged food and non-alcoholic beverages, which entered into force on 1 October 2020, we should point out once again that, in accordance with Article 2.2 of the Agreement on Technical Barriers to Trade, measures applied by Mexico must not be more trade-restrictive than necessary. For economies like ours, new regulations containing labelling requirements generate concern because they create a lack of harmonization among such provisions worldwide, making it difficult for small and medium-sized producers to gain access to the international market because of different labelling requirements and restrictions. We refer, above all, to the points raised at the last meeting in May, regarding the discontinuation of the use of adhesive labels in order to ensure compliance with the requirements set out in NOM-051-SCFI/SSA1-2010. In this regard, we wish to refer to notifications G/TBT/N/MEX/178/Add.13 of 10 July 2020 and G/TBT/GEN/302 of 19 October 2020, which provide information on the publication of the Amendment to the Agreement under which the Ministry of the Economy issues general rules and criteria in respect of foreign trade. Both notifications indicate that until 31 March 2021 goods with adhesive transfers or stickers affixed to product labels may be presented for customs clearance provided that they comply with the provisions of NOM-051-SCFI/SSA1-2010.

2.422. Paragraph 8.2.1 of Codex Standard CXS 1-1985: General Standard for the Labelling of Prepackaged Foods, states that "If the language on the original label is not acceptable, to the consumer for whom it is intended, a supplementary label containing the mandatory information in the required language may be used instead of relabelling", while paragraph 8.2.2 states that "In the case of either relabelling or a supplementary label the mandatory information provided shall […] fully and accurately reflect that in the original label". With the provision established in the current Standard, Mexico is departing from the international reference standard and establishing an unnecessary obstacle to international trade. In this regard, at the national level, Mexican food products sent to the Guatemalan market are able to comply with the labelling requirements established by Central American regulations through the use of supplementary adhesive labels, instead of being required to have permanent labels affixed in the country of origin exclusively for the Guatemalan market. This measure facilitates trade and is proportionate to the level of protection sought, and we therefore request reciprocal treatment.

2.423. Following on from its remarks at the last meeting in May, Guatemala also wishes to make the following comments: With regard to warnings concerning the use of sweeteners, the standards developed within the framework of the Codex Alimentarius – including Codex Stan 192-1995, General Standard for Food Additives, 2019 revision - are based on solid scientific data. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an independent international scientific committee that conducts risk assessments and advises on exposure assessment. It is therefore considered that the information provided to consumers in terms of warnings concerning the use of sweeteners aimed at children over three years of age is not scientifically based. The General Standard for the Labelling of Prepackaged Foods CXS 1-1985, revised in 2018, clearly establishes that pre-packaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression for consumers regarding its character in any respect. We therefore reiterate that in the new regulations on labelling, the reference to an imitation product is inconsistent with the Codex Alimentarius, when the pre-packaged food product is not based on compliance with existing Mexican standards. Furthermore, we believe that establishing typographical characteristics for the denomination "imitation" constitutes an unnecessary restriction on international trade.

2.424. The limits set for nutrients on labels reflect the thresholds established by the WHO on the basis of the global daily diet of an individual, a parameter that was transferred proportionally to the specific product, when it is not a parameter established within the Codex Alimentarius framework. It should be taken into account that each food product brings different nutrients to a diet, i.e. a food product may contain one specific nutrient, but not another. The values established in the WHO criteria should not therefore define a characteristic of a specific food or beverage. The restriction on the use of children's characters limits the use and enjoyment of an intellectual or industrial property

right (e.g. mark, caricature, cartoon) and not only inhibits the intellectual development of creators, but also prevents any contribution to ensuring distinctive elements between products for consumers, as provided for in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). We reiterate that some provisions of the existing regulations depart from the content of the Codex Alimentarius, which has the solid backing of the relevant scientific bodies. The aim of the Codex Alimentarius is to ensure international harmonization and the elimination of trade barriers.

2.425. The representative of Colombia provided the following statement. Colombia supports Mexico's public health objective of reducing diet-related non-communicable diseases. However, our country wishes to support the trade concern raised by the European Union and Costa Rica on the amendment to Mexican Official Standard NOM-051-SCFI/SSA1-2010, "General specifications for the labelling of pre-packaged food and non-alcoholic beverages - Commercial and health information", which establishes a front-of-pack labelling scheme for pre-packaged food and non-alcoholic beverages containing sugars, fats or sodium. In this regard, our industry has expressed concern about the implementation of the measure adopted by Mexico, not least given that this technical regulation may be more trade restrictive than necessary to fulfil public health objectives, as it does not appear to be based on relevant international standards or sound scientific evidence, running contrary to Article 2.4 of the Agreement on Technical Barriers to Trade TBT/WTO ("TBT Agreement"), which provides that: "Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations". However, this measure stigmatizes foods developed by the industry based on non-technical classifications and criteria, because they refer to systems that are not clear or precise, causing confusion among consumers.

2.426. In view of the above, we consider it important that such measures use as a benchmark the standards issued by the Codex Alimentarius to ensure that they are based on scientific and technical evidence, or on other technical or scientific evidence, as the nutrient profiles proposed in the measure are being called into question due to their lack of technical rigour. This is because the measure means applying the recommendations made by experts on the total diet to particular foods, ignoring the fact that many factors contribute to overweight and obesity, with bad eating habits and a sedentary lifestyle, total food intake or the quantity and frequency of its consumption being relevant factors. Therefore, when addressing such problems, account should be taken of the intrinsic levels that some foods contain and which are not the result of an industrial process. Colombia considers that the measure is more restrictive than necessary and may become an unnecessary obstacle to trade, violating Article 2.2 of the TBT Agreement, which states that: "(…) Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective".

2.427. Finally, we consider that the measure could also have shortcomings from the point of view of competition, as it could limit the number of enterprises in the market, inhibit the ability of one or more enterprises to compete, limit the options and information available to consumers and reduce incentives for enterprises to innovate and compete. The design of the nutrient profiles of the Mexican regulation discourages the reformulation of products because, as they are based on a percentage in relation to their total energy content, there will always be the requirement to include warning labels, despite industry innovation efforts. It is impossible to change the composition of some foods, owing to their nature and characteristics. In light of the above, Colombia requests Mexico to review the regulation, taking into account the comments submitted by Colombia during the international public consultation phase. I would also like to request that the industry be granted a longer period of time to make the adjustments in the production process that are required under the regulation, with a minimum of two years.

2.428. The representative of Paraguay provided the following statement. Paraguay supports Mexico's objective of protecting public health and considers nutritional information provided to the consumer to be an appropriate strategy. However, Paraguay shares the concern of other countries over the mandatory declaration of added sugar, which is not provided for under Codex guidelines. Also, it concerns Paraguay that no analytical method can differentiate between total sugar and sugar added to a food, thus complicating taxation, as it would depend on the information provided by industry. The nutritional labelling's lack of harmonization with international guidelines could impede trade between countries.

2.429. The representative of El Salvador provided the following statement. El Salvador once again wishes to express its concern regarding Mexico's notification in document G/TBT/N/MEX/178/Add.9 of 14 October 2019, which concerns an amendment to Mexican Official Standard NOM-051-SCFI/SSA1-2010: General specifications for the labelling of pre-packaged food and non-alcoholic beverages - Commercial and health information, published on 5 April 2010. The amendment was subject to public consultation for 60 calendar days until 10 December 2019. El Salvador submitted a number of comments on the amendment to the above-mentioned Standard, pointing out that while one of the aims of the amendment, according to Mexico, is to prevent and control obesity, there is, to date, and in El Salvador's view, no technical and scientific proof of a direct link between the establishment of a warning label and a reduction in, or the control of, this disease; it is therefore questionable whether these measures would achieve any legitimate health-related objective. In addition to this, there are other factors, such as sedentariness, which play a more prominent role in obesity. The warning label is not a comprehensive solution to the problem and would have serious implications for trade.

2.430. El Salvador recognizes that another of Mexico's objectives is to provide consumers with accurate information so that they can make good nutritional decisions with a view to preventing non-communicable diseases such as obesity. Nevertheless, El Salvador considers that the use of front-of-pack labelling will not necessarily help consumers to make good choices regarding what they consume. On the contrary, such choices are linked, in many cases, to consumers' socio-economic standing and level of education. We therefore reiterate that warning labels lack a sound scientific basis for meeting the legitimate objective pursued, and diverge from applicable international standards in this area, in particular the Codex Alimentarius. El Salvador is also concerned to see that the front-of-pack labelling system proposed by Mexico is based largely on the Pan American Health Organization's Nutrient Profile Model, which lacks the appropriate scientific basis to be used as a suitable document for setting maximum nutrient parameters for the specific diet of the Mexican population and does not reflect international standards and guidelines, thus not ensuring the promotion of more healthy diets. Furthermore, Mexico's proposed front-of-pack labelling system covers only processed products, and excludes non-processed products, which are produced domestically, thereby implying clear discrimination. El Salvador recognizes the efforts made by the Government of the Republic of Mexico to gather together all the comments on the above-mentioned Standard and to respond to them in the document notified in G/TBT/N/MEX/178/Add.10 of 16 March 2020. However, given the length of that document, it is quite difficult to identify the individual responses to each of the comments made.

2.431. The representative of Switzerland provided the following statement. Switzerland would like to reiterate its concerns regarding the amendment of the Mexican Official Standard NOM-051-SCFI/SSA1-2010 "General specifications for the labelling of pre-packaged food and non-alcoholic beverages - Commercial and health information". The first phase of NOM-051 entered into force on 1 October. The rest of the provisions are foreseen to enter into force in April 2021. First, and despite Mexico's earlier efforts to explain that the amendment is in line with international guidelines, we are unconvinced that NOM-051 is in line with international guidelines since the Codex Guidelines on Nutrition Labelling do not foresee the use of warning labels as proposed by the amendment. The Codex Guidelines on Nutrition Labelling further state that the information contained in the nutrient declaration "should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product". We also note that no explanation has been given concerning the motivation behind choosing a label with warnings, such as "exceso en". As mentioned previously, consumers may come to believe that these foods should be avoided altogether, while they can be part of a balanced diet.

2.432. Second, we call on the Mexican authorities to consider extending the cut-off date beyond the 30 November 2020 for food and non-alcoholic beverages produced or imported before the 1 October 2020. On this date, the first phase of NOM-051 entered into force. Relabelling food and non-alcoholic beverages with a shelf life of 12 or more months would come at a considerable cost to businesses, when more cost-efficient options are possible. Third, we have received conflicting reports that raw materials fall under the scope of, and need to comply with, NOM-051. Other reports suggest that this is in fact not the case. Switzerland therefore seeks clarifications from the Mexican authorities whether raw materials are excluded from the application of NOM-051. In light of these comments, Switzerland encourages Mexico to review the amendment of the Mexican Official Standard NOM-051-SCFI/SSA1-2010 in order to ensure an adequate supply of food and beverages to the Mexican market in particular during the COVID-19 pandemic.

2.433. In response, the representative of Mexico provided the following statement. The delegation of Mexico thanks Costa Rica, the United States and the European Union for sharing their observations, on which it has the following comments: It is possible to carry out labelling in the country, in private homes or general bonded warehouses; the details of these procedures are described in section 6, subsections II and III, of the amendment to the NOM Annex. As for the two-month grace period, this is only applicable to products that are already warehoused or at the final point of sale to the consumer in order to facilitate inventory turnover. Regarding the use of stickers or adhesive materials, it is important to bear in mind that, on 1 October 2020, only the front-of-pack labelling system (stamps and warnings) entered into force. In order to facilitate implementation for domestic producers and importers, the labelling currently employed for marketing purposes may continue, with stamps and warnings being affixed if applicable, using stickers or adhesive materials. This will be possible until 31 March 2021. Due to the entry into force on 1 April 2021 of all the changes relating to commercial and health information that should appear on the labels of products subject to NOM-051, the use of stickers or adhesive materials is no longer permitted, as there will be a complete change in labelling. However, it will be possible for imported products to continue to use adhesive materials for labelling to comply with all the changes in commercial and health information set out in NOM-051. It will also be possible to comply before 1 April 2021.

2.434. In other words, in accordance with the provisions of the agreement published in the Official Journal on 10 July 2020, importers will be able to continue to use adhesive materials, but no longer only to comply with the requirements of the front-of-pack labelling system (stamps and warnings); rather, it will be to comply with all commercial and health information requirements. This benefit has no cut-off date. As an example to clarify the situation, importers may use adhesive materials to cover all of the current label or label of origin (if they so wish), to cover all that is prohibited under NOM-051 (cartoon characters, for instance) and include all commercial and health requirements (for instance, octagon symbols, warnings, nutritional information). In short, from 1 April 2021, all products (domestic and imported) that are marketed to the end consumer in the United Mexican States should meet all the requirements provided for in NOM-051. In the case of importers, they will be able to use adhesive materials to cover the label of origin to comply with all provisions of the applicable technical regulations.

2.435. As regards the request for a certificate of compliance granted by an inspection unit, the certificate is conditional on opting for labelling in the country, be that in a private home or in a general bonded warehouse. However, if the option of bringing the label from the country of origin is taken up, then the certificate is not necessary, nor is it necessary to use the services of an inspection unit. More detailed information on this can be found in the first paragraph of section 6 and subsections II and III of the amendment to the NOM Annex. Information on verification units to assess NOM-051 can be found in the following link.[96] As previously indicated by Mexico and some Committee Members in their statements, discussions are taking place in the Codex Alimentarius framework and there is currently no international reference standard that may be used as a basis for establishing front-of-pack labelling. Regarding Mexico's position concerning the work under way in that forum, we refer Members to the response given during the written procedure, which states that, during the 45th Session of the Codex Alimentarius Committee on Food Labelling, the delegation of Mexico expressed its support for work on the paper on "criteria for the definition of 'high in' nutritional descriptors for fats, sugar and sodium". Lastly, the relevant authorities of the Government of Mexico worked on the issuance of criteria that will clarify any doubts concerning the application of NOM-051, on goods such as "in bulk", "raw material" and "end consumer", which have been published and are available in the Integrated System for Standards and Conformity Assessment (SINEC), in the section on relevant documents.

2.1.3.44 United States - Act to amend the environmental conservation law, in relation to regulation of toxic chemicals in children's products (State of New York – Senate Bill 501B/Assembly Bill 6296A), G/TBT/N/USA/1581, G/TBT/USA/1581/Add.1 (IMS ID 610[97])

2.436. The representative of the European Union provided the following statement. The European Union acknowledges the bilateral dialogue held with the United States, leading to the notification, in accordance with the WTO TBT Agreement, of the State of New York Act to amend the environmental

[96] https://www.snice.gob.mx/~oracle/SNICE_DOCS/uvasnoms-noms_20201002-20201002.xlsx
[97] For previous statements follow the thread under IMS ID 610 (under dates raised and references).

conservation law, in relation to regulation of toxic chemicals in children's products. The European Union welcomes initiatives that increase the knowledge about hazardous chemicals in products targeted to consumers, and in particular to vulnerable groups, like children. However, the European Union would like to reiterate its concerns as the Act introduces a further layer of regulation, in addition to the regulations on toys that are already in force at federal and different States' levels. This proliferation of rules and requirements on toys leads to a regulatory fragmentation that renders more burdensome and complex the sales and imports of toys in the United States. In particular, the law includes a reporting requirement for the presence of any intentionally added chemicals identified as either a chemical of concern or a high-priority chemical by the Department of Environment and Conservation.

2.437. In this context, the European Union considers necessary that any future proposal for the listing of chemicals of concern, high-priority chemicals or prohibited chemicals by the State of New York should be notified in accordance with the WTO TBT Agreement, so as to allow WTO Members to comment on the proposed listing within a 60-day comment period. Following the bilateral we had with the United States last week, the European Union understands that the State of New York is aligning with other US State approaches and welcomes this effort. As mentioned in our written statement uploaded in eAgenda, the EU still has a few remaining concerns, both on procedural issues, and substance. The European Union believes that the remaining concerns should be clarified in the act or at least that the Children Product Safety Council should provide guidance on the notions of trace contaminants and practical quantification limits in order to ensure clarity and predictability in the implementation of the measure. Finally the EU would like to thank the US for the further information provided during the bilateral and is keen to continue this dialogue.

2.438. The representative of China provided the following statement. China appreciates the efforts made by the United States in protecting lives and health of children. However, China would like to ask the US to clarify four points: the first is to further clarify the relationship between this regulation and the federal and state regulations that have been implemented, as well as the participation procedures of stakeholders, so as to avoid complicating market access procedures; the second is to clarify the criteria in defining priority and list of banned chemicals; the third is to provide a reasonable transition period for the industry to adapt to the launch of new chemicals or to annually review and update such lists; the fourth is about the qualification and measurement methods or guidelines of "trace pollutants".

2.439. In response, the representative of the United States provided the following statement. The bill at issue, "An act to amend the environmental conservation law, in relation to regulation of toxic chemicals in children's products," was signed into law on 7 February. The law adopted a new Title 9 in Article 37 of New York's Environmental Conversation Law titled, "Toxic Chemicals in Children's Products." New York State amended Title 9 of Article 37 on April 3 as Chapter 55 of the Laws of 2020. The enacted language may be found in S.7505-B/A.9505-B as Part XX, Subpart AA. The amended law is now in effect. The amendments included substantial changes in part to address concerns raised by stakeholders. This state-level measure is now more similar to Washington and Vermont measures regulating chemical disclosure. The text of the final bill can be found in G/TBT/N/USA/1581/Add.1, notified to this Committee on 26 October 2020. The revised law exempted additional items from the definition of children's product subject to the measure, narrowing the scope. The law does not apply to manufacturers that employ five or fewer people and are independently owned and operated or to used children's products, and it also exempts retailers in most circumstances.

2.440. The law sets a process for determining a "chemical of concern" based on hazard, clearly defines trace contaminants, and provides that the Department has two years from the effective date to promulgate a list of chemicals of concern. In addition to requiring the list of chemicals of concern, the law identifies specific high-priority chemicals and directs the Department to periodically review and add to that list. The law requires that manufacturers report to New York the use of chemicals on either list at or above PQLs in children's products, and further requires notice to retailers of the use of a high-priority chemical in a children's product. Manufacturers may request a waiver of the reporting requirements for one or more uses of a high-priority chemical. The law designated Tris phosphate; Benzene; Mercury; Asbestos; Arsenic; Cadmium (other than toy coatings); and organohalogen flame retardants in upholstered bedding and furniture as high-priority chemicals. The law authorizes the Department to ban chemicals on the list. In addition, effective 1 January 2023, the law prohibits the distribution or sale of children's products in which tris phosphate, benzene or asbestos is intentionally added. This prohibition does not apply to enclosed batteries and enclosed

electronic components; trace contaminants; and inaccessible components of a children's product that during reasonable, foreseeable use and abuse of the product would not come into direct contact with a child's skin or mouth. The Department may request a manufacturer to provide a statement of compliance with this prohibition. The law additionally establishes a children's product safety council to make recommendations to the Department on chemicals that should be listed as high-priority chemicals and chemicals that should be prohibited from use in children's products. Any further changes to the law would require legislation by the New York State Legislature.

2.1.3.45 Kingdom of Saudi Arabia – Electrical Clothes Washing Machines – Energy and Water performance Requirements and labelling (IMS ID 619[98])

2.441. The representative of Mexico provided the following statement. The delegation of Mexico reiterates the views it expressed during the written procedure of this Committee held in May 2020 concerning the amendment to technical regulation SASO 2885/2018 of the Kingdom of Saudi Arabia. We thank the delegation of Saudi Arabia for its openness to providing information on this measure. However, Mexico's concerns remain. The amendments to the SASO technical regulation would preclude the importation of washing machines from Mexico, which could contravene Article 2.2 of the WTO TBT Agreement by introducing a measure that is more trade restrictive than necessary in view of the objective pursued. In previous comments, Mexico has questioned the proportionality of the measure in relation to the objective pursued. It has also requested that information be shared to better understand the issues that brought about such changes to the regulation. Furthermore, the Mexican delegation reiterates the importance of implementing the commitments of the TBT Agreement on transparency in and conformity with international standards.

2.442. In view of the above, the delegation of Mexico requests the delegation of Saudi Arabia to: Reconsider the amendments made to technical regulation SASO 2885/2018 to avoid unjustified barriers to trade; and Establish a channel of communication through which the concerns of the Government of Mexico can be discussed. We are aware that a grace period has been granted, which expires at the end of November of this year. What is expected to happen when this grace period comes to an end? We request information on the status of the notification of the amendments to the technical regulation to this Committee, and on how to allow for a period of public consultation for submitting comments on the measure in question. The delegation of Mexico thanks the delegation of the Kingdom of Saudi Arabia for giving its consideration to this statement and to the requests made therein.

2.443. The representative of the United States provided the following statement. The United States supports the statement of Mexico on this concern.

2.444. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. As a continuation of the Kingdom's efforts to create fair competition between manufacturers, protect consumers and raise energy efficiency in the Kingdom, we confirm that the clarifying circular issued is just an explanation and relaxation of what was stipulated in the Technical Regulations SASO 2885/2018 in Annex A.2, which was issued based on the cases discovered as a result of consumer complaints. This circular was issued to clarify the technical requirements for temperatures, which are included in Annex A.2 for manufacturers and laboratories. It seems from the calculation example provided within the TBT issue, that there is a confusion from the manufacturer side about the temperatures and the water quantities by changing the total water used (full load/partial). SASO always opens the door to listen to all concerned parties therefore SASO welcomes a direct communication channel with the concerned manufacturer to explain this issue.

2.1.3.46 Mongolia - Mandatory Requirement for Enrichment of Agricultural Products with Vitamins (IMS ID 616[99])

2.445. The representative of the Russian Federation provided the following statement. The Russian Federation reiterates its statements made during the previous meetings of the Committee on TBT and the Council for Trade in Goods regarding the requirements on the mandatory fortification of wheat flour applied in Mongolia. According to the information provided by Mongolia, the standard for wheat flour enrichment, which defines the complex of vitamins and mineral compounds for the product, was adopted in accordance with World Health Organization recommendation about food

[98] For previous statements follow the thread under IMS ID 619 (under dates raised and references).
[99] For previous statements follow the thread under IMS ID 616 (under dates raised and references).

nutrition. In light of this the Russian Federation would like to request Mongolia to clarify the reasons why the dosage of vitamins as well as the respective measurement units used in Mongolian standard differ from the WHO recommendations. The Russian Federation would like to highlight its concern with respect to capability of national producers of wheat flour to follow the fortification requirements. The fact that Mongolian producers have the right to sell their un-labelled non-enriched wheat flour, while import of the same product is not allowed, in fact accords less favourable treatment for imported flour and thus contravenes Article 2.1 of the TBT Agreement.

2.446. We would like to request information about the list of accredited laboratories which examine and perform certification tests of the enriched products. We also request further information about the certification procedure of the fortified product in Mongolia as per our bilateral request that was sent previously. The Russian Federation would also like to express its concern about the lack of provided reasonable period between publication of new requirements for wheat flour fortification (both the mandatory standard and the rules for production, storage, transportation and labelling requirements) and their entry into force. The timeframe for producers and exporters of wheat flour to adapt their products and production methods to new requirements was just one day, which made impossible to follow this technical regulation from the day it entered into force. Therefore, Mongolia acted inconsistently with its obligations under Articles 2.9, 2.11 and 2.12 of the TBT Agreement by failing to make the regulation publicly available and provide reasonable timeframe for adaptation and comments. The Russian Federation expects Mongolia to take promptly all necessary steps to bring its measures in compliance with WTO provisions and is looking forward to getting further clarifications regarding the issues raised in our statement today. We urge Mongolia to intensify bilateral dialogue on these issues.

2.447. In response, the representative of Mongolia provided the following statement. We will forward the statement to the capital and will revert with a reply to the issues raised. We would like to reiterate that the import quotas on wheat flour were removed since the beginning of this year. In this relation, we would like to refer to our statements given at the TBT Committee meeting of February 2020, as well as the meetings of the Committee on Trade in Goods (CTG) in June 2020, the Committee on Agriculture in July and September 2020, the Committee on Market Access in June 2020. With regard to bilateral request, the replies are about to be submitted. It involved coordination of various agencies. We thank the Russian Federation for kind understanding.

2.1.3.47 Kingdom of Saudi Arabia - Saber Conformity Assessment Online Platform / Saleem Product Safety Program (IMS ID 615[100])

2.448. The representative of the European Union provided the following statement. The European Union remains concerned by the difficulties related to the implementation of the electronic certification system Saleem through the web-portal Saber that was recently launched by the Kingdom of Saudi Arabia. While the European Union would like to thank Saudi Arabia for engaging constructively in bilateral talks on the issues raised, these difficulties still have a major negative impact on the imports of several products from the European Union to Saudi Arabia. Toys and ceramics are particularly affected, but the system is being gradually extended to other products, many of them exported by EU companies. While the conformity assessment requirements differ depending on the sector, several EU industries coincide in reporting their overly costly, burdensome and time-consuming nature in particular in view of the COVID-19 outbreak and the global crisis this has created. Notably, EU toy manufacturers continue to report difficulties related to obtaining a GCC Conformity Tracking Symbol (so-called GCTS) from NBs authorized by SASO. In particular, EU exporters report that such NBs continue to find new ways to increase costs when carrying out conformity assessment procedures. However, the EU would like to commend that from our understanding new guidelines for the GCTS have been released, which will simplify the requirements of the new system in order to address in particular the specificities of the toy sector. This includes allowing for an efficient system of grouping several stock-keeping units (SKUs) with similar characteristics under one GCTS, as well as a possibility of adding new products to an existing GCTS covering a similar group.

2.449. The EU will monitor the implementation of this new guidance closely and further requests that documentation during the GCTS certification process should be kept to the minimum necessary to assess the safety of products. In this regard, no additional certificates of conformity, such as product certification of conformity (PCOC), should be requested, when the GCTS had already been

[100] For previous statements follow the thread under IMS ID 615 (under dates raised and references).

issued. The registration and renewal costs for GCTS should also be minimized and proportionate to the service provided. There is no justification for the GCTS renewal costs since this is just a formal process, executed online by the manufacturer. As previously reported, the ceramic sector is also very significantly affected by recent introduction of significantly stricter conformity assessment requirements by Saudi Arabia that require complex certification by conformity assessment bodies of products that are in their majority considered low-risk. EU companies are still facing long delays with regard to their on-going applications for the Saudi Quality Mark, reporting difficulties related to communication with authorized conformity assessment bodies and with the Saudi administration, unclear requirements regarding documents to be submitted, disproportionate fees, transparency issues where information for producers based outside Saudi Arabia is made available only in the Arabic language as well as different treatment between exporters and domestic manufacturers in Saudi Arabia in terms of conformity assessment for the products at stake. Moreover, EU exporters are reporting a limited availability of accredited certification bodies.

2.450. In this regard, the EU side has sent a set of questions to Saudi Arabia on this topic on 9 September 2020 and would welcome close cooperation of Saudi Arabia's authorities in this respect. In addition, the EU would again like to ask Saudi Arabia for a clarification whether it would be obligatory for importing companies to have a legal representative established in Saudi Arabia and if yes, which would be the legal requirements and obligations of such representative. In conclusion, the European Union would like to kindly invite the Kingdom of Saudi Arabia to ensure efficient and less costly procedures for all products included in the new conformity assessment system and looks forward to further cooperation with the Saudi authorities for this purpose and thanks again to Saudi Arabia for the bilaterals we had last week.

2.451. The representative of Switzerland provided the following statement. Switzerland would like to reiterate its concerns over the implementation of the Saleem Product Safety Programme on the Saber Conformity Assessment Online Platform. Our industry, in particular the textiles and machinery sector, reports persisting problems with the implementation of the registration and certification process. The registration and certification process remains costly, burdensome and time consuming for our exporters. In particular for companies exporting quality products in small quantities, the registration and certification process leads to disproportionate costs and documentation requirements which may be prohibitive to enter the market. According to the Saber Conformity Assessment Online Platform each product that is allocated to another six-digit customs tariff number requires a new certification process. In certain cases, the certification and registration costs amounted up to 40% of the order volume. Moreover, the certificates of conformity are valid only for 12 months, which creates additional burdens to the industry. Switzerland again calls on the Kingdom of Saudi Arabia to simplify the registration and certification process, to implement clear and transparent guidelines and to ensure that the requirements are applied in an equal and uniform manner. The documentation and certification requirements, as well as registration and certification fees should be kept to what is necessary to assure an effective implementation of the requirements. Switzerland looks forward to further cooperation on this topic and would appreciate if the Kingdom of Saudi Arabia could take these comments into account.

2.452. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saleem programme works through the development of integrated systems of regulations and standards that conform to internationally recognized professional practices by developing a highly efficient system for measuring product safety indicators in the market through mechanisms and procedures that comply with the technical regulations of each product. Saber is an electronic platform that helps the local supplier and the factory to register the required conformity certificates electronically for consumer products, whether imported or locally manufactured, in order to enter the Saudi market. The platform also aims to increase the safety level of products in the Saudi market. Saber Platform was developed according to the highest standards of efficiency in terms of registration speed, as well as in reducing the time spent for beneficiaries. The platform was created to ease export/import and traceability to ensure product compliance. Multiple organizations are involved in the process and linked to the Saber platform to assure ease of communication and to improve the services provided to the consumer.

2.453. The validity of the certificate is one year for the certificate of conformity and three years for the Saudi quality mark. However, the test report can be valid for three to five years if nothing has been changed in the production line or the composites of the product. It should be noted that Saudi Arabia has launched several initiatives to minimize the impacts of the COVID-19 pandemic, such as reducing the costs of the shipment conformity certificate by 30%, acceptance of commodities test

reports issued by accredited laboratories in the country of export for three previous years without the need for new tests, and postponing visits to production lines for products subject to this condition before obtaining conformity certificates, and issuing conformity certificates without this condition as well as carrying out online auditing for products subject to Quality Mark. Regarding the ceramic products, Saudi Arabia facilitates and expedites the procedures for granting SASO Quality Mark in European countries by authorizing several conformity assessment bodies (CABs) based in EU, to carry out SASO quality mark inspection procedures on behalf of SASO, and serve ceramic manufacturers located in EU. In terms of GSO toy regulation, GCTS tracking symbol must be issued through GSO platform. Once the GCTS is obtained, the shipment certificates can be easily issued through Saber platform. The GCTS validity harmonized with the validity for the certificate (five years); the economic operator (EO) has the right with a flexible mechanism to choose the activation for GCTS up to the EO choice. Following the mandatory implementation of the new guidance since 1 October 2020, we will work together to observe the implementation for these procedures, the feedback important from all parties for SASO and GSO to ensure continuous improvement. We strongly advise all toy factories to contact the NBs according to the GSO Technical Regulation for Toys scheme (listed in Saber platform) for detailed explanations regarding the test report and GCTS requirements. In respect of the legal representative requirements for importing companies, it is mandatory to have Saudi commercial registration number (CR) in order to access to the Saudi Arabia market. Saudi Arabia is always willing to cooperate with EU and Switzerland, and we will take all the above remarks and comment under the highest consideration.

2.1.3.48 India – Toys (Quality Control) Order, 2020 (G/TBT/N/IND/131); Amendment in Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017- Schedule-I (Import Policy) (G/TBT/N/IND/143) (IMS ID 632[101])

2.454. The representative of the European Union provided the following statement. The European Union is strongly concerned about India's Toys (Quality Control) Order, 2020 (QCO), and the Amendment in Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017- Schedule-I (Import Policy). The EU outlined its concerns already during bilateral talks with India in the margins of the WTO TBT Committee in February 2020 and submitted written comments on 30 and 31 March 2020. So far, the EU is not aware of any response of India to our concerns. In addition, the EU would like point out further concerns. The BIS has recently released its product manual and the situation seems deteriorating due to the following elements: (i) the label needs to be printed on the primary packaging and cannot be applied with a sticker; (ii) the QCO requires factory audits, and BIS does not know how its officers will travel overseas with global travel restricted due to the pandemic; (iii) according to the available information, it seems that only three of the 15 accredited laboratories in India are running normally and will be responsible for testing all the SKUs for the entire industry. Moreover, despite the extension of the entry into force of the system until 1 January 2021, there is no clarity on the procedures and timeline, especially for foreign audits. Also, there is a lack of clarity in relation to if the products already placed on the market before 1 January 2021 (existing stock) can continue to be sold. The EU would be grateful if India could respond directly to the concerns mentioned in the previous EU written comments, as well as to the new concerns.

2.455. The representative of China provided the following statement. The Toys (Quality Control) Order stipulated that toys for use in play by children under 14 years of age shall conform to the corresponding Indian standards and obtain compulsory certification. Manufactures exporting toy to India are faced with repeated testing, factory inspections, the payment of an additional USD 10,000 deposit, application fee, annual licence fee, ISI logo fee. China kindly requests that India considers the burdens on enterprises, especially small and medium enterprises, cancels the compulsory certification, or only selects high-risk toy categories for mandatory certification. The Toys Order requires that the goods or articles shall bear the Standard Mark under a licence from the Bureau as per Scheme-I of Schedule-II of BIS (Conformity Assessment) Regulations, 2018, and the Bureau shall be the certifying and enforcement authority for the goods or articles. As of now, there are two to eight third-party laboratories certified by BIS for IS 9873 and IS 15644, which is not sufficient. As National Accreditation Board for Testing and Calibration Laboratories (NABL) is a member of ILAC, it is recommended that the definition of third-party labs includes both NABL-accredited laboratories and all ILAC-accredited laboratories.

2.456. The Toys Order came into force on 1 September 2020. However, due to the impact of COVID-19 epidemic, international travel restrictions still exist, and it is difficult in arranging factory

[101] For previous statements follow the thread under IMS ID 632 (under dates raised and references).

inspections in time. The transition period currently granted by the Order is not enough. According to Article 5.9 of the TBT Agreement, China requests that India grants a transition period of at least two years from the date of entry into force of the order. According to the new policy, sample should be randomly selected from each consignment and be sent to NABL-accredited laboratories for testing, while customs clearance could only be given against passing the sample testing. China is concerned about the potential delay to customs clearance and storage costs resulted from the random checks and testing. In addition to the certificate of NABL-accredited Labs, China requests that India recognizes the certificate issued by a laboratory accredited by ILAC. As NABL is a member of ILAC, it is recommended that India accepts the results of foreign laboratories accredited by ILAC.

2.457. The representative of the United States provided the following statement. The United States has repeatedly raised concerns with India's treatment of imported toys since 2017. With each new iteration of its QCO, India has made it more difficult for exporters to successfully bring safe toys to market. On 7 February 2020 India notified the QCO, which we understand to have entered into force on 1 September 2020. During the May 2020 TBT Committee meeting, India noted that industry could request an additional transition period beyond 1 September. However, on 21 August, India denied industry's request for an extension of the final implementation date for an additional 9-12 months. On 28 August, the United States submitted a request for an extension of four to six months to India's Enquiry Point. India has not replied to the request. On 16 September, India published an Order in the Indian Gazette which postponed the implementation date of the QCO from 1 September to 1 January 2021. Although we appreciate this additional time, it is not adequate. We request that India extend the implementation date by at least another four to six months.

2.458. US industry estimates that it will take at least another four to six months beyond 1 January 2021, if not longer, to bring products into compliance with the QCO, given the unanticipated and unprecedented disruptions caused by the COVID-19 pandemic. The additional time will also help avoid a major disruption to India's toy market. The QCO disproportionately impacts foreign manufacturers. The licensing process required to obtain a BIS mark is lengthy. Securing timely inspections of foreign manufacturing facilities by BIS will likely not be possible in the near future due to the pandemic. US industry also anticipates delays in conducting testing and certification in laboratories accredited by India's National Accreditation Board for Testing and Calibration Laboratories (NABL). US industry reports that only three of the 15 NABL laboratories are operating at normal capacity due to the pandemic. Therefore, we reiterate our request that India extend the transition period an additional four to six months. We also request that India clarify how QCO is affecting products that are already in India's retail supply chains and outlets.

2.459. The representative of Canada provided the following statement. Canada supports the concerns raised by other Members and wishes to reiterate its statement from the May 2020 meeting.[102] Canada kindly requests that India provide responses to Canada's concerns with regard to this measure.

2.460. In response, the representative of India provided the following statement. India would like to thank the EU, the US and China for their continued interest in the India Toy market. However, India would like to state that there is no proposal to further extend the QCO on Toys beyond 1 January 2021. A four-month extension beyond 1 September 2020 is provided to clear the inventories and get a BIS licence.

2.1.3.49 Australia - Maturation requirements for imported alcohol (IMS ID 636[103])

2.461. The representative of Brazil provided the following statement. Brazil shares Australia's legitimate concerns with ensuring high-quality standards for the commercialization of alcoholic beverages in its domestic market. Notwithstanding, when applied to cachaça, Australian technical requirements for imported alcohol are more trade restrictive than necessary to protect such legitimate objectives. Currently, the Australian Customs Notice Nº 2007/19, following up on Section 105A of the Customs Act 1901, requires that some alcoholic beverages must be matured in wood for a minimum of two years before delivery from Customs control. This covers all beverages under tariff classifications 2208.20.10, 2208.30.00 and 2208.40.00. Even though said Notice only refers directly to brandy, rum, and whisky, it encompasses tariff line 2208.40.00 (rum and other spirits obtained by distilling fermented sugarcane products), under which cachaça is classified in Australia.

[102] G/TBT/M/81, para. 1.84.
[103] For previous statements follow the thread under IMS ID 636 (under dates raised and references).

By granting the same treatment to cachaça and rum, the Australian government does not allow imports of cachaça that are not matured for at least two years in wood. Such a requirement does not relate to any quality standard or sanitary requirement applicable to cachaça.

2.462. Following a public consultation in late 2019, the Australian Border Force (ABF) is now further exploring a potential avenue to amend the Customs Act 1901 (Customs Act) that would enable the legitimate importation of certain alcohol products into Australia whilst retaining the maturation requirements for brandy, whisky, and rum. According to a more recent public consultation, the Australian government is developing an approach that is looking to retain Australia's existing maturation requirement for imported brandy, whisky, and rum, but would establish a list of products exempt from this maturation requirement. The proposed list of exempt products would include cachaça and pisco and bourbon. Brazil acknowledges progress in the course of action proposed in its most recent public consultation. Our private sector will continue to provide inputs to this regulatory process. In light of the above-mentioned concerns, could Australia please confirm if this new regulation will also establish new labelling requirements for products other than rum, brandy and whisky? Could Australia provide timeframes for the publication of the final text? We look forward to continuing our bilateral engagements with Australia on this matter. Brazil will continue to raise this STC until current maturation requirements for imported alcohol no longer apply to cachaça.

2.463. In response, the representative of Australia provided the following statement. We thank Brazil for its interest in Australia's review of maturation requirements for imported alcohol and we would be happy to further discuss Brazil's concerns regarding this matter. Australia's review of its legislative framework for the importation of unmatured alcohol products under section 105A of the Customs Act is on-going. Australia applies equivalent requirements on domestic manufactured products and imported products that are classified as whisky, brandy or rum to be matured in wood for a period of at least two years. The review process is considering potential pathways to enter unmatured spirits without undermining Australia's consistent approach to maturation requirements. Australia acknowledges Brazil's engagement with the review of Australia's maturation requirements for alcohol. Representatives from the Brazilian Embassy participated in the 2019 consultation sessions on the review process led by the ABF. The issues raised in those consultation sessions, as well as written submissions, will be taken into consideration. The Australian Government has recently commenced a further stakeholder consultation, through the release of a consultation paper, to seek views on a refined proposed approach to amend s105A of the Customs Act. The consultation paper was sent directly to the participants of the 2019 consultation sessions, including the Brazilian Embassy in Canberra. It is also available on the Department of Home Affairs website.[104] Written submissions are due to the ABF by 11:59 pm AEDT 18 November 2020. The Government will consider any potential legislative changes following the outcome of this consultation.

2.1.3.50 European Union - EU Commission Regulation (EU) 2019/2013 for Energy Labelling of Electronic Displays, G/TBT/N/EU/610 (IMS ID 634[105])

2.464. The representative of the Republic of Korea provided the following statement. Korea would like to make some comments regarding this regulation as follows. According to your reply on 12 August 2020, the EU told that the amendments of test methods would be published in early September. However, they have not been published yet, so the Korean companies have faced difficulties in compliance with EU regulations. Korea would like to ask the EU to give a transition period for compliance with regulations at least six months after the final announcement of the official test methods or suspend the implementation of labelling regulation until 1 March 2021.

2.465. In response, the representative of the European Union provided the following statement. The draft amending acts clarifying a range of aspects including some relating to the test methods have in the meantime been published and are available online for public feedback until 3 November.[106, 107] In this context, we would like to stress that the clarifications relating to the test methods referred to in Annex IV to the Regulation are the same as those mentioned in, and attached

[104] www.homeaffairs.gov.au/reports-and-publications/submissions-and-discussion-papers
[105] For previous statements follow the thread under IMS ID 634 (under dates raised and references).
[106] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12471-Energy-efficiency-updated-EU-rules-on-ecodesign-and-energy-labelling
[107] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12499-Energy-efficiency-updated-EU-rules-on-energy-labelling

to, the Commission's response from 12 August[108], and which have been available publicly online since early July. In terms of timing, we can only reiterate that there are currently no plans to delay the date of application of the concerned regulations, which therefore remains 1 March 2021. However, as regards compliance with the 1 November 2020 deadline for certain obligations relating to labelling and product registration, the Commission has already called upon national market surveillance authorities to show flexibility taking into account the particular situation.[109] We remain confident that this approach will be sufficient to provide the flexibility needed by manufacturers. Finally, let me once again express our appreciation for your efforts to ensure timely compliance and our desire to assist, to the extent possible, should new difficulties arise.

2.1.3.51 India – FSSAI's Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and the new implementing veterinary certificate for dairy products, G/SPS/N/IND/236 (IMS ID 633[110])

2.466. The representative of the European Union provided the following statement. India has in December 2019 adopted a new veterinary import certificate for milk and milk products based on Food Safety and Standards Regulation 2011, that is of great concern to the EU. The provisions of FSSAI's Regulation defines cheese as a "product produced from non-animal rennet or another suitable coagulating agent, which applies equally to both domestic and imported foods" (as reflected in the notification G/SPS/N/IND/236). It was however still possible for cheese containing animal rennet to access the Indian market provided that it was correctly labelled. The new veterinary certificate requires that milk products have not been manufactured using animal rennet. As most European cheese is traditionally made with animal rennet, this means that there is a de facto ban for European cheese entering the Indian market. Similar difficulties arise for cheese by-products, such as whey and lactose. While the EU fully supports the importance of labelling the presence of animal rennet, the EU considers that this new certificate is not proportionate and not in line with the TBT Agreement. Veterinary certificates are to address sanitary (human or animal) health issues. There is no scientific evidence that cheese produced with animal rennet is harmful to health, or more harmful than cheese produced with artificial/vegetal rennet. We therefore would ask India to change the provisions of that veterinary certificate and allow for a label clearly indicating the presence of animal rennet in the cheese and its by-products, as it was previously the case. This label would allow consumers to make an informed choice.

2.467. The representative of the United States provided the following statement. The United States appreciates the discussion related to India's market access requirements for dairy imports, and shares concerns that India's requirements may be more trade restrictive than necessary to fulfil its legitimate objective. The United States is concerned that the India Certificate for Import of Milk and Milk Products into India contains the statement "The source animals have never been fed with feeds produced from internal organs, blood meal and tissues of ruminant origin". While we recognize India's domestic cultural and religious sensitivities, India has acknowledged that there is no scientific evidence that dairy products produced from source animals fed with feeds that include products of ruminant origin present a sanitary or health risk. Therefore, this language is inappropriate for inclusion in an import certificate. The United States also shares concerns with the European Union that the new veterinary import certificate for milk and milk products based on Food Safety and Standards Regulation 2011 does not allow cheese containing animal rennet to be exported to India. The United States requests that India allow the entry of these dairy products as long as they are clearly labelled.

2.468. In response, the representative of India provided the following statement. EU had raised this STC in the last meeting, and India gave its reply. Since the statement presented by the EU is not materially different than it did in the May meeting, India believes there is no more additional information to be provided.

[108] Commission reference Ares(2020)4225702

[109] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2020.182.01.0002.01.ENG&toc=OJ:C:2020:182:TOC

[110] For previous statements follow the thread under IMS ID 633 (under dates raised and references).

2.1.3.52 Myanmar - Regulation on importation of alcoholic beverages (IMS ID 640[111])

2.469. The representative of Mexico provided the following statement. The delegation of Mexico refers to the draft procedures on the importation of spirits conveyed by the Government of Myanmar to the Asia Pacific International Wines and Spirits Alliance on 20 June 2019. The Government of Mexico sent a communication on 20 September 2019 (523/01/058/20.IX.2019) containing its concerns regarding this measure and has not received a reply. The delegation of Mexico reiterates its concern regarding the 12-year ageing requirement contained in the draft procedures. This requirement would imply that the importation into Myanmar of such products aged less than 12 years will not be permitted. In Mexico's case, the ageing requirement would prevent tequila imports into this market, as none of the types of tequila produced under the corresponding technical regulation (Official Mexican Standard NOM-006-SCFI-2012 Alcoholic beverages - Tequila - Specifications) would be able to meet such a requirement. It is also important to mention that, should this requirement be linked in some way to the quality of the products, in the case of tequila, quality is not strictly related to years of ageing. The official communication sent by the Government of Mexico in September 2019 contains further details on this matter.

2.470. The representative of Mexico would also like to reiterate its concern over Myanmar's failure to comply with the transparency commitments contained in Article 2.9 of the WTO Agreement on Technical Barriers to Trade (TBT Agreement). The draft procedures on the importation of spirits establishes mandatory specifications that must be met for products to be imported into that country, which is why it constitutes a "technical regulation" under the terms of the above Agreement. In light of the above, the delegation of Mexico kindly reiterates the following requests to the delegation of Myanmar: It requests a response to official communication 523/01/058/20.IX.2019 or, failing that, follow-up information on the consideration being given to that communication. It requests clarification on the scope of application of the measure, specifically if it applies to imports of tequila or if it is limited to some categories of alcoholic beverages or spirits. It requests that the Members of the WTO's TBT Committee be notified of the draft procedures, and that information be provided on their entry into force, the next steps to be taken and the process for their implementation. The delegation of Mexico thanks the delegation of Myanmar for considering this statement and the requests made therein.

2.471. The representative of Myanmar did not provide a response to the concerns raised. These concerns were subsequently transmitted to the relevant authorities.

2.1.3.53 European Union - Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products, G/TBT/N/EU/211/Add.1, G/TBT/N/EU/713, G/TBT/N/EU/748 (IMS ID 614[112])

2.472. The representative of Mexico provided the following statement. The delegation of Mexico refers to Regulation (EU) 2018/848 of the European Parliament and of the Council on organic production and labelling of organic products, which was notified to WTO TBT Committee Members as document G/TBT/N/EU/211/Add.1 on 18 February 2019, and to Draft Commission Delegated Regulation amending Part I of Annex II to Regulation (EU) 2018/848 as regards the use of in-conversion and non-organic plant reproductive material, notified on 22 April 2020 in document G/TBT/N/EU/713. The Government of Mexico sent a communication on 31 August 2020 to the Directorate-General for International Cooperation and Development in the European Commission, in which concerns were raised regarding: Restricting participation to producers with less than five hectares of farmed land; Limiting the maximum number of members per organization to 1,000 producers; The imprecise frequency of internal monitoring of certifications; Defining the geographical proximity of group members; and Limiting the income of small farmers. While the Government of Mexico appreciates that the European Union has shown a bilateral openness to discussing this topic, it reiterates its concerns over the proportionality of the measure in relation to the objective pursued, and its potential implications for international trade in organic products, with a focus on small producers. Furthermore, we consider it vital to reiterate the importance of meeting international commitments, particularly on conformity with international standards and developing measures on a technical and scientific basis. In light of the above, the delegation of Mexico requests that the delegation of the European Union give due consideration to the comments submitted

[111] For previous statements follow the thread under IMS ID 640 (under dates raised and references).
[112] For previous statements follow the thread under IMS ID 614 (under dates raised and references).

concerning this regulation. The delegation of Mexico thanks the delegation of Myanmar for considering this statement and the requests made therein.

2.473. The representative of the Dominican Republic provided the following statement. The European Union will implement secondary legislation under Organic Regulation (EU) 2018/848, which includes fundamental changes to the group certification system in third countries. These measures presented by the European Commission would undoubtedly have a severe, negative and immediate impact on organic exports from the Dominican Republic to countries in the European Union. The Dominican Republic is one of the world's leading producers of organic bananas and cocoa. These sectors constitute the two main exports to the European market, representing approximately 33% of the value of total exports, and creating 350,000 direct and indirect jobs. Within the Organisation of African, Caribbean and Pacific States (OACPS), our country is the largest exporter of organic products to the European Union, accounting for 62% of total imports. Globally, it is only surpassed by China and Ukraine. European consumers have favoured Dominican organic products because they come from sustainable programmes that comply with both international certification and Fairtrade standards. There can be no doubt that the Dominican Republic's success is closely linked to the way in which the country's small-scale farmers have been able to group together in cooperatives or associations. The changes proposed in the European Union's draft secondary legislation pose a serious challenge to our farmers' living standards, their families, their business models, rural communities and their participation in global value chains.

2.474. The Dominican Government is deeply concerned by the nature of the implementing and delegated acts of Regulation 2018/848, which contains proposals that would undermine efforts made over many years by these cooperatives to develop environmentally sustainable agriculture and communities that are social and economically viable. A further cause of particular concern is the administrative and financial implications for groups of producers that are currently certified as "processor/exporter managed groups", since they would either have to form separate legal entities or rely on third parties to carry out the processing and exportation of their products. Not only does this significantly raise transaction costs and affect the management of the production process, but it also has a negative impact on traceability and the bargaining power of farmers, resulting in decreased revenue and increased costs, and thereby threatening the sustainability of their businesses. Moreover, the establishment of a maximum limit of five hectares for each member of the group would affect the viability of many producer associations, because it would exclude those farmers who grow organic products on larger areas of land, for whom obtaining individual certification is not economically feasible. In some cases, the cost of certification could represent 60% of their net revenue, which would prevent them *de facto* from exporting to the European Union. Consequently, we suggest that the maximum limit of hectares be increased, or that the requirement be removed for associations of small-scale producers.

2.475. These proposed changes to group certification standards create an unnecessary administrative and financial burden for organic producers in developing countries, and especially small-scale farmers. Moreover, they are not conducive to achieving the objective set out in the secondary legislation of Regulation 848/2018. The Dominican Republic questions whether these requirements are necessary for achieving the relevant objective. The implementing and delegated legislation of Regulation (EU) 848/2018 on organic production and the labelling of organic products would have a severe impact on the banana and cocoa sector in the Dominican Republic. It would result in a loss of competitiveness in relation to other countries producing the same goods. Some members of associations or cooperatives would be under a group certification scheme and a collective internal control system (ICS), while other members would hold independent certification. The association or cooperative would have less control over and a reduced ability to monitor the latter in areas such as farm management, completing registers and product sales. Producers with independent certification may sell their fruit to others, which would have negative implications for the collective commitment to the organization's clients. This change undermines the strong trade ties that have been established over many years, through which associations and cooperatives guarantee the sale and supply of products, as well as compliance with various types of standards and certification schemes.

2.476. The legislation would also have a negative impact on the management of other types of certification that, until now, have been managed by a single internal control system (such as global GAP, Rainforest or biodynamic certification). Cooperatives and associations would have different lists of members and registers for the various certification schemes, which very often are audited by the same monitoring body. This would have negative consequences for inspection, increasing its

complexity, and for the unified management of registers and data. Moreover, 44% of producers run the risk of being excluded from banana production because they lack the economic and administrative capacity required for individual certification. The livelihoods of over 15,000 families, particularly those in the country's banana-producing border areas, could be adversely affected. As a result, there would be a fall in remittances sent by migrant workers to the Republic of Haiti, thereby increasing poverty in the Dominican Republic's most marginalized provinces and causing a decline in foreign exchange by over 110 million dollars annually. Lastly, the measures that the European Union is seeking to adopt constitute provisions subject to the TBT Agreement. They would thus run counter to Article 5.1.2 of this Agreement, which prohibits WTO Members from adopting conformity assessment procedures "with a view to or with the effect of creating unnecessary obstacles to international trade". These measures also appear to be incompatible with Articles 2.1 and 2.2 of the Agreement.

2.477. The representative of Paraguay provided the following statement. My delegation wishes to thank the delegation of Mexico for including this item on the agenda and to register our interest in it. We will be following this matter closely, as the regulation is still being analysed in our capital to determine how both the five-year maximum limit and the limits established for producer group certification would affect trade. The considerable increase in the costs of certification would make this economically unviable for our producers.

2.478. The representative of Jamaica provided the following statement. I make this statement on behalf of the African, Caribbean and Pacific (ACP) Group. We take note of the EU's notification under G/TBT/N/EU/748 of 18 September 2020 providing information on rules for the implementation of Regulation (EU) 2018/848 regarding controls and other measures in respect of traceability and compliance in organic production and the labelling of organic products. The organic sector in our countries is an important driver of sustainable production and trade and plays a leading role in our national strategy towards sustainable food systems. In respect of the proposed regulation, two of our main concerns are: Article 4 (Composition and maximum size of a group of operators) which requires a member of a group of operators to register to only one group of operators for the same activity for a given product, as well as requiring the maximum size of a group of operators to be 2,000 members. Article 7 (minimum percentages of controls and sampling) which requires a minimum of 5% of operators that are members of a group of operators, and requiring that not less than 10 members shall be controlled in connection with the verification of compliance referred to in paragraph 3 of Article 38 every year. We understand that where the group has 10 or less than 10 members, all members shall be controlled in connection with the verification of compliance referred to in paragraph 3 of Article 38.

2.479. The provisions for group certification under the current EU organic rules have enabled many small-scale farmers and MSMEs in developing countries to become organic certified and to access the EU market. These players risk being disproportionally affected by the new rules under Regulation (EU) 2018/848. While we accept that improvements are needed in the management of group certification, these proposed changes risk creating unnecessary barriers, and disproportionately increases certification costs for the many small-scale farmers that make up our exports, and who operate primarily through organized groups or cooperatives. It is not at all clear to those who have experience on the ground how these proposed changes will address the main concerns expressed by the European Commission about the quality of group certification, or why they cannot be resolved through other means that are more sensitive to the context in which many of the smallest and most vulnerable organic players operate. We feel that these proposed changes will exacerbate the negative impact of changes already made to the rules, which means that cooperatives, federations of cooperatives, and processors/exporters with affiliated farms are no longer recognized as certifiable legal group entities. Such arrangements are very common in developing countries, and the norm in sectors such as fruit and vegetable. They are crucial in linking groups to marketing and advisory services, and there is no evidence that control systems in such groups are weaker.

2.480. With this said, we believe that there should be no maximum group size. One of the possible less-restrictive alternatives could be a situation where large groups have clustered structures that ensure appropriate management. We reiterate the importance of continuing to recognize cooperatives, federations of cooperatives, and processors/exporters with affiliated farms as certifiable legal group entities. The new rules should not be more trade restrictive for groups of over 400 members. In light of the fact that these issues would negatively affect the participation of developing countries and least developed countries (LDCs) in organic trade, we are calling on the EU to make the appropriate revision to the draft regulation in order to synchronise it with the

principles governing the multilateral trading system, especially in the context of facilitating the successful integration of our members in global trade.

2.481. The representative of Colombia provided the following statement. The delegation of Colombia would like to express its interest in this trade concern. In particular, we are raising concerns about how the criteria for obtaining certifications for small producers and associated costs would be defined. We will be following up on the EU's replies and any developments concerning this matter.

2.482. The representative of Ecuador provided the following statement. As the European market is very important for Ecuadorian organic products, we have been active in Brussels, sending observations and comments during the consultations with parties concerned by this draft Regulation. I wish to highlight that my country will be following developments on this matter.

2.483. In response, the representative of the European Union provided the following statement. As explained in the TBT Committee meeting last February, under the current EU organic regulation, group certification is not currently possible for operators in the EU. They must be certified individually, regardless of their activity and size. However, group certification has been made possible in third countries. The Commission published guidelines in 2008 providing for specific requirements. The new organic Regulation (EU) 2018/848 establishes a system of group certification in the EU, aiming at reducing the inspection and certification costs for small farmers and operators. This possibility has been accompanied by conditions for the system to offer guarantees in terms of control efficiency that are comparable to individual certification and to limit the group certification only to small producers. We referred in detail to those conditions at the TBT Committee meeting last February. The Commission is empowered to adopt secondary legislation concerning, in particular, the set-up, composition and functioning of the internal control system and to lay down specific rules regarding the dimension of a group of operators. The aim is to conclude the on-going technical discussions with EU member States and to adopt the relevant legislative acts at the end of March 2021. Third countries are free to set up their own standards for organic farming. Organic is a voluntary scheme. However, when an organic product originating in a third country is exported to the EU by means of control bodies certified by the Commission, this product must comply with EU organic production rules, including provisions on group certification.

2.484. The Commission is considering concerns expressed by WTO Members very carefully and takes them into account in the preparatory work and discussions with EU member States. The objective is to achieve the best possible compromise between the need for group certification that provides with the same level of assurance as individual certification, while facilitating access to organic production by small producers, including in third countries. The European Union would like to clarify that to import organic products from third countries, the Certificate of Inspection (COI) shall be issued before the consignment leaves the third countries. This requirement has always been enshrined in Commission Implementing Regulation 1235/2008 to ensure traceability. Commission Implementing Regulation (EU) 25/2020 has not added any new requirement, but only a legal clarification to avoid misinterpretations. As to the potential delay of the issuance of the COI, the Commission has already included a provision allowing to notify the transport information within 10 days from issuance of the COI and, in any case, before MS authorities endorse it. Meanwhile, the Commission has communicated to the Control Bodies how to proceed from a technical point of view.

2.1.4 Report on eAgenda

2.485. The Secretariat provided an update regarding enhancements to the eAgenda platform. There was strong engagement and use of eAgenda by Members. He reported that 97% of STC statements were uploaded by Members to eAgenda, and there were 178 eAgenda users from 69 Members. In light of the feedback provided by Members at the June 2020 informal meeting (JOB/TBT/367), the Secretariat implemented some enhancements to eAgenda, outlined in document JOB/TBT/368.

2.2 Exchange of Experiences

2.2.1 Technical assistance

2.486. The Chair provided the moderator's report on technical assistance. The full report is contained in G/TBT/GEN/306.

2.2.2 Technical Regulations

2.487. The Committee heard the moderator's report on technical regulations. The full report is contained in G/TBT/GEN/307.

2.2.3 Conformity assessment procedures

2.488. The Chair recalled previous submissions made by Members for the development of guidelines on conformity assessment (European Union in JOB/TBT/322, the United States in JOB/TBT/326, Australia in JOB/TBT/347, Japan in JOB/TBT/349 and Canada in JOB/TBT/358). He noted, too, that there was a submission pending from China. In addition, the Secretariat had presented, at the Committee's informal meeting of 24 September, its background note providing an overview of the TBT's Committee's work on conformity assessment procedures (JOB/TBT/224/Rev.1). He reaffirmed his intention, as Chair, to work closely with Members to bring this work to fruition; he said that the conclusion of the Ninth Triennial Review next year could provide a natural target for completing this work.

2.489. The representative of the Chile thanked delegations for their proposals. He said that Chile was currently reviewing these proposals and looked forward to submitting its own proposal in due course.

2.490. The representative of the United States stressed the importance of the submission of papers before making a determination of how the Committee would move forward. There were still many Members that had not offered any views, including on National Quality Infrastructure (NQI); it was important, she said, to hear about national practices and the experiences of Members. She also noted that the Committee was likely to spend more time in upcoming meetings on the 9th Triennial Review. And, in addition, there had been 80 specific trade concerns at the current meeting – and that number continued to grow. There was a question of how much time would be available for the negotiations. She wondered if the Committee could suspend work on the guidelines while work on the 9th Triennial Review was ongoing.

2.491. The representative of Colombia acknowledged the importance and the utility of the Committee's work on the guidelines. She welcomed all national experiences and information that could be shared from other Members. Colombia, she said, was currently reviewing the proposals on the table. In her delegation's view, the guidelines would need to be non-binding and not favour a particular focus (for the elaboration of conformity assessment procedures). They would, at the very least, need to take into account best practices and successful experiences, both regional and national. It would also be important for the guidelines to go into depth on risk-based conformity assessment procedures, in other words, they would need to take into account the cost and risks of non-conformity, as well as incentives to adopt conformity mechanisms. In this regard, Colombia was of the view that it would be timely to go into detail and consider impacts also on human, animal and plant health – as well as environmental considerations. Colombia was also of the view that it would be important to deepen discussions on mutual recognition agreements and arrangements.

2.492. On terminology, Colombia stressed the importance that the guidelines be developed – and structured – with simple terminology. This could include checklists, graphical or other visual elements. A simple approach would ensure better understanding of these topics, not only by regulators, but also by SMEs which, for Colombia, were at the heart of the economy. These enterprises often saw regulations and standards as barriers to trade.

2.493. The representative of the European Union recalled their written submission and said that her delegation was keen to see submissions from other Members. While she acknowledged the burden of the Committee's work, she stressed the importance of this work continuing along with the triennial review.

2.494. The representative of Paraguay stressed that the guidelines needed to take into account the needs and specific regulations in different Members; it needed to be considered that Members had different types of economies, different industrial bases, different regulatory frameworks – as well and varying capacity. There should not be, she said, any "one-size-fits" all approach – and it was important to allow all Members the opportunity to contribute to the process.

2.495. The representative of the United States stressed that her delegation was not in a position to agree on a target date for completing the work on the guidelines by the 9th Triennial Review. She reiterated her earlier comment on the overall work burden before the Committee – and said that despite the virtual meetings working well, this was not a substitute for in-person meetings.

2.496. The representative of Ecuador stressed the importance of maintaining an active debate on conformity assessment so as to move forward with the work on the practical guidelines; Canada's proposal, in particular, was very constructive. For Ecuador, policy flexibility was very important – the guidelines would need to support various policy objectives.

2.497. The Chair requested the Secretariat, in response to the various comments from Members about the need for more time, to extend the Committee's meetings in 2021 by half a day. He said, too, that the Committee could work on both the guidelines and the triennial review in parallel; and informal meetings, such as the one on 8 December, could provide further opportunities for advancing work.

2.498. Regarding the upcoming 8 December informal, the Chair recalled that at the informal meeting on 24 September, it had been suggested that delegations in the TBT Committee be given an opportunity (similar to what had been done in other Committees) to share experiences on measures that had been adopted in response to COVID-19. The idea was to take some time to reflect on actions taken to facilitate trade, for instance in the trade of essential medical goods, in the context of the continuing pandemic. He recalled that the Secretariat had put together a factual information note on TBT notifications related to COVID-19 which had been introduced to the Committee at the 24 September informal meeting. This information note (*Standards, Regulations and Covid-19 – What Actions Taken by WTO Members*) was available on the WTO webpage.[113]

2.2.4 Transparency

2.499. Regarding statements from Members under Article 15.2 of the TBT Agreement, the Chair recalled that the Annual Review, circulated on 19 February 2020 (G/TBT/44), contained, amongst other information, details on Members' statements of implementation. Since the TBT Committee's meeting in February 2020, Burkina Faso had submitted its statement, contained in G/TBT/2/Add.130. In addition, the interventions from the United Kingdom and Cote d'Ivoire had been circulated as supplements (G/TBT/2/Add.128/Suppl.1 and G/TBT/2/Add.127/Suppl.1, respectively.

2.500. With respect to follow-up on some of the transparency-related recommendations, which this Committee had adopted in 2018 in the context of the Eighth Triennial Review, the Chair recalled that Section 3 of the Aide-Memoire (JOB/TBT/273/Rev.6) provided a record of the Committee's work on transparency. One of the recommendations had been for the Committee to adopt a revised addendum template. In line with this, at its November 2019 meeting, the Committee had adopted a new format for this purpose, which can be found in document G/TBT/35/Rev.1. This had enabled Members to indicate more clearly when a notified measure entered into force and where it could be obtained, amongst other changes.

2.501. The Secretariat confirmed that the revised Addendum format (G/TBT/35/Rev.1) had become operational on 16 July following the completion of adjustments to various online systems. The main difference with the earlier version of the format was that when providing updates on notified measures, Members could now indicate the reason for the Addendum by selecting from among a series of tick-box options and complement with any relevant dates and links – making it easier to track the evolution of notified measures. The new format had required notifying authorities to adjust their practices somewhat. A total of 318 notifications had been circulated with the new format; about half had specifically referred to the entry into of force of previously notified measures and included final texts. The remaining had indicated updates such as on change of comment period, change of scope or withdrawal of a measure. Further details on the use of the new Addendum format would be provided in the Annual Review report to be issued early 2021.

2.502. The Secretariat went on to note that the online Notification Submission System, through which 88% of TBT notifications had been submitted in the previous year, had also undergone a

[113] https://www.wto.org/english/tratop_e/covid19_e/standards_report_e.pdf

series of enhancements. One of the most significant changes related to the incorporation of more recent versions of HS Codes into the system, making it easier for Members to find the specific codes for products they intend to regulate. This was related to another Triennial Review recommendation of the Committee, on improving product information provided in notifications.

2.503. The Chair encouraged Members to make use of the new addendum format and to provide feed-back to the Secretariat. He recalled that another triennial review recommendation had been for Members to discuss the dissemination of comments on notified measures and replies thereto on a voluntary basis, possibly via ePing. It was suggested that increased transparency on exchange of comments and replies could allow for more efficient discussion and resolution of specific trade concerns. This could enhance coordination between Members, helping to avoid unnecessary barriers to trade. It could also help Members observe and learn from the process. He noted that also here the Secretariat had introduced some enhancements to ePing to facilitate the process.

2.504. The representative of Switzerland referred to the video prepared by the Secretariat to demonstrate the sharing of comments feature of ePing.[114] His delegation encouraged Members to use ePing to publish their comments on notifications and replies on such comments. Members could decide to publish the entire comments or replies, or only parts of these – or they could simply indicate that they had provided comments (or replies). He stressed that there was added value to an increased transparency of handling of comments because this allowed for more efficient discussions, better coordination between interested Members and thus helped to avoid unnecessary obstacles to trade. The Swiss delegation proposed that the Secretariat prepare a draft document further clarifying the purpose and the practical steps for sharing comments and replies via ePing, underlining its voluntary nature as well as benefits. Such a document could be helpful for Members who intend to implement this recommendation.

2.505. The representative of the European Union thanked the Secretariat for the new video and for the work they were carrying out to extend the functionalities of ePing. The EU was of the view that ePing should provide a comprehensive support to all TBT notifications, throughout their life-cycle and allow for the complete treatment of and follow-up to TBT notifications. The EU encouraged the Secretariat to pursue these efforts and remained available for support that could be needed in the development and testing phases of an ePing updated tool.

2.506. The United States said that her delegation had held a session with the WTO Secretariat on the use of ePing and posting comments to the system. The US was very encouraged by the function. One outstanding issue, however, was how comments would be treated and privacy of those comments. This was something the Committee needed to further discuss before the United States would be comfortable with posting its comments on ePing. This was different than, for example, eAgenda which was an exclusive WTO tool.

2.507. The representative of Canada appreciated Switzerland's proposal and fully supported the facilitation of Members' ability to comment – this was an important part of the implementation of the transparency procedures under the TBT Agreement, and it did contribute to avoiding unnecessary obstacles to trade. Existing tools such as ePing already provided Members the opportunity to publish comments – if they wished – in line with their own domestic procedures. Nevertheless, as the US had pointed out, there were still some outstanding issues that might need to be discussed, such as privacy issues, so some time allocated to this for discussion would be good.

2.508. The Chair thanked delegations for their input. He noted the suggestion, from Switzerland, for the Secretariat to produce a practical document on how to provide comments using ePing. As this could be helpful to delegations, he asked the Secretariat to produce such a draft as a basis for further discussions.

2.509. Regarding next steps on transparency, the Chair recalled that the Committee was scheduled to hold a thematic session on 4 February 2021. The last thematic session the Committee had taken place in June 2019; that session had addressed a number of recommendations from the Triennial Review (the moderator's report is contained in G/TBT/GEN/265). He asked Members to come forward with any ideas or suggestions for specific areas that they would like the Committee to focus on in February. For example, in looking at the range of recommendations from the Triennial Review, and in particular those that the Committee had not yet addressed in detail, he suggested that the

[114] https://www.youtube.com/watch?v=it5PN-vazuA&feature=youtu.be

thematic session could consider the question of how to improve product coverage information contained in notifications (G/TBT/41, 6.19.d.ii). Another recommendation, which was under the section on Technical Assistance (see G/TBT/41, 7.12.c), was to develop a good practice guide on how to prepare a comment on a notified measure.

2.3 Other Matters

2.510. The representative of Chile suggested that the Committee revert to its earlier work on Good Regulatory Practices during 2021.

3 NINTH TRIENNIAL REVIEW

3.1. The Committee adopted the timeline for the 9th Triennial Review as contained in document G/TBT/W/735.

3.2. The representative of the European Union emphasized the role of the Review exercise in reinvigorating the regular work of the TBT Committee, as well as in reinforcing its deliberative function – the consolidated achievements so far had been substantive. She noted, in particular, the Committee's work on the Guidelines for conformity assessment as important.

4 TECHNICAL COOPERATION ACTIVITIES

4.1. The Secretariat provided an update on technical assistance. The full statement is contained in document G/TBT/GEN/305.

5 UPDATING BY OBSERVERS

5.1. The Committee heard updates from BIPM, IEC, CODEX (RD/TBT/328) CROSQ (RD/TBT/331) and UNIDO (RD/TBT/332).

5.2. Regarding pending requests (G/TBT/GEN/2/Rev.14 and RD/TBT/1/Rev.6), the representative of Turkey reiterated her delegation's support, as stated in previous meetings, for the request for observer status from the Standards and Metrology Institute for Islamic Countries (SMIIC). The United States noted that her delegation was not currently in a position to accept this request. The Chair urged Members to consult with each other so that the Committee would be able to more constructively engage on this matter; he remained available to facilitate any such discussions.

6 ANNUAL REPORT (2020) OF THE COMMITTEE TO THE COUNCIL FOR TRADE IN GOODS

6.1. The Chair drew the Committee's attention to a draft of the Committee's 2020 report, circulated on 6 October and contained in document JOB/TBT/376. It was proposed that the draft be adopted on an *ad referendum* basis. This meant, the Chair explained, that unless any delegation objected, in writing, to the Secretariat before 20 November 2020, it would be considered adopted as contained in the draft. The report was so adopted and circulated on 23 November 2020 in G/L/1379.

7 DATE OF NEXT MEETING

7.1. The next regular meeting of the Committee will take place on 24-26 February 2021. It will be preceded by a thematic session on Transparency on 4 February 2021 and an informal meeting on 23 February. All scheduled dates of meetings in 2021 are listed in JOB/TBT/364/Rev.2.