



Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 24-26 FEBRUARY 2021

CHAIR: MR LAURENCE SANDRAL

Note by the Secretariat¹

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1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/TBT/19.

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2.1.1 Withdrawn concerns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 The Chair reported that the following STCs had been withdrawn from the agenda at the request of the concerned Member:

- Colombia - Good Manufacturing Practices of overseas production establishments - Draft Decree of the Ministry of Health and Social Welfare partially amending Decree No. 1686 of 2012

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.

- United States - Energy Conservation Program for Appliance Standards: Energy conservation standards for residential furnaces and commercial water heaters
- Israel - Particular requirements for dishwashers of SI 900
- Israel - General requirements for boxes and enclosures for electrical accessories for household and similar fixed electrical installations of SI 60670

2.1.2 New Specific Trade Concerns

2.1.2.1 China - CSAR - Draft Specifications for Cosmetic Registration and Filings; Draft Specifications for Registration and Filing of New Cosmetics Ingredients; Draft Specifications for Cosmetic Efficacy Claim Evaluation, Provisions for the Supervision and Administration of Toothpaste, [G/TBT/N/CHN/1454](#), [G/TBT/N/CHN/1524](#), [G/TBT/N/CHN/1525](#), [G/TBT/N/CHN/1526](#), [G/TBT/N/CHN/1527](#) (ID 665²)

2.2. The representative of the United States provided the following statement. The United States appreciates China's notification of these four CSAR regulations, which contain requirements for companies placing general and special use cosmetic products and ingredients, including toothpaste, on the Chinese market. We understand that the measures notified to the WTO as [G/TBT/N/CHN/1524](#), [G/TBT/N/CHN/1525](#) and [G/TBT/N/CHN/1526](#) are implementing measures for the Administrative Measures on Cosmetics Registration and Notification notified as [G/TBT/N/CHN/1454](#), which was published as final on 12 January 2021. United States' comments on these notifications, and [G/TBT/N/CHN/1527](#) on toothpaste were submitted to China through the US Enquiry Point on 14 January 2021. The United States notes the new language on intellectual property (IP) protections in Article 55 of the Administrative Measures, stating that the National Medical Products Administration (NMPA) shall not, with some exceptions, disclose confidential business information, or trade secrets submitted by a registration or notification applicant. We ask that China please confirm if this provision includes when these types of information are submitted by local agents in accordance with Article 8.

2.3. We remain deeply concerned however that companies' intellectual property is still at risk, due to the large number of people who may have access to it. Article 55 suggests that companies' registration and notification documentation may be shared with the medical products administration departments of provinces, autonomous regions, and municipalities where products and ingredients are filed; professional technical institutions and their staff; and potentially others who participate in the review. Further, the requirement that local agents file all products and ingredients, and are responsible for the veracity of the filing and product safety, may result in these agents also having access to companies' intellectual property. Could China confirm that any entity or individual that has access to these types of information will be subject to Article 55's non-disclosure requirements? The extent of the information that companies are required to provide under the measures notified in the aforementioned notifications is not appropriate for cosmetic products, which are relatively low risk; we note that the approach China has taken is similar to what would be required for drugs and medical devices. The information requirements may also create significant and unnecessary obstacles to international trade by increasing the registration and filing costs for cosmetics companies. We therefore ask that China pare back the information that companies are required to provide in pre-market product and ingredient filings via the requirements in these technical regulations with only information that is necessary for the legitimate objective of China's regulatory authority with respect to the product at issue.

2.4. We are also highly concerned by Article 19 of the measure notified in [G/TBT/N/CHN/1526](#), which requires that companies publicly disclose proprietary test methods and results used to validate their product claims on NMPA's website. The information that will be posted on the website, as described in Annex 3, is extremely detailed and includes companies' trade secrets and CBI. We again ask that NMPA remove Article 19 and Annex 3. We note that the public has many means to engage companies when they have questions on product claims. We again urge China to engage directly with the United States and US industry to identify a viable means for US companies to demonstrate conformity with CSAR and the implementing measures through compliance with Good Manufacturing Practices (GMP), which do not require animal testing. A regulator-issued GMP certificate may be an unnecessary obstacle to international trade, as GMP certificates issued by third parties use the same

² For previous statements follow the thread under [ID 665](#).

requirements as GMP certificates issued by regulators. The final version of [G/TBT/N/CHN/1454](#) stipulates that the measure will go into effect on 1 May 2021. We ask that China delay implementation of the measure until China addresses Member concerns with these measures, and consults with industry on a reasonable implementation timeline.

2.5. The representative of [Australia](#) provided the following statement. The Australian Government has submitted written comments to China on notifications [G/TBT/N/CHN/1524](#), [G/TBT/N/CHN/1525](#), [G/TBT/N/CHN/1526](#), [G/TBT/N/CHN/1527](#) and other previous draft implementing regulations relating to China's Cosmetics Supervision and Administration Regulation (CSAR). Could China please advise when the draft regulations referred to in [G/TBT/N/CHN/1524](#), [G/TBT/N/CHN/1525](#), [G/TBT/N/CHN/1526](#) and [G/TBT/N/CHN/1527](#) are to be finalized and begin operating? We would also welcome a response from China on how it plans to take account of the comments of other WTO Members prior to the entry into force of these regulations. For example, will China issue revised drafts prior to these regulations entering into force? While Australia is pleased that China is looking to provide alternatives to mandatory animal testing for imported cosmetics, we are also mindful that such alternatives should not in themselves raise new barriers that constitute an unnecessary impact on trade.

2.6. Australian cosmetics businesses have concerns that the measures outlined in these four draft regulations, combined with the CSAR and previous draft cosmetics regulations released by China for comment in 2020, will introduce new and burdensome measures that will impact on their trade to China. Some key concerns include the requirement for government certification of Good Management Practice (GMP) of cosmetics production facilities, requirements to register and certify low-risk cosmetic products even when these include already approved ingredients, restrictive testing requirements and requirements for businesses to provide commercially sensitive information. Australian industry is also concerned that China's information requirements are excessive for certifying production facilities, products and ingredients, and for registering and filing cosmetics for sale in China. These overly burdensome information requirements would compromise the intellectual property of businesses. The Australian Government would welcome the opportunity to work with China and discuss in more detail to exchange information on our respective Health regulatory systems, including our respective systems for cosmetics regulation and GMP certification.

2.7. The representative of the [Republic of Korea](#) provided the following statement. Korea would like to support the delegations of the United States and Australia. Korea welcomes the series of measures that support the cosmetic regulatory framework following the implementation of the CSAR. Considering the trade implications of the regulations, Korea has continuously engaged in the regulations of China on cosmetics and provided comments through bilateral and multilateral channels. However, the recent regulations of China on cosmetics ([G/TBT/N/CHN/1526](#), [G/TBT/N/CHN/1525](#), [G/TBT/N/CHN/1524](#)) continue to include the concerns that Korea has raised. Thus, Korea would like to reiterate our concerns regarding the Regulations, including but not limited to the following concerns. First, the Regulations stipulate that a party who exports cosmetics to China is required to specify the manufacturers and quality data of all ingredients of their products in the application. Unlike other countries, however, the Regulations of China require disclosing more information than necessary to secure the safety and quality of products and to regulate the market. Since such information contains a number of trade secrets or undisclosed business information, Korea would like to request China to explain the justification for such requirement. Specifically, according to Appendix 12 to 16 in the Regulations, a party is required to submit information on safety profile and standard operating procedures, which have to describe manufacturing processes and control standards in detail. Such information, however, potentially contains commercially sensitive information. Korea would like to recall that trade secrets or undisclosed business information should be respected in a manner that legitimate commercial interests are protected.

2.8. Second, according to the Regulations, the test results for the registration must be issued by the testing laboratories accredited by the China Metrology Accreditation (CMA). Korea would like to request China to accept the test results performed by laboratories outside China that comply with Good Clinical Practice (GCP) or Good Laboratory Practice (GLP) in applying for cosmetic registration in China. Third, pursuant to Article 13 of Specifications for Registration and Filing of New Cosmetic Ingredients, a party who exports cosmetics to China is required to provide evidence which proves that their test results are equivalent to the results of *in vivo* test method, or animal testing, when using alternative test methods. Korea requests that alternative test methods that are recognized by international organizations such as OECD be accepted. Fourth, Korea calls on China to maintain its current regulation on the labelling of ingredients in cosmetics. According to the new Regulation, all

ingredients present at a concentration of 0.1% or more must be declared in the label, and ingredients at a concentration of less than 0.1% are declared as "and other ingredients". In many countries, however, cosmetic ingredients are declared only when they are present at a concentration of 1% or more. Korea is concerned with China's requirement as it is inconsistent with international practices. We would like to request China to exempt the labelling of the ingredients that are used during manufacture but present only at an insignificant level and not having any functional effect in the finished cosmetics.

2.9. Korea would like to kindly ask China to notify all of its next steps in the development of the Regulations and to provide time frames for the publication of the final Regulations and their entry into force. We also call on China to grant a reasonable transitional period for the industry to prepare to comply with the new requirements according to Article 2.12 of the TBT Agreement. Considering the aforementioned concerns, Korea urges China to take into account Article 2.2 of the TBT Agreement when drafting regulations, 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. We request China to consider Korea's comments and look forward to receiving a response from China.

2.10. The representative of Japan provided the following statement. Regarding China's implementing regulations of "Cosmetics Supervision and Administration Regulation", we appreciate that China provided the opportunity to provide comments to the WTO/TBT notification. As we have noted in the comment to WTO/TBT notification, Japan would like to express its following concerns. Regarding article 25 (II) (Product category) of "Specifications for Cosmetics Registration and Filing (Draft for Comments)", Japan would like to request that China clarify the rule for a product with multiple efficacies. Since the majority of cosmetics have multiple efficacies, Japan requests that rules for the indication of each product category will not become more restrictive than necessary. Annex 5 "Information Form for Registration or Notification of New Cosmetic Ingredients" has an item to report whether it contains nano ingredients and Annex 7 provides definition of such. Article 27 of "Specifications for Cosmetics Registration and Filing (Draft for Comments)" provides the rule for naming of nano ingredients in product formulas for registration or filing and also Article 27 of "Standards of Information File for Toothpaste Notification (Draft for Comments)" provides the rule for naming of nano ingredients in the product formulation table. Japan considers that a more detailed and concrete standard is necessary to judge which ingredients fall under the definition of nano ingredients. In addition, Japan would like to request that the standard will be formulated in a way that reflects international trends and comments from all stakeholders.

2.11. Article 27(II) of "Specifications for Cosmetics Registration and Filing (Draft for Comments)" and Article 27(II) of "Standards of Information File for Toothpaste Notification (Draft for Comments)" provide that the ingredient quality and safety information document issued by the ingredient manufacturer shall be submitted during registration or filing process. Therefore, when registrants or filers change their ingredient manufacturer, it is necessary to submit the document again even if the quality and safety are the same. This causes unnecessary burdens for registrants or filers. Since registrants or filers are responsible for quality and safety of the final products, excessive demand for proof of quality and safety of ingredients is not necessary. Therefore, the same as in international practice, Japan considers that the information of ingredients should be submitted when requested by the NMPA after launch, not at the time of registration or filing. Regarding Article 31 (II) (Exemption from submitting toxicological testing documents) of "Specifications for Cosmetics Registration and Filing (Draft for Comments)", since the legal system and enforcement system for cosmetics differ by country or region, some countries may not have the relevant authority. Therefore, Japan would like China to accept a certification document on the quality management system or good manufacturing practice qualification which is issued by an authorized international organization or an industry association which is authorized to issue the certifications by government agencies of the country or region where the registering or filing company is located, instead of a national institution.

2.12. Regarding the test of freckle-removing/whitening products, Japan would like to request that China adopt the approach of Read-Across that was provided in article 16 (freckle-removing/whitening effect cross-reference) of "Specifications for Cosmetic Efficacy Claim Evaluation (Draft for Comments)" last September. Freckle-removing/whitening is affected by active ingredients included in the cosmetics and the Read-Across approach will help shorten the application to permission process. Annex 1 of "Standards of Information File for Toothpaste Notification (Draft for Comments)" provides a catalogue of toothpaste efficacy classifications (toothpaste positive list).

Since new efficacies might be added in the future, Japan would like to request clarification of the concrete update process of the catalogue. It is also not clear how to deal with the safety monitoring of new toothpaste ingredients. Like Article 26 of "Provisions for Cosmetics Registration" and Article 27 of "Specifications for Cosmetics Registration and Filing (Draft for Comments)" on how to deal with the new cosmetic ingredients, Japan would like to request clarification with respect to new toothpaste ingredients as well. Finally, as the "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.

2.13. The representative of the European Union provided the following statement. The EU would like to support the delegations of Japan, Korea, the United States, Australia and New Zealand. The notified drafts contain rules for the implementation of the new Cosmetics Supervision and Administration Regulation (CSAR). The EU is of the opinion that the clear steps outlined in the implementing rules for product and ingredient registration 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, such as the disclosure of "the source of the ingredients and their quality specifications", go beyond the CSAR principles in a way that would create problems for the operation of cosmetic companies, including both domestic manufacturers and importers. The EU would like to point out that this kind of information, on a raw-material-by-raw-material basis is commercially sensitive and touches on intellectual property rights of the companies involved (suppliers and cosmetic manufacturers). Mandatory disclosure of this information in the registration and filing process is therefore a significant concern for the EU. The EU is of the opinion that including this kind of information, as part of the pre-market registration or filing dossier, is not necessary to ensure consumer safety and traceability of the ingredients used in cosmetics.

2.14. The EU has noted that no specific transition periods are indicated in the notified draft measures, however, they will be a crucial "workability" factor for the successful implementation of CSAR and its implementing legislations. Given the amount of changes to industry practice that this implementing legislation will induce, the EU is of the opinion that a differentiated approach is needed between new products (two years) and products on the market (three years). This will avoid a situation (like in 2009) when product supply was interrupted for an extended period of time due to insufficient preparation time for both industry and supervision authorities. 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 in January 2021.

2.15. The representative of New Zealand provided the following statement. New Zealand welcomes China's endeavours to modernise its regulatory system for cosmetics and also welcomes the opportunity to comment on China's proposed cosmetics measures notified under [G/TBT/N/CHN/1524](#), [G/TBT/N/CHN/1525](#), [G/TBT/N/CHN/1526](#) and [G/TBT/N/CHN/1527](#). 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 and implementation of the regulations. New Zealand understands that under the measures, non-animal tested cosmetics are able to enter China's market only on the basis that regulator-issued GMP certification accompanies these products. Like others, New Zealand is concerned, however, that the measures do not provide for non-regulator issued GMP certification. New Zealand would like to better understand what consideration China has accorded to less trade-restrictive alternatives for those Members that do not have a domestic mechanism for regulator-issued GMP certification. To further advance trade facilitation, New Zealand encourages China to accept non-regulator issued GMP certification for cosmetics imports, without requiring mandatory animal testing.

2.16. New Zealand requests that China also provide further clarity on the proposed testing measures. In particular, we encourage China to clarify in the regulation that test reports can be accepted from accredited laboratories situated outside of China. If test reports from internationally accredited bodies outside of China are not accepted, then this will create trade barriers for exporters who send products to China as well as multiple other markets. Building in flexibility to accept test reports from accredited laboratories outside of China would be trade facilitative and in accordance with international best practice.

2.17. In response, the representative of [China](#) provided the following statement. Product formula, production process and other materials of cosmetics as health-related products are important evidence for carrying out safety technical review of products. It is also a common rule of Members to require registrants and filers to submit safety-related materials so as to carry out the safety review of health-related products. Safety materials related to products submitted by companies are not information to be disclosed by the relevant authorities. Disclosure of government information is a measure for the Chinese Government to accept public supervision and guarantee the public's right to know. In accordance with the Regulations of the Government of the People's Republic of China on Information Disclosure, an administrative agency shall not disclose government information involving trade secrets, personal privacy and other information that will cause damage to the legitimate rights and interests of a third party. NMPA has also fully considered reasonable suggestions from parties, and added relevant provisions on confidentiality of the registration and filing materials in the Provisions for Cosmetics Registration.

2.18. According to scientific research data, there are some differences in skin texture between different races. During its supervision, NMPA also found that the sunscreen index reports issued by some laboratories are significantly different to the results obtained by Chinese laboratories based on tests on Chinese subjects. To protect the legitimate rights and interests of Chinese consumers, ensure the accuracy of test results, etc., NMPA requires the efficacy testing of special cosmetics in cosmetics registration and filing inspection institutions. However, foreign-funded inspection institutions are not prohibited from serving as cosmetics registration and filing inspection institutions. At present, many laboratories of foreign-funded inspection institutions in China have obtained the CMA certification of cosmetics and undertaken cosmetics registration and filing inspections. As to the reports from overseas institutions being accepted for evaluating the sunscreens, freckle-removing, whitening and anti-hair loss products, the Draft Guidelines for Claims Efficacy Evaluation has actually set reasonable evaluation requirements according to the categories of cosmetics efficacy claims. For most efficacy claims with low safety risks, no requirements have been imposed on the evaluation methods and evaluation test institutions, while it is only required that the test results shall be issued by the registration and notification inspection institutions for the efficacy evaluation test of some special cosmetics with relatively high risks.

2.1.2.2 Kingdom of Saudi Arabia - Technical Regulation for limiting and restricting hazardous materials in electrical and electronic equipment, [G/TBT/N/SAU/1048](#), [G/TBT/N/SAU/1166](#), [G/TBT/N/SAU/1166/Corr.1](#) (ID 666³)

2.19. The representative of [Japan](#) provided the following statement. Japan expresses the following concerns regarding the draft Technical Regulation for Restriction of Hazardous Substances in Electrical and Electronic Equipment (EEE). The proposed draft technical regulation (TR) stipulates type approval as conformity assessment procedures, which includes either a) examining a complete sample of the product or b) reviewing the TR and evidence, and examining one or more of risky elements of the product. In each case, Japan understands that the test is required to be conducted for each homogeneous material. For option a), in many cases, thousands to tens of thousands of homogeneous materials are contained in one EEE. Based on this feature, mandatory testing for all homogeneous materials requires a tremendous increase in workload and cost. Therefore, it is not feasible. On the other hand, regarding option b), when the test is performed on limited parts only, it cannot be the conformity assessment for the entire product. In order to resolve the situation, Japan would like to request that the manufacturer's self-declaration of conformity based on the international standard IEC63000 be accepted as a systematic approach to assure compliance for all parts. Many regulations restrict hazardous substances in other countries and allow exemptions of substances for certain uses, when they do not have alternatives based on scientific and technical studies. On the other hand, since the proposed TR does not have such exemptions, it may be technically impractical to fulfil the requirements. Japan would like to request that the technical regulation be harmonized with international standards and practice and it not be more trade-restrictive than necessary to fulfil a legitimate objective.

2.20. The representative of [China](#) provided the following statement. Regarding testing report requirements described in notified regulation, in case test data is required, it is important to note that a full product test report means that companies need to test every single component, at the homogenous material level. Testing all homogeneous materials fractions is extremely time- and resource-consuming. Instead, as described in IEC 63000, manufacturers work with their supply

³ For previous statements follow the thread under [ID 666](#).

chains to manage compliance and compile technical documentation as evidence of compliance. This is an internationally implemented and accepted process to restrict the hazardous substances. Therefore, it is highly recommended that the conformity assessment procedure is based on submission of a declaration of conformity provided by manufacturers, and harmonized with current industry practice globally. The preparation of the technical documentation is fully aligned with IEC 63000:2018 on "technical documentation for the assessment of electrical and electronic products concerning the restriction of hazardous substances". Some Members provide exemptions for the cables and spare parts for the repair, reuse, updating of functionalities or upgrading of capacity of the equipment which have been on the market before the Regulation. The purpose of these is to extend the lifetime of the equipment and it is beneficial to the environment. It is recommended that Saudi Arabia adds the spare parts and cables for the repair, the reuse, the updating of functionalities or upgrading of capacity of the equipment which were placed on the market before the notified regulation enters into force to the exempted equipment list. Considering the impact of COVID-19 on the global supply chain, China suggests the transitional period for the implementation of the regulations is extended from six months to 18 months, in order to provide sufficient time for manufacturers to replace raw materials and upgrade products in accordance with regulatory requirements.

2.21. The representative of the United Kingdom provided the following statement. The United Kingdom would like to thank the Kingdom of Saudi Arabia for the opportunity to submit written comments on the notification [G/TBT/N/SAU/1166](#), which sets out technical requirements for the restriction of hazardous substances in electrical and electronic equipment. Due to the complexity of the sector covered by these measures, and given the nature and structure of manufacturing activity and global supply chains for these goods, the United Kingdom encourages alignment with international best practices in the relevant regulatory requirements, wherever possible. This facilitates global trade in these particular goods and their components, and reduces the risk of potential barriers to trade. With regards to this measure, it is our view that it could have a significant impact on imports from the United Kingdom to the Kingdom of Saudi Arabia. We share some of the concerns raised by other Members on this notification. In particular, a type-approval conformity assessment procedure diverges from international best practice. We would appreciate further discussion on the viability of a system of manufacturer self-declaration of conformity aligned to the appropriate relevant international standard.

2.22. The United Kingdom is also concerned that the transition time between adoption and entry into force is too short for industry to adjust to the conformity assessment procedures foreseen in the measure. We understand that the Kingdom of Saudi Arabia is considering an extension to the transition period, which we welcome. We believe that a transition period of at least 18 months from the publication of this technical regulation would allow for a smooth and effective implementation of the new requirements. The United Kingdom, observing that the measure was notified under Article 2.10 of the WTO TBT Agreement as urgent, seeks further clarity on the reasons for this urgency. The United Kingdom greatly appreciates our recent constructive engagement on this matter, and the Kingdom of Saudi Arabia's openness to collaborate. We look forward to continued discussions in this respect.

2.23. The representative of the United States provided the following statement. The United States supports the interventions of other Members on the Kingdom of Saudi Arabia's (KSA) emergency notification of its "Technical Regulation for the Restrictions of Hazardous Substances (RoHS)", which noted an implementation date of 7 January 2021. US industry provided comments on Saudi Arabia's notification on 30 December 2020 through the United States Enquiry Point. US industry's most significant concerns about the KSA RoHS were potential deviations from international standards, lack of clarity regarding the scope of the regulation, and inconsistencies between the KSA RoHS requirements and the EU RoHS requirements, from which the KSA has modelled its regulation. The KSA RoHS deviates from the EU RoHS conformity assessment requirement, changing from self-declaration to a certificate of conformity, yet fails to clearly specify how manufacturers can demonstrate conformity. The United States shares concerns with the draft regulation, particularly regarding the conformity assessment regime and the lack of clarity regarding scope and product exemptions. Given the 30-day comment period and US industry concerns, on 3 February, the United States requested Saudi Arabia extend the comment period to 5 March 2021. The United States intends to submit comments on the draft measure. We request SASO take comments into consideration as it finalizes the regulation.

2.24. We understand there have been revisions to the draft since it was notified, and request that the current version be re-notified with an additional comment period as recommended in the TBT Committee's Coherent Use of Notification Formats. Does Saudi Arabia have an update on when it intends to finalize the regulation and how much time will be provided before it enters into force? We request a reasonable interval for implementation of no less than six months to allow time for industry to adapt to these new certification requirements. The testing and factory certifications laid out in the draft regulation raise concerns regarding feasibility, and potentially create unnecessary obstacles to trade. The United States requests that these requirements be clarified and avoid creating any duplicative or unnecessary conformity assessment requirements.

2.25. The representative of [Canada](#) provided the following statement. Canada took note of Saudi Arabia's notification [G/TBT/N/SAU/1166](#) and subsequent corrigendum issued 1 and 4 December 2020, regarding the Technical Regulation for Restriction of Hazardous Substances, issued by the Saudi Standards, Metrology and Quality Organization. While Canada supports WTO Members' efforts to protect human health and safety, as well as the environment, by regulating to ensure that hazardous substances are not present above certain levels in consumer products such as electrical and electronic equipment, Canada would like to raise the following concerns related to this measure. Canada is concerned that Saudi Arabia failed to allow WTO Members and stakeholders the appropriate period of time of at least 60 days to review the measure and provide comments. In addition, the proposed date of adoption of the measure (7 January 2021) was only seven days after the closure of the allowed period for comments, which in Canada's view does not provide sufficient time for Saudi Arabia to fully consider the input and comments received to inform the development of the measure.

2.26. Canada also questions the rationale behind Saudi Arabia's justification that the products covered by the regulation are "high risk" and that the measure needed to be developed and adopted on an emergency basis. Could Saudi Arabia provide more details as to what urgent situation in late November/early December prompted the development of the measure covering such a wide area of products? With respect to the substance of the measure, Canadian stakeholders have noted concerns regarding testing for compliance, which defer from the widely accepted EU RoHS Directive. We understand that under the measure, testing would need to be done through the Saber system, as opposed to the RoHS self-certification scheme. We further understand that the required testing would need to be performed at one of Saudi Arabia's Notified Bodies – can Saudi Arabia confirm this information? We welcome any further information and clarification on the measure that Saudi Arabia can provide to the Committee today.

2.27. The representative of the [European Union](#) provided the following statement. The European Union would like to join the other delegations (Japan, China, the UK, the US and Canada) and express concerns regarding the draft Technical Regulation for Restriction of Hazardous Substances, notified by Saudi Arabia on 1 December 2020. The European Union regrets that Saudi Arabia only provided 30 days for comments to the WTO Members. It appears from the information published on the website of the Saudi Standards, Metrology and Quality Organisation (SASO) that the technical regulation was adopted in January 2021. Could Saudi Arabia clarify the status of the notified text and the expected date of its publication and entry into application? Due to concerns expressed by EU industry, the EU would like to ask Saudi Arabia whether written comments could still be sent. The European Union would like to raise the following points. The notified text requires a mandatory third party conformity certificate, issued by a body approved by SASO and based on test reports from an accredited laboratory. This would deviate from common international practice, followed also by the European Union, which relies on first-party declaration of conformity drawn up by the manufacturers or their authorized representatives and would bring significant hurdles on businesses. The EU therefore invites Saudi Arabia to consider limiting the conformity assessment requirements to the submission of a first-party declaration of conformity to be provided by manufacturers. In addition, the EU would like to ask whether conformity assessment bodies not established in Saudi Arabia can be approved by SASO and under which conditions.

2.28. The EU also invites Saudi Arabia to provide for a sufficiently long transition period that would ensure a smooth implementation and adaptation for economic operators. The proposed six-month transitional period would not allow companies sufficient time to prepare for the conformity assessment procedure proposed in the notified text, which differs significantly from European practice. In that respect, a deadline of at least 18 months would be necessary. Notification [G/TBT/N/SAU/1166](#) provides under point 4 a list of HS codes of products covered by the draft technical regulation. The EU would like to ask whether this list of products under the scope of the

draft regulation is exhaustive and whether the same products are covered as in Annex I to the European Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EU RoHS) and whether the restricted substances and their maximum concentration values tolerated by weight in homogeneous materials are identical to those in Annex II to EU RoHS. The EU would like to ask whether the exemptions in the notified text are the same as the exemptions included in the Annexes III and IV of the EU RoHS. The EU would also like to know whether Saudi Arabia plans to align to the future exemptions under the EU RoHS.

2.29. Finally, the EU would like to know what is the relation of this notified text to the draft GCC Technical Regulations for the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment, notified to the TBT Committee in March 2018 ([G/TBT/N/SAU/1048](#)). What is the status of the GCC draft technical regulation and the timeframe for its adoption? When adopted, will Saudi Arabia replace its national rules with the GCC ones? The EU would like to invite Saudi Arabia to promote the GCC harmonized requirements, which should also guarantee their uniform application and a mutual recognition of conformity assessment results in the region. The European Union is available to discuss this issue with Saudi Arabia bilaterally.

2.30. The representative of Switzerland provided the following statement. Switzerland would like to support the interventions made by previous speakers on the Kingdom of Saudi Arabia's Technical Regulation for limiting and restricting hazardous materials in electrical and electronic equipment. While we share the Kingdom of Saudi Arabia's legitimate objective to protect the environment and public health and safety, Switzerland is concerned that these requirements may have a negative impact on trade for a wide range of products. We note in particular that the testing and certification requirements seem to deviate from the widely internationally accepted RoHS requirements, which are also used in Switzerland and elsewhere in Europe. We encourage the Kingdom of Saudi Arabia to consider less trade-restrictive alternatives and take these practices into account. Switzerland thanks the Kingdom of Saudi Arabia for its response on our written comments and looks forward to further cooperation on this topic.

2.31. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia would like to express appreciation on the concerns addressed by the UK, Japan, China, Canada, the US, the EU and Switzerland for their valuable comments on the urgent notification issued 1 and 4 December 2020 regarding the Technical Regulation for Restriction of Hazardous Substances. Moreover, Saudi Arabia is aiming at protecting human health and safety, and the environment, by regulating to ensure that hazardous substances are not above certain levels in consumer products such as electrical and electronic equipment, as implemented by WTO Members. Consequently, Saudi Arabia would like to clarify the following: Saudi Arabia submitted under the emergency/urgent notification provisions of the TBT Agreements (Article 2.10) in response to the pressing health problems posed by non-conforming products detected by National Surveillance Authorities. In addition, WTO Members can develop measures directly and immediately notify the WTO with such regulations, without providing the usual 60-day comment period (or six-month transition period prior to entry into force). SASO notified the measure on 4 December 2020 and approved it on 28 January 2021, which is considered sufficient under the emergency/urgent notification. However, Saudi Arabia takes into consideration that emergency measures still need to comply with the other provisions of the TBT Agreements, such as avoiding discriminatory or unnecessary barriers to trade, ensuring a scientific basis for measures, and harmonizing with international standards. The TBT notification alert system, ePing, facilitates swift access to these notifications by both public and private stakeholders so that they can react and adjust as necessary to the requirements and procedures under development. In regard to the proposed date of adoption of the regulation mentioned in the notification, this has been amended. Saudi Arabia is fully considering the inputs and welcome all comments, where they will be considered in developing our technical regulations.

2.32. Saudi Arabia has aligned the amended version of the Saudi Technical Regulation with global practices such as EU RoHS Directive, taking into consideration compatibility with national deviations such as conformity assessment schemes. As for the conformity assessment procedures, SASO has chosen to apply the international standard ISO/IEC 17067 for granting certificates of conformity (Type Approval) to products issued by Notified Conformity Assessment Bodies. Within the framework of SASO, conformity assessment activities (certification, audit and inspection, and testing activities) have been developed to raise the level of quality in the national industry and the safety of imported goods presented in the Saudi market. By accepting conformity assessment bodies under the various conformity assessment activities, this process aims to ensure the efficiency of the outputs of the

accepted conformity assessment bodies within the systems and requirements of the technical regulations, according to the scopes of acceptance of these bodies. Therefore, SASO chose to engage a notified third party responsible for granting conformity certificates in the non-existence of a legal representative from the foreign manufacturers. Having said that, SASO reserved its right to enforce the technical regulation for Restriction of Hazardous Substances on the specified date (six months after publishing in the official Gazette) and during this period SASO is committed to review some details of these procedures of conformity assessment to extend the validity of test reports.

2.1.2.3 India – Draft Food Safety and Standards (Import) Amendment Regulation, 2020, [G/TBT/N/IND/180](#) (ID 667⁴)

2.33. The representative of the United States provided the following statement. The United States has several questions and concerns regarding India's draft amendment "Registration and Inspection of Foreign Food Manufacturing Facilities" to its Food Safety Standards (Import) Amendment Regulation, 2020, notified to the WTO TBT Committee as [G/TBT/N/IND/180](#). In response to India's notification, we submitted comments on 22 January 2021. This draft regulation leaves many unanswered questions for foreign food manufacturing facilities, competent authorities, and other stakeholders. Today we will discuss only a handful of those questions. The draft regulation states that India may identify categories of "risk" for food products "from time to time... for which inspection or audit of foreign food manufacturing facilities producing such categories of foods shall be mandatory." We are concerned about the open-ended nature of the scope of this proposed technical regulation. Please clarify how India will determine the specific "risk" for food product categories imported into India, and how this information will be communicated to the public. Will India publish updated lists of such food product categories? Will stakeholders have an opportunity to submit comments on these categories?

2.34. Will Indian domestic facilities manufacturing categories of food products determined to be of a sufficient "risk" also be required to apply for FSSAI registration? In addition, could India please clarify what is meant by "from time to time"? Does India intend to undertake regularly scheduled systemic reviews of food categories? Will these systematic reviews and changes to the regulatory system be notified to the WTO for a notice and comment period? With regard to the registration process, will India require paper copies of applications, or will foreign manufacturing facilities be allowed to submit electronic versions of these documents? If applications cannot be submitted electronically, India should consider the burden for competent authorities involved in reviewing the documentation, and whether the reviews can be carried out in a timely manner. Finally, we ask that India please provide clarity regarding its ambiguous inspection and audit procedures, including the frequency at which India anticipates to conduct such audits, who is financially responsible for a food facility's audit expenses and a proposed timeline when audits are first required to take place. We look forward to India's consideration of and response to the United States comments.

2.35. The representative of Mexico provided the following statement. The delegation of Mexico refers to the Draft Food Safety and Standards (Import) Amendment Regulation, notified by the Government of India on 25 November 2020 to Members of this Committee in document [G/TBT/N/IND/180](#). The Government of Mexico would be grateful if the delegation of India could provide more clarity on the products subject to this Regulation and confirm whether alcoholic beverages are part of this list. We understand that the Government of India will determine, on the basis of risk, the categories that are subject to the Regulation. In this regard, we would also welcome information on the procedure that will be followed for such a determination and on when the Government of India will announce the categories for which the procedure must be carried out. The procedure for registering and inspecting food manufacturing facilities abroad has caused doubts and uncertainty for the Mexican industry. It is therefore important to have information on how these processes will be conducted. We also consider it important for the Government of India to share information on how this procedure is necessary to achieve the objective pursued, and whether consideration was given to alternatives to this procedure which would be less restrictive for importers. In light of the above, we would be grateful if the delegation of India could share information on the Regulation, the manner in which it will determine the product categories or types of products that will be subject to compliance, as well as information how the on-site inspections or visits will be conducted, and on the entry into force and the current status of this Regulation. The

⁴ For previous statements follow the thread under [ID 667](#).

delegation of Mexico thanks the delegation of India for giving its consideration to this statement and the requests made therein.

2.36. 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 provided comments on India's draft amendments and provided a written submission within the TBT notification comment period. Australia wishes to emphasize the importance of compliance with WTO obligations, in particular that measures be implemented in a way that is no more trade-restrictive than necessary. Australia is concerned that as drafted, aspects of the proposed Regulations are more trade restrictive than necessary to fulfil India's food safety objectives. Australia believes the Regulations will create an additional burden on both producers and exporters in Australia, and cause disruption for Indian importers and customers. Clarity on the categories of food manufacturers and the basis for determining when the Regulation applies is lacking. Australia is concerned that the proposed measures may not be linked to the risks posed by the imported food. Australia welcomes India's consideration of our comments and looks forward to India's response and continued engagement on the issue. Australia is happy to work with India to support a more risk-based approach to food safety.

2.37. The representative of Canada provided the following statement. Canada welcomes the opportunity to comment on India's recent notification amending its Food Safety Standards (Import) Regulations pertaining to the registration, inspection and/or audit of foreign food manufacturing facilities producing food products destined for India. While Canada recognizes India's right to take necessary measures to protect public health and safety, we are concerned that these new requirements will create an unpredictable and disruptive trading environment. There are a number of ambiguities in India's proposed order and details on its implementation elements such as target commodities, source-countries, implementation plan, audit rates, compliance actions and appeals, are lacking or insufficient. Specifically, it is unclear what criteria would be used, what circumstances would instigate an audit or an inspection of a foreign manufacturing facility or how such actions will be taken given the ongoing travel restrictions resulting from the pandemic. In addition, further information is required on the process by which "auditing agencies" will be recognized by the Food Authority and whether competent foreign authorities would be eligible for this designation. Detailed comments, questions and concerns were submitted to India's Enquiry Point on 21 January 2021 in an effort to gain a better understanding of the scope and intended objective of this order. Canada looks forward to receiving a timely response. In closing, given that India's proposed regulation covers food safety measures aimed at protecting human health and safety, Canada respectfully requests that it be notified to the WTO SPS Committee in order to provide an opportunity for Members to comment.

2.38. The representative of Argentina provided the following statement. We share the concerns raised by the different delegations. Argentina has a number of doubts about giving effect to and putting into operation the provisions contained in the draft standard notified in document [G/TBT/N/IND/180](#), particularly with regard to the products covered and the provisions on registration, inspection and audit of exporting establishments. All our questions have been passed to India's TBT Focal Point before the deadline for comments and we look forward to receiving the replies and clarifications as soon as possible. We also hope that the provisions contained in the draft standard do not become unjustified restrictions on trade, since India is a very important trading partner for our country and the agricultural sector is the main export item.

2.39. 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 support to the comments made by the United States, Mexico, Australia and Canada. Our comments on the proposed measure were sent to India's TBT Enquiry Point on 30 December 2020, which sought clarifications from India on a number of implementing issues. We appreciate an update of the status of this draft and look forward to a written response from India.

2.40. The representative of the European Union provided the following statement. The European Union would like to support former interventions and highlight its concern with this Indian measure. We sent you written comments and I just want to highlight our main elements of concern: (i) the transition period is too short and should be extended to 18 months; (ii) India should further clarify the scope of products/food categories; (iii) a list of low risk products should be defined that should be exempted. An example would be wines and spirits due to their inherent stable nature; and (iv)

inspections and audit of foreign food manufacturing facilities as well as registration need to be clarified and simplified.

2.41. In response, the representative of India provided the following statement. Our response is as follows. The comments received from various stakeholders are currently being examined.

2.1.2.4 Kingdom of Saudi Arabia - Air Conditioners - Minimum Energy Performance, Labelling and Testing Requirements for Low Capacity Window Type and Single-Split, [G/TBT/N/SAU/526](#), [G/TBT/N/SAU/774](#), [G/TBT/N/SAU/1167](#) (ID 668⁵)

2.42. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of Kingdom of Saudi Arabia to protect the environment and Korean companies are fully committed to complying with the regulations of Saudi Arabia. However, Korea would like to make some comments regarding this regulation as follows. Firstly, Korea humbly requests that Saudi Arabia reconsiders the introduction of the new regulation, which is "AC setting for partial load operation" in Clause 7.4. In accordance with Article 7.4 of standard (SASO 2663:XXXX) notified as [G/TBT/N/SAU/1167](#), the AC setting information for partial load operation test shall be provided both on the product packages and registration system of SASO website. Korean companies are fully committed to complying with the new regulations of Saudi Arabia, but they are concerned about the possibility of infringement of intellectual property. The partial load operation can be controlled only through Test Mode. If the information about Test Mode is exposed, other performance tests results and control technologies could be disclosed. The exposure of the intellectual property of manufacturers is inevitable. Due to the facts mentioned above, when applying for a certification in the European Union and the United States, testing bodies do not ask manufacturers for information on air conditioner settings for partial load operation. Despite the review, if Saudi Arabia decided to introduce additional regulation related to the AC setting for partial load operation, Korea would like to request that Saudi Arabia consider more reasonable alternatives to avoid the risk of disclosing the confidential information of manufacturers. One alternative may be that an engineer of the manufacturers directly participates in the local testing process to set it up, or that the manufacturer provides a method for performing partial load operation without exposing the setting information to the outside.

2.43. Secondly, Korea would like to request either exempting the certificate renewal or relaxing the certificate renewal requirements by allowing the use of test reports submitted for initial certification, of products with the same specifications as the original certified product, which require energy efficiency regulations including air conditioners. In most countries such as the European Union and the United States, Korea, and UAE, certificate renewal is not required unless a change has been made to the product or the relevant regulation. Especially, for renewing certification in your neighbouring countries such as Qatar and Bahrain, manufacturers are permitted to apply for certificate renewal using test reports that had been submitted for initial certification, provided there are no changes to their products or related regulations. Currently, Korean manufactures exporting their products to Saudi Arabia must renew their energy efficiency certificates every year and take product testing again even if the specifications are same as the original certified products. These create administrative burdens and additional costs on the manufacturers and also against international common trends. Korea is willing to actively participate in movements of the international societies by reinforcing energy efficiency regulations to protect the environment. However, Korea thinks that the energy efficiency regulations should be harmonized with the relevant international common practices and should not cause excessive burdens on companies.

2.44. The representative of China provided the following statement. It is suggested that Saudi Arabia pays attention to the impact of barometric pressure on the cooling capacity of air conditioners. The climate in Saudi Arabia is mainly tropical desert. SASO's official lab is located in Riyadh and its typical barometric pressure is about 700mmHg (the millimetre of mercury). The test condition at a lower barometric pressure shall change the fan speed or system resistance of tested air conditioner, which probably causes deviation of test result if there is no correction for variation. During the verification test to the recalled or returned products conducted in China, it is found that the cooling capacity of some air conditioners measured at 700mmHg barometric pressure (without correction) and standard barometric pressure (760mmHg) deviates by -4% or more, which is close to or over the 5% tolerance that Saudi Arabia allows. To ensure the consistency of testing methods of SASO-certified air conditioning products between certification test and market supervision test, it is

⁵ For previous statements follow the thread under [ID 668](#).

suggested that Saudi Arabia specifies the barometric pressure when conducting energy efficiency tests according to the standards in SASO 2663 and allows the correction to the test results of cooling capacity at all kinds of working conditions measured under barometric pressure lower than standard. Article 8.1.2 of ISO 5151:2017 which serves as source of SASO 2663 and Article 8.5.4 in American society standards of heating, air conditioning and refrigeration engineers ANSI/ASHRAE 16-2016 could be taken as reference for correction methods: the tests shall be conducted at the specified temperature conditions with no changes in fan speed nor system resistance, the related test results could be corrected for variations based on the standard barometric pressure of 101.325 kPa (29.92 in.Hg). The cooling capacity tested below standard barometric pressure 101.325kPa (29.92 in.Hg) could be increased 0.24% for each kPa (0.8% for each in.Hg).

2.45. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia would like to thank the Republic of Korea and China for their valuable comments regarding the "Air Conditioners - Minimum Energy Performance, Labelling and Testing Requirements for Low Capacity Window Type and Single-Split". Since this standard is still at the comments review stage, we will discuss these comments deeply with all concerned entities. We will provide you with our answers regarding these comments via each Member's TBT Enquiry Point.

2.1.2.5 India - Flat Transparent Sheet Glass and Safety Glass (Quality Control) Order, [G/TBT/N/IND/118](#), [G/TBT/N/IND/119](#) (ID 669⁶)

2.46. The representative of the Republic of Korea provided the following statement. Korea would like to make some comments regarding these regulations as follows. First of all, Korea respects the efforts of India to introduce transparent flat glass and safety glass quality control orders (QCOs) for the health and safety of Indian people. Furthermore, Korean companies are committed to comply with the regulation of the Indian authority. However, Korean companies has the following difficulties regarding the enforcement date of transparent flat glass and safety glass quality control orders, 2020 of India. The enforcement dates of transparent flat glass and safety glass QCOs are scheduled to take effect in 1 March 2021 and 1 April 2021, respectively. However, Korea understands that it is difficult for local BIS to provide normal services due to COVID-19. The Korean companies completed the certification application in June last year, but additional certification procedures such as factory audit have not been conducted yet after the document screening was completed. In particular, if the grace period is not extended at a time when the effective date is imminent, it is almost impossible to export to India. Therefore, Korea requests that India postpone the implementation of transparent flat glass and safety glass QCOs by more than six months or to take alternative measures such as temporary factory audit exemption for a limited period, considering the delay in certification process due to COVID-19. In addition to this, Korea would like to deliver requests as Korean companies has difficulties regarding the scope of safety glass QCO 2020 of India. According to the scope of Indian standard IS 2553-Part 1 (safety glass-specification, Part1: architectural, building and general uses) referred by the safety glass QCO, parts and components used in appliances should comply with this regulation. However, this standard mainly prescribes test requirements for the safety glasses used in architectures and buildings, so applying this regulation to the glasses used in appliances is not appropriate. Therefore, Korea requests India to exclude the application of this regulation for parts and components of appliances.

2.47. In response, the representative of India provided the following statement. The standards have been made mandatory after carrying a review of existing standards and following stakeholder consultation. This exercise is completed in consultation with various leading manufacturers to ensure to reflect new testing methods. Quality Control Orders on sheet glass and safety glass envisage conformity assessment Scheme-1 of BIS (Conformity Assessment) Regulations 2018. As per QCOs, the product specified therein shall conform to the corresponding Indian Standard and shall bear the standard mark under the licence from BIS 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 Scheme-1 of BIS (Conformity Assessment) Regulation 2018, BIS grants a licence to the manufacturer based on the successful assessment of the manufacturing infrastructure, production process, quality control, and testing capabilities of a manufacturer through a visit to its manufacturing premises. 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

⁶ For previous statements follow the thread under [ID 669](#).

both. There is no provision under Scheme-1 of BIS (Conformity Assessment) Regulation 2018 to accept quality control assessments conducted by foreign firms and Labs.

2.48. Foreign inspection visits are on hold due to international travel restrictions. Once the COVID-19 situation improves and the restriction is lifted, India will plan the inspections (factory visit). This standard (Part 1) prescribes the requirements, method of sampling, and test for safety glass meant for general purposes, such as for use in architectural purposes, furniture, display boards, railway coaches, earthmovers, lighting fixtures, parts and components of appliances, equipment and machines, etc. As from the scope above and from the footnote given in the scope of the standard that "Thermal shock test may be additionally carried out in the case of appliances", it is evident that "Appliances" are presently covered under the scope of IS 2553 (Part 1).

2.1.2.6 United States - Energy Conservation Program: Energy conservation standards for residential dishwashers, [G/TBT/N/USA/945/Add.3](#), [G/TBT/N/USA/1505/Add.2](#) (ID 670⁷)

2.49. The representative of China provided the following statement. We suggest that the US (i) further improve product classification and provide corresponding testing procedures for sink dishwashers; (ii) clarify the differences and classification basis between dishwashers with a washing process of less than one hour and those currently containing a quick cleaning function of less than one hour, and (iii) clarify energy consumption and water consumption limits of the dishwashers with a washing cycle of less than one hour.

2.50. In response, the representative of the United States provided the following statement. The United States thanks China for its comments submitted through the WTO TBT Enquiry Point on 7 December 2020 on [G/TBT/N/USA/945/Add.3](#) announcing the request for information on whether the US Department of Energy should amend energy conservation standards for dishwashers. In response to a petition for rulemaking received from the Competitive Enterprise Institute, the Department of Energy (DOE) published a final rule in 2020 that created a new product class for dishwashers whereby the "normal cycle" for such dishwashers would be 60 minutes or less. Manufacturers and consumer groups commented that the "quick or short cycle" that is present on over 80% of dishwashers offered for sale already meet the 60 minute or less threshold and are presently unregulated by DOE, and therefore can use as much energy and water as designed by the manufacturer. When publishing the final rule for the new product class, DOE did not specify standards or certification requirements for any products that could fall into this new product category - meaning that there are no new requirements or burdens placed on manufacturers who may choose to bring to market dishwashers that meet the new threshold. Furthermore, subject to Executive Order 13992, DOE plans to review the final rule establishing the short cycle dishwasher product class. On 8 February 2021, DOE published in the Federal Register a petition for waiver and granted an interim test procedure waiver to Ningbo FOTILE Kitchen Ware Co. Ltd., establishing a new test method for very small "in-sink" dishwashers. On 9 December 2020, DOE published in the Federal Register decision and order granting a test procedure waiver to CNA International, establishing a new test method for very small, manual fill dishwashers.

2.1.2.7 India - Refrigerating Appliances (Quality Control) Order, 2020, [G/TBT/N/IND/173](#) (ID 671⁸)

2.51. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of India to protect customers and Korean companies are fully committed to complying with the regulations of India. However Korea would like to make some comments regarding this regulation (Refrigerating Appliances (Quality Control) Order, 2020 of India) as follows. On 28 January 2021, through Indian WTO TBT Enquiry Point, Korea requested that the High Voltage Test Time specified in Clause 14.8 of the Indian standard IS 1476(Part1):2000 and Clause 19.8 of IS 15750:2006 be revised to be one second, in line with the international standard (IEC 60335-1). Korea is grateful for the written response of India on 2 February 2021, that it will review the revision of the High Voltage Test Time to one second in order to be harmonized with the international standard. The Korean once again requests that the standard be revised to harmonize with the international standard. In addition to the response of India, Korea also requests that the

⁷ For previous statements follow the thread under [ID 670](#).

⁸ For previous statements follow the thread under [ID 671](#).

Refrigerating Appliances (Quality Control) Order, 2020 of India be implemented after the relevant Indian standard revision is completed and an appropriate transition period is provided.

2.52. In response, the representative of India provided the following statement. The standards have been made mandatory after carrying review of existing standard and following stake holder consultation. This exercise is completed in consultation with various leading manufacturers to ensure to reflect new testing methods. This measure does not hinder the ability of foreign manufacturer to penetrate and reach into Indian market.

2.1.2.8 Thailand - Ministerial Regulation Prescribing Description, Production, and Method of Displaying of Standard Marks on the Industrial Products, [G/TBT/N/THA/577](#) (ID 672⁹)

2.53. The representative of the United States provided the following statement. The United States appreciates Thailand's notification of its Ministerial Regulation prescribing the description, production and method of displaying of Standard Marks on its Industrial Products. The United States industry has submitted several comments through the US and Thai Enquiry Points beginning in October 2020, through January 2021. We appreciate the exchange through that mechanism and the recent extension of the effective date for implementation of the QR Code requirement to 20 July 2021. However, the United States does have continued concerns regarding QR requirements. We encourage Thailand to consider other approaches that may meet consumer protection goals in a less trade-restrictive manner. In particular, a voluntary e-labelling approach in line with international best practices and standards could be considered. An e-labelling programme can help consumers discover important information without unnecessarily raising compliance costs and slowing time to market.

2.54. If a QR code requirement is to be maintained, efforts should be made to ensure that the specifics of the requirements are reasonable for the products within scope. For example, US industry representatives are concerned with the physical size and location requirements of Thailand's proposed approach, as the physical marking requirements are large in comparison to marks and labels used in other global markets. We request the QR code be eliminated for batteries, as the packaging is too small to accommodate the code. Regarding small audio-visual equipment, we request TISI to reduce the size restrictions for TISI logo and QR code on small AV products. We request TISI remove the requirement for the importer name to be imprinted on the power cord and ask that the requirement for labelling of the importer name be moved to the label. We are seeking confirmation that a paperwork factory inspection is allowed in lieu of onsite factory inspections. If a paperwork inspection is acceptable, could you kindly provide TISI's guidelines on the process and what is required in the submission? We have heard that the price of a factory paperwork inspection is almost three times higher than the usual onsite factory inspection price. Can TISI please provide more explanation about this cost structure and explain the difference in scope and objectives between these two inspection processes? The United States requests Thailand to continue to examine the regulation and consider less trade-restrictive conformity assessment and labelling requirements to meet the legitimate objective of consumer protection.

2.55. 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 echo the comments made by the United States. We share the same concern on the requirement for the size of Standard Mark, which includes TISI logo, QR code and TIS number. We seek clarification from Thailand on the method of displaying the Standard Mark if the body of the commodity is too small or to accommodate such Mark.

2.56. In response, the representative of Thailand provided the following statement. Thailand would like to thank the United States for valuable comments with regard to the Ministerial Regulation Prescribing Description, Production and Method of Displaying of Standard Marks on the Industrial Products B.E.2563 (2020). We reiterate that the regulation is promulgated to fulfil legitimate objective under the scope of the TBT Agreement, Article 2.2, whose purpose is to prevent deceptive practices and consumer protection. Therefore a licensee shall display the standard mark and the information of industrial products in electronic format (QR Code) to comply with the Ministerial Regulation. Due to the United States' concerns about the preparation of the manufacturers in displaying QR Code, we therefore extended the date of enforcement to 20 July 2021. And our responses to those concerns from the United States have been forwarded to its respective TBT

⁹ For previous statements follow the thread under [ID 672](#).

Enquiry Point. We reaffirm that the notified Ministerial Regulation is issued in accordance with TBT Agreement and all those concerns from the United States have been taken into our consideration.

2.1.2.9 Oman - Water heaters-energy performance requirements; Electrical Clothes Washing Machines Energy and Water performance requirements and Refrigerators, Refrigerator-Freezers and Freezers-Energy Performance, Testing and Labeling Requirements, [G/TBT/N/OMN/412](#) (ID 673¹⁰)

2.57. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of Oman to protect the environment and Korean companies are fully committed to complying with the regulations of Oman. Korea submitted the comments on Omani standards for "Electrical Clothes Washing Machines Energy and Water performance requirements" and "Refrigerators, Refrigerator - Freezers and Freezers -Energy Performance, Testing and Labelling Requirements" notified to the WTO on 27 July 2020 as [G/TBT/N/OMN/412](#). The comments were submitted to the Oman TBT Enquiry Point in November 2020, and the main contents are as follows. Firstly, regarding Clause 3.4 of electrical clothes washing machine energy efficiency standard, Korea has requested clarification of the water temperature requirements and allowance of the test at the supply water temperature specified by the manufacturer. Since the relevant international standards (IEC 60456, etc.) also allow the supply water temperature specified by the manufacturer, Korea has requested that Oman modify Clause 3.4 to be harmonized with the international standard. Additionally, regarding Clause 4.5, Korea has requested clarification of some misused or ambiguous market surveillance terms and additional information on input power testing method. Secondly, as for the refrigerators, clarification of some misused or ambiguous market surveillance terms has been requested.

2.58. Also in the standard annual energy consumption (SAE) formula applied in Oman, confirmation of the part that differs from the calculation formula applied in the international standards and neighbouring countries has been requested. In addition, detailed information on temperature and humidity conditions regarding the anti-condensation heater power consumption has been requested. Thirdly, as common issues for both electrical clothes washing machine and refrigerator, modification of typo in energy labelling (water extraction efficiency class unit, annual water consumption and water efficiency class unit, etc), confirmation of energy labelling size, and possibility of modifying air conditioner energy efficiency labelling which in already in effect have been requested. Lastly, confirmation as to whether the multi-drum washing machine is subject to the energy efficiency regulations of Oman has been requested. For the details of the above four requests, please refer to documents submitted to Oman TBT Enquiry Point in February this year and please review requests of Korea again.

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

2.1.2.10 India - Caustic Soda Quality Control Order, 2017, [G/TBT/N/IND/69](#) (ID 674¹¹)

2.60. 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 its concerns about the Order issued by India's Ministry of Chemicals and Fertilizers on Caustic Soda on 3 April 2018. The draft measure was notified by India to the TBT Committee as [G/TBT/N/IND/69](#) on 7 December 2017. Although this measure is not one of India's notified measures subject to STC 630, we are of the view that it is also part of the policy to require compliance of chemicals with BIS standards. Our industry has been encountering difficulties in obtaining certification even though all procedures had been completed prior to the outbreak of COVID-19, and no information seems to be available up to this date from the authority on the current stage of the application and the subsequent processes to go through before approval is granted. The lengthy and non-transparent conformity assessment procedures are creating unnecessary burdens as well as uncertainties for manufacturers located outside India. We urge Indian authorities to observe the obligations stated in Articles 5.2.2 of the TBT Agreement by establishing a reasonable standard processing period of each conformity assessment phases and communicating the results of assessment promptly in a precise and complete manner to the applicants. In particular, we would

¹⁰ For previous statements follow the thread under [ID 673](#).

¹¹ For previous statements follow the thread under [ID 674](#).

like to request India provide a contact point for foreign manufacturers to enquire and follow up their application cases. We thank India for taking into account our comments.

2.61. In response, the representative of [India](#) provided the following statement. The STC is noted and is presently being examined.

2.1.2.11 European Union - Non-recognition of test certificates (by Italy and the Netherlands) issued to electrical equipment by Central Power Research Institute (CPRI) (ID 675¹²)

2.62. The representative of [India](#) provided the following statement. The Republic of India is deeply concerned with the EU's refusal to recognize the test certificates issued by the CPRI (Central Power Research Institute) for electrical equipment. This non-recognition adversely affects the Indian exports to the EU. Italy and the Netherlands reject the design and acceptance certificates issued by CPRI to Indian manufacturers for electrical equipment such as power/distribution transformers, cables, conductors, disc insulators, circuit breakers, energy meters, capacitors, etc. Exporters are being asked to obtain international certificates from ASTA/UK, KEMA/Netherlands, CESI/Italy. The Central Power Research Institute (CPRI) is the Indian National Institute for research and development in electrical power engineering. It is an Intertek Recognized Testing Laboratory (Level 4) for certain electrical products. Consequently, CPRI is empowered to issue ASTA Certificates provided that testing occurs in the presence of an ASTA Observer. CPRI has facilities in Bhopal and Bengaluru, both of which are accredited by ASTA.

2.63. The non-acceptance of CPRI certificates by Italy and the Netherlands adds an extra testing cost for exporters, which can be avoided. Additionally, these unnecessary procedures make Indian exporters ineligible to participate in tenders in these countries. Therefore, Italy and the Netherlands' non-recognition of test certificates issued by CPRI is trade-restrictive. It is violative of Article 2.2 of the WTO-TBT Agreement, which specifies members must not prepare, adopt or implement any provisions that would create unnecessary international trade barriers. Hence, we request the EU share the reasons for the non-acceptance of CPRI certificates for electrical equipment. India would appreciate it if the EU could respond to this concern in writing.

2.64. In response, the representative of the [European Union](#) provided the following statement. Thank you to the delegation of India for its comments on the refusal to recognize the test certificates issued by the Central Power Research Institute for the electrical equipment. We have not yet received any information regarding the rejection of the design and acceptance of certificates by member States. The EU would like to ask the Indian delegation to indicate bilaterally which organisations are rejecting the certificates. The EU is liaising with the competent national authorities and will get back to India in due time with a more detailed reply based on additional information received.

2.1.2.12 Canada - Medical Device Single Audit Program (MDSAP) (ID 676¹³)

2.65. The representative of [China](#) provided the following statement. According to the "Principle of minimum trade restriction" and the acceptance level of MDSAP in other members concerned, it is recommended to use either MDSAP or former Canadian Medical Devices Conformity Assessment System (CMDCAS) to obtain a quality system certificate. The reasons are as follows. Firstly, the MDSAP certifications system in five related Members is still in the trial operation, MDSAP certification has a very limited acceptance level on a global scale at this stage. By now, only in Canada is MDSAP certifications mandatory. The other 4 Members, United States, Japan, Australia, and Brazil only use it as an optional method to get a quality system certificate. Secondly, the implementation of the MDSAP is intended to allow for a single audit to satisfy the regulatory requirements and to ease the burden of repeated certifications in different Members. However, the earlier implementation of mandatory MDSAP certification requirements has become an unnecessary burden for medical device manufacturers and organizations, especially small and medium-sized ones. Thirdly, before 1 January 2019, the auditing model CMDCAS is adopted to fulfil the requirements of Article 32 (Application for a Medical Device Licence) of Medical Devices Regulations (SOR/98-282). No single case indicates that this auditing model cannot fulfil the regulation goals.

¹² For previous statements follow the thread under [ID 675](#).

¹³ For previous statements follow the thread under [ID 676](#).

2.66. In response, the representative of [Canada](#) provided the following statement. The transition from the Canadian Medical Devices Conformity Assessment System to the Medical Device Single Audit Program (MDSAP) was announced in December 2015 and took effect on 1 January 2019, giving the industry over three years to make the transition. The MDSAP represents a significant milestone in international regulatory cooperation and work-sharing. The MDSAP has enabled us to transition from a solely Canadian programme to one aligned with other major international markets through the use of the same ISO standard. By accepting the results of these audits, the participating countries (Canada, Australia, Brazil, Japan and the United States) have demonstrated their commitment to reducing the number of inspections and audits faced by medical device manufacturers. The MDSAP enhances the monitoring of the quality of medical device manufacturing by applying a coherent, targeted and risk-based approach to audits, which was absent from the previous approach. The MDSAP also provides for the standardization of reports on audit results, allowing for the use of reporting tools to identify and explore industry compliance trends, in addition to a coherent grading system for audit results. The programme also includes an early warning system for regulators when serious negative results are found during audits, which enables regulators such as Health Canada to promptly investigate and take measures to mitigate emerging risks. The Canadian Medical Devices Conformity Assessment System no longer exists as it has been replaced by the MDSAP. Canada does not intend to revert to this programme and ISO standard 13485 alone does not sufficiently satisfy our requirements.

2.1.2.13 China - Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) requiring mandatory registration of certain chemicals for import and not notified at WTO (ID 677¹⁴)

2.67. The representative of [India](#) provided the following statement. The Chinese Ministry of Ecology and Environment (MEE) (erstwhile Ministry of Environment Protection or MEP) issued its Order 12 (MEE 12). This order came into force on 1 January 2021 and replaced the earlier order MEP Order 7. The MEE Order 12 was first notified to the WTO on 2 September 2019 and was followed up with an implementation guideline that was also notified to the WTO on 4 September 2020. China maintains a list of "Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)". India is concerned about the limited number of items included in this list. This list does not contain many chemicals that China regularly imports. The chemicals not listed under IECSC require registration. New substances become eligible for IECSC five years after first approval (as per MEE 12). However, in practice, the process of adding new chemicals to the IECSC even after the completion of five years is prolonged. The regulatory and administrative system for chemicals in China thus adds unnecessary delays and costs to the exporters.

2.68. *Concerns:* When adding new substances meeting PB, PT, or BT criteria to IECSC, the MEE will also specify allowed uses in IECSC. Should these substances be put to other uses, they will be subjected to new use management rules and require notification. Despite being on the list already, a substance has to undergo the same procedure as a new substance only because it is put to a different use. This is burdensome. Once the substance has completed the due procedure for being included in the IECSC list, the new use addition procedure may be simplified. This issue becomes all the more important because adding more chemicals to the list of IECSC is already prolonged. This is also evident from the fact that during the last ten years, only 573 new chemicals are added to the list of IECSC. The IECSC was officially provided in 2013 by the Ministry of Ecology and Environment. It contained 45,612 chemicals. This was then subsequently updated with additions in 2016 (31 substances), 2018 (45 substances), January 2019 (28 substances), January 2020 (47 substances), May 2020 (156 substances), October 2020 (28 substances), and December 2020 (238 substances). In view of this, China is requested to consider simplifying the process for adding new uses of existing substances in the list of IECSC.

2.69. Under MEE 12, notified new substance would be added to IECSC five years from its approval date. However, the process does not appear to be an automated one. Once a new substance is eligible to be included in the IECSC, the Chinese regulatory body, in consultation with appropriate technical committees, considers whether such substance should be included in the IECSC. Further, there is no clarification on how much time it may take for a product to be included in the list of IECSC. In view of this, China is requested to make the process of adding new substances to the list of IECSC systematic, time-bound, and transparent. Thirdly, there is no clarity about whether the new substances that have completed five years as per MEP 7 will be automatically included in the

¹⁴ For previous statements follow the thread under [ID 677](#).

IECSC under MEE 12. If not, what further procedural obligations (and why) are expected before these substances are included in the list. Article 2.2 of the TBT Agreement lays down certain objectives deemed "legitimate" for regulatory purposes. The TBT Agreement acknowledges Members' right to fulfil these objectives by regulating through technical regulations; however, the Agreement also emphasizes that such regulations shall not be implemented with a protectionist intention. Technical regulations are not to be formulated and implemented to make them more trade-restrictive than necessary to achieve a policy goal. In the case of this Chinese measure, new substances become eligible for addition onto IECSC five years from the date of the first commencement of manufacturing or importation (as per MEP 7). However, in practice, China is very slow in adding new chemicals to the IECSC even after the completion of five years. The regulatory and administrative system for chemicals in China adds unnecessary delays and costs to the exporter. Further, there is also no clarity on these aspects under MEE 12. In view of the above, China is requested to make the process of adding new substances to the list of IECSC systematic, time-bound, and transparent.

2.70. In response, the representative of China provided the following statement. According to the Measures on the Environmental Management Registration of New Chemical Substances (Order No. 12 of the Ministry of Ecology and Environment), China implements an environmental management registration system for new chemical substances. The new substances refer to substances that are not included in the "Inventory of Existing Chemical Substances in China", which was formulated, adjusted and published by the competent authority of ecology and environment. It includes chemical substances that had been produced, sold, processed, used or imported in China before 15 October 2003, as well as those listed in accordance with relevant regulations on environmental management of new chemical substances afterwards. In line with the TBT Agreement, China made a TBT notification on the Measures on the Environmental Management Registration of New Chemical Substances in September 2019, and notified the Guidance for Environmental Management Registration of New Chemical Substances in September 2020.

2.1.2.14 Mexico - Conformity Assessment Procedure under Mexican Official Standard NOM-223-SCFI/SAGARPA- 2018, "Cheese Names, Specifications, Commercial Information, and Test Methods," published on 31 January 2019, [G/TBT/N/MEX/465](#) (ID 678¹⁵)

2.71. The representative of the United States provided the following statement. On 5 May 2020, Mexico notified the WTO of its draft conformity assessment procedures for cheese included in its Official Mexican Standard (NOM)-223, including name, specifications, commercial information and test methods in [G/TBT/N/MEX/465](#). In response, the United States and its industry submitted timely comments to Mexico on 3 July 2020. In addition, the United States and its industry participated in the NOM-223 working group that was convened by the Ministry of Economy and the Ministry of Agriculture and Rural Development between 14 August and 11 September 2020, including providing expert presentations on standards of identity for cheese by the Agricultural Marketing Service and the Food and Drug Administration, and the Department of Agriculture was a regular participant. The opportunity to provide comments to the Mexican regulatory process and participate in the working group are greatly valued and we take sincere interest in participating. The United States and its stakeholders also participated in the early drafting of the NOM and provided comments to Mexico's National Commission for Regulatory Improvement (CONAMER) in 2018. In its notification, Mexico listed the objective of the conformity assessment procedures to be prevention of deceptive practices and consumer protection. Our understanding is that the conformity assessment procedures are required to determine the quality and truthful marketing of products called "cheese," and not for food safety. Mexico is proposing to establish consumer confidence in the marketing of cheese products through a certification scheme and self-documented declaration of conformity. The question is whether Mexico found any evidence of relevant scientific and technical information and incidence of non-compliant products to justify this onerous certification scheme for the objective of preserving quality of cheese in the market?

2.72. In July 2020, the United States commented on the draft NOM-223 and questioned the need for: (i) mandatory conformity assessment procedures that were originally listed as voluntary in the initial 2018 draft; (ii) mandatory testing procedures, particularly with newly improved NOM-51 labelling requirements to label cheese made from vegetable fat as "imitation", and existing requirements for certificates of analysis, which include information on cheese formulation, including

¹⁵ For previous statements follow the thread under [ID 678](#).

fat and moisture content; and (iii) the need for the fatty acid testing, as it is not recommended by Codex and it is unclear how it will improve the quality of cheese or inform consumers. We also made less trade-restrictive suggestions to improve Mexico's labelling practices for cheeses derived from vegetable versus animal fats, and noted that the CONAMER analysis of the measure considered that mandatory testing procedures could increase the price of cheese in the Mexican market, which would further force consumer substitutions for lower-quality products. Our industry also recommended conformity assessment alternatives that would achieve the objective pursued by NOM-223, in a less trade-restrictive manner, including the: (i) recognition of documentation already delivered or available to the authorities; (ii) application of market surveillance by the competent authorities; (iii) preparation and issuance of a specific NOM for products made with vegetable fat, which would provide separate requirements for cheese considered "imitation"; (iv) application of the voluntary scheme in the original draft CAP-NOM-223; or (v) requirement for a declaration of conformity by the producer. All of these alternative measures are less strict as they do not require the submission of performance reporting or additional testing to which the industry is already exposed; they contribute to the objective of avoiding misleading labelling of imitation products; and are reasonably available to competent authorities.

2.73. We recommended and requested Mexico continue the use of international standards and test methods, and consider suppliers' declaration of conformity as a means to attest that any required testing procedures had been performed. When we met bilaterally with Mexico in October 2020, we asked that Mexico recognize and accept testing from conformity assessment bodies located outside of Mexico, to ensure testing could be performed at the point of production. Despite participating in early 2018 drafting, providing comments to CONAMER in 2018, providing comments in response to WTO TBT notification in July 2020, expert participation in the working group in August through September 2020, the United States remains extremely concerned that the final draft shared with working group members by Mexico on 26 January with a slightly modified text on 11 February have not reflected our consistent comments, or those of our stakeholders, in the Mexican regulatory process.

2.74. We note that this is the first time we have raised these conformity assessment procedures in the WTO TBT Committee at this late stage. It is not because we just became aware of this measure. It is because we have been diligently participating in the Mexican regulatory process for over two years, at every stage. We have had past success working within the Mexican system and believed our comments, and the comments of other WTO Members and interested parties, would be taken into consideration in the final measure. Unfortunately, it is now our understanding that they have not been taken into account, which is especially unfortunate in this circumstance and at this late stage. Our understanding is that Mexico is considering the conformity assessment procedures to include an annual cheese certification. In 2021, cheese will be required to have a third-party certification per batch and family of products, and in the alternate year, for example in 2022, cheese will be required to have a suppliers' declaration of conformity per batch and family of products. We note, certifying and auto-declaring per batch and family of products means continuous certification and auto-declaration, as production lines at some facilities can start a new batch every 24 hours. The third-party certification scheme will also require an initial plant inspection of the cheese production facility. Product surveillance and traceability will also be the responsibility of the certification body. The type of certification scheme and facility inspection for every batch and family of products contemplated in these final conformity assessment procedures is the kind of scheme created and intended for situations where the objective is safety. An example of the type of product that usually carries this type of certification scheme is a product that could electrocute or explode. The type of scheme contemplated by Mexico in this instance does not appear to be proportionate to the risks that non-conformity would create and may be considered more trade restrictive than necessary to fulfil the legitimate objective of the regulation.

2.75. We request that Mexico halt the issuance of the final cheese conformity assessment procedures, re-consider the risks that non-conformity would create before issuing the final conformity assessment procedure, and go back to drafting the conformity assessment procedure with trading partners and stakeholders. What risk would non-conformity create? Is that risk of fraud or consumer information proportionate to requiring every cheese production facility exporting to Mexico to be inspected, every batch of every product family required to undergo expansive and expensive battery of testing, and also employ a certification body for post-market surveillance and traceability? Has labelling been fully explored to meet consumer needs for information to meet some of the objectives this certification scheme would attempt to achieve? Further, this would be an entirely new certification scheme that has never existed in any other country previously for cheese.

If this certification scheme contemplated is included in the final regulation, it would be extremely onerous, if not impossible, to put into force within 60 days or even by the end of 2021. We have surveyed the capabilities and accreditations for the appropriate scope of testing in the United States. While the United States has capabilities, none of the laboratories or certification bodies would be immediately familiar with this new certification scheme and it would take time for producers to employ testing and certification bodies and to inspect the production facilities. Given the limited number of accredited laboratories and certification bodies available to do the work, there would likely be a delay or suspension of exports of cheese to Mexico.

2.76. Additionally, any product sold to Mexico would suffer increased prices to offset the cost of these conformity assessment procedures. Those additional costs, for testing, services of a certification body for facility inspection, certification, surveillance, and traceability, would put some US producers of cheese entirely out of the market. Since these requirements will also apply to domestic products, cheese may become unaffordable and consumers may resort to purchasing less expensive substitutes, as CONAMER has predicted, perhaps leading to an increase of adulterated cheese on the market. The United States exported US\$428 million in cheese to Mexico in 2020. We again request Mexico suspend the final measure, keep drafting with trading partners and stakeholders, and consider the low-risk nature of cheese and allow for suppliers' declaration of conformity to attest compliance to the testing procedures required in NOM-223.

2.77. The representative of the European Union provided the following statement. The European Union would like to join this trade concern, as some aspects of the conformity assessment procedure established by the Procedure for the Evaluation of Conformity of the Official Mexican Standard NOM-223, in particular high frequency of product testing and production facilities inspections, would cause difficulties for EU exporters. We would appreciate a possibility to work bilaterally with Mexico to receive some clarifications and find a satisfactory solution.

2.78. The representative of Australia provided the following statement. Australia would like to note its concerns that Mexico's measure notified as [G/TBT/N/MEX/465](#) appears discriminatory and more trade restrictive than necessary. We provided comments Mexico's notification detailing our specific concerns with the measure. Australia welcomes Mexico's consideration of, and response to, these comments and looks forward to continuing our successful trade relationship.

2.79. In response, the representative of Mexico provided the following statement. The delegation of Mexico welcomes the comments made by the delegation of the United States of America on the conformity assessment procedure for the technical regulation on cheese, which seeks to address the problems identified in the verification processes for this product at the points of sale to the final consumer. Several irregularities have been detected in these processes regarding products that do not provide truthful information to consumers. The objectives pursued through this measure include the prevention of misleading practices, on the basis of cases of non-compliance detected in products of both domestic and foreign manufacture. It is vital to demonstrate the compliance of any product bearing the name "cheese" with the relevant technical regulation, which, in this case, is Mexican Official Standard NOM-223. Regarding the specific questions raised by the United States of America, the following comments have been made: (1) NOM-223-SCFI/SAGARPA -2018 does not establish that conformity assessment is voluntary. The second transitional article provides that the authorities shall initiate work on the development of the conformity assessment procedure within 60 calendar days following the publication of the Mexican Official Standard in the Official Journal.

2.80. (2) The changes in commercial information set out in Mexican Official Standard NOM-051-SCFI/SSA1-2010 will enter into force on 1 April 2021, and it has now been verified that the product labels do not provide consumers with accurate information. It is therefore necessary that all products known as "cheese" be certified, due to the constant and increasing level of non-compliance that has been officially documented by the Federal Consumer Protection Agency (PROFECO), to the detriment of Mexican consumers and healthy competition between producers. (3) Fatty acid profile tests demonstrate that the product has not been altered or adulterated in its butterfat (milk fat) composition with vegetable fat to reduce costs. Mexico has officially documented that the product known as "cheese" is adulterated with vegetable fat and, in many cases, the consumer is not informed. It has therefore been determined that this test is necessary to demonstrate the authenticity of the cheese marketed in the national territory. The technical evidence is contained in the various quality studies carried out by PROFECO, which is the consumer defence authority in Mexico. We are able to share this evidence with any interested parties.

2.81. With regard to the use of test methods and international standards, test methods from international standards have been included for each of the physico-chemical specifications established in the Mexican Official Standard and its normative references. In addition to the above, the foreign standards requested by the United States of America, which have proven to be equivalent to international standards, have been included, thus demonstrating the Mexican authorities' commitment to ensuring effective compliance for foreign countries. Moreover, the procedure provides for the recognition of conformity assessment bodies located abroad and does not require the presence of offices in Mexico. Similarly, regarding the points made by the United States of America, there are two different certification schemes as set out in section 4.2.1: I. Periodic inspection of the product and audit of the product manufacturing process. This scheme provides for the initial inspection of the product, with an assessment carried out at the industrial plant of the control that the manufacturer has over the manufacturing process, followed by an inspection during the certification year of the certified product. II. By batch. This scheme provides for the inspection of a particular batch of products. A product batch certificate is not required. It is for domestic or foreign producers to choose the most appropriate scheme for their production.

2.82. It also states that the certification body must determine the size of the sample and carry out periodic inspections all the way from the plant to the point of final delivery to the importer (in the case of foreign importers) and at point of sale to the final consumer (in the case of domestic importers), in order to verify that the product continues to comply with the same conditions under which a certificate was issued. This is complemented by the verification and monitoring activities undertaken by the authorities of the Mexican Government in the national territory. The entry into force of this procedure will be amended to address the comments and concerns expressed by the domestic and foreign industries, given the importance of ensuring sufficient infrastructure for conformity assessment bodies both in the national territory and abroad to guarantee effective implementation. Concerning the costs of conformity assessment, based on the evidence presented during the development of the conformity assessment procedures, it was determined that product certification does not represent a significant economic cost or have a high impact on producers or the final consumer. However, we invite the delegation of the United States of America to present its technical evidence on the high economic cost of this procedure.

2.1.2.15 Nigeria - Onerous testing and conformity requirements by société générale de surveillance, (SGS) for machinery and their parts (ID 679¹⁶)

2.83. The representative of India provided the following statement. The Republic of India is deeply concerned about Nigeria's onerous certification and conformity requirements, which adversely affect Indian exports to Nigeria. Under the current regime in Nigeria, all importers must obtain a Product Certificate (PC) and a SONCAP Certificate (SONCAP is a pre-shipment verification of conformity to Nigerian standards) for each consignment. The process of obtaining PC and meeting the conformity assessment requirement is onerous, intensive, and expensive. It involves an elaborate two-step process which is explained below.

2.84. The first step is obtaining a PC. To place an order for the import to Nigeria, the importer needs a Bank in Nigeria to issue Form M. This Form M can only be issued based on the PC. The PC is issued based on the test report. The test report can be issued only once the actual production has started. The actual production will begin only after receiving Form M which is an intent for payment. From this, it is clear that obtaining a PC is a circulatory and highly trade-restrictive process. Secondly, the validity of a PC issued by Nigerian authorities is only six months, which is a very short time. This adds an extra burden on the exporter both in terms of cost and time required for obtaining another PC. We consider that these measures are highly trade-restrictive and create unnecessary obstacles to trade. Hence, Nigeria is requested to consider simplifying the procedure for obtaining the PC and sharing the risk assessment done to arrive at the PC's six-months validity.

2.85. The second step is obtaining a SONCAP Certificate. Once the order for a product is placed and the PC requirement is met (as mentioned in the first step), before the product can be exported to Nigeria, a SONCAP Certificate for each consignment is required. This requirement of obtaining a SONCAP certificate is in addition to the PC requirement. This process of conformity assessment for each shipment is cost-intensive and involves onerous procedures.

¹⁶ For previous statements follow the thread under [ID 679](#).

2.86. Countries establish such onerous conformity assessment requirements for products that have implications for human health upon consumption, plant/animal health or environment, restricted or prohibited category of products, or products originating from restricted countries into their territory. In other words, the degree of risks upon importation must be determined for placing such stringent conformity assessment requirements. In Nigeria's case, except for a few products, each consignment is required to obtain a SONCAP certificate. We request Nigeria to share the risk assessment to mandate such intensive conformity assessment requirements. Further, the Nigerian requirement of SONCAP certificate for each consignment appears to violate Article 5.2 of the TBT Agreements, requiring that a WTO Member's conformity assessment procedures do not create unnecessary obstacles to international trade. Additionally, Article 2.2 of the TBT Agreement specifies that Members must not prepare, adopt or implement any provisions that would create unnecessary international trade barriers. In view of the above, Nigeria is requested to share the risk assessment for the following: (a) requirement of a PC for all products; (b) six months validity of PC; (c) the requirement of obtaining a SONCAP certificate for each consignment; and (d) the less trade-restrictive measures that were considered before finalizing the present mechanism.

2.87. In response, the representative of Nigeria provided the following statement. We take note of India's comments and concerns raised. We have notified capital on this issue. We shall revert back to the meeting as soon as we get a response from Capital.

2.1.2.16 European Union - Testing methods for prohibited chemicals of regulation on cosmetic products, [G/TBT/N/EU/752](#) (ID 680¹⁷)

2.88. The representative of China provided the following statement. We suggest that the EU clarify the testing method for volatile nitrosamines in nail polish products. As it was clearly indicated that the storage conditions and stability under in-use conditions can result in hydroquinone formation, we suggest that the EU clarify the conditions and scientific principles for the conversion from deoxyarbutin to hydroquinone in cosmetics. As Chinese labs do not find the evidence of this conversion in practices, it is also suggested that the EU could provide the testing methods for the conversion in cosmetics.

2.89. In response, the representative of the European Union provided the following statement. The EU would like to remind China that a written reply to their comments of 16 December 2020 was submitted via the TBT Enquiry Point on 4 February 2021. As stated in the reply, the EU observes that the draft is based on the Opinion of the Scientific Committee on Consumer Safety (SCCS) on deoxyarbutin Tetrahydropyranyloxy Phenol (SCCS/1554/15). In this Opinion the SCCS concluded that: "hydroquinone will be formed at levels which raise concerns with regard to the safety of such products during life-cycle of the product (e.g. storage conditions and stability under in-use conditions)". Considering that hydroquinone is among the substances prohibited for use in cosmetics products, listed under entry 1339 of Annex II to the Cosmetics Regulation – with solely the exception of entry 14 in Annex III – the conclusion of the SCCS clearly implies the need to regulate the use of deoxyarbutin in the Cosmetics Regulation. This is in accordance, notably, with Article 31(1) of the Cosmetics Regulation, according to which where there is a potential risk to human health, arising from the use of substances in cosmetic products, which needs to be addressed on a Community-wide basis, the Commission may, after consulting the SCCS, amend Annexes II to VI accordingly.

2.90. In that respect, the EU also observes that whilst the Opinion of the SCCS was adopted in 2015, it is solely for administrative reasons that the Commission did not proceed immediately to adopt a measure prohibiting the use of deoxyarbutin in cosmetics. The current draft legislative measure is, therefore, aimed at reflecting the SCCS Opinion mentioned above without further delays. In addition, the EU would like to recall that a large body of scientific evidence shows that hydroquinone is a known clastogenic and cytotoxic agent *in vitro* and *in vivo*. This fact does not depend on the detection method. Hydroquinone has been classified under the "Classification, Labelling and Packaging" (CLP) Regulation (Regulation (EC) No 1272/2008) both as mutagenic (Muta.2) and carcinogenic (Carc.2). It is the responsibility of the industry to use the appropriate validated method and quantify the conversion of deoxyarbutin to hydroquinone or invest in the relevant R&D in order to stabilize the deoxyarbutin and hinder its conversion to hydroquinone. The SCCS Opinion clearly indicated that the storage conditions and stability under in-use conditions can result in hydroquinone formation, which "raise concerns".

¹⁷ For previous statements follow the thread under [ID 680](#).

2.1.2.17 India - Plain Copier Paper (Quality Order) 2020, [G/TBT/N/IND/140](#) (ID 681¹⁸)

2.91. The representative of [Indonesia](#) provided the following statement. Indonesia thanks India for notifying the draft of Plain Copier Paper Quality Control Order on 14 February 2020 to TBT WTO Members through notification [G/TBT/N/IND/140](#). However, Indonesia regrets that enquiries made to the responsible minister are receiving no response. Indonesia as one of the largest paper-exporting countries in India is greatly affected by this regulation. India is one of the largest trading partners of Indonesia and is the sixth largest export destination country for paper products. Unfortunately, in the current development, several policies that have been issued by India have impacted and become trade barriers for Indonesian paper exports such as the mandatory implementation on Indian Standards regulation. The value of Indonesian exports in the period January-November 2019 was US\$201.9 million, meanwhile the value of Indonesia's exports to India in the same period in 2020 was only US\$74 million or decreased by 63%. The procedures required by India Trade Policy significantly create obstacles for Indonesia's paper export to India. In accordance with the provisions of the conformity assessment, certification shall be carried out by Bureau of Indian Standard based on the Conformity Assessment Regulation 2018 through the Scheme 1 of Schedule-II which shall require factory visit, sampling and testing of products as well as licensing procedure.

2.92. Indonesia requests clarification from India on whether this certification scheme applies equally both to local and foreign manufactures, or only applies to foreign paper procedures. Indonesia views that the scheme used may cause foreign producers to experience difficulties in implementing the scheme. Moreover, India's hesitation to replace factory visit requirement with remote assessment during COVID-19 pandemic has caused registration and testing procedures to take longer than it should be and can potentially disrupt flow of goods to India. Therefore, Indonesia urges India to consider the implementation of remote assessment or any relaxation policy during COVID-19 pandemic. Indonesia also requests India to consider providing a longer transition time, for at least 24 months, and allow adequate time for foreign producers to adjust their products. Indonesia also requests India to provide the information on the harmonization of testing methods used in the IS 14490:2018 to ISO standards. Lastly, we noticed that India, through the Ministry of Commerce and Industry, had published mandatory implementation of Plain Copier Paper (Quality Control) Order 2020 Regulation on 5 June 2020. This regulation will come into force after six months from the date of its publication, which is 5 December 2020. In this regard, we kindly remind India to notify this technical regulation to this Committee, as the addenda of the previous notification.

2.93. In response, the representative of [India](#) provided the following statement. Under the provisions of Scheme-1 of BIS (Conformity Assessment) Regulation 2018, BIS grants a licence to the manufacturer based on successful assessment of the manufacturing infrastructure, production process, quality control and testing capabilities of a manufacturer through a visit to its manufacturing premises. 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 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 labs. Presently foreign inspection visits are on hold due to the prevalent restrictions on international travel in view of the ongoing COVID-19 pandemic. As soon as the situation of COVID-19 improves and the restrictions are lifted, BIS will plan the inspections.

Sl. No.	Requirement	Indian Standard	Corresponding ISO Standard
1	Moisture	IS 1060 Part 5/Sec 2:2014	ISO 287:2009
2	Thickness	IS 1060 Part 5/Sec 3: 2014	ISO 534:2011
3	One minute Cobb test (both sides)	IS 1060 Part 5/Sec 4:2014	ISO 535:1991
4	Surface Strength, Dennison, (Wax pick)	8 of IS 1060 (part 3) (No corresponding ISO)	
5	Grammage	IS 1060 Part 5/Sec 5: 2014	ISO 536:2012
6	Smoothness for both sides (Bendsten)	3 of IS 9894 (ISO 2494, now withdrawn)	Indigenous (ISO 8791-2:2013)

¹⁸ For previous statements follow the thread under [ID 681](#).

Sl. No.	Requirement	Indian Standard	Corresponding ISO Standard
7	Ash content (at 900°C)	11 of IS 1060 (Part 1)	Indigenous (ISO 2411:2019)
8	Taber Stiffness	Appendix D of IS 4658	Indigenous (2493-2:2020)
9	Tear Index	IS 1060 Part 6/Sec 1:2014	ISO 1974:2012
10	Tensile Index	IS 1060 Part 5/Sec 6:2014	ISO 1924-2:2008
11	ISO Brightness	IS /ISO 2470 (Part 1):2009	
12	Opacity	IS/ISO 2471: 2008	

2.1.2.18 Morocco - Automotive glass testing requirements (ID 682¹⁹)

2.94. The representative of China provided the following statement. China appreciates Morocco's adoption of international standards. However, the application of the standard for automotive glass in Morocco is inconsistent with international practice, which has led to deviation of the testing results. In this regard, it is suggested that Morocco applies the standard in a manner that is consistent with international practice, i.e., whether the intermediate layer is torn or not shall be used as a basis for judging whether it is necessary to weigh the fragments of the sample after impact, and not as a basis for judging whether the sample is qualified.

2.95. In response, the representative of Morocco provided the following statement. I wish to clarify that, in order to protect consumers, Morocco carries out these checks under Law No. 24-09 on the safety of products and services. Morocco has already been contacted by the Chinese authority regarding automotive glazing checks and we have sent the reply through diplomatic channels. The reply provided information on the reference standard used in the automotive glazing conformity checks. This reference standard is Moroccan Standard NM No. 22.4.003 "Road vehicles - Safety glazing materials - Mechanical tests", which is consistent with UN Regulation No. 43 and with the provisions on the 227 g ball test in international standard ISO 3537. All three of the following conditions, rather than just two out of three, must be met in order for the test to be passed: (i) condition 1: the ball does not pass through the test piece; (ii) condition 2: the test piece does not break into several pieces; and (iii) condition 3: if the interlayer is not torn, the weight of fragments detached from the side of the glass opposite to the point of impact shall not exceed the appropriate values specified by the standard. Consequently, the test result is considered non-conforming if the third condition is not met. As soon as the ball perforates the external glazing of the interlayer, the result is considered unsatisfactory. This test must also be repeated ten times and the results of eight out of ten of the tests must be conforming. This interpretation is also shared by international laboratories.

2.1.2.19 Kingdom of Saudi Arabia - Concerns on conformity assessment practices of Saudi Arabia against Turkish products (ID 683²⁰)

2.96. The representative of Turkey provided the following statement. Turkey regrets that it has to bring this item to the agenda of this meeting due to trade-restrictive practices of Saudi Arabia in recent months. As Turkey also outlined at the last Council for Trade in Goods meeting, particularly since November last year, the restrictive practices against Turkish products have augmented. These include unreasonably long delays at Saudi customs and burdensome and discriminatory product safety inspections. We have been informed by Turkish exporters that some Turkish products are inspected in accordance with the conformity assessment procedures applied for a different product. These products thus fail in conformity inspections because of the application of improper conformity assessment procedures. To exemplify, industrial kitchen equipment is tested in accordance with the standards applied to household kitchen appliances. Another such case has been experienced during the conformity assessment of liquid hand soap, which apparently was evaluated as a medical product and rejected on the grounds that it did not meet the labelling standards required for medical products. Additionally, some Turkish products are rejected at customs due to problems related to

¹⁹ For previous statements follow the thread under [ID 682](#).

²⁰ For previous statements follow the thread under [ID 683](#).

labelling, despite bearing the exact same labelling as before. In one such case, although all warning signs stipulated in the relevant technical regulation were included on the product label, the product was denied stating that these signs were not in the sequence shown in the technical regulation. As a result of these practices, Turkish products are not allowed to be placed on the market on the grounds that they do not comply with the standards specified in the technical regulation. When Turkish exporters uphold that the product in question is interpreted within the wrong product group and request a re-testing, this request is also not accepted.

2.97. Given all the restrictive practices of Saudi Arabia against Turkish products, including burdensome product safety inspections, Turkish exports to Saudi Arabia decreased by more than 79% in December 2020 compared to the same month in 2019. We have also witnessed a 93% decrease in our exports to Saudi Arabia in January this year as compared the same month of 2020. As known, the TBT Agreement aims to ensure that technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles and to prevent Members from creating arbitrary or unjustifiable discrimination between countries in international trade. We are of the opinion that Saudi Arabia unjustifiably discriminates Turkish products from any like product of national and other Member origin, in violation of the TBT Agreement articles that foresee equal treatment of like products. As is well known, the TBT Agreement envisages preparation, adoption and application of regulations and conformity assessment procedures so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin or originating in any other country. We are also of the view that Saudi Arabia is in breach of TBT Agreement articles foreseeing that regulations and conformity assessment procedures should not be more strict, or be applied more strictly than necessary, taking account of the risks non-conformity would create. In this respect, Turkey invites Saudi Arabia to bring its policies and practices concerning Turkey in line with its WTO TBT obligations and to ensure smooth flow of trade for Turkish goods.

2.98. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. We take note of all concerns raised and we will convey them to the capital.

2.1.2.20 Turkey - Eco-design regulation, [G/TBT/N/TUR/162](#), [G/TBT/N/TUR/163](#) (ID 684²¹)

2.99. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of Turkey to protect the environment and Korean companies are fully committed to complying with the regulations of Turkey. Korea would like to make some comments on the Turkish Ecodesign regulation of refrigerators, washing machine, dishwasher, display products which is scheduled to take effect on 1 March 2021, as Korea had received information from unofficial sources that Turkey will implement revised Ecodesign and energy labelling regulations on refrigerators, washing machines, dishwashers, and display products from 1 March 2021. Korea enquired about the implementation of the regulations and whether to notify the draft regulations for each product to the WTO, and Turkey replied on 10 February that the regulations will take effect on 1 March 2021 as planned and will be notified to the WTO. Korea also received answers that Turkish Ecodesign and energy labelling regulations are almost identical to EU regulations. However, as regulation will take effect without any official notification to the WTO, Korean companies will have difficulties that sufficient time for complying with this regulation has not been provided at all. Therefore, Korea would like to request that Turkey make official notification of the draft regulations for each product to the WTO according to the WTO TBT Agreement and provide a comment period to Members and/or a reasonable transition period prior to implementing the regulations after adoption. If it is difficult for Turkey to postpone the scheduled enforcement date, Korea would like to request more reasonable alternatives, such as temporary recognition or exempting from market surveillance in order to manufacturers to comply with the regulations.

2.100. In response, the representative of Turkey provided the following statement. The legitimate objective of the draft Regulations is to contribute to sustainable development by increasing energy efficiency, the level of protection of the environment, and the security of the energy supply. Through providing information regarding energy efficiency of the products, the regulations aim to enable customers to choose products that are more efficient. Both Energy Labelling and Eco-Design Regulations of Turkey have been prepared in line with the EU regulations, since the harmonization of the EU's technical legislation is a requirement for Turkey under the EU-Turkey Customs Union

²¹ For previous statements follow the thread under [ID 684](#).

Agreement. Turkey recently conveyed to the WTO the official WTO/TBT notifications of both regulations and provided the full text of the draft regulations in English. These notifications were circulated by the WTO on 25 February 2021. Besides, Turkey has also recently submitted the notifications of the draft regulations for each product, which will be circulated by the WTO very shortly. Concluding my remarks, I would like to reiterate Turkey's willingness to work together with the membership to address any specific concerns they may have on Turkey's Eco-Design and Eco-Labeling Regulations.

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) (ID 294²²)

2.101. The representative of the European Union provided the following statement. Regarding the Multi-Level Protection Scheme, the EU would like to refer to its comments raised at previous TBT Committee meetings, namely concerns around (i) the nature of the expert review that the Guidelines prescribe, (ii) the lack of clarity in certain definitions, and (iii) the subsequent unwarranted and significant market entry restrictions. The EU calls for enhanced proportionality and transparency in the implementation of the Cyber-MLPS. 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.

2.102. 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 we made at the last TBT Committee in October 2020. We recognize that the public consultation of "Regulation on the Administration of Commercial Cipher Codes" had lasted until 19 September 2020. Japan would like to request that China consider the comments we provided and reflect them in the regulation. Japan would like to request that China provide relevant information regarding the current revision process and that the regulations would be implemented transparently.

2.103. 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 and comments widely and ensure the stakeholders' participation in legislative activities through legal means. Now, as the revision of the Regulation is still under research, it will be open for public opinions in due course. Regarding the MLPS, with technology development, in response to more complicated cyber security circumstances, information security multi-level protection scheme needs to be improved. Based on past experience 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, the regulation 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 European Union - Hazard-based approach to plant protection products and setting of import tolerances, [G/TBT/N/EU/383](#), [G/TBT/N/EU/384](#) (ID 393²³)

2.104. 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 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.

²² For previous statements follow the thread under [ID 294](#).

²³ For previous statements follow the thread under [ID 393](#).

2.105. The representative of [Costa Rica](#) provided the following statement. As on previous occasions, Costa Rica would once again like to reiterate its support for the trade concern raised by the United States, Canada and Australia. Costa Rica is concerned about the hazard-based approach adopted by the European Union, given that, under the multilateral system obligations, all technical requirements must be based on the relevant international reference standard or a risk assessment providing the scientific evidence to support the measure. Costa Rica reiterates its request to the European Union 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.

2.106. 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. A solid risk analysis, consistent with Codex guidelines, is important to ensure transparency and predictability in the regulatory processes regarding plant protection products and MRLs. Brazil believes that 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 a serious impact on trade.

2.107. The representative of [Canada](#) provided the following statement. As stated in the previous TBT Committee, the importance of ensuring access to safe and nutritious food has been further amplified by the challenges brought on by the current pandemic. In our view, the use of plant protection products can play an effective role in addressing some of these challenges while helping increase global food security. Canada acknowledges the EU's recent efforts at clarifying the process for establishing import tolerances, particularly for active substances that are not re-authorized due to the hazard-based criteria or that are no longer supported by the applicant. Canada is pleased that the EU intends to conduct risk assessments for all import tolerance requests, and that such requests, including those for active substances that meet the EU's hazard-based criteria, will be impartially reviewed in accordance with internationally-accepted risk assessment principles and EU legislation. We would like to thank the EU for honouring its commitment to host seminars with third countries and stakeholders last month. Canada appreciated the level of detail shared during these discussions and welcomed the opportunity to participate and ask questions. While we recognize that the EU has a process for import tolerances, Canada requests that the EU consider maintaining MRLs for substances that do not pose unacceptable dietary risks. In this context, a dietary risk assessment as part of the re-authorization process would likely be needed, regardless of the results of the hazard screen. This would eliminate the need for import tolerance requests for some substances and minimize disruptions to trade. We look forward to continuing our engagement with the EU and welcome any information on upcoming regulatory or policy changes to ensure that unnecessary trade barriers are minimized and that measures are consistent with international trade obligations.

2.108. The representative of [Paraguay](#) provided the following statement. Paraguay wishes to reiterate its deep concern regarding this measure and refers to its statements made at previous meetings. 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. There is a need to consider 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. The European approach to limit the use of pesticides is more trade-restrictive than necessary to fulfil its legitimate objectives under the TBT Agreement. We stress that the pursuance of such policies will cause significant trade damage to the economies of developing countries and jeopardize their ability to achieve the 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.

2.109. The representative of Guatemala provided the following statement. Guatemala reiterates its concern about 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 European Union, in that we do not have a harsh winter to help control pests. Geographical location, namely, the distance and time needed to export a product to the European Union, is another factor that should be taken into consideration to avoid applying measures that unnecessarily restrict trade.

2.110. The representative of Chile provided the following statement. As in previous Committees, and like other delegations that have taken the floor before me, Chile wishes to echo the trade concern raised concerning the implementation of maximum residue levels set for various agricultural products by the European Union, as well as their implementation periods and periods of validity. We will continue to monitor developments in this Committee and other relevant committees.

2.111. The representative of Colombia provided the following statement. Colombia once again shares this concern regarding the approach taken by the European Union (EU) for identifying plant protection substances. As we have stated across different items on the agenda of this Committee, we reiterate the need to use risk analysis as a methodological tool for decision-making under the 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 measures 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.

2.112. The representative of Uruguay provided the following statement. Uruguay thanks Australia and Costa Rica for once again including this specific trade concern on the Committee's agenda. 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 reiterate the need to base such determinations on conclusive scientific evidence, gathered from an assessment of the actual risks, to avoid some of these active substances, which remain important components of pest management systems, being withdrawn despite their safe use. This is due to the fact that 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 agree with Canada on the importance of ensuring and facilitating the access of the population to safe and nutritious food, produced in accordance with good agricultural practices, especially at the present time. Uruguay continues to support any multilateral work undertaken by the Codex Alimentarius to develop a harmonized, risk-based approach that ensures the protection of health, while facilitating international trade in food products. In the meantime, we once again call on the European Union to listen to and address the concerns expressed by a number of Members, 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 social and economic consequences of such an approach for other Members, in particular developing and least developed countries, for which the European Union is a key market.

2.113. The representative of Ecuador provided the following statement. As this is the first time I have taken the floor, I would like to extend our greetings to all and our thanks to the Chair and the WTO Secretariat for the excellent manner in which these meetings have been conducted. Ecuador shares the concerns raised in the statements made by the Members who have spoken before me regarding this specific trade concern. My country recognizes the importance of protecting human health and the environment. However, we consider that regulatory decisions taken on the basis of hazard-based criteria are inconsistent with international risk-assessment practices. Ecuador urges the European Union (EU) to take into account scientific information emanating from the international

specialized bodies recognized by the WTO, such as the Codex Alimentarius, which has relevant information on pesticides. Ecuador also urges the EU to take into account the recommendations of the Committee on Technical Barriers to Trade related to good regulatory practice, particularly with regard to carrying out a Regulatory Impact Analysis prior to the issuance of regulatory proposals, which examines all possible social, economic, environmental and health impacts. This is to ensure compliance with the obligation not to be more trade-restrictive than necessary to fulfil a legitimate objective, in accordance with Article 2.2 of the TBT Agreement. Lastly, my country once again calls on the EU to ensure that, in cases where there is a lack of scientific information, EFSA does not make a recommendation on the maximum residue limit (MRL), since decisions on regulatory measures must be based on conclusive risk analyses that provide real health protection and do not constitute a technical barrier to trade.

2.114. In response, the representative of the European Union provided the following statement. The European Union thanks the WTO Members for their interest in the ongoing work in the EU on identifying endocrine disruptors for plant protection products. The EU reiterates that the scientific criteria to identify endocrine disruptors for plant protection products based on the WHO definition are applicable since 10 November 2018 onwards and included in Regulation (EU) No 2018/605. We are aware of general concerns on EU policy on plant protection products for the definition of scientific criteria to identify endocrine disruptors and on the establishment of import tolerances for substances not authorised 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, which include a risk assessment by an Evaluating EU member State and a scientific opinion by the European Food Safety Authority (EFSA). The granting of the import tolerance is then 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 keep Members duly informed about future developments.

2.1.3.3 China - Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council), [G/TBT/N/CHN/1313](#) (ID 428²⁴)

2.115. The representative of the Republic of Korea provided the following statement. Korea would like to thank China for the notification [G/TBT/N/CHN/1313](#). Korea has continuously engaged with China on the Regulations for the Supervision and Administration of Medical Devices. With the notification, the draft of the revision of the regulation was announced in 2019. With regard to the Regulations, Korea has repeatedly requested China since 2015 to accept the test results of laboratories outside China in applying for cosmetic registration in China, but no clarified explanation has been given from China. Thus, we would like to reiterate the concerns as follows. Korea requests China to accept the test results from laboratories outside China. Specifically, internationally accredited laboratories outside China should be recognized by the National Medical Products Administration (NMPA). This would reduce compliance costs, thereby facilitating trade. Korea would like to be informed about the time frames for the publication of the final Regulations and their entry into force.

2.116. In response, the representative of China provided the following statement. At present, "Regulations on the Supervision and Administration of Medical Devices" is still under revision. While the whole process is completed, China will promptly publicize the regulation.

2.1.3.4 China - Cyberspace Administration of China – Draft implementing measures for the Cybersecurity Review of Network Products and Services (ID 533²⁵)

2.117. 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, which entered into force on 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 may pose a risk to Chinese

²⁴ For previous statements follow the thread under [ID 428](#).

²⁵ For previous statements follow the thread under [ID 533](#).

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 clarity, transparency and objectiveness in the security review so that the measure does not become a new market access barrier. The EU also seeks an update of this measure from China.

2.118. The representative of [Japan](#) provided the following statement. Japan has its interest in and concern with regard to the Cybersecurity Review and would like to refer to the previous statement we made at the last TBT Committee in October 2020. At the last TBT Committee, China explained that 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 Chinese market. Japan would like to request that China provide relevant information regarding the current revision process and that the regulations would be implemented transparently.

2.119. The representative of [Canada](#) provided the following statement. Canada remains concerned by the absence of the following in the Implementing Measures for the Cybersecurity Review: (i) clarity regarding what constitutes Critical Information Infrastructure; (ii) defined criteria that operators of Critical Information Infrastructure are to use in assessing a security threat; and (iii) a clear commitment to national treatment, MFN treatment and the use of international standards. Canada continues to believe that the definition of Critical Information Infrastructure is an open-ended, imprecise list of broad sectors, which does not permit operators to assess adequately whether their infrastructure is critical information infrastructure. In addition, Canada is of the opinion 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 shared detailed comments to China on these implementing measures in June 2019, and to date, Canada has not received any response. Does China intend to respond to Members' comments at some point? Canada continues to look forward to receiving a response from China. Furthermore, is China considering formally notifying the measure under the TBT Agreement? Any additional information that China is able to share with the Committee today would be most welcomed.

2.120. In response, the representative of [China](#) provided the following statement. In recent years, with the development of network information technology, more and more network products and services have entered into the key information infrastructure field to serve the operation. However, at the same time, some take the advantage of providing network products and services to obtain important data of users illegally, to control and interfere with the key information infrastructure operation, for non-technical or commercial reasons, to stop the supply of technology, products, and services, which brings great risks and challenges to national network security. In order to adapt to the present situation and safeguard the national network security, especially the supply chain security of key information infrastructure, the Cybersecurity Law clearly requires the establishment of a security review system. In April 2020, the relevant authorities issued Cybersecurity Review Measures, and the former Cybersecurity Review of Network Products and Services has been repealed at the same time. "Cybersecurity review measures" provide an important institutional guarantee to carry out the review. The establishment and implementation of network security review system are not to restrict or discriminate against foreign products and services. Opening up is China's fundamental national policy. As always, China welcomes foreign products and services to enter the Chinese market in compliance with the requirements of Chinese laws. In addition, China has always adopted a responsible attitude to actively promoting IPR protection. Business secrets, intellectual property rights and other undisclosed information are fully under protection in the process of review.

2.1.3.5 European Union - Amendments to the Directive 2009/28/EC, Renewable Energy Directive (ID 553²⁶)

2.121. 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 Council, which provides that, as from 2021, first-generation biofuels will 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) will 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 Article 2.1 and 2.2 of the WTO TBT Agreement. We therefore reaffirm the detailed arguments that have been presented at the TBT Committee

²⁶ For previous statements follow the thread under [ID 553](#) (under dates raised and references).

meetings concerning this matter, which appear in document [G/TBT/W/714](#) dated 2 March 2020. Colombia 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, and to review the use of other raw materials with a more severe negative impact than palm oil on deforestation. We have been asking the EU for a number of months to share information on the internal process to review the delegated act, with no response. In fact, we have learned that the Committee has already taken steps to hold consultations, in line with its internal procedures, but it has not informed the partners concerned about these or submitted the relevant notification to this Organization. We would like to take this opportunity to express our concern regarding the regulatory process followed by the European Union in this matter and the gaps in the logical process of promulgation of these regulations. In particular, we see that the Directive and its delegated act do not correlate with the stated policy objective of environmental protection, and even appear to offer perverse incentives that may lead to greater and worse deforestation and more greenhouse gas emissions. While we understand that some of these matters are being addressed under WTO dispute settlement procedures, we reiterate our request for information on the internal process to review standards, which has been undertaken without taking into account the comments submitted.

2.122. The representative of [Guatemala](#) provided the following statement. We thank Colombia for including this item on the agenda. The systemic concern regarding this measure has been noted and will be followed up accordingly.

2.123. 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 Directive is now subject to WTO dispute settlement proceedings, notably under DS593 (EU – Certain measures concerning palm oil and oil palm-based biofuels) as brought by Indonesia and DS600 (EU and certain Member States – Certain measures concerning palm oil and oil palm crop-based biofuels) as brought by Malaysia. In order to preserve the integrity of such proceedings, the European Union will defer all discussions to these fora and accordingly refrain from discussing this matter in this Committee.

2.1.3.6 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](#) (ID 575²⁷)

2.124. The representative of [China](#) provided the following statement. China thanks the EU for the reply in previous meetings, and after a study of the accompanying annexes, China suggests EU to delete or suspend the ban of halogenated flame retardants in D4 of Annex II. In EU's eco-design regulations and its accompanying annexes which closed public consultation in November of 2020, the above banning requirement is elaborated as: the determined value for such homogeneous material attributable to flame retardants shall not exceed, as 0.1% by weight of bromine, 0.1% by weight of fluorine, and 0.1% by weight of chlorine. These thresholds are not consistent with EU RoHS. The Eco-design sets the threshold value on some elements, while EU RoHS sets on specific flame retardants like PBB or PBDE. Plastics usually contain various additives, therefore not only flame retardants may contain halogens, some other additives may also contain halogens. Although it is stipulated that the thresholds are set for fluorine, bromine and chlorine attributable to flame retardants, in practice it is difficult to differentiate to which additives fluorine, bromine and chlorine are attributable. International Bromine Council (BSEF) recently released the Study on the Impacts of Brominated Flame Retardants on the Recycling of WEEE plastics in Europe by leading consultancy SOFIES. One of the key findings from the Study is: the presence of BFRs (Brominated Flame Retardants) in WEEE plastics does not reduce recycling yields than other FRs (Flame Retardants) in FR-containing plastics. In addition, plastics containing other additives in significant loads (e.g. fillers), are also sorted out in the conventional density-based recycling process. This research has shaken the basis of banning the halogenated flame retardants in e-displays in EU eco-design. China suggests that the EU re-evaluates the scientific nature of this term.

2.125. In response, the representative of the [European Union](#) provided the following statement. As explained at previous Committee meetings, 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,

²⁷ For previous statements follow the thread under [ID 575](#) (under dates raised and references).

establishing a framework for the setting of eco-design requirements for energy-related products. Energy-related products account for significant volumes of sales and trade in the Union, 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 their own measures with a higher level of environmental ambition. The proposed Eco-design requirement restricting the use of halogenated flame retardants 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.²⁸

2.1.3.7 Colombia - Food Prioritized for its Sodium Content, Certification Requirements G/TBT/N/COL/238, G/TBT/N/COL/238/Add.1, G/TBT/N/COL/238/Add.2 (ID 609)²⁹

2.126. The representative of Costa Rica provided the following statement. Costa Rica reiterates its 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 firmly believes in implementing strategies aimed at protecting public health by reducing the underlying factors of arterial hypertension and related non-communicable diseases. However, it is concerning that the proposed maximum sodium levels for the selected products are not substantiated by scientific evidence. Costa Rica also does not consider them to be 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. We would be grateful if the delegation of Colombia could provide us with information on the status of this Regulation and the possible date for its entry into force.

2.127. The representative of the European Union provided the following statement. The European Union would like to thank Colombia for the clarifications provided with regard to this notification. The European Union would like to reiterate 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. The European Union would like to ask for further clarifications with regard to Article 8 of the Resolution No. 2013 of 2020, adopted on 7 November 2020. First, the European Union does not require mandatory third party certificates for sodium content. Could Colombia confirm that certificates issued by conformity assessment bodies established in the EU would be accepted under the point 8.2, as the reciprocity requirement is not relevant in such situation? Second, the EU invites Colombia to clarify the meaning of the last paragraph of Article 8. Does it mean that until a first conformity assessment body is accredited in Colombia to issue certificates according to this regulation, a first-party declaration of conformity will be accepted? Finally, the European Union would like to invite Colombia to provide timely guidance to food manufacturers and importers to help them prepare for the implementation of the new technical regulation.

2.128. 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 recognizes the legitimate objective of the Colombian authorities to ensure human health, and the efforts made to reduce hypertension, and, in accordance with the technical regulations notified, to establish a maximum sodium content for certain processed foods. A revision was made to the Technical Regulation approved by Resolution No. 2013 of 2020 notified in document [G/TBT/N/COL/238/Add.2](#) of 22 January 2021, which advised of the adoption of the Regulation on 9 November 2020. The Resolution states that, in order for a product to be put into circulation or imported, a third-party certificate of conformity must be obtained from an accredited entity to demonstrate compliance with regulatory requirements, which we

²⁸ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52019SC0354>

²⁹ For previous statements follow the thread under [ID 609](#).

continue to consider as an unnecessary barrier to international trade. Guatemala therefore requests the Government of Colombia to consider first-party conformity assessments.

2.129. In response, the representative of Colombia provided the following statement. We thank the EU for the advance submission of the questions and comments on this STC, and Costa Rica and Guatemala for their statements. It is a matter on which Colombia has been in constant dialogue with all WTO Members that have submitted comments. Regarding the question on whether certificates issued by conformity assessment bodies established in the EU would be accepted under item 8.2, the answer is yes, provided that they belong to the International Accreditation Forum's (IAF) mutual recognition agreements (MRAs). For example, the certification bodies of the European co-operation for Accreditation (EA) are part of these agreements and would therefore be accepted. With respect to the second point mentioned, the reply is also yes, the first-party certificates will be accepted for up to 24 months after a certification body is accredited in Colombia. Currently, the country does not have certification bodies accredited with the scope of this technical regulation. However, this information can be viewed via the link below.³⁰ Lastly, on Colombia's side, the TBT contact point and the Ministry of Health and Social Welfare will provide all the necessary guidance and information for the implementation of the technical regulation.

2.1.3.8 Russian Federation - Law No. 425 - on Amending Article 4 of Russian Federation Law "On Protecting Consumer Rights" (ID 612³¹)

2.130. 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. Our understanding is that the current implementation deadline is 1 April 2021. While this deadline is quickly approaching, many concerns and questions remain. We presented our concerns to Russia in writing in March 2020 and raised them again during the 2020 meetings of the TBT Committee, but Russia has not yet provided an adequate response. Russia has continually 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 technically complex goods 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.

2.131. 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 technically complex goods targeted by this technical regulation already feature software from Russian developers and include app platforms which encourage participation by Russian companies. We ask Russia to provide evidence that Russian developers are being denied access to develop software for technically complex goods. We also ask Russia to explain how the requirement is not more trade restrictive than necessary and does not create unnecessary obstacles to trade. 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 delay implementation of the measure until such written comments and the results of such discussions may be taken into account. Finally, we request that Russia provide a reasonable period of at least six months between publication of any amended regulation and its entry into force.

2.132. 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", which mandates pre-installation of Russian software. These include mainly certain discriminatory aspects as well as the questionable proportionality of the measure. Moreover, we call on Russia to comply with its WTO transparency 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.

³⁰ <https://onac.org.co/directorio-de-acreditados>

³¹ For previous statements follow the thread under [ID 612](#) (under dates raised and references).

2.133. 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.

2.134. In response, the representative of the Russian Federation provided the following statement. Russia is convinced that this measure cannot be considered as the technical regulation under Annex 1 of the Agreement on Technical Barriers to Trade and reiterates its statements made at the previous meetings of the Committee on TBT. Also, we would like to inform Members that the measure enters into force on 1 April 2021 instead of earlier proposed date of 1 June 2020. The decision on postponement of the date of entry into force of this Law was made, *inter alia*, at the request of foreign stakeholders. We consider this period as sufficient for such stakeholders to adapt to this legislation.

2.1.3.9 Bangladesh - Hazardous Waste (E-waste) Management Rules, 2019, [G/TBT/N/BGD/3](#), [G/TBT/N/BGD/3/Add.1](#) (ID 620³²)

2.135. The representative of the United States provided the following statement. The United States again acknowledges that Bangladesh notified the Hazardous Waste (E-waste) Management Rules, 2019, including a summary, excerpted translation of two clauses, and a threshold limits schedule for the management of electronic waste products. However, because Bangladesh did not notify the entire text of the proposed E-waste rules, stakeholders cannot fully evaluate the changes from previous versions. We again ask that Bangladesh submit the full text of the measure to the WTO TBT Committee, provide a public comment period of at least 60 days, and take such comments into account before finalizing the measure. Can Bangladesh provide an update on the implementation status of the draft E-waste rules? The United States is concerned that by restricting 15 substances and broad categories of substances, the draft rules may disrupt or prevent the sale of many important electrical and electronic goods in Bangladesh, including certain medical devices, liquid crystals for liquid crystal displays, and PVC parts for washing machines. Given the broad definition of some of the restricted categories, such as "copper beryllium alloys," the draft rules may disrupt the supply of cellular telephones. The draft rules also appear to lack provisions for the use of certain restricted substances where there are no substitutes, such as lead shielding for X-ray equipment.

2.136. Additionally, the proposed rules appear to ban the import of used or refurbished electrical and electronic equipment. The proposed rules do not indicate whether industry will be able to import refurbished and repaired electrical and electronic equipment, a practice which could extend the operational life of millions of dollars of valuable equipment. In view of the potential disruption this measure may have on the sale of many important electrical and electronic goods in Bangladesh, has the Ministry of Environment, Forest and Climate Change consulted with other relevant Bangladeshi ministries, such as the Ministry of Health and Family Welfare and the Ministry of Commerce, to ensure that the rules accomplish the intended regulatory objectives without creating unnecessary obstacles to trade?

2.137. The representative of the Russian Federation provided the following statement. The Russian Federation reiterates its statements made during the previous regular meetings of the TBT Committee regarding the draft Hazardous Waste Management Rules of Bangladesh notified in documents [G/TBT/N/BGD/3](#) and [G/TBT/N/BGD/3/Add.1](#). The draft rules establish a list of "hazardous" substances restricted for use in enlisted categories of electrical and electronic products. However, the document does not provide any explanation as to what criteria have been used to identify hazardous substances and the reasons to set specific levels for each substance. Some substances, like nickel, should not be classified as hazardous in this regulation and should not be subject to any restrictions, as there is no scientific, including laboratory and epidemiological, justifications for this. Russia sent detailed comments on the draft rules to the Bangladesh TBT enquiry point on 10 March 2020 and we still expect substantive feedback on these comments. Russia

³² For previous statements follow the thread under [ID 620](#).

encourages Bangladesh to share with the Committee information on the developments in the drafting of the Hazardous Waste (E-waste) Management Rules.

2.138. The representative of the Republic of Korea provided the following statement. Korea would like to make some comments regarding this regulation as follow. Korea highly regards the efforts of the Bangladesh and competent authorities to introduce electronic waste management rules for protecting the environment and managing recycling resources. Furthermore, Korean companies are committed to fully comply with the rules of Bangladesh. However, as Korean companies have raised the following concerns regarding the proposed rules of Bangladesh, we would like to request that Bangladesh take into consideration these concerns and take appropriate actions. We would also like to emphasize that the same comments were made at the 3rd WTO TBT Committee Meeting in 2020, but there has been no response since then. First, no specific enforcement date has been provided for these proposed rules. Although their enforcement date has been stipulated as 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 regulation and their entry into force, and we ask Bangladesh if there is any information regarding the specific date of enforcement.

2.139. 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 stipulated 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 to the total amount of the hazardous substances.

2.140. 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. To that end, Canada would refer to its previous statements on this STC, and ask if Bangladesh is now in a position to share new information and additional supportive documentation on the draft Management Rules, including timelines for consultations on the full regulatory text. Canada notes that the proposed date for entry into force of the rules, as identified in Bangladesh notification, referred to the year 2020. Now that we are in 2021, could Bangladesh provide any indication regarding the timeframe for the implementation of the rules, and that it will take place at least six months after final publication of the rules?

2.141. 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.

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

2.1.3.10 India - Draft Chemicals (Management and Safety) Rules, 2020 (ID 622³³)

2.143. The representative of the United States provided the following statement. We refer to previous statements on this measure and continue to have concerns.

2.144. The representative of Canada provided the following statement. Canada would like to refer to its previous statement from the October 2020 TBT Committee meeting.³⁴ Canada remains concerned that, despite numerous requests, India has yet to notify this measure to the TBT Committee. Can India provide an update on when it expects to formally notify the measure and

³³ For previous statements follow the thread under [ID 622](#).

³⁴ [G/TBT/M/82](#), paras 2.192 and 2.193.

allow WTO Members and stakeholders an appropriate period for comments, as per India's obligations under the TBT Agreement?

2.145. The representative of Japan provided the following statement. Japan would like to request India to clarify the timeline for notification of India's Draft Chemicals (Management and Safety) Rules to the WTO TBT Committee. Japanese industry has concerns on the Draft Chemical Rules due to its potential to strongly influence export and sales in India. Japan would like to request India to ensure enough time for comment after notification and to consider opinions from all stakeholders.

2.146. In response, the representative of India provided the following statement. The Draft Chemicals (Management and Safety) Rules 2020 has been circulated among the industry associations. Extensive stakeholder consultation is being done to finalize the draft before putting it up on the WTO TBT website with a reasonable comment period.

2.1.3.11 Australia - Maturation requirements for imported alcohol (ID 636³⁵)

2.147. 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 that are currently in force are more trade-restrictive than necessary to protect such legitimate objectives. The Australian Customs Notice N° 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. 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 2 years in wood. Such a requirement does not relate to any quality standard or sanitary requirement applicable to cachaça.

2.148. Following a public consultation in late-2019, the Australian Border Force (ABF) further explored 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. We support the creation of a list of exceptions to the rules set out today in section 105A, thus allowing certain cultural and geographical indications (i.e. Cachaça) that are not traditionally described as brandy, whiskey or rum to be imported into the Australian market. In order to avoid any confusion in the Australian market or among Australian consumers, we support that none of the sugar-cane products imported to Australia (matured or unmatured) that are not specifically "rum" should be labelled or marked as "rum". In previous interventions regarding this STC, Australia has failed to provide clarification on a few points: 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? Could Australia indicate why it has not notified said public consultations to the TBT Committee? 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.

2.149. 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 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. These requirements are applied through the Excise Act 1901 and Customs Act 1901 (Customs Act) respectively. Australia is continuing to review its legislative framework for the importation of

³⁵ For previous statements follow the thread under [ID 636](#).

unmatured alcohol products under section 105A of the Customs Act. The review process is considering potential pathways to enter unmaturing spirits without undermining Australia's consistent approach to maturation requirements. In November 2020, the Australian Government undertook a stakeholder consultation, through the release of a consultation paper, to seek views on a refined proposed approach to amend section 105A of the Customs Act. The consultation paper was sent directly to the participants of the previous consultation sessions, including the Brazilian Embassy in Canberra and is available on the Department of Home Affairs Website.³⁶ The Government will consider potential reforms following the outcome of this consultation. Any proposed changes will be notified to the Committee in accordance with our obligations under the TBT Agreement. Australia acknowledges Brazil's engagement on the review of Australia's maturation requirements for alcohol. Representatives from the Brazilian Embassy participated in both the 2019 and 2020 consultation processes, led by the ABF. The ABF is taking the issues raised by Brazil into consideration as part of the reform process.

2.1.3.12 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](#) (ID 643³⁷)

2.150. 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 comments on the draft GCC Technical Regulation on Halal Feedstuff and refers 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 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 a condition would require a significant alteration to the feeding regime for food-producing animals in the EU and would negatively affect EU exports. The EU would also like to enquire about the timeline for adoption and implementation of the draft including the grace period that would be applied. The European Union remains available to discuss this issue.

2.151. The representative of the United States provided the following statement. The US supports the statement made by the EU.

2.152. In response, the representative of the Kingdom of Bahrain provided the following statement. I deliver this statement on behalf of the member states of the Gulf Cooperation Council. We would like to thank the United States and the European Union for their valuable comments, which have been sent to their respective TBT Enquiry Points, and is pleased to clarify the following. The draft regulation "Halal Feedstuff" covers the requirements to be followed in the production, preparation, handling, transport and storage of Halal feed for food-producing animals. This draft regulation is under review at GSO level and it is not intended to result in trade restrictions. It is rather based on Islamic laws and covers the Halal requirements which must be abided by during the production of feed for food-producing animals. In regard to meat products, please refer to GSO-993:2015 (Animal Slaughtering Requirements According to Islamic Rules), which stipulates that "animals should be fed forages from Halal sources" as a requirement for slaughtered animals. The GCC member states would like to invite interested Members to discuss this matter bilaterally.

2.1.3.13 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](#) (ID 649³⁸)

2.153. The representative of the European Union provided the following statement. India has adopted a number of measures in the automotive sector that raise important concerns across the EU industry. These Quality Control Orders in the automotive sector regard mandatory markings for wheel rims, new standards for safety glass, and BIS compulsory certification for helmets for two wheeler riders. All three notifications from India foresaw only 30 days for comments. The EU recalls

³⁶ www.homeaffairs.gov.au/reports-and-publications/submissions-and-discussion-papers

³⁷ For previous statements follow the thread under [ID 643](#).

³⁸ For previous statements follow the thread under [ID 649](#).

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. The EU would like to underline that all measures in question have protectionist orientation and are sending very worrying signals to EU industry, 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.

2.154. As regards the wheel rims, the draft Quality Control Order (QCO) issued by the Department of Heavy Industries (DHI) would make mandatory ISI marking on all automotive wheel rims. It is important to highlight that substantively the Quality Control Order is very similar to established international standards with which all EU exports already comply, the main element introduced by the Order being the ISI mark. The QCO therefore will generate important additional costs for European automotive manufacturers while the qualitative reasons for the introduction of such a measure are not evident. The EU would therefore like to ask India to reconsider the introduction of this QCO. Furthermore, the EU would like to stress 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. The EU would like to suggest to India to keep the BIS marking as optional for components, which are already in compliance with the current marking requirements.

2.155. The European Union appreciates the decision to postpone the introduction of the mandatory Indian Standards Institution (ISI) marking for automotive Safety Glasses to April 2021. According to the new Quality Control Order, automotive glass not mounted in vehicles (loose or spare parts) sold in India will have to obtain a new national licence and marking. Despite the delay of the entry into force, the European companies face important difficulties to prepare for the new certification system due to extraneous factors related to the pandemic that are not within their control. In order to obtain the ISI marking, the Quality Control Order mandates an in-person audit by auditors from BIS on the basis of a rather cumbersome application process requiring local presence. EU companies have nonetheless complied and made the necessary applications, however the prohibition to travel from and to India due to the COVID-19 restrictions makes physical audits difficult to envisage in the coming months. EU companies require a timeline of 4 months from the completion of the audit to ensure the certified product on the factory floor. Taking into account the time required for retooling, production and shipping, an entry into force on 1 April 2021 implies that rapidly, imports of safety glass will come to standstill with important economic impact on auto production plants.

2.156. While acknowledging the purpose of Bureau of Indian Standards (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 is difficult for EU companies to comply with the new requirements within the deadlines set by the Quality Control Order. Furthermore, the new requirements generate additional costs to EU automotive glass manufacturers, as they would require complex procedures such as audits, tooling changes, etc., without clear qualitative improvements. In this light, the European Union would like to ask India to reconsider the implementation of the Quality Control Order. The European Union would like to request India to at least 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. Finally, the EU would urge India to consider virtual audits or audits by recognised third party certification experts in the location of the manufacturing plants. The Quality Control Order on Protective Helmets for Two Wheeler Riders is now set to come into force on 1 June 2021. The EU welcomes this delay in its implementation. 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 disproportionate and cause obstacles to trade. The European Union would very much appreciate if India could reconsider the mandatory introduction of Quality Control Orders on the wheel rims, automotive safety glass, and helmets.

2.157. In response, the representative of [India](#) provided the following statement. *Safety Glass*. The QCO on Safety Glass was issued on 12 March 2020 with its implementation date of 16 September

2020. Further, it was extended for implementation with effect from 1 April 2021. The QCO has been amended on 18 September 2020, which 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 are not covered under QCO of safety glass. *Wheel Rims*. The testing and certification system in India is in line with the global regime. The component certification is an important 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. Unlike in European Union, where the wheel rim is not identified as a separate safety-critical component in UNECE, in India, the wheel rim is identified as one under CMVR. This has been warranted keeping in view the local road infrastructure, variety of tyres used and driving behaviour in India. Wheel rim is a critical part of influencing driving safety. These Indian standards have been prepared to ensure the quality, reliability and consistency required, keeping in view human safety and consumer protection. These standards prescribe the general and performance requirements of wheel rims intended for use on two, three, and four-wheeled motor vehicles. The Quality Control Order (automotive wheel rims) is non-discriminatory in nature, both at the original fitment level of automobiles as well as in the after-sales/repair service, to ensure supply of only quality product in the Indian market duly certified and approved by Indian implementing agency. The QCO also provides for market surveillance in order to check entry of sub-standard product into the Indian market. This was necessitated to protect human life and consumer interest. The Quality Control Order 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.

2.158. *Helmets QCO*. India is the largest two-wheelers 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 1.5 lakhs per year, are the highest in the world, which is about 11% of the total global road accident fatalities. And further, the deaths involving two-wheelers are a significant number, and further fatalities without helmets or helmets of low quality are also very high. The Government and the Apex Court, i.e, 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 helmets' maximum weight so that people should use helmets and BIS had issued the notification in this regard which prescribed for the max weight of helmets to 1200 from earlier 1500 grammes. But due to the demand from the foreign helmet importers, the cap on weight from 1200 was extended to 1500 grammes. Now there is a proposal for including helmets in the compulsory certification regime. This will ensure that the helmets are manufactured or imported only with the specifications of BIS standard and would ensure good quality helmets, ensuring proper protection and reducing fatalities. The BIS provides for a mechanism for the foreign manufacturers to obtain BIS certification, which enables them to sell in India. Considering India's road safety scenario as above, which is quite different from any European countries, the requirements for certified helmets are a high priority.

2.1.3.14 China - Encryption Law of the People's Republic of China by the Office of State Commercial Cryptography Administration (OSCCA) (ID 534³⁹)

2.159. 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 recognise 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 State Cryptography Administration (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. The EU urges China to guarantee the possibility for foreign-invested enterprises (FIEs) to participate on an equal footing with domestic companies in the production, research, development and sale of cryptography products on its market.

2.160. The representative of the United States provided the following statement. The US continues to be concerned, and supports the statements of the EU and Japan.

³⁹ For previous statements follow the thread under [ID 534](#).

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

2.162. 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. China encourages technical cooperation in commercial cryptography 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.

2.1.3.15 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](#), [G/TBT/N/CHN/1515](#) (ID 576⁴⁰)

2.163. The representative of the United States provided the following statement. The United States recognizes that although China's Cosmetics Supervision Administration Regulation (CSAR) entered into force in January, its implementing measures are not yet finalized. We ask that China work with the United States and other WTO Members to address outstanding concerns before these implementing measures are finalized, so as to provide certainty to the industry and US companies in future trade with China. The United States emphasizes that it is inappropriate to apply a similar regulatory approach to cosmetics as is applied to medical devices or drugs because cosmetics are considered low-risk products. This has resulted in an overly burdensome application process that does not provide adequate protections for the intellectual property of cosmetics rightsholders and mandates animal testing, even when alternatives exist. As we noted in an earlier intervention on the newest implementing measures of the CSAR, the United States notes the new language on intellectual property (IP) protections in Article 55 of the Administrative Measures (1454), stating that the National Medical Products Administration (NMPA) shall not, with some exceptions, disclose confidential business information (CBI) or trade secrets submitted by a registration applicant or a notification applicant. We ask that China please confirm that this provision also applies to information submitted by local agents in accordance with Article 8. Has China offered or developed specific standard operating procedures or explicit steps to ensure the protections for CBI that can be tracked and are legally enforceable within China? NMPA's requirement in Article 8 of the Administrative Measures that importers use local agents to file their application increases the risk of unauthorized disclosures. NMPA should re-consider whether its extensive disclosure requirements are necessary.

2.164. We thank China for its response to US comments on [G/TBT/N/CHN/1453](#) and [G/TBT/N/CHN/1454](#) and ask that China consider the comments we sent back. We, as well as other WTO Members, continue to urge that China does not require cosmetics rightsholders to publicly disclose the proprietary study designs, protocols, data and analysis used to verify their product claims. We are also concerned that China is requiring companies to provide animal testing to establish conformity for imported products that cannot provide a regulator-issued good manufacturing practices (GMP) certificate. Trade associations and other third parties issue certificates of compliance with international cosmetics GMP standards, which are widely referenced by other WTO Members in their GMP requirements, and which do not require animal testing. If China will not accept these certificates, we ask that China explain why these international standards are inappropriate for the fulfilment of China's regulatory goals. NMPA should consider how its requirements in the Classification Rules and Catalogue of Cosmetics (1460) may impact innovations in new products and ingredients, if NMPA limits the means by which companies can verify their claims. Companies should be provided flexibility in claims verification and the use of international labs that follow Good Clinical or Good Laboratory Practices, so long as they can provide, as needed, the verification information requested by Chinese regulatory authorities. Further in China's draft Administrative Measures on Cosmetics Labeling (1515), the United States is concerned that the proposed regulation regarding foreign language text and misleading use of trademarks or suggestive

⁴⁰ For previous statements follow the thread under [ID 576](#).

words, graphics or symbols, is overly burdensome. We appreciate China's most recent notifications of CSAR implementing measures and request that China continue to notify all CSAR implementing measures and standards with a minimum of 60 days for comment, and that China take these comments into account before final versions are adopted.

2.165. The representative of [Australia](#) provided the following statement. Over several years Australia has raised concerns about China's measures requiring mandatory testing on animals before registering imported cosmetics for sale in China. This measure discriminates in favour of Chinese products which are not required to undertake mandatory animal testing. It is also more trade restrictive than necessary given that general cosmetics are low-risk products, and that there are other internationally recognised methods of ensuring that skincare products are safe. The animal testing measure has had a major impact on Australian cosmetics exporters, effectively preventing them from entering and competing in the Chinese market. We had hoped that the CSAR and its related implementing regulations would result in the complete removal of China's animal testing measure and replace it with less trade-restrictive appropriate measures. However, exporters are still concerned that China's new cosmetics regulations will result in further trade barriers. It appears that the animal testing requirement for imported general cosmetics will be effectively retained for those countries where Good Manufacturing Practice (GMP) is not certified by the cosmetics regulator of the exporting country. It also appears that mandatory animal testing will continue to be a requirement for all cosmetics classified by China as special use.

2.166. Because many countries (including Australia) consider general use cosmetics to be low-risk products, they do not require GMP certification of these products. Could China please explain why it would require GMP certification for low-risk skincare and cosmetics products? Further, assuming that GMP certification is required in the final regulations, could China please advise why it would need this certification to be provided by a government regulator, rather than an industry organisation or private provider that could certify in accordance with international practices and standards? Australia would also like to understand why China considers animal testing and GMP certification to provide equivalent levels of safety assurance for Chinese consumers. Australia understands that China intended for the CSAR to enter into force on 21 January 2021. Could China please advise whether there have been any issues with implementing the CSAR given that many of the implementing regulations are still in draft form? Australia would also welcome any details from China on when it expects to revise and finalise these draft regulations and whether it intends to release any further draft cosmetics regulations. The Australian Government has previously submitted written comments on China's Cosmetics Supervision and Administration Regulation (CSAR) and its various implementing regulations. We would welcome a response from China on how these comments have been taken into account by the Chinese Government and an opportunity to discuss the comments bilaterally.

2.167. The representative of the [Republic of Korea](#) provided the following statement. Korea would like to support the delegation of the United States. With regard to the notifications [G/TBT/N/CHN/1310](#) and [G/TBT/CHN/1331](#), Korea has found that many provisions in the regulations include same obstacles to trade which were already indicated in other cosmetics regulations of China. Korea wishes to reiterate concerns as follows. Two among the following concerns are the same as what we raised in STC 1.⁴¹ First, Korea requests China that the labelling of cosmetic ingredients be consistent with international practices. Second, under the Regulations, China requires the disclosure of the summary of scientific evidence that supports cosmetic efficacy claims on the websites designated by the NMPA. However, the information China claims to be minimal may contain a number of trade secrets or undisclosed business information that are critical to our industry. Korea therefore urges China to remove the provisions requiring the disclosure of information. Third, Korea would like to request China to accept the test results by laboratories outside China that comply with Good Clinical Practice (GCP) or Good Laboratory Practice (GLP) in applying for cosmetic registration in China. Fourth, given that the licence issued by most of the countries including Korea, the U.S., and European states do not have a determined validity period, Korea requests China to provide the rationale or justification for setting the validity periods of the license for special use cosmetics. Korea would like to kindly ask China to notify all of its next steps in the development of the Regulations and to provide time frames for the publication of the final Regulations and their entry into force. We also call on China to grant a reasonable transitional period for the industry to prepare to comply with

⁴¹ China - CSAR - Draft Specifications for Cosmetic Registration and Filings; Draft Specifications for Registration and Filing of New Cosmetics Ingredients; Draft Specifications for Cosmetic Efficacy Claim Evaluation, Provisions for the Supervision and Administration of Toothpaste ([ID 665](#)).

the new requirements according to Article 2.12 of the TBT Agreement. Considering the aforementioned concerns, Korea would like to refer to our previous comments submitted to China's Enquiry Point for TBT. Korea calls on China to consider the comments from Korea and other Members into revision, and to notify the finalization of the revision to the TBT Committee.

2.168. The representative of Japan provided the following statement. With respect to "Cosmetics Supervision and Administration Regulation" and its implementing regulations, Japan continues to express the following concerns. The "Cosmetics Supervision and Administration Regulation" provides that the registration or filing information on cosmetic products or new ingredients shall be published. The regulation also provides that the abstract of scientific basis of efficacy claims shall be published online and accept social supervision. Therefore, 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. Japan appreciates China's reflection that article 55 of "Provisions for Cosmetics Registration", which was promulgated on 7 January 2021, provides that confidential information for companies or unpublished information must not be published. Japan would like to request that "Cosmetics Supervision and Administration Regulation" and its other implementing regulations provide the same rule. In addition, in case that disclosure of such specified confidential information is exceptionally necessary, registrants or filers should be given the opportunity to consult with the NMPA in advance. Furthermore, Japan would like to request that China clarify that the abstract of scientific basis of efficacy claims should be disclosed by the time of launch of products in the market.

2.169. "Management Rules for Testing required for Cosmetic Product Registration and Notification", which was promulgated on 12 September 2019, provides that microbiological, physical and chemical tests, toxicological tests and human safety and efficacy evaluation tests relevant to cosmetics registration and filing shall be conducted by the testing laboratories in China that obtained China Inspection Body and Laboratory Mandatory Approval (CMA). Japan would like to request a more flexible framework in which test results obtained by foreign laboratories with the equivalent qualifications and abilities as those of Chinese testing laboratories are accepted. In addition, regarding test methods, the implementing regulations of the "Cosmetics Supervision and Administration Regulation" provides that test methods including test items other than those stated above, should be conducted in accordance with China's national standard or relevant regulations, and that various restrictions and conditions are imposed in the case of conducting a test method which is not specified in the regulations. Japan would like to request that China accept internationally accepted methods such as alternative test methods established by the OECD, or the ISO. Furthermore, China has not finalized 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. The sales certification that proves the products have been sold on the market in the country of production is only imposed on imported cosmetics. Japan requests that China treat imported products no less favourable than products produced in China.

2.170. In addition, regarding China's draft of the "Administrative Measures on Cosmetic Labeling", Japan appreciates that China provided the opportunity to give comments to WTO/TBT notification. As Japan has noted in the comment to WTO/TBT notification, Japan would like to express its following four 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 that China assure 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. Regarding Article 6. In order to avoid confusion among consumers, Japan would like to ask China that the label indicates a single responsible person ("cosmetics registrants or filers" or in the case of imported products, "responsible person in China"), and Japan considers that the label requirements regarding producers are 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 be listed in no particular order. However, Article 12 provides that only ingredients with a compounding amount of 0.1% or less are allowed to be listed in no particular order. Japan would like to request that China assure that the rules for labelling follow the internationally recognized practice so as not to be more trade restrictive than necessary.

2.171. 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. However, "Specifications for Cosmetic Efficacy Claim Evaluation (Draft for Comments)", which was notified to the TBT Committee on 18 November 2020, provides that all efficacy should be confirmed by appropriate test methods. Japan would like to make a request that permits the indication of "evaluated and verified efficacy" on the efficacy that is confirmed by appropriate test methods according to the "Specifications for Cosmetic Efficacy Claim Evaluation (Draft for Comments)", not limited to the one confirmed by the qualified testing laboratory in China. Furthermore, "Provisions for Cosmetics Registration", which was promulgated on 7 January 2021, Japan continues to express the following concerns. Japan would like to request that it is not necessary to cancel original registration or filing if changes are not related to product safety, for example if a change is only related to a product's name. Moreover, the "Provisions for Cosmetics Registration" provides that overseas inspections are to be conducted in accordance with relevant regulation of overseas inspections. Regarding "Interim Measures on the Administration of Overseas Inspections of Cosmetics", Japan would like to continue to express concerns on the following three points.

2.172. Japan would like to request that China clarify which laws and regulations are used 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 subject of the inspection including the product research and development stage is broader than necessary, and it causes unnecessary burdens for companies. The main purpose of the inspection seems to ensure product safety but information related to research and development is not necessarily essential for product safety assurance. It is the most confidential corporate information. Therefore, R&D departments of companies should be excluded from the subject of overseas inspections. Furthermore, inspections for domestic Chinese companies are only conducted on production sites. Japan would like to request that China provides equal treatment to both domestic and overseas companies. Japan requests that China ensures that confidential information will not be disclosed to anyone other than those who are necessary for the legitimate purpose of the inspection, since production sites also contain a lot of confidential corporate information. Finally, as the "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 provides 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 that have already been registered and filed based on current regulations are not subject to measures under the new regulations.

2.173. The representative of New Zealand provided the following statement. New Zealand again welcomes China's undertaking to modernise its regulatory system for cosmetics and again welcomes the opportunity to provide further comments on China's proposed measures. In addition to comments previously made under agenda item 1 at this Committee and also during the October 2020 TBT Committee, New Zealand also holds concerns, that we understand are shared by a number of Members, around the issue of having more detailed disclosure of formulas than is required in other markets, including specific sources of each ingredient. New Zealand encourages China to limit disclosure requirements, particularly that of sensitive information, to that which is required to assure product safety in China's domestic market and so as not to compromise intellectual property. New Zealand looks forward to engaging further with China on its proposed CSAR measures. This will enable New Zealand and other WTO Members to assess in greater detail the potential impact on trade of these measures.

2.174. The representative of the European Union provided the following statement. The EU would like to support the delegations of Japan, Korea, the United States, Australia and New Zealand. 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 fully achieve 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 cosmetics. 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. 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.

2.175. In most countries, including the EU, companies manufacturing cosmetic products are obliged to follow Good Manufacturing Practices (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 organisation 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.

2.176. In response, the representative of China provided the following statement. We would like to clarify the following points. Regarding the protection of trade secrets in the registration and filing materials. As cosmetics are health-related products, materials such 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 the 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 for 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 imported and domestic ordinary products are required to hold production licences or documents of good manufacturing practice issued by government supervision departments.

2.1.3.16 European Union - Transitional periods for MRLs and international consultations (ID 580⁴²)

2.177. 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, Indonesia, Brazil and Guatemala, 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. It is impossible for agricultural production in Costa Rica 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. This relates to the European Union's process to revise the tolerances for different substances used in agricultural production. In the current historical context in which the international community

⁴² For previous statements follow the thread under [ID 580](#).

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.

2.178. The representative of the United States provided the following statement. We continue to raise our concern about the European Union's (EU) transition measures and request adequate time for US and third-country producers to modify their pest management programmes to move their products through the channels of trade, including shelf stable products with years long shelf lives. We recall longstanding concerns that trading partners do not know with certainty the impact of non-renewal decisions on future MRLs even when they are published as both TBT and SPS notifications. Applications for import tolerances remain active and the review of additional data are often considered after a non-renewal notice has been issued. Foreign growers cannot make informed decisions on their food production practices until the MRL is notified and then typically only a six-month compliance period is extended. Trading partners have found themselves racing to move shipments through customs fast enough to prevent rejections or turning back orders because a product that complies with an existing EU MRL standard at the time of production will face rejection at EU borders. EU growers do not face these restrictive timelines under the current regulatory provisions. Once again, the United States reiterates our request that the EU retain existing MRL levels while Import Tolerances are under consideration, conduct full risk assessments prior to setting new MRLs, and extend its MRL transitional measures to account for realistic production and processing times for food and agricultural products. The United States requests imported products' MRLs to be considered on the EU market at the time of production, the same as for European products.

2.179. The representative of Colombia provided the following statement. Colombia reiterates 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 producing 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 for the entry into force of standards that do not allow for the marketing of certain plant protection products and the subsequent reduction of MRLs is a matter of 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. Moreover, the situation arising from the COVID-19 global health emergency has forced the health and scientific authorities of all countries, including Colombia, to focus attention on that crisis. In line with the statements made in communication [G/TBT/GEN/296/Rev.3](#), 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.

2.180. Furthermore, Colombia maintains that notification to the WTO of non-renewal or on MRLs to be applied, and of transition periods, should not be made by the EU as a simple formality within the regulatory process. As provided in Articles 2.9.2 and 2.9.4, the notification must be submitted within a time limit that allows Members concerned to submit substantive observations and comments for genuine consideration by whoever is developing the technical regulation, in this case the Committee. 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 must first be notified to the WTO and the public consultation period held. Nor is it acceptable for the EU to publish the final regulation the day immediately after the end of the international consultation period, as this shows

that the comments submitted have not been taken into account. We invite the EU to follow the recommendations of good regulatory practices, under which standards must be based on clear and objective information and on the promotion of open dialogue with stakeholders, transparency and the minimizing of market distortions. In accordance with the provisions of Articles 2.5 and 2.12 of the TBT Agreement, Colombia considers that there should be technical discussions, which take into consideration the arguments and technical, scientific and economic evidence submitted by the Members concerned, in order to review the time limits for bringing into force the regulatory changes to MRLs, so as 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.

2.181. The representative of Brazil provided the following statement. Brazil supports the concerns raised by the US, Colombia and Costa Rica, and we would like to refer to its 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 that the EU provides adequate transitional periods, 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". Transitional periods should also be compatible with the production processes, so as to allow producers – and especially small farmers – to adapt to the new regulations.

2.182. 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. Canada seeks confirmation from the EU that transition periods will provide sufficient time for producers and exporters to adapt to the new requirements and allow for trade to continue uninterrupted, where the risks of dietary exposure are acceptable. In our view, the sudden deletion of MRLs and import tolerances is disproportionate to the level of risk and more trade-restrictive than necessary. At a time when ensuring food security is paramount, we urge the EU to 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.

2.183. The representative of Guatemala provided the following statement. Guatemala reiterates its concern about 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 European Union, in that we do not have a harsh winter to help control pests. Geographical location, namely, the distance and time needed to export a product to the European Union, is another factor that should be taken into consideration to avoid applying measures that unnecessarily restrict trade.

2.184. The representative of Paraguay provided the following statement. Paraguay wishes to reiterate its deep concern regarding this measure and refers to its statements made at previous meetings. 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. There is a need to consider 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. The European approach to limit the use of pesticides is more trade-restrictive than necessary to fulfil its legitimate objectives under the TBT Agreement. We stress that the pursuance of such policies will cause significant trade damage to the economies of developing countries and jeopardize their ability to achieve the 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.

2.185. The representative of El Salvador provided the following statement. El Salvador thanks the delegations of Costa Rica, the United States of America and Colombia for bringing this concern to the attention of Committee members once again. 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.

2.186. The representative of Chile provided the following statement. As in previous committees, and like other delegations that have taken the floor before me, Chile wishes to echo the trade concern raised concerning the implementation of maximum residue levels set for various agricultural products by the European Union, as well as their implementation periods and periods of validity. We will continue to monitor developments in this committee and other relevant committees.

2.187. The representative of Panama provided the following statement. The delegation of Panama echoes the comments made by all the delegations that spoke before me on the new maximum residue limit tolerances established by the European Union. These concerns have already been discussed at length, so, in the spirit of brevity, we reiterate the statements that we made in the past in this regard.

2.188. The representative of Ecuador provided the following statement. Ecuador thanks Colombia, Costa Rica and the United States for including this item on the agenda and we echo our previous statements on this specific trade concern. In order to establish reasonable transition periods, several factors must be taken into account, such as harvest times and when agrochemicals are applied. The transition periods granted by the EU fail to provide sufficient time for producers to adapt so as to prevent their access to the European market from being unnecessarily affected. It is important to note that the impact of the non-renewal decision on future MRLs is unknown, and foreign producers cannot make informed decisions about their food production practices in the present. Once again, Ecuador urges the EU to provide a period of at least 36 months, which is the time needed to develop a new phytosanitary pest control product. Ecuador is aware that the EU allows its farmers to request emergency authorizations so that, in certain particular situations, they can use active substances that have already been banned in the European market. For Ecuador, it is important to know whether these authorizations could be used by third countries (outside the EU) when the amended MRLs enter into force. 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 European Union regulations.

2.189. The representative of Uruguay provided the following statement. Uruguay wishes to thank the United States of America, Colombia and Costa Rica for including this item on the Committee's agenda. 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. Like other Members, Uruguay does not consider six months to be a sufficient period in this regard. My delegation reiterates its call on Members 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 their 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 need to grant transitional periods that are sufficiently long to make the relevant adjustments.

2.190. In response, the representative of the European Union provided the following statement. At the TBT Committee meeting in May 2020, the EU provided detailed information on transitional periods for Maximum Residue Levels (MRLs). As clarified in previous Committees, the EU considers that concerns on the setting of Maximum Residue Levels (MRLs) for pesticides – and any details regarding their implementation – to 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 notifies 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, matters on approvals of active substances should be discussed exclusively in the TBT Committee, while matters on the setting of MRLs for pesticides should be discussed exclusively in the SPS Committee.

2.1.3.17 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](#) (ID 594⁴³)

2.191. The representative of the United States provided the following statement. 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 US\$125 billion medical device market, US\$20 billion of which is supplied by US products. The 11 January 2021 Commission Notice permitting remote audits by Notified Bodies (NBs) is a welcome development. In acknowledging the significant obstacles travel restrictions and quarantine orders pose to on-site audits during the pandemic, this temporary allowance may help facilitate safe and timely product approval. We are eager to see how remote audits proceed in practice to alleviate the assessment backlog and ultimately ensure patients' continued access to much needed medical devices and *in vitro* diagnostic tools. While we are encouraged that 18 NBs have been approved to assess conformity to the MDR as of January 2021, the rate of new approvals is slow. For example, only one NB has been added since our last meeting in October. Does the EU have a sense of how Notified Body applications are moving through the review process and whether adequate capacity will be in place for manufacturers to meet the May 2021 implementation date? We note that as of January 2021 there are only four NBs approved to assess conformity to the IVDR. In view of this lack of testing capacity, we again recommend serious consideration also be given to a significant extension of the implementation date for the IVDR. By extending the implementation date to May 2023, the EU may help alleviate concerns regarding insufficient testing capacity.

2.192. We are also concerned about the status of standards that companies can use to demonstrate compliance with the general safety and performance requirements. When will the new standardization request be released, and will the request be based upon the latest international standards? In addition, we understand that the Commission intends to create harmonized European standards to demonstrate compliance with EU legislation rather than use existing international standards. We urge the Commission to use internationally recognized standards where possible to avoid duplicative efforts and additional burden on manufacturers to comply with separate harmonized standards - one for the EU and others for other international regulatory authorities. Further, we understand that standards would not be in place until earliest 2024, three years after the MDR goes into effect, even with the one-year delay. What is the EU doing to address this? We note that in preparation for the implementation of MDR, the Commission issued a guidance in January 2020, announcing it selected the *Classificazione nazionale e internazionali* (CND), a Unique Device Identifier (UDI) system that is not harmonized with the well-established UDI system that utilizes the Global Medical Device Nomenclature (GMDN).⁴⁴ GMDN was developed with the support of ISO 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 that EU's selection of CND 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 will encourage other regulators and entities, like the World Health Organization, to adopt CND, creating duplicative requirements for the medical device industry, and thus ultimately harming public safety.

⁴³ For previous statements follow the thread under [ID 594](#).

⁴⁴ The European Commission announced its decision to adopt CND via guidance: https://ec.europa.eu/health/sites/health/files/md_topics-interest/docs/md_emdn_eudamed_nomenclature_en.pdf

2.193. The representative of Japan provided the following statement. We request that MDGC guidance be issued in accordance with the ongoing guidance development and other relevant work within MDCG Subgroups. Since the date of application of MDR is approaching, we request a clarification of the issue date of the MDCGs and other guidance in the "Post Market Surveillance Requirement" and that proper transition periods are to be set in the guidance. The harmonized standard for MDR has not been published yet. We request that it be published as soon as possible and that proper transition periods are to be set along with the publication of standards. We welcome the fact that the review of MDR by NBs had already started in Japan, and the number of cases where on-site audits have been completed has been increasing. On the other hand, in the MDR, strict clinical evaluation is required for Class I, IIa and IIb medical devices. We are concerned that since the end of last year, there has been an increasing number of cases where the review of clinical evaluation, one of the required technical documents, has not been completed. In order to prevent the MDR from becoming more trade-restrictive than necessary, we request that the MDR be applied in the same way as other countries' regulations on medical devices with the same level of risk, such as exempting or simplifying the clinical evaluation requirement for medical devices that can be shown to be equivalent to medical devices that are already on the market with a CE mark (equivalent medical devices) based on Directive 93/42/EEC. The workload of NBs is still focused on the MDR because the expiration date of the transition period for the MDR has been postponed. We request an extension of the transition period for the IVDR until May 2023. We also request the prompt issuance of guidance documents for the IVDR and that the timeline for their issuance be provided as soon as possible.

2.194. 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 notified bodies 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?

2.195. The representative of the Republic of Korea provided the following statement. Korea would like to support the delegations of the United States, Japan and Canada. Given that the new Regulation emphasizes the importance of patient safety, traceability and transparency, it will have a great impact on our manufacturers. Therefore, it is in our interest to better understand and prepare for the potential impact the Regulations will have on our industry. We hope that the MDR and IVDR will successfully enter into force, as expected for May 2021 and May 2022 respectively, and that the EU will provide comprehensive regulatory information including MDCG guidance to help the industry well prepare for the upcoming entry into force. We expect that EU's efforts will lead to a smooth transition from the Directives to the Regulations.

2.196. The representative of China provided the following statement. China would like to thank US and Japan for raising this STC. China would also like to thank EU for the replies to our previous concerns on in vitro diagnostic medical devices. However, we still remain concerned about the Medical Device Regulation (MDR) and in vitro diagnostic medical devices regulation (IVDR). For MDR, China suggests that EU level guidance for the requirements of CE technical documentation with uniform requirements, standards for auditing and conformity assessment of NBs, and specific product guidance should be established as applicable. The long-term planning and annual planning of the guidance should be prepared. The reasons are as follows: (i) lack of unified requirements or guidance leads to significant differences in auditing standards among NBs; and (ii) lack of guidance documents related to specific products, which leads to the differences in the audit of general safety and effectiveness among different NB when they audit the same products. The establishment of the guidance document, especial for the technical documentation guidance, is a process of continuous improvement. Therefore, the formation of long-term planning and annual planning of the guidance document can be important to support the continuous improvement and unification.

2.197. Postpone the transition deadline of high-risk devices for class III and class IIB devices by one year, the reasons are as following. In the MDR regulation, the evaluation and audit of devices of class III and class IIB rely heavily on local European experts, especially the audit of clinical data

and CER (Clinical Evaluation Report), which requires the intervention of the medical device expert group. In particular, the examination on high-risk products of class III are basically dependent on the European local experts. However, due to the spread of COVID-19 epidemic, it is difficult for European experts to conduct on-site audits in third countries, besides, the current arrangement for remote auditing cannot ensure timely certification and effective audition. China suggests postponing the listing of high-risk class III and IIb devices for one more year.

2.198. For IVDR, postpone the transition deadline of IVDD and IVDR for 2 years. Manufacturers are facing a huge amount of certification work before the implementation of the IVDR. However, at present, the EU has announced only 4 Notified Bodies and has neither issued nor updated the list of EU harmonized standards nor the more detailed certification guidelines, and no laboratory has been authorized by the EU as a reference laboratory yet. Importantly, considering the pressure on national authorities of EU member States, Notified Bodies, manufacturers, and other actors and the impact of COVID-19 epidemic, it would be difficult for manufacturers to rectify conduct tests in authorized laboratories and obtain certificates issued by the notified body in a timely manner. Manufacturers are unable to complete a conversion review of all the products before the implementation of IVDR. Therefore, China requests that EU postpones the transition deadline of IVDD and IVDR from May 2022 to May 2024. Expedite the announcement of laboratory authorization and preparation: manufacturers need to consider the allocation of laboratory resources in advance while applying for product certification. As EU has not announced any laboratories, and certification of high-risk products takes a relatively long time, manufacturers cannot choose the suitable laboratory configuration and optimize them, which will increase the difficulty of certification.

2.199. The representative of Singapore provided the following statement. Singapore appreciates the European Commission's one-year delay in the implementation of the MDR until 26 May 2021, which has allowed for relevant stakeholders to prioritise the ongoing COVID-19 pandemic. We also acknowledge the EU's continued efforts in the designation of Notified Bodies (NBs) under the MDR and IVDR. However, we support the concerns raised by other Members, and remain concerned that there is still an insufficient number of designated NBs under the MDR, despite its looming implementation date. We note that to date, only 19 NBs have been designated under the MDR, which is significantly lesser than the number of designated NBs under the MDR. This has led to concerns over bottlenecks in the certification of medical devices, and the resultant risk towards continued access to the EU's medical device market. We seek the EU's consideration of this issue, and look forward to further developments to facilitate the smooth transition to the MDR.

2.200. In response, the representative of the European Union provided the following statement. As regards the date of application of the MDR, on April 2020, and due to the exceptional COVID-19 circumstances, and with patient health and safety as a guiding principle, a postponement of the date application, until 26 May 2021, was agreed upon by the EU co-legislators. The IVDR's corresponding date of application remains the same (26 May 2022). The Commission continues to monitor the impact of the COVID-19 crisis and is working closely with competent authorities, notified bodies and industry to continuously assess the situation. The Commission is not currently considering a postponement of the MDR or the IVDR. The postponement which took place in April of last year was exceptional in its nature and essential to ensure continued patient care by allowing the significant scaling up of medical device production in the EU. Currently, we are not aware of such needs as the availability of COVID-19 critical medical devices seems to have stabilized in the EU. Additionally, the different activated crisis mechanisms have now allowed the EU to form stockpiles should such a need arise again. Furthermore, and pursuant to a January 2021 Commission notice on audits and surveillance assessments under the MDR and IVDR, the text provides for some more flexibility to member States to allow remote audits carried out by Notified Bodies, if the conditions set out within the notice are met.

2.201. As regards implementation work, the Commission and member States are continuing work on implementing acts and guidelines. To date, there have been above 60 published guidance documents, including several key guidance on clinical requirements. In addition, the expert panel representatives, who have a role in the conformity assessment procedures of certain high risk products have been announced and the registration module of the EUDAMED database was made available on December 2020. As reported in previous meetings, the other parts of the EUDAMED database will be made available in a gradual manner, with the Unique Device Identification module being released next. As regards Notified Bodies' availability, there have been 23 designations made thus far, 19 under the MDR and four under the IVDR. Of the Notified Bodies that also have a Medical Device Single Audit Program (MDSAP) designated auditing organization within their organization, 11

out of 13 have so far been designated under the MDR. These organisations cover some of the EU's trade partners such as Australia, Brazil, Canada, Japan and the US. It is important to underline that the EU does not expect to maintain the same number of Notified Bodies as currently existing under the Directives. Therefore, under the MDR/IVDR, the numbers will go down. Quantity is not and never has been an indication of capacity. As with anything related to demand and supply, the market will adjust and has in fact already done so as the 23 Notified Bodies already designated under the regulations reportedly hold more than a significant share of the market and have in addition considerably up-scaled their capacity. Finally, it is also important to remind that the grace mechanism, similar to but more stringent than the grandfathering concept, remains in order to smoothen the transition period. This means that the date of application is not a hard stop and that products certified today under the directives and prior to 26 May 2021 can remain on the market until at the latest 2025, if they respect the conditions set out in the Regulation. The EU is fully committed to ensuring that the new system provides a higher level of patient protection and counts on trade partners to encourage their manufacturers to meet these new requirements to ensure trade continuity.

2.1.3.18 China - Draft Administrative Measures for Registration of Overseas Producers of Imported Foods, [G/TBT/N/CHN/1522](#) (ID 611⁴⁵)

2.202. The representative of the European Union provided the following statement. The EU is highly concerned about this measure as this will have a serious impact on importers into China. 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.⁴⁶ Accordingly, registration, inspection and certification regimes applied to particular categories of products and processing methods must be in proportion to the associated risks. As presented, the measure would put a substantial additional administrative burden on companies and competent authorities, including China Customs. The already long and time-consuming registration process will therefore be further extended. As regards the scope, the EU is seeking clarification as to which facilities the registration obligations would apply. The EU understands that the notified measure is applicable to all types of foods and beverages. If this is the case, the EU underlines again its concern that pertinent administrative procedures must be practicable, retain the current well-established practices to the extent possible, and be accompanied by clear guidance and adequate transition measures. Otherwise there will be total chaos. More concretely, the EU strongly recommends that the current, single entry point for registration⁴⁷ be maintained and any duplication of data entry, through additional channels or unnecessary additional registration requirements, be avoided. Additionally, regarding the notified registration of businesses on the basis of guarantees provided by the competent authority of the exporting country, whilst the EU supports these provisions in principle, we consider that the range of products covered by this registration regime is grossly disproportionate and very unclear. As outlined in more detail in our written comments, many of the product categories listed in Article 6 of the notified measure are inherently safe, low-risk products that can be exported by China to the EU without authorization, prior inspection or official guarantees in support of the listing of establishments. The EU strongly requests that China revises the scope of the measure in full consideration of Codex guidance and standards.

2.203. The representative of the United States provided the following statement. The United States thanks China for notifying to the TBT Committee its draft "Administrative Measures for Registration of Overseas Producers of Imported Foods" (Administrative Measures). We remain concerned with this draft measure and urge China to carefully consider the finalization of such a restrictive regulation without a clear food safety and public health benefit. The proposed measure appears to affect all food products, regardless of risk or whether foods are already subject to additional import certification requirements. We anticipate that the draft measure, if implemented, would likely create a major trade disruption 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. The United States urges China to consider taking a risk-based systems approach to determine what measures may be required for individual trading partners to meet China's appropriate level of consumer protection, focusing on particular high-risk foods. Could China please provide an update regarding its comment review process and timeline for next steps? This measure appears to overlap with other similar measures, notably Decree 177 on the

⁴⁵ For previous statements follow the thread under [ID 611](#).

⁴⁶ i.e. CAC/GL 20-1995 on principles for food import and export inspection and certification.

⁴⁷ i.e. <http://ire.customs.gov.cn/>.

import/export of grain and the "Administrative Measures on Import and Export Food Safety" recently notified to the WTO SPS Committee as [G/SPS/N/CHN/1191](#). How does [G/TBT/N/CHN/1522](#) relate to these other measures?

2.204. 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 providing Members with the opportunity to comment on this proposed measure, which we have been following closely since February last year. As this proposed measure ([G/TBT/N/CHN/1522](#) on 16 November 2020) will be affecting a wide range of our food-related industry, we are still consolidating the feedback from our manufacturers and will provide our written comments formally as soon as possible via the TBT Enquiry Point and bilateral channel for China's consideration. In addition to express our support to the concerns raised by other Members, we would like to highlight the most important ones at this occasion. Firstly, to relieve regulatory authorities of other Members from the heavy burden of providing the statements mentioned in Subparagraph (4), Paragraph 2, Article 6 of the draft, we would like to request that the statements regarding compliance of the business operators with the requirements of the draft do not need to be provided if the food safety management system of exporting Members have already been assessed by China and confirmed to be equivalent to China's regulatory system.

2.205. Secondly, the draft regulation covers a very broad scope of food products and we call for China to adopt a risk-based approach to align with international practices. In particular, we seek clarification from China of the following issues. Please define the scope of "special dietary foods" and "health foods" mentioned in Paragraph 2, Article 6 of the draft. Are these products subject to approval or regulatory control before they can be labelled as special dietary food or health food and placed on the market of China? If approval is required, are foreign manufacturers of such food that have been granted approval by the relevant authority still subject to this draft regulation of registration? Please provide the following clarifications: (i) the definition of each regulated food categories as mentioned in Paragraph 2, Article 6, and the foods that are not applicable as mentioned in Paragraph 2, Article 2; (ii) the definition of a change in risk as mentioned in Paragraph 4, Article 6; (iii) the frequency of the list of registered overseas business operators that will be published by the General Administration of Customs, as mentioned in Article 15; (iv) the given time period of rectification mentioned in Paragraph 1, Article 23, if the facility is no longer conformed to the registration requirements; and (v) the judgment principles for the revocation of registration mentioned in Article 24. Please clarify whether the correction reports mentioned in Paragraph 2, Article 23 are to be submitted by the registered business operators recommended by the competent authority or by the competent authority. We would be grateful if the above-mentioned comments could be taken into account. We look forward to continuing bilateral engagements with China on this matter.

2.206. The representative of Brazil provided the following statement. Brazil thanks China and appreciates the recent public consultation notified under Chinese notification 1522. In this new draft regulation, we value the further detailing of the scope of the measure, the specification of product categories in the role of the exporting country competent authority, and the removal of punitive measures for importers who import product from unregistered food exporting facilities. We also take good note of the withdrawal of requirements for annual verification by GACC and annual reporting by the exporting country's competent authority. We also thank China for notifying its new draft measure to the TBT Committee. However, we still believe said regulation might complicate the registration and supervision of high-risk food products exported to China. If adopted, Brazilian food producers who intend to export to China might need to provide pre-export registration following stricter requirements. Based on the Chinese statement in the last Committee meeting, China 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.

2.207. The new draft could grant discriminatory treatment towards imported food products in relation to those produced in China, which are not subject to the rules of such 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 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. We also urge China to consider defining reasonable transitional periods for producers and exporters to adapt to the regulation. We would deeply appreciate it 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. Finally, could China also commit to notify the TBT Committee of 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?

2.208. The representative of the [Republic of Korea](#) provided the following statement. Korea thanks China for providing the notification. Korea would like to support the delegations of the EU, the United States, Chinese Taipei, and Brazil. The COVID-19 pandemic has highlighted the importance of uninterrupted supply of commodities. Against this backdrop, China's revised Measures appear to place a larger strain on food supply chains as they require the registration of all imported food products. The revision would expand the scope of preliminary review and registration recommendation by the exporting country's government, from the current animal products to agricultural foods, special dietary foods, dietary supplements and condiments. Such requirement would impose an enormous administrative burden and incur excessive time and cost on both importing and exporting authorities responsible for food trade and could create an unnecessary barrier to trade. Korea would like to hear a detailed explanation from China on how it decided to include new food categories and we request China to provide scientific evidence such as risk assessments that underpins the decision. Considering that only foods of animal origin are required in other countries, we urge China to maintain the current scope of food categories. According to the revised Measures, competent authorities for export are required to notify to the Chinese Government and suspend export if hazards associated with food safety are found in food products. Although Korea understands China's legitimate objective of promoting food safety, such Measures would place an undue burden on exporting countries. Also, our industry is concerned with the current lack of clarity around the definition of "food safety hazards". Korea therefore requests China to provide further clarity and details on the scope of application and requirements by the revised Measures. Korea also requests China to notify to the SPS Committee given that it is associated with sanitary and phytosanitary measures. As we are aware that Members had submitted comments to China by 15 January 2021, Korea requests China to take into account the received comments. Korea also calls on China to notify all of its next steps in the development of the Regulations and to provide time frames for the publication of the final Regulations and their entry into force. Considering the possible entry into force, Korea would like to request that the exporters registered by the General Administration of Customs be permitted to retain their status without additional evaluation or registration processes. Korea also asks China to allow reasonable time for the industry to adapt to the new Regulation ([G/TBT/N/CHN/1522](#)) under Article 2.12 of the TBT Agreement.

2.209. The representative of [Australia](#) provided the following statement. Australia welcomes China's notification of the Regulation on Registration and Administration of Overseas Manufacturers of Imported Food ([G/TBT/N/CHN/1522](#)). Australia provided comments on China's draft Administrative Measures for Registration of Overseas Producers of Imported Foods on 15 January 2021. Australia recognizes the right of governments to take measures necessary to protect public health, including food safety and hygiene measures. However, we are concerned that, as drafted, aspects of China's proposed Regulation are more trade restrictive than may be necessary to fulfil China's food safety objectives. In particular, we request China provide details of the risk analysis, scientific data and technical information used to develop this Regulation, and why the measures are not linked to the risks posed by the different categories of imported food. Australia wishes to emphasise the importance of compliance with WTO obligations, including adopting or recognizing international standards to ensure any requirements implemented are no more trade restrictive than necessary. We are concerned that the proposed Regulation as drafted does not recognize equivalent national food safety systems based on Codex risk analysis principles, which meet the same objectives as Chinese food safety requirements and regulations.

2.210. For some foods, aspects of the proposed measures do not appear to be linked to the risks posed by the category of imported food. As such, Australia believes the requirement for registration of all overseas food manufacturers, including those of highly processed food, would place an unnecessary regulatory burden on the competent authorities. This increased regulatory and administrative burden on competent authorities has the potential to lead to administrative delays and restrict trade. Further, we are concerned that the proposed Regulation would treat imported foods less favourably than China's domestic products. Australia reminds China that its regulations must not be used to discriminate against imported goods. Accordingly, Australia urges China to

reconsider this Regulation and to revise it in accordance with its WTO obligations. We note that Australia's export and domestic food production systems are underpinned by a robust legislative framework. This framework provides confidence to our trading partners that exported products are safe, traceable and meet the requirements of the importing countries, including China. Australia has an established and successful history of trade in food products with China and seeks to continue this strong bilateral trading relationship. We look forward to China's feedback on our comments and the opportunity to engage with the competent authority of China to meet the objectives of the proposed measures while safeguarding trade.

2.211. The representative of Mexico provided the following statement. The delegation of Mexico refers to the Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufactures of Imported Food, notified to the Members of this Committee on 16 November 2020 in document [G/TBT/N/CHN/1522](#). The Government of Mexico thanks the Government of China for its compliance with the transparency commitments and the opportunity to comment on this Regulation. However, we would like to share our main concerns about the Regulation, which relate to: *The scope of application*: The Regulation lacks clarity with respect to the products covered. While Article 6 contains a list of products, there is no certainty that these are the only products that must comply with this measure. We would therefore welcome confirmation from the delegation of China on the products covered by the Regulation, as well as on whether alcoholic beverages are excluded from the Regulation. *Additional administrative procedures for the competent authorities in the country of origin*: Article 5 of the Regulation provides for the issuance of various documents by the competent authority of the country of origin, including a letter of recommendation, a statement confirming that the enterprise in question meets the requirements established by China, and a review and inspection report. These requirements would represent an additional burden not only for the industry, but also for the competent authority in Mexico, which, in addition to verifying normal export procedures, would have to focus its efforts on a separate process solely for China. Furthermore, exporters would have to certify their products twice. They would firstly have to complete a procedure to comply with the export requirements contained in the domestic regulations, followed by second procedure to comply with the export requirements requested exclusively by China. This process would impose burdensome workloads on exporters and the Mexican authorities, and could therefore contravene the principle of proportionality contained in Article 2.2 of the Agreement on Technical Barriers to Trade (TBT Agreement) by establishing mechanisms that could be considered more restrictive than necessary for an export process.

2.212. *Risk assessment*: Article 6 of the Regulation refers to a risk analysis that may be a determining factor for the method of application for the registration and documentation to be requested from enterprises for such a procedure. However, no information has been provided on this risk analysis, the manner in which it is determined, the scientific or technical basis used for the determination of the proposed assessment, or whether it is based on an international standard. In light of the above, the delegation of Mexico kindly requests the delegation of China to: (i) clarify the scope of the products covered by the Regulation, and confirm whether alcoholic beverages are included in this list of products; (ii) explain how the measures contained in the Regulation are effective and proportionate in terms of meeting China's legitimate food safety objective; (iii) share technical and scientific information, as well as the international standards that form the basis for the development of this Regulation. The delegation of Mexico thanks the delegation of China for giving its consideration to this statement and the requests made therein.

2.213. The representative of Canada provided the following statement. Canada appreciates the opportunity to comment on China's World Trade Organization (WTO) notification [G/TBT/N/CHN/1522](#) and urges China to consider the significant negative impacts that these regulations could have on trade. Canada is disappointed that China has implemented these regulations immediately following the deadline of 15 January 2021 for comments from WTO Members. As a result, Members' comments and concerns have not been taken into consideration in the final implemented regulation. As per WTO transparency obligations, a reasonable amount of time, normally understood as a period of not less than six months, should be provided between the publication of a regulation and its entry into force to allow time for industry and Members to review and implement the new requirements. On 14 January 2021, Canada submitted comments on the proposed measure highlighting that a number of the requirements in the draft regulation needed further clarification by China in order for industry stakeholders and foreign competent authorities to better understand and comply with the requirements. In particular, Canada is concerned that the additional oversight imposed by China is unjustified, overly burdensome and could create serious impediments to trade, such as, the maintenance and approval of establishment eligibility lists and additional audits and/or inspections,

and other activities which are not commensurate with the level of food safety risk associated with the notified products. As foreign competent authorities are responsible for ensuring that exported food and food products comply with the regulations of the importing country, additional oversight due to China's new regulations has created an immediate and long-term administrative burden on both Canadian industry and Canada's competent authority. For instance, Article 6 in the regulations is so broad that these new regulations will result in regulatory oversight for a significant number of products with an inherently low food safety risk, effectively becoming a barrier to trade with limited apparent benefit to mitigate food safety risks.

2.214. Canada appreciates and recognizes China's overall objective to protect human health. As such, Canada would appreciate an explanation as to how increasing the administrative management and oversight of foreign food establishments that export to China will contribute to meeting food safety objectives and whether these new measures are the least trade-restrictive option. In light of these concerns, Canada requests that China suspend the implementation of these regulations to allow trading partners sufficient time to engage with China and have their concerns taken into account, including discussions on whether alternate, least trade-restrictive measures were considered in the finalization of the measure. Canada also calls on China to notify the final measure and provide a transition period for the entry into force of no less than six months to allow time for industry and other Members to adapt. In closing, given China's stated objective of protecting human health, Canada is of the view that the proposed measure should also be notified to the WTO Sanitary and Phytosanitary (SPS) Committee in order to provide further opportunity for Members to comment.

2.215. The representative of Japan provided the following statement. Japan shares the concerns expressed by other Members, regarding China's draft regulations on the registration and administration of overseas manufactures of imported food. The proposed regulations would impose an obligation on foreign competent authorities to inspect and supervise manufacturing companies in their territories in accordance with Chinese laws and regulations, and to confirm them to the Chinese Government. In addition, the regulations would expand the scope of food subject to the evaluation and inspection, without providing the scientific basis. In addition, there are many unclear points from the operational aspects, which may impose heavy burden on overseas manufactures, processors, and storage facilities as well as the competent authorities of foreign countries if implemented. Japan has been seriously concerned that the China's proposed regulations would create unnecessary trade barriers and have negative impacts on food trade between China and WTO Members. Japan would like to request China to provide necessary information and reconsider the draft regulation taking into account the comments and concerns of Members. Also, Japan would like China to provide sufficient transition period and set a clear timeline toward implementation of the regulation.

2.216. The representative of Switzerland provided the following statement. As in previous meetings of the WTO TBT Committee, Switzerland maintains its concerns regarding the proposed registration of overseas manufacturers of imported food. Switzerland understands and supports China's objective to ensure that only safe food is imported. We regret that the proposed measure continues to include all food categories irrespective of their risk-profile and seems to be more trade-restrictive than necessary to ensure the safety of imported food products. We therefore reiterate our concerns and refer to previous statements for more detailed comments. Switzerland encourages 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.

2.217. In response, the representative of China provided the following statement. I would like to thank all relevant WTO Members for their concern about China's revision of the Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufactures of Imported Food (hereinafter referred to as the Regulations of Registration). It is a clear requirement of the Food Safety Law of the People's Republic of China to implement the registration and administration for overseas manufacturers of imported food. With China's further opening-up, the trade volume of food imports and the number of registered overseas food production enterprises have increased rapidly, and the original Regulations of Registration fail to meet the requirements of the new situation. The purpose of China's revision of the Regulations of Registration is to effectively implement the legal provisions, improve the management system, optimize the registration procedures, clarify the responsibilities of all parties, and promote enterprise registration and trade development. On 16 November 2020, China notified the WTO the revised draft of Regulations of

Registration (Notification [G/TBT/N/CHN/1522](#)). During the comment period, China received 14 written comments from Members. China is making in-depth study on the above comments, and will positively consider the suggestions raised by all Members.

2.1.3.19 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](#) (ID 618⁴⁸)

2.218. The representative of [Costa Rica](#) provided the following statement. Costa Rica wishes to thank Peru for keeping it 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 nonetheless to 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.

2.219. The food industry has informed us of the negative repercussions on trade that a potential discontinuation of the use of adhesive labels would have. 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, or in cases where the language on the original label is not acceptable to the consumer for whom it is intended. 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.

2.220. 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. 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 above reasons, we respectfully request that the Peruvian authorities provide an update on the current status of the draft Regulation amending the Manual of Advertising Warnings and the entry into force of the requirement prohibiting the use of adhesive labels.

2.221. The representative of the [European Union](#) provided the following statement. The European Union (EU) appreciates that Peru extended 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-Minsa). EU recognizes that reliable information to the Peruvian consumer is a legitimate objective. However, the practical effect of not allowing the use of stickers is a disproportionate burden for foreign manufacturers, in particular SMEs, that have to print the information on the

⁴⁸ For previous statements follow the thread under [ID 618](#).

product package itself before the product is shipped to Peru. In the EU and in most countries around the world, stickers are allowed for food products, provided that the information is accurate, and the stickers are not easily removable. The EU would like to repeat the invitation to Peru to provide for a permanent possibility to use stickers. We are committed to working with Peru bilaterally on this issue.

2.222. The representative of Brazil provided the following statement. Brazil regrets having to once again express its concerns regarding labelling requirements expressed in the Manual of Advertising Warnings approved by Supreme Decree 012-2018-SA (notified under [G/TBT/N/PER/97/Add.1](#)) and amended by Supreme Decree 015-2019-SA (unnotified). Brazil shares Peru's endeavour to ensure the highest health standards through technical regulations that help better inform consumers. We would like to thank Peru for clarifying, in the last Committee meeting, the reasons for forbidding the use of stickers. We also appreciate its willingness to engage bilaterally with Brazil on this topic. The use of stickers is a widespread practice internationally, as 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 labels or stickers, 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. Despite Peruvian legitimate concerns with deceptive practices, advances in labelling technologies allow for their safe affixation. Brazil would be willing to share with Peru its regulatory experience related to such labelling requirements. We acknowledge that, according to Supreme Decree 021-2020-SA, the entry into force of the prohibition on stickers was delayed until 30 June 2021. However, 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 stickers for the products under the scope of the Manual of Advertising Warnings. Brazil considers such postponement a provisional solution and will continue to raise this STC until Peru permanently removes its burdensome requirements for food labelling.

2.223. The representative of Colombia provided the following statement. Colombia would like to reiterate its 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](#). Under the above-mentioned regulations, the deadline was set for 30 June 2021 for the use of adhesive advertising warning labels that was provided for in paragraph 8.3 of Supreme Decree No. 012-2018 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. 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 considers that the non-acceptance of stickers is a provision that is more restrictive than necessary and may become an unnecessary obstacle to trade, violating Article 2.2 of the TBT/WTO Agreement on Technical Barriers to Trade, 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 (...)".

2.224. A technical measure on labelling that is so specific, which must be implemented in the country of origin and does not allow the use of alternatives such as stickers with the required information, is a technical barrier to trade. It constitutes a major barrier to market access for products from countries such as Colombia, especially for small and medium-sized 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. It should be recalled that most exporters to Peru are 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. 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 view of the foregoing, Colombia once again requests Peru to extend the application of the rule allowing the indefinite use of adhesive labels or stickers with warning icons and messages on food packaging.

2.225. The representative of the United States provided the following statement. The United States supports the interventions of other Members, and notes our previous TBT Committee interventions on this measure. We request that Peruvian authorities modify the provisions established in the Manual, so as to allow compliance with labelling requirements through an extension for the use of stickers.

2.226. The representative of Chile provided the following statement. Chile would like to support and share the trade concern raised by the European Union, Costa Rica, Brazil, Colombia and the United States regarding the proposal to implement front-of-pack nutrition labelling for food products in PERU. The notified draft sets out a mandatory front-of-pack nutrition labelling system indicating that the products are in "excess of" or "high in" certain nutrients for prepacked foods whose content of energy, sugars, saturated fats, trans fats and sodium exceed certain parameters. In this regard, Chile shares the ultimate public policy objective sought, recognizes the importance of the relationship between diet and health, and acknowledges that providing the elements of the nutrition information front-of-pack can be a useful tool for consumers, as part of a multidimensional strategy to address overnutrition. As is well-known, Law No. 20.606 on the nutritional composition of foods and food advertising came into force on 27 June 2016 in Chile. This law was the subject of extensive debate, both nationally and internationally, including in this Committee, and in this regard we would like to highlight that its implementation has been gradual, divided into three incremental phases. On this point, and in order, on the one hand, to achieve the objective of the public health policy and, on the other, to avoid creating an additional barrier to trade in goods, the law in question provided for the use of stickers or adhesive labels within its implementation mechanisms as a way to comply with the front-of-pack labelling of food. This measure is generally applied to imported products that will be sold on the domestic market that are covered by this law and its respective regulations (DECRETE13/2015).

2.227. Regarding entry into force, the proposed Regulation allowed for an additional implementation period for its entry into force, which ends on 1 July of this year. This responds to the importance of adaptation and the conditions specified for amending the front-of-pack labelling of foods, while allowing time for the technological adaptation of food products. In light of the above, Chile requests PERU to consider this mechanism as a permanent measure, taking into special consideration Chile's successful experience, which is aimed at meeting policy objectives without creating an unnecessary barrier to trade (relabelling/repackaging), which will mean higher final product costs. There are trade facilitation measures – such as the use of stickers/adhesive labels – that have been implemented successfully without losing sight of the objective of complying with the public policy on front-of-pack labelling of "high in" foods. Chile has been, and is, willing to collaborate and share its experience in this regard, and to establish a mechanism of information exchange at a technical level between the competent regulatory authorities. Independent studies show the positive impact of allowing the use of self-adhesive labels or "stickers" indelibly marked on the packaging of products imported into the country on its implementation in Chile and inclusion in the Regulation. This alternative measure emerged in response to the problems raised by the international food industry in the process of public consultations on the draft regulation before this Committee. This authorization of "stickers" provided for in the Regulation has so far been found to be helpful in supporting its implementation, and avoiding a technical obstacle to trade, taking account of the principles of evaluation of food labelling policies, and demonstrates a positive response to the first stages of implementation of this law (since 2016). Furthermore, it can be said that the labelling policy followed by Chile is on the right track, according to the expected results for this type of policy. Therefore, the use of another front-of-pack labelling mechanism is not recommended, without prior scientific evaluation, or changing the strategies for its implementation. In other words, allowing the use of self-adhesive stickers in the labelling of imported products is recommended, in order to adapt the labelling of the products to the domestic regulation, is recommended. In light of the above, Chile requests Peru to reconsider the measure and to allow the use of stickers on a permanent basis.

2.228. 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 deadline for the use of adhesive advertising warning labels established in the Supreme Decree has been extended until 30 June 2021. Guatemala recognizes Peru's legitimate objective of protecting human health and providing consumer information. The notification [G/TBT/N/PER/97/Add.2](#) extends the deadline for the use of stickers on packaging in compliance with the regulation to 30 June 2021. As mentioned, CODEX CXS 1-1985, General Standard for the Labelling of Prepackaged Foods, states that a supplementary label containing the mandatory information in the required language may be used and shall fully and accurately reflect the information on the original label. Peru is requested to reconsider the measure established as it is more trade-restrictive than necessary. The use of such labels is widely recognized internationally, as they fulfil the same public health protection and consumer information purposes with the application of supplementary adhesive labels. Regarding the points made to Peru at previous meetings on Supreme Decree No. 015-2019-SA, Guatemala's position remains the same.

2.229. In response, the representative of Peru provided the following statement. As we have done in previous meetings, Peru wishes to reiterate that it is committed to its work to protect the health of its citizens and vulnerable groups, such as children and adolescents, through public policies aimed at achieving this goal, in accordance with its international trade commitments in this domain. In this connection, Peru is seeking to ensure that the information contained in the Manual of Advertising Warnings reaches consumers clearly and effectively, so that they can make informed choices. As has been pointed out, 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. However, with regard to the concerns expressed by some Members, Peru is currently taking the necessary action in order to assess the best mechanisms for achieving its legitimate objective and enhancing trade facilitation. Lastly, we reiterate 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 trade, as established in the Agreement on Technical Barriers to Trade.

2.1.3.20 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](#),
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[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](#),
[G/TBT/N/IND/175](#), [G/TBT/N/IND/176](#), [G/TBT/N/IND/177](#), [G/TBT/N/IND/186](#),
[G/TBT/N/IND/187](#), [G/TBT/N/IND/188](#), [G/TBT/N/IND/191](#), [G/TBT/N/IND/193](#),
[G/TBT/N/IND/194](#), [G/TBT/N/IND/199](#) (ID 630⁴⁹)

2.230. The representative of the European Union provided the following statement. The European Union would like to recall 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. Between April 2019 and November 2020, India has made to the WTO 32 notifications concerning chemical products. Of these, 22 are covering petrochemicals (HS chapter 29), including such important mass products like methanol, toluene, ethylene glycol, acetic acid, terephthalic acid, acetone and melamine, and another 10 deal with inorganic chemicals (HS 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 Indian standards which are now 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 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. The EU would like to recall Article 2.2 of the TBT Agreement, according to which Members shall ensure that

⁴⁹ For previous statements follow the thread under [ID 630](#).

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.

2.231. 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 postponing the implementation of a number of chemical and petrochemical Orders for another 180 days, which were announced at (website) on 24 December 2020. The measures of our specific concern are those regarding phthalic anhydride, n- Butyl Acrylate and terephthalic acid (notified by [G/TBT/N/IND/116](#), [G/TBT/N/IND/123](#) and [G/TBT/N/IND/124](#)). It gives our manufacturers more time to prepare, yet we are still concerned about whether all the procedures can be completed in time considering the persistent impact of the pandemic. Besides, the following concerns that we have raised in previous meetings remain and a response by India would be much appreciated. Firstly, we would like to seek information from India on the rational and risk assessment of changing the current voluntary system to a compulsory certification system, which to our knowledge has never been adopted by any WTO Members for the management of chemicals, and where less trade-restrictive alternative approaches exist, for example, registration of chemicals. Secondly, the requirement for annual "on-site" factory visit/inspection is costly to fulfil especially for manufacturers located outside India. As BIS Conformity Assessment Regulations 2018 (BIS Regulations) 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 Orders' decision that there is a need to carry out annual factory visit/inspection. 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.

2.232. Thirdly, according to BIS Regulations, the license is valid for one to two years for initial application, and one to five years for renewals. In practical, the short validity of license and lengthy certification procedures, which also include on-site inspection, make it difficult for foreign manufacturers to obtain approval for a renewal within 12 months after the issuance date. We urge India to give reasonable validity period of licence for both domestic and foreign applicants on a non-discriminatory basis taking into account the practical difficulties faced exclusively by foreign manufacturers. Fourthly, India indicated that there is no provision under Scheme1 of BIS Regulation to accept conformity assessment results conducted by foreign bodies. As this creates a significantly higher burden for manufacturers located outside India, we once again urge India to consider providing opportunities for testing laboratories and inspection bodies from other WTO Members to participate in the conformity assessment procedures by accepting conformity assessment results from accredited bodies under the ILAC MRA framework. Fifthly, we would like to call for India's attention to the on-going impact of COVID-19 on conformity assessment activities. The access of products manufactured outside India to Indian market is tantamount to a factual denial when arrangement for a factory inspection visit by BIS is still not possible due to the travel restrictions. Hence, we would like to suggest that the Indian Government consider postponing the implementation date of the measures mentioned above until a time when foreign manufactures are on the same level playing field with its domestic manufacturers, or adopting temporary measures to address the unique situations faced by foreign manufacturers. Such measures may include exempting the on-site factory visit requirement for foreign manufacturers, authorizing 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 so as to mitigate the problem. We would be grateful if the above-mentioned comments could be taken into account and look forward to a written response.

2.233. 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 Bureau of Indian Standards (BIS) standards mandatory for 72 identified chemicals and petrochemicals. We are also aware that, as of February 2021, India's MoCF has notified 35 Quality Control Orders (QCO) to the WTO TBT Committee. Each QCO appears to identify substances that correspond to or fall under the 72 identified substances in the October 2019 meeting notice. We understand that each QCO proposes to mandate compliance to BIS standards for the identified substance. We continue to appreciate India's efforts to notify these QCOs to the WTO TBT Committee and to provide stakeholders with the opportunity to submit comments. However, we note that India's notified QCOs do not include links to and/or copies of the referenced standards that the QCOs seek to mandate. U.S. industry reports that the referenced standards are either infrequently

posted to the BIS website or require BIS credentials for access. Unless India makes readily available the BIS standards that the QCOs propose to mandate, interested parties will be unable to become fully acquainted with the QCOs or to provide meaningful comments. We kindly request that India provide links to and/or copies of the BIS standards identified in the 35 previously notified QCOs and for all future QCO notifications. With respect to the previously-notified QCOs, we would recommend that such links and/or copies be notified as addenda. We request that India explain how it will engage with international stakeholders in developing these technical regulations and conformity assessment procedures and to provide details regarding the specific timeline and implementation dates for the notified QCOs. We encourage India to use relevant international standards and relevant guides or recommendations issued by international standardizing bodies when revising BIS standards and conformity assessment procedures. The United States refers to its previous interventions on this matter, including the concerns raised in the October 2020 WTO TBT Committee meeting.

2.234. The representative of Canada provided the following statement. Canada reiterates the concerns it raised at the May and October 2020 TBT Committee meetings regarding all "Quality Control Orders" on chemical and petrochemical substances notified by India since November 2019. While drawing the attention of Members to our previous statements on the overall approach taken by India to make standards mandatory, we want to take this opportunity to again highlight that we remain deeply concerned with the method followed by India in notifying the Quality Control Orders to interested Parties. The one-page model document provided by India to explain its Quality Control Orders notifications does not appear as a genuine exercise of transparency. The document fails to explain the new measures and its objectives, except for statements such as: "the Central Government [...] is of the opinion that it is necessary or expedient to do so in the public interest". These declarations of the new mandatory nature of the Indian Standards are made without facilitating stakeholders' access to any related information on them, including directions on where the latest official version of the now-mandatory Standards can be found - some of which are decades old. If interested parties and stakeholders are not provided with the relevant information that led to the regulatory proposal, then they can hardly provide substantive comments and new information that could inform India's decision-making process. This situation generates significant concerns vis-à-vis the obligations of the TBT Agreement, notably Articles 2.2 and 2.5, which state that Members must provide interested parties and stakeholders a genuine consultation period to review the measures and provide comments.

2.235. Despite concerns raised at the TBT Committee meeting since May 2020, India continues to replicate this one-page notification method, as seen in the recent notifications on Quality Control Orders, such as Polyester Industrial Yarn (Quality Control) Order, 2020 ([G/TBT/N/IND/188](#)) and Synthetic Micro-Fibres for use in Cement-Based Matrix (Quality Control) Order, 2020 ([G/TBT/N/IND/194](#)), both published on 12 January 2021. 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 by India on these measures goes against this international regime. Therefore, Canada urges India to revise and modernize the way it notifies its measures on Quality Control Orders to make them transparent and accessible for all stakeholders.

2.236. The representative of the Republic of Korea provided the following statement. Korea would like to support the delegations of the EU, Chinese Taipei, United States and Canada. First of all, Korea highly appreciates India for the postponement of enforcing the Toluene and Terephthalic Acid Quality Control Order (QCO), which resolves difficulties of Korean companies. Korea respects the efforts of India to introduce Acetone QCO for the health and safety of Indian people. Furthermore, Korean companies are committed to comply with the regulation of India. However, Korea would like to deliver requests as Korean companies have difficulties regarding the enforcement date of Acetone QCO, 2020 of India. Implementation of Acetone QCO has been postponed and it is scheduled to take effect in 14 March 2021, however, Korea understands that it is still difficult for local BIS to provide normal services due to COVID-19. The Korean companies completed the certification application in June last year, but additional certification procedures such as factory audit have not been conducted yet after the document screening was completed. Therefore, Korea requests again that India postpone the implementation of Acetone QCO by more than six months or to take alternative measures such as temporary factory audit exemption for a limited period, considering the delay in certification process due to COVID-19.

2.237. In response, the representative of India provided the following statement. 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 Bureau of Indian Standards (BIS) standards mandatory for 72 identified chemicals and petrochemicals. In line with this notice, India so far has issued 35 (February 2021) Quality Control Order for chemicals and petrochemicals of chapters 28 and 29 as mandatory, which is in line with international practices. India has formulated individual standards of specific chemicals indicating discreet and separate numbers under the BIS Act, giving technical characteristics and details of testing methods. Since each chemical has different BIS standard number, possesses different characteristics and different testing methods, India has not preferred to file a single comprehensive mandatory notification. As per Article 2.2 of TBT agreement, Members are allowed to formulate Technical Regulations to fulfil legitimate objectives *inter alia* national security requirements, prevent deceptive practices, protect human health or safety, animal or plant life or health, or environment. As per the laid down procedure, the draft Quality Control Orders (QCO) were notified to the WTO TBT Committee, giving opportunity to Members to give their comments and objections within 60 days. These standards are made mandatory to protect human health and the environment. Even if other countries have not formulated TRs for such chemicals, the number of TRs of chemicals and petrochemicals in India is less than other nations. In the past, for a long time, the Indian standards of chemicals and petrochemicals were voluntary in nature. The trade of chemicals and petrochemicals usually takes place as per the specifications settled between the manufacturer and buyer irrespective of the specifications stipulated in the BIS standard, which sometimes resulted in dumping poor quality chemicals into India. Many chemicals are toxic and hazardous in nature. The impurities such as heavy metals, cyanides, isocyanates, halides, etc. enter the human and plant chain thereby harming the human and animal life.

2.238. Under mandatory standards regime, safe, reliable and quality chemicals are expected to be available. TRs for chemicals and petrochemicals have not been formulated to create unnecessary obstacles to international trade. The standards have been made mandatory after carrying review of existing standard and following stake holder consultation. This exercise is completed in consultation with various leading manufacturers to ensure to reflect new testing methods. This measure does not hinder the ability of foreign manufacturer to penetrate and reach into Indian chemical market. There would be no delay on the part of Indian regulator in clearance of import consignments, provided the supplier satisfies the conditions stipulated in the QCO. Regarding the scope of the QCOs, there is no discrimination as they apply to domestic and foreign manufacturers. The BIS formulates the standards by studying all available international standards. Finally, standards are aligned with the international standards. Presently India is in the process of formulating Chemicals (Management and Safety) Rules. The aspect of unnecessary animal testing and the aspect of Mutual Acceptance of Data will be looked into.

2.239. As regards the links for the information of the QCO, the BIS standards are available at the link below.⁵⁰ DCPC has notified the draft Quality Control Orders on chemicals and petrochemicals under the provisions of BIS Act 2016 and Rules and Regulations framed there under, which envisages conformity assessment Scheme-1 of BIS (Conformity Assessment) Regulations 2018. As per draft QCOs, the product specified therein shall conform to corresponding Indian Standard and shall bear the standard mark under the licence from BIS as per Scheme-1 mentioned above. This QCO is equally applicable to domestic and foreign manufacturers who intends to export their products in India. Under the provisions of 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 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 use of Standard Mark as per Scheme -1 is given in BIS (Conformity Assessment) Regulations 2018. The copy of the same is available on BIS website.⁵¹ 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.

2.240. Under the provisions of Scheme-1 of BIS (Conformity Assessment) Regulation 2018, BIS grants a licence to the manufacturer based on successful assessment of the manufacturing

⁵⁰ <https://standardsbis.bsbedge.com/>

⁵¹ www.bis.gov.in

infrastructure, production process, quality control and testing capabilities of a manufacturer through a visit to its manufacturing premises. 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 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 Labs. As per Quality Control Orders on chemicals and petrochemicals, every product shall conform to corresponding Indian standards specified therein and shall bear the standard mark under the licence from BIS as per Scheme-1 of BIS (Conformity Assessment) Regulation 2018. The standards of chemicals and petrochemicals which were notified by DCPC, were reviewed by BIS and due consideration were given to international standards like ISO/ASTM, wherever available.

2.1.3.21 European Union - Non-renewal of the approval of the active substance mancozeb, [G/TBT/N/EU/712](#) (ID 627⁵²)

2.241. The representative of [Australia](#) provided the following statement. Australia reiterates previously-raised concerns and supports the concerns raised by other Members.

2.242. 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 international markets. To assess just how crucial the substance mancozeb is to agricultural production in Costa Rica, it is sufficient to note that it 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. Mancozeb is also used to combat pests of economic importance, particularly in banana production. Costa Rica is the world's second largest exporter of bananas, and the first country to have obtained a geographical indication for this product. 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 Costa Rica's many reservations about the reasoning behind EU regulations, the Costa Rican 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 once again 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.

2.243. The representative of [Brazil](#) provided the following statement. Brazil regrets having 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](#). We thank the EU for responding to our comments in October 2020. As stated in our comments, 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. 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. 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

⁵² For previous statements follow the thread under [ID 627](#).

urge European authorities to consider establishing transition periods that are adequate to the production cycle of the affected crops. 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. Does the EU consider that the TBT notification was made at an early stage in order to take other Members' views into consideration? What other less trade-restrictive alternatives were considered in the development of said draft regulation?

2.244. 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 April 2020 relating to the non-renewal of the approval of the active substance mancozeb. The EU has been adopting measures resulting in the non-approval of the use of plant protection products, which is affecting exports from Colombia. Measures to suspend or not approve the placing on the market of many active substances, and the subsequent reduction of their MRLs to the minimum level of detection, are being taken without strong scientific evidence and without demonstrating that they are indeed the least trade-restrictive measures to achieve an appropriate level of protection. Mancozeb is a fungicide used in more than 70 fruit and vegetable crops to control over 400 phytopathogenic fungi that attack the crops. Its main use is to prevent the fungi from developing resistance to curative fungicides. In Colombia, the active substance mancozeb is essential to protect banana crops against pests and diseases such as "Black Sigatoka". Recently, the EU also banned the marketing of chlorothalonil, which is the main tool for controlling this fungus.

2.245. Banning mancozeb would leave banana-producing countries without any phytosanitary tools to control this disease, resulting in significant economic losses and highly regrettable consequences for the environment and the economic sustainability of banana crops, with their respective social implications. 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. It also constitutes a violation of Article 2.2 of the TBT Agreement, given that, 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. Even though in this and various other cases we have requested the EU to provide information on the deadline for adoption of the standard and on the implementation of maximum residue limits, the EU has failed to respond to these requests. We recall that Article 2.12 of the TBT Agreement provides that "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".

2.246. The information available indicates that the European Food Safety Authority (EFSA) has initiated the procedure for revising MRLs for mancozeb. In this regard, we ask the European Union how, as interested trading partners, we can participate in this process, how our comments will be taken into account and what time frames are envisaged for a decision by EFSA. As the procedure currently being followed by EFSA is different from the international public consultation process that should be followed under the TBT Agreement, we urge the EU to notify the relevant standards at an early appropriate stage and take into account Members' comments, in line with Article 2.9. We also recall that, in the context of the COVID-19 pandemic, Colombia, together with a broad group of countries, requested the EU to temporarily suspend review processes of market approvals for plant protection substances, as well as the entry into force of regulations in this area. This call has also not been taken into consideration and we therefore reiterate our invitation to the EU to provide us with a response and to initiate a dialogue to allow us to explore alternatives. Lastly, we invite the EU to follow the recommendations of good regulatory practices, under which standards must be based on clear and objective information and on the promotion of open dialogue with stakeholders, transparency and the minimizing of market distortions.

2.247. The representative of Guatemala provided the following statement. Guatemala shares the concern regarding the absence of information on the scientific evidence of harm to human health caused by the consumption of fruit and vegetables, particularly those produced in Latin America. The European Union has previously mentioned that it has identified potentially negative health effects of mancozeb. It has failed to provide countries affected with information on the contamination of products that have been assessed with the scientific information available. Moreover, the

European Union has not presented any scientific evidence of the supposed danger and harmful nature of mancozeb in the production and exportation of fruit and vegetables in Latin America. The European Union has notified the Committee on Technical Barriers to Trade of the non-renewal of the approval of the active substance mancozeb. This will lead to a subsequent revision of the current permitted MRLs, which will have a direct impact on agricultural exports to the European Union. Mancozeb is key for the production of a number of strategic agricultural crops that are exported to the European Union, such as fruit (bananas and plantains, among others) and vegetables, which would affect other countries in Latin America.

2.248. In terms of other types of agrochemicals, there are very few alternatives with multi-site properties available for the control of fungi. Mancozeb, as a multi-site fungicide, attacks different parts of the fungus and creates no resistance. In the case of plantains and bananas, mancozeb is essential given the absence of alternatives offering the same effectiveness. Black Sigatoka is caused by the fungus *Mycosphaerella fijiensis*, which invades and necrotizes the leaf tissue, causing leaf death in perennial banana and plantain crops. Black Sigatoka is the disease that has the greatest economic impact on banana and plantain crops worldwide and can only be successfully controlled with mancozeb. The ban on the use of mancozeb will have an economic and social impact on Guatemala, given that both plantain and banana crops are a significant source of job creation, foreign exchange and food for the country. The growth of these crops creates over 280,000 direct and indirect jobs and therefore affects over 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 maintain the current MRLs for mancozeb so as to avoid affecting the production and exports of Guatemala and other Latin American countries, particularly in view of the economic and social impact that this type of measure will have on developing countries. We reiterate the request made in documents [G/SPS/GEN/1778](#) and [G/TBT/GEN/296](#), especially given the current COVID-19 situation.

2.249. The representative of [Ecuador](#) provided the following statement. We thank Australia, Brazil, Colombia and Costa Rica for including this item on the agenda. 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 and maintain its MRLs as a risk management measure to protect the health of consumers in the EU and avoid possible effects that could result in barriers to trade. 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 socioeconomic consequences, given that this sector creates a significant number of jobs, since Ecuador is, as is well known, the world's top exporter of this fruit. Lastly, we reiterate the questions we posed 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.

2.250. The representative of [Paraguay](#) provided the following statement. Paraguay co-sponsors this trade concern relating to the substance mancozeb. Paraguay refers to its previous statements. Like other Members, we are concerned by the EU's decision to base measures on a hazard-based approach without a proper risk analysis and without complying with scientific principles. This has resulted in the reduction of MRLs and the non-renewal of substances such as mancozeb, chlorothalonil and picoxystrobin, which will cause significant damage to Paraguay's export sector. As we have previously stated, 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. We urge the EU to consider less trade-restrictive alternatives and base its measures on conclusive scientific evidence.

2.251. The representative of Chile provided the following statement. As noted in previous TBT committees, Chile would like to echo the comments made by Costa Rica, Australia, Brazil, Colombia, Guatemala, Ecuador and Paraguay. We should again like to express our ongoing concern and will continue to follow up on this matter, especially with regard to establishing a reasonable period of time to find potential alternative substances for the development of productive processes, in this case for mancozeb.

2.252. In response, the representative of the European Union provided the following statement. We have provided detailed explanations on this issue in previous meetings. 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. Implementing Regulation (EU) No 2087/2020 entered into force on 4 January 2021. The non-renewal was based on a scientific assessment conducted under Regulation (EC) No 1107/2009 by experts from the EU member States and the European Food Safety Authority (EFSA). Since 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 was not renewed. EU member States must withdraw existing authorizations for plant protection products containing Mancozeb at the latest by six months from the date of entry into force of the Implementing Regulation (by 4 July 2021). The grace period, in line with Article 46 of Regulation 1107/2009, shall expire, at the latest, after 12 months from its entry into force (by 4 January 2022). The withdrawal period for existing authorisations and the grace period have been extended, when compared to the original proposal, in order to accommodate requests. Following non-approval and the expiry of all grace periods for stocks of products containing this substance, separate action will likely be taken on Maximum Residue Levels (MRLs) and a separate notification will be made in accordance with SPS procedures.

2.1.3.22 China - Commercial Cryptography Administrative Regulations (ID 644⁵³)

2.253. The representative of the European Union provided the following statement. The EU is 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, concerns relate to (i) the scope of the law; (ii) the lack of clarity of concepts & precision of procedures; (iii) the protection of intellectual property; (iv) the imposition of pre-market & export controls; (v) the requirements around testing & 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 organisations. 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 applied 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 Standardisation 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 WTO.

2.254. 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 August 20, 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 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. The draft measure would establish a licensing scheme for all

⁵³ For previous statements follow the thread under [ID 644](#).

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 not be operated as an unnecessary obstacle to trade?

2.255. 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 standard-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.

2.256. The representative of [Canada](#) provided the following statement. On 17 September 2020, Canada provided comments to China's State Cryptography Administration on the draft revised Regulations on the Administration of Commercial Cryptography promulgated on 20 August 2020. Canada continues to 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 standards; and (iv) indicating whether core and ordinary cryptography (as defined in China's Cryptography Law) will, along with commercial cryptography, also be subject to new regulations. Furthermore, Canada would encourage China to notify the measure to the WTO TBT Committee, with a view to providing Members and stakeholders the appropriate time to review and comment on the measure. Canada would also like to take this opportunity to note its ongoing concerns with China's Cryptography Law and its request that China: (i) define the scope of application in a way that ensures only legitimate objectives pertaining to cryptographic goods would be pursued; and (ii) clarify that standards formulated pursuant to the law's provisions would be consistent with the TBT Agreement's transparency requirements.

2.257. In response, the representative of [China](#) provided the following statement. Please see statement delivered under STC 294.⁵⁴

2.1.3.23 Russian Federation - Draft Technical Regulation on Alcohol Drinks Safety (published on 24 October 2011), [G/TBT/N/RUS/2 \(ID 332⁵⁵\)](#)

2.258. 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 trade-related aspects of intellectual property rights. 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. In particular, the EU would like to ensure that enriching wine with concentrated grape must or rectified concentrated grape must or sucrose to attain a higher alcohol content level is an authorised practice for imported wines. The EU is concerned by the mandatory labelling requirements, which are not in

⁵⁴ Para. 2.103.

⁵⁵ For previous statements follow the thread under [ID 332](#).

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. 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.

2.259. In view of these inconsistencies, the EU understands that the Russian authorities have postponed the entry into force of this measure by one year, and grant a transitional period to further discuss the standards and explore whether business operators can progressively adapt them. It appears that the discussion in Duma on the so-called Bakharev amendment to the Federal Law N° 468 of 27.12.2019 on wine making and wine growing in the Russian Federation is delayed. Can the Russian authorities inform if this delay would affect the timing of the amendment of the draft technical regulation on alcohol products safety? If yes, could you please inform when the final decision will be taken and formalized? The European Union would like to ask Russia to take these comments into consideration and to renotify the new version of the measure, under the TBT agreement as well as under the TRIPS agreement.

2.260. In response, the representative of the Russian Federation provided the following statement. The Technical Regulation has been raised in this Committee many times and we commented on most of the arguments put forward today. Let me underline the main points that we made previously on this issue. The Technical Regulation was adopted in December 2018 and is planned to enter into force on the 1st of January 2022. The draft measure was notified back in 2012 as per Russia's obligations under the Agreement on TBT. There are no plans to renotify adopted text of the Technical Regulation in the TBT Committee. In case amendments to the Technical Regulation are developed, Russia will submit relevant notification. With regards to notification in the Council for TRIPS, as we stated previously multiple times, we fail to see grounds set out in Article 63 of the TRIPS Agreement for such notification of the Technical Regulation. 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. Core aim of such requirements is to provide 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. We would like to stress that this Technical Regulation contains no discriminatory provisions aimed to restrict trade.

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/EEC/264](#), [G/TBT/N/EEC/264/Add.1](#), [G/TBT/N//EU/44](#), [G/TBT/N/EU/570](#), [G/TBT/N/EU/571](#) (ID 345⁵⁶)

2.261. The representative of the United States provided the following statement. European Union Regulation 2019/33 supplementing Regulation No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation (and its accompanying annexes) and Commission Implementing Regulation 2019/34 laying down the rules for the application of Regulation (EU) No 1308/2013 as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, amendments to product specifications, the register of protected names, cancellation of protection and use of symbols, and of Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards an appropriate system of checks. It is very disappointing that the United States must again raise its concerns with the EU's 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 but to keep this item on the WTO TBT Committee's agenda, as well as the agenda of the WTO Council for Trade in Goods. 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 nearly three years? What does the EU mean

⁵⁶ For previous statements follow the thread under [ID 345](#).

when it says "under consideration?" Are they being actively considered, or have they been put on hold? If the applications have been put on hold, please explain why.

2.262. As we have indicated at each TBT Committee since November 2019, 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, May, and October 2020 TBT Committee meetings, please tell us the following: (i) how many applications for traditional terms have been lodged over the last ten years; (ii) how many of those applications have been approved, rejected, or remain pending; (iii) what is the average time between application and a final decision; (iv) for pending applications, how long have they been waiting; and (v) how many of the applications have come from member States? Can the EU confirm how the processing of these applications has changed, if at all, over the last two years following the adoption of Implementing Regulation 2019/34? The United States has asked for clarification on this point during each TBT Committee meeting since November 2019 but has not received clarification from the EU.

2.263. We again thank the EU for its response to our TBT comments, and clarification that our pending applications would not be subject to any new rules. However, several concerns remain, to include: Confirmation that US producers can continue to use any generic term, such as a grape variety, that is part of a compound term protected as a GI by the EU. For example, US producers could still use the grape variety "Montepulciano," even though the EU protects the compound name "Montepulciano d'Abruzzo." How do third countries find out about amended changes with respect to EU Protected Designations of Origin (PDO) and Protected Geographical Indications? In its response to our TBT comments, the EU indicated that parties "... may submit an application to the Commission objecting to [an] application ... within two months of the date of publication in the Official Journal of the European Union." We would like to remind the EU of its obligations under Article 2.9 of the TBT Agreement to notify the WTO of these changes in draft form so that parties may comment through the formal WTO process. What is the definition of "generic?" This question was not addressed in the EU's response to our TBT comments. Lastly, we continue to seek confirmation that the revised regulation will not alter the ability of US producers to use terms such as "barrel aged" as provided for in Appendix II of the Protocol on Labelling to the 2006 U.S./EU Wine Agreement. In its response to our TBT comments, the EU indicated that "consumers' expectations have been taken into account by reserving some labelling particulars concerning specific production methods." Based on this response, we remain unsure if the term "barrel aged" can still be used and ask that the EU please clarify.

2.264. The representative of Brazil provided the following statement. Brazil would like to support the concerns raised by the US and refers 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.

2.265. The representative of New Zealand provided the following statement. We refer the European Union to New Zealand's statement on this trade concern made at preceding TBT Committees, most recently in October 2020: New Zealand recognizes that Members have the right to protect their consumers from deceptive practices in line with their obligations under the World Trade Organization. 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.

2.266. The representative of Argentina provided the following statement. We thank the United States for including this specific trade concern (STC) on the Committee's agenda. Argentina reiterates 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 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.

2.267. 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/IND/44](#), [G/TBT/N/IND/44/Add.1](#), [G/TBT/N/IND/44/Add.2](#), [G/TBT/N/IND/44/Add.3](#), [G/TBT/N/IND/44/Add.4](#), [G/TBT/N/IND/44/Add.5](#), [G/TBT/N/IND/44/Add.6](#), [G/TBT/N/IND/44/Add.7](#), [G/TBT/N/IND/47](#), [G/TBT/N/IND/47/Add.1](#), [G/TBT/N/IND/47/Add.1/Corr.1](#), [G/TBT/N/IND/47/Add.2](#), [G/TBT/N/IND/47/Add.3](#), [G/TBT/N/IND/58](#) (ID 367⁵⁷)

2.268. The representative of the United States provided the following statement. We understand that on 1 October 2020 the Ministry of Electronics and Information Technology (MeitY) published Phase V of the Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order (CRO), effective 1 April 2021, which expands the CRO requirements to include seven additional product categories, including digital cameras, video cameras, Bluetooth speakers, and smart speakers. While we appreciate MeitY's provision of six months for US industry to comply with Phase V of the CRO, we note that this timeframe is insufficient because India has yet to provide the necessary resources and guidance for compliance, namely: 1) product series guidelines and FAQs from MeitY; 2) the new Test Report Format from the Bureau of Indian Standards (BIS); 3) a BIS portal for submitting applications; 4) and laboratories that are accredited by BIS and ready to accept products for testing. According to US industry, without these necessary resources and guidance, it will be impossible to fully comply with the CRO's registration requirements within the allotted timeframe. With respect to Phase V and all future Phases, we ask that MeitY provide a transition period of at least one year from the date on which all four of the necessary resources and guidance listed above have been made available. We also understand that US industry has expressed concerns regarding how the scope of Phase V appears to be based on HS codes rather than individual products, potentially including a wider scope of products than intended. Specifically, we note that Phase V includes the product categories "digital cameras" and "video cameras." We encourage MeitY to instead consider categorizing these cameras based on their end use, e.g. professional cameras or security cameras, to accurately refine the Phase V scope. The United States also understands that, beginning in the spring of 2020, Indian authorities began requiring final application approval by MeitY after BIS approval. This added requirement has extended the review process from four weeks to six-nine weeks. According to US industry, India did not provide any notice concerning this added requirement or its impact on the anticipated processing period. We ask that India provide greater transparency when introducing changes to its review process to ensure that the process does not have the effect of creating unnecessary obstacles to international trade and that applicants are aware of the anticipated processing period, especially ahead of major sales seasons.

2.269. The representative of Canada provided the following statement. Canada would like to reiterate longstanding concerns raised by Canada and other WTO Members regarding the Compulsory Registration Order since 2012, and which can be summarized as follows: (i) high cost for operators associated with mandatory testing in India; (ii) requirement that product testing be done only by Bureau of Indian Standards-accredited labs located within India; (iii) Order does not allow for the use of international standards; and (iv) the failure on BIS's part to recognize test results from internationally accredited labs. Canada continues to urge India to adopt IEC standards and to recognize test results from internationally accredited labs.

2.270. In response, the representative of India provided the following statement. MeitY has notified seven product categories under phase V Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order (CRO) on 1 October 2020, scheduled to be effective from 1 April 2021. The series guidelines and test report formats for product categories notified under CRO Phase-V are available in the public domain at <https://www.meity.gov.in/esdm/standards> and <https://bis.gov.in/index.php/laboratorys/utrf>, respectively. FAQs just provide clarification to the queries of the industry. The product categories are notified under CRO irrespective of their HS codes. The digital and video cameras are separate product categories. It would not be feasible to categorize the products according to their end use.

⁵⁷ For previous statements follow the thread under [ID 367](#).

The same product may have different end-uses. For concerns of Canada: The testing charges are market-driven. The Compulsory Registration Scheme (CRS) as laid down requires testing to be conducted at BIS-recognized labs. There is no requirement for in-country testing in the notification. There is a provision for overseas labs also to seek recognition from BIS based on the qualification criteria. The sample of the notified goods must be tested from any laboratory recognized by the BIS or any laboratory abroad covered under a mutual recognition agreement with the Bureau. Indian standards regulated under Compulsory Registration Order (CRO) are harmonized with or based on relevant international standards. Components certified under the IECEE CB Scheme are being accepted for the purpose of product approvals under the CRS.

2.1.3.26 China - Registration Fees for Drugs and Medical Device Products (ID 466⁵⁸)

2.271. The representative of the Republic of Korea provided the following statement. Korea has continuously raised concerns on China's Registration Fees for Drugs and Medical Devices through bilateral and multilateral channels and would like to refer to our statements made during the last meeting. Korea wishes to request China to take into account Korea's comments on the revision of the Charging Standards for Drug and Medical Device Registration from 2015.

2.272. 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 minor difference of the registration fees is due to different workload and price level.

2.1.3.27 Indonesia - Halal Product Assurance Law No. 33 of 2014, [G/TBT/N/IDN/123](#), [G/TBT/N/IDN/131](#) (ID 502⁵⁹)

2.273. The representative of the European Union provided the following statement. The EU thanks Indonesia for a fruitful bilateral meeting. The European Union reiterates 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, implying strong repercussions and difficulties in EU trade with Indonesia. The EU regrets that, contrary to Article 2.9 of the TBT Agreement, Indonesia failed to notify to the TBT Committee the Halal Product Guarantee Law and Implementing Regulation No 31/2019. Indonesia notified Implementing Regulation 26/2019 on the Facilitation of Halal Product Assurance and Regulation 31/2018 on Processed Food Labelling to the TBT Committee and the EU invites Indonesia to reply to its comments of 27 April and 12 May 2020. The EU acknowledges the recent notification to the TBT Committee of a draft Government Regulation (RPP) on Halal Product Assurance implementing the Omnibus Bill on Job Creation (Law 11/2020). The EU stresses the excessive restrictive impact on trade of the 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. Among the main issues of concern, we can mention the "non-Halal" information requested for non-Halal products or the extension of Halal requirements to products other than food and beverages. In particular, the need for a government-to-government arrangement as a pre-condition for recognition of foreign Halal certificates represents an excessive burden for economic operators and does not facilitate trade. The EU appreciates some flexibility from Indonesia on this issue. The additional registration requirement for Halal certifications by foreign bodies appears unjustified, costly and duplicative. 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 International Laboratory Accreditation Cooperation (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. The EU indicates its willingness to further discuss and cooperate on Halal issues with Indonesia, with the aim of finding a practical way forward and to resolve concerns.

2.274. The representative of Australia provided the following statement. Australia welcomes ongoing discussions on the Indonesian Halal Product Assurance Law no.33 of 2014 (Halal Law) and

⁵⁸ For previous statements follow the thread under [ID 466](#).

⁵⁹ For previous statements follow the thread under [ID 502](#).

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.

2.275. 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 the recent notifications of a new draft implementing regulation for the Halal Law, submitted to the Committee as [G/TBT/N/IDN/131](#). We hope all comments submitted to this notification are taken into consideration as the regulation is finalized. We understand that Indonesia finalized and issued: (i) Government Regulation 31 of 2019 in May 2019 on "Implementation Provisions of Law 33/2014 regarding Halal Product Assurance" related to the Halal Law; and (ii) Ministry of Religious Affairs (MORA) Decree no. 464, a positive list for products requiring halal certification. We ask that Indonesia notify these measures and any additional implementing measures to the Committee. We understand that the Halal Product Assurance Agency is starting to develop implementing measures and guidance for specific product categories. We ask that Indonesia specify the process and timeline for notifying and soliciting public comment on the implementing measures regarding the certification, packaging, and labelling requirements for specific product categories. 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?

2.276. We also await clarification about the status of proposed legislation connected with "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 understand that on 5 October 2020, Indonesia finalized an Omnibus Job Creation Bill that modifies the original Halal Law. How does the Omnibus Job Creation Bill modify the original Halal Law? 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? In view of these regulations, are manufacturers of products and ingredients that contain denatured alcohol required to label such products and ingredients as haram as specified in Indonesian Ulema Council (MUI) Fatwa 11 of 2009? Will the requirements for non-Halal labels be applied equally to both imported and domestically manufactured products? We also ask that the aforementioned BPOM/NADFC regulations for cosmetics be notified for comment, if they will result in new labelling requirements for US cosmetics imported into Indonesia. We ask that Indonesia consider the industry and US Government comments submitted expressing concerns as to the feasibility and necessity of requiring that all categories of covered products have separate Halal versus non-Halal manufacturing, processing, storage, packaging, and distribution facilities. Did the January 2021 draft implementing regulation of the Halal Law exclude the requirement for separate sales facilities for Halal versus haram products?

2.277. 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. We are also concerned about the inclusion of genetically engineered (GE) products on the list of products requiring certification under the MORA Decree no. 464. Could Indonesia provide its justification for requiring the certification of GE products? Previously, the MUI issued Fatwa 35/2013, which declares that GE products are Halal provided that they are useful and do not cause harm. The United States notes that requiring certification of GE products could cause trade disruptions and adversely impact Indonesia's textile and livestock industries that utilize US GE commodities, such as soybeans and cotton. Therefore, the United States requests the removal of GE products from the list of products requiring halal certification in Decree no. 464. 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. It is unclear whether their current recognition in Indonesia will expire immediately upon the MORA implementing regulation's enactment, or whether a grace period for the application process will be provided. Can Indonesia provide clarity on the application status of the US-based Halal certifiers, and whether a grace period will be provided that will allow the continuation of imports during the application process? Does the January 2021 draft implementing regulation of the Halal Law extend this recognition to other products these certification bodies cover, including cosmetics?

2.278. 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. 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's December 2019 letter 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. 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? 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.

2.279. The representative of Canada provided the following statement. Canada would like to thank Indonesia for its continued engagement on this issue. However, a number of concerns pertaining to the law are still outstanding and we would appreciate further clarification from Indonesia on implementing regulations. 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. As this would be beneficial to importers, we would appreciate if Indonesia could inform whether this specification will be included in the forthcoming implementing regulations for the Halal Product Assurance Law. However, concerns remain with the requirement that non-Halal products must include non-Halal information in the form of "pictures, signs, or writing" as this may be overly burdensome and restrict mutually beneficial commerce. In Canada's view, products that do not display a Halal certification can be safely assumed to be non-Halal. We look forward to further constructive dialogue on other outstanding issues, including the Halal certification requirements for single-ingredient frozen foods, accreditation requirements for certification bodies accredited by a third-party accreditor and discussions on further implementing regulations. Any information Indonesia is able to share on the expected timelines for the pending implementation regulations of the Halal Product Assurance Law would be most welcome. This will help Canadian producers comply with the new law and allow trading partners to comment and seek the necessary clarifications.

2.280. The representative of New Zealand provided the following statement. New Zealand would like to thank Indonesia for its ongoing engagement to date regarding this matter. In reference to the response Indonesia provided in the previous committee 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 Organisations whose certification will soon expire or has already expired with 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 also 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.

2.281. In response, the representative of Indonesia provided the following statement. Indonesia would like to refer to its statement on the last TBT meeting on October. Indonesia is aware of its transparency obligations as mandated in the TBT Agreement. Thus, Indonesia has notified draft Regulation of Minister of Religion Affairs through document [G/TBT/N/IDN/123](#) as one of the

implementing provisions of Halal Law. However, the status of this provision is yet to be enforced as the draft is still being reviewed. Recently, Indonesia has also notified draft of Government Regulation regarding Implementation of Halal Product Assurances as the implementing provisions of Halal Law in document [G/TBT/N/IDN/131](#). This aforementioned regulation will revoke Government Regulation No. 31/2019. Indonesia would like to reiterate 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.

2.1.3.28 Russian Federation - Rules of cement certification, [G/TBT/N/RUS/48](#), [G/TBT/N/RUS/49](#) (ID 497⁶⁰)

2.282. 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 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 notification to this day, as well as the explanations provided by the Russian Federation during the last TBT Committee meeting, referring to delays caused by the COVID-19 pandemic, 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.

2.283. In response, the representative of the Russian Federation provided the following statement. As the issue has been considered multiple times in this forum, we refer to our previous statements and have nothing new to report.

2.1.3.29 India - Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulations, 2015, [G/TBT/N/IND/51](#), [G/TBT/N/IND/104](#) (ID 494⁶¹)

2.284. The representative of the European Union provided the following statement. The EU would like to reiterate some remaining concerns regarding this measure. We took note of the new amendment regarding alcoholic beverages that was published on 18 December 2020 and will apply as from 1 July 2021. Several of our concerns for wine have been taken into account and an alignment to OIV standards took place for large parts. This is a large step in the right direction. There remain however some issues, described in EU comments on [G/TBT/N/IND/104](#), for which we would welcome a reply. We 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 (to allow the sale of products already present on the Indian market until stocks are exhausted in order to minimise the impact for economic operators) and transition period. The presence of some technical specifications (the maximum alcohol content, some spirits definitions) that may not be in line with international widely accepted practices and could result in an adverse impact for international trade. We hope that we can continue our discussion and find an acceptable solution to the outstanding issues.

2.285. The representative of Mexico provided the following statement. We thank the European Union for including this matter and share the concerns expressed. For the delegation of Mexico, the amended version gives rise to the following concerns: The limitation of percentage alcohol by volume (ABV) in all categories to a maximum of 50% ABV restricts the importation and sale of barrel-aged whiskies and premium expressions. The minimum alcohol content for aperitifs, currently set at 15%, is also limiting. The analytical parameters that are established for a number of categories and that do not exist in other countries. Definitions that are inconsistent with international practices and

⁶⁰ For previous statements follow the thread under [ID 497](#).

⁶¹ For previous statements follow the thread under [ID 494](#).

national standards. The requirement that all beverages produced in pot stills must include the description "Pot-Distilled" on the back label. There is no such requirement in Mexico and it will lead to an unnecessary and costly adjustment of labels for various categories of alcoholic beverages. Requirements relating to the duration of the maturation process, which does not reflect the fact that the time required for a product or ingredient to mature to obtain a certain flavour depends on the type of product and cannot be laid down by a generic provision. In light of the above, Mexico would appreciate information on the status of this regulation and on whether it is possible to extend the time period for its entry into force until July 2022. We thank India for giving its attention to this statement and for the response to the concerns raised.

2.286. In response, the representative of India provided the following statement. The majority of the standards prescribed in the FSSAI Alcoholic Beverages Regulations, 2018, have been aligned with OIV in line with WTO commitments. The issues highlighted have been discussed several times in Scientific Panel meetings on Alcoholic Beverages and the alcohol content, sugar content, etc., have been established after extensive deliberations. In addition to this, alignment of the methods of analysis of alcoholic beverages with the OIV is under process.

2.1.3.30 Egypt - Manufacturer Registration System (Decree No. 43/2016 and Decree No. 992/2015), [G/TBT/N/EGY/114](#), [G/TBT/N/EGY/115](#) (ID 505⁶²)

2.287. 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. The EU calls on Egypt to immediately register all EU companies that have updated or will update their quality certificates, without discrimination in relation to the sectors of their activity and without the need of restarting the application process. The EU reiterates furthermore 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, lack of a clear appeal procedure, and a high level of discretion in granting registrations. As such, the measure raises questions of compatibility with the WTO TBT Agreement. 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.

2.288. The representative of the Russian Federation provided the following statement. The Russian Federation reiterates the statements made during the previous meetings of the Committee on Technical Barriers to Trade and the Council for Trade in Goods on the Egyptian registration procedures under the Decree № 43/2016. The registration procedure is burdensome, time consuming, untransparent and represents discriminative barrier for trade. Companies that provided full set of documents for registration to Egypt's authorities have been denied market access for years without providing proper reasons. We question the consistency of the measure with Egypt's obligations under, *inter alia*, Articles 5.1 and 5.2 of the Agreement on Technical Barriers to Trade, Article I, III and XI of GATT 1994. We request Egypt to reconsider this registration system and ensure its compliance with the rules of this organization.

2.289. The representative of Turkey provided the following statement. Turkey would like to thank Egypt for constructive engagement on this issue. However, we join the EU and Russian Federation to emphasize our ongoing concerns on Egypt's Decree on manufacturer registration system, as the structural problems related to this Decree and implementation still continue. In this regard, it is still unclear how the applications are evaluated, whether the completion of the process is subject to any time limits and which steps should be followed to complete a registration process. In addition, companies are not informed on the status of their application and no notification is made to companies whether their application is approved or not. Expectedly, companies face long delays and bear additional costs in the registration process. Therefore, Turkey would like to reiterate its expectations from Egypt to review this measure considering the principles and obligations in the WTO Agreements and ensure its implementation in full transparency.

2.290. In response, the representative of Egypt provided the following statement. We thank the European Union and Russia for maintaining this item on the agenda, and we would also like to express our appreciation for the bilateral exchanges we have had with a couple of delegations in this

⁶² For previous statements follow the thread under [ID 505](#).

respect. We will refrain from repeating the points raised in previous statements concerning the rationale and administration of Decree 43/2016. Instead, we will focus our intervention today on the steps undertaken to enhance the transparency of the Decree implementation. Starting last year, and due to demands by some WTO Members, Egypt's General Organization for Export and Import Control (GOEIC) has commenced to publish via its official website lists of the companies whose registration was suspended due to documentation issues, as well as those who are in need to renew the required certificates to avoid the registration process re-initiation, granting them grace periods for the certification renewal. Earlier this year, GOEIC published a list of companies whose applications have been pending due to the need for valid documents, granting them a grace period from 17 January until 28 February 2021, and we invite Members with pending companies' applications to consult this list.

2.291. Moreover, in previous committee meetings a couple of Members expressed concern over the publication of the aforementioned lists in Arabic only, and in this vein GOEIC has started to share an English translation to the published Arabic lists for the sake of facilitating and accelerating the access to such information. And finally, a number of exchanges have recently taken place on the level of capitals or via Members' embassies in Cairo, both to acquire the needed clarifications and to address company-specific problems. It is worth highlighting that transparency enhancement efforts have been slowed down and hindered by the COVID-19 pandemic and the subsequent containment measures that complicated further the coordination process among the concerned governmental authorities. To conclude, we renew our invitation to the concerned Members to reach out to us both on the level of permanent missions as well as capitals to address the specific problems facing companies with regard to the registration process.

2.1.3.31 China - Cybersecurity Law (ID 526⁶³)

2.292. The representative of the European Union provided the following statement. The EU would like to refer to its comments at 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 of 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 as to what is considered as critical information infrastructure and which kinds of cross-border data transfers are affected. The definition of critical information infrastructure appears to cover many commercial activities and whole sectors that have no connection to national security. Additionally, the list of what is considered important data is open-ended and this has not been further clarified by the released draft for the Data Security Law in July 2020. As a result of the data localisation 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). Furthermore, 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 WTO in order to give adequate opportunity to Members and their stakeholders to comment on any subsequent developments.

2.293. The representative of Japan provided the following statement. Japan continues to have concerns regarding the China's "Cybersecurity Law" and would like to refer to the previous statement we made at the last TBT Committee in October 2020. Japan is concerned with the related enforcement regulation as well. 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.

2.294. 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 Personal Information Protection Law, on which Australia made a submission in November 2020. Australia reiterates our previous position regarding China's Cybersecurity Law and related laws. Australia respectfully reiterates our concerns that some

⁶³ For previous statements follow the thread under [ID 526](#).

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 measures that are reasonably available to achieve its objectives.

2.295. 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 sometime 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 Multi-Level Protection Scheme (MLPS). 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.

2.296. 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 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.

2.297. The representative of Canada provided the following statement. Canada echoes comments made by previous Members and reiterates concerns made in previous meetings.

2.298. In response, the representative of China provided the following statement. The "Cybersecurity Law" has been implemented since 1 June 2017. It is a basic, framework and comprehensive law in the field of cybersecurity in China. It clarifies the responsibilities and obligations of all aspects in safeguarding cybersecurity, and puts forward a series of institutional arrangements and key tasks. Since the implementation of the cybersecurity law, it has played an important role in safeguarding the national cyber security. Drawing on international practices, in response to national conditions, it is entirely within the sovereignty of each Member to formulate relevant network laws and administrative regulations and manage the network according to law. The purpose of enacting and implementing the cybersecurity law is to safeguard the national cyberspace sovereignty, national security, social and public interests, and to protect the rights and interests of citizens, legal persons and other organizations. "Cybersecurity Law" is a law to promote development and opening up, that is, to be based on opening up and globalization to safeguard national cyber security. China welcomes enterprises from all over the world to invest in China, welcome all kinds of products and services to enter Chinese market, taking the opportunities and sharing the development benefits.

2.1.3.32 European Union - Regulation (EC) No 1272/2008 (CLP Regulation), G/TBT/N/EU/629 (ID 539⁶⁴)

2.299. The representative of the Russian Federation provided the following statement. The Russian Federation reiterates its statements made during the previous regular meetings of the Committee on Technical Barriers to Trade and the Council for Trade in Goods on cobalt classification approved under the 14th Adaptation to Technical Progress to the CLP Regulation and notified in the document [G/TBT/N/EU/629](#). The EU adopted this classification in the absence of comprehensive scientific and epidemiological data. Based on this classification, it is clear that the European Commission will go further and develop industrial, product-specific and technical regulations, which will set unjustified restrictions or prohibit cobalt use. Moreover, as a result of stigmatization, even without further restrictions cobalt and cobalt-containing products consumption will suffer due to deselection of these products by manufacturers of the final goods, such as, electric vehicles' batteries, energy storage units and similar equipment critical to fight the climate change and achieve green sustainability. Although we welcome European Commission's efforts to approve gastric bioelution, we note that this methodology has not been approved yet. In this regard, could the EU inform the Committee on the state of work on bioelution? Finally, the Cobalt Institute completed all the formal procedures under the legislation of the European Union to initiate scientific study on carcinogenicity of cobalt metal for oral route of exposure. In this regard, we request the European Union to confirm that adopted cobalt classification for all routes of exposure will be reconsidered in case of shown negative carcinogenicity of this metal for oral route of exposure.

2.300. 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 affect nickel production in Brazil. From 1 October 2021, cobalt metal will no longer be allowed to be placed on the market on its own or in alloys (above the concentration limits in Table 3 below) for supply to the general public and must be labelled as "Restricted to professional users". 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 US\$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 a significant impact on trade.

2.301. The representative of Australia provided the following statement. Australia would again 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. Australia and other WTO Members have raised concerns on multiple occasions in this and other forums that these measures remain 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 once more urge the EU to ensure that the implementation of the regulation, including associated labelling and packaging requirements raised in October, are no more trade restrictive than necessary. We again 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. There are remaining concerns among the Australian chemical, cosmetic, medicament, paint and resources sectors.

2.302. We welcome a further response to our 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. Further, while we welcomed the final EU classification being limited to mixtures containing titanium dioxide

⁶⁴ For previous statements follow the thread under [ID 539](#).

that are placed on the market in powder form (with a diameter smaller than 10 µm), 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.

2.303. In response, the representative of the European Union provided the following statement. 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. 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 harmonised 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).

2.304. 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. 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 has been 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.

2.305. 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 Risk Assessment Committee (RAC) opinion.

2.1.3.33 European Union - Organic production and labelling - Maté (erva-mate), G/TBT/N/EU/738 (ID 524⁶⁵)

2.306. The representative of Brazil provided the following statement. Brazil regrets having to raise STC 524 after being consistently reassured by the EU that Regulation (EU) 2018/848 would come to force on January 1st, 2021. Brazil had raised this STC for the last time in the TBT 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. 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 force on 1 January 2021, Regulation (EU) 2018/848 will now 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. Brazil kindly asks the EU if it intends to once again put off the entry into force of said regulation.

2.307. In response, the representative of the European Union provided the following statement. 55 The European Union reiterates 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. 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. The EU 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). As explained by the EU in its reply of 5 January 2021 to Brazil's written comments, the new organic rules will enter into application on 1 January 2022. From this date, Erva-Mate will be included in the scope of Regulation (EU) 2018/848, as it is listed in Annex I as a product closely linked to agriculture.

2.1.3.34 China - Catalogue of Solid Wastes Forbidden to Import into China, G/TBT/N/CHN/1211 (ID 545⁶⁶)

2.308. 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 understands that China itself is the largest global producer of vanadium slag, and that its production has reportedly increased over 30 percent since 2018. 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

⁶⁵ For previous statements follow the thread under [ID 524](#).

⁶⁶ For previous statements follow the thread under [ID 545](#).

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.

2.309. The representative of Canada provided the following statement. Canada would like 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 regarding the inclusion of wood pellets for energy production on the list of banned waste products. As we previously noted, Canada does not wish to dispute China's willingness to protect the environment, including by limiting harmful impacts resulting from contaminated waste material. Canadian wood pellets, however, are not contaminated. They are made from pure forest fibre, such as logging residuals (small diameter stems and branches) and residues (sawdust) from logs being converted into lumber in sawmills. Wood pellets are beneficial for the environment and can contribute to China's goal of enhancing environmental protections. Wood pellets are a renewable, low-carbon resource and switching from coal to wood pellets reduces GHG emissions significantly. We urge China to consider other mechanisms to address the very specific problem of contaminated materials, while ensuring that mutually beneficial trade can continue in a predictable manner and fulfilling environmental protection goals. We would be pleased to provide additional information on the nature of wood pellet production in Canada.

2.310. In response, the representative of China provided the following statement. China has been pushing for ecological progress, pro-actively practicing 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 the purpose of safeguarding the ecological safety and population health to the maximum extent possible.

2.311. 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 and issued the relevant national standards as recycling materials for copper, recycling materials for brass, recycling materials for cast aluminium alloys, recycling iron-steel materials and etc. It has been noticed internationally that cross-border transfers of wastes to developing Members brings serious environmental pollution problems, and international society is actively taking measures against it. 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. 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.

2.1.3.35 Viet Nam - Cybersecurity Measures (ID 544⁶⁷)

2.312. 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 Vietnam have any updates to share on the status of the draft decree?

2.313. 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 Cyber Security Law and thank Viet Nam for its engagement on this matter.

2.314. 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 information on whether Viet Nam has adopted the Implementing Decree on Cybersecurity and invites Viet Nam to seriously consider EU concerns and continue the dialogue to ensure alignment to international best practices. We would also appreciate information on any other draft implementing measures and on whether comments from interested parties, including industry and stakeholders, are considered. 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.

2.315. The representative of Canada provided the following statement. Canada recognizes the importance of cybersecurity and appropriate measures to preserve it, and appreciates the efforts Viet Nam is undertaking to develop measures implementing its Cybersecurity Law. Nonetheless, Canada shares other WTO Members' concerns and continues to have issues with the compatibility of Viet Nam's measures with its WTO commitments. In line with our previous statements, Canada continues to seek: Viet Nam's recognition that, as currently drafted, the law and implementing decree could have very extensive product coverage; notification by Viet Nam of the law and implementing decree to the TBT Committee; and the use of international standards and conformity assessment frameworks including the CCRA certification process; Could Viet Nam please update the Committee on the status of the implementing decree and what steps it plans to take next?

2.316. In response, the representative of Viet Nam provided the following statement. The Vietnamese Law on Cybersecurity and the draft Decree for implementing certain articles of this Cybersecurity Law have not regulated technical requirements with regard to information technology products or equipment. Viet Nam would like to reiterate that our process has been transparent with an open mind. All stakeholders' comments have been reviewed for internal consideration. The draft Decree for implementing certain articles of Viet Nam's Cyber Security Law has been developed in a manner of being suitable to reality and creating the most auspicious conditions for foreign enterprises operating in Viet Nam, without any obstacle to the development of the Digital Economy. The draft Decree for implementing certain articles of this Cybersecurity Law was submitted to the Prime Minister of Viet Nam in November 2020 and will be issued soon.

⁶⁷ For previous statements follow the thread under [ID 544](#).

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 (ID 567⁶⁸)

2.317. 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. 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 Russian Government adopted Resolution No 515 on 26 April 2019 on the "marking of goods subject to mandatory labelling by means of identification". 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. 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 been considerably affected by the outbreak of the COVID-19 and all corresponding consequences, such as lockdowns, availability of employees, transport disruptions, etc. Disruptions in the supplies of medicines to the Russian market that occurred in autumn 2020, as a direct consequence of shortcomings on both sides, the businesses and the operator of the system, fully demonstrated the need for sufficient transition periods. 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.

2.318. 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; bottled water- pilot project until the end of February 2021; beer – pilot planned to start as of 1 April 2021. We ask the Russian Federation to take into consideration the European Union's comments, to ensure that the implementation of this measure is not unnecessarily trade-restrictive, in accordance with the WTO TBT Agreement.

2.319. 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 Technical Barriers to Trade and sticks to the position that this measure cannot be considered as the technical regulation due to the fact that the system does not meet the requirements for technical regulations set out in Annex 1 of the Agreement on TBT. We do not consider the system as disproportionate. The concept of the system in respect of each product category is elaborated in collaboration with companies involved in manufacturing, import and distribution of the respective product. The business community is extensively consulted before the approval of the system for each product. Mandatory implementation of the system for each product category is preceded by voluntary experiment with importers, manufacturers and representatives of foreign stakeholders in order to ensure system performance and adjust it to specificities of production and distribution process of each product. Also, transition periods for stocks are provided. All described steps allow interested companies to shape new requirements as well to prepare to

⁶⁸ For previous statements follow the thread under [ID 567](#).

them beforehand. To address the EU's claim that the system is not operational, we would provide the following data. According to the statistics of the Operator of the System, to date approximately 19 billion codes have been issued for tobacco products, 2 billion codes for shoes, 6.7 billion for pharmaceuticals, about 1.4 billion codes for textiles, 86 million for perfumes, 66.3 million for tyres. Figures show that the system is up and running with no major problems unsolved. Temporary difficulties in pharmaceutical market right after the system became operational for medical products, as mentioned by the EU, were promptly addressed by the Government of the Russian Federation through the Resolution № 1779 on the 2 November 2020. Faithful manufacturers and importers should benefit from the system as illicit products are removed from the market.

2.1.3.37 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/918](#), [G/TBT/N/KOR/919](#), [G/TBT/N/KOR/937](#) (ID 588⁶⁹)

2.320. The representative of the European Union provided the following statement. The EU strongly supports actions taken to protect 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. However, the EU remains concerned about the negative impact that the notified measure would have on trade. The EU welcomes the exemption from the labelling requirement given to producers of wine and whisky. However, the EU continues to be concerned about the requirements for olive oil bottles. These too can 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 the Environment in June 2020, and EU producers and importers of olive oil are currently making individual exemption requests as well. The EU would appreciate a positive review of these exemption requests without further delay for olive oil bottles, and for other producers that have made an exemption request. The EU would also like to know when the next meeting will take place of the Packing Materials Review Committee, who process these exemption requests.

2.321. 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 that the labelling exemption provided to wine bottles is provided on the basis that the wine bottles, being made of glass, are not "difficult to recycle". Australia seeks clarification that in the case that a labelling exemption is provided on the basis that the bottles are not "difficult to recycle", that this exemption would also be applied consistently to the environmental fee.

2.322. The representative of Mexico provided the following statement. The delegation of Mexico refers to the amendments to the implementing regulations of the Act on the Promotion of Saving and Recycling of Resources, notified by the Republic of Korea on 9 September 2019 to the Members of this Committee in notification [G/TBT/N/KOR/857](#). Regarding recycling criteria, this measure requires materials and packaging structures to be classified and evaluated in accordance with a criterion of recyclability, and that once the degree of recyclability of a packing material has been determined, it must be displayed on the labelling of the products, except for a specific group of products that have been exempted from this requirement. This measure is in the interest of the Mexican industry exporting alcoholic beverages to the Republic of Korea, due to the financial impact that it represents for its production, and the Government of Mexico is therefore interested in knowing whether tequila will be exempt from this requirement.

2.323. In light of the above, the Government of Mexico requests the delegation of the Republic of Korea to: Share the list of products exempt from the requirement for the degree of recyclability to be included on labelling, as well as clarify whether there are any procedures to be followed to request the exemption of certain products from this requirement, which in this particular case, would be an exemption for tequila. Share the status of the measure. The latest update was notified in November 2019. We would therefore like to have information on the expected date of entry into force, as well as the latest version of the measure, preferably in English. The delegation of Mexico thanks the delegation of the Republic of Korea for giving its consideration to this statement and the requests made therein.

⁶⁹ For previous statements follow the thread under [ID 588](#).

2.324. 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. New Zealand would like to thank the Republic of Korea for providing a response to our written comments and providing a copy of the standard for the quality structure and recyclability of packing materials. New Zealand would appreciate clarification as to whether further specificity will be added to the guidelines contained within the standard. We would also appreciate confirmation of the length of time that will be provided as a transition period before the measures come into force. It is important that traders have both sufficient time and the necessary information to adapt their practices to comply with the regime and do not experience unnecessary barriers or costs to trade.

2.325. The representative of the United States provided the following statement. The United States recognizes the importance for Korea to work towards reducing waste. We thank Korea for its response to U.S. industry comments on the recent notifications of the draft partial amendment of the Act on the Promotion of Saving and Recycling of Resources, and for the recent notification of additional changes to this draft amendment in [G/TBT/N/KOR/937](#). In its response to industry comments, the Ministry of Environment (MOE) suggests that "simplified methods" such as QR codes may be allowed for more flexibility for small-capacity products. Does the MOE intend to release implementing guidance? We appreciate the opportunity to provide comments on any draft implementing guidance as soon as it becomes available. We understand that the implementation date in [G/TBT/N/KOR/918](#) was six months after the date of adoption and in [G/TBT/N/KOR/919](#) was one year from the date of adoption, but the recent [G/TBT/N/KOR/937](#) notification indicates both a date of adoption and implementation of 1 April 2021. Industry will need a minimum of one year from the date of adoption of implementing regulations to incorporate additional labelling, and we urge a reasonable timeline to allow producers to adapt. MOE states in its 29 December response to US industry comments, "Newly released products will be given a one-year grace period ... and existing products will be flexibly applied with a three-year grace period after the revision." Will that three-year grace period begin on the proposed date of entry into force of 1 April 2021? How does MOE define "newly" in "newly released products"? What does "flexibly applied" mean? Will all existing products be afforded the three-year grace period? How will the grace periods be reconciled with inspection requirements in Article 9-(4)? The requirements to include all relevant testing information on a mandatory label increases production timelines and complexities. A company will need to complete all testing before finalizing the labels, extending the timeline and adding additional administrative costs. MOE's response to US industry comments states that "Mandatory labelling is intended to encourage product manufacturers to reduce packaging waste by checking compliance with criteria for packaging materials and methods of packaging in advance." We understand that the Recycling Act currently requires a check of compliance and has a mechanism to have a product inspected if it is believed that a company is not following the requirements of the Recycling Act. How does the proposed amendment for additional labelling help further the stated objective?

2.326. The representative of Chile provided the following statement. Chile thanks the Republic of Korea for its notifications submitted to the Committee on this matter. Chile shares the concerns expressed by other delegations that have already taken the floor. Chile recognizes the right of the Republic of Korea to implement regulations that promote waste reduction and the production of easily recyclable packaging materials. It should be noted that the Ministry of the Environment in Chile has a particular interest in the development of public policies that encourage the circular economy; however, this type of regulation should not be an unnecessary obstacle to trade, which, as indicated by the Chilean wine and drinks industry, this measure will create.

2.327. In response, the representative of the Republic of Korea provided the following statement. Korea would like to thank member States for their interest to this regulation, and would like to deliver official announcement from the competent authority. A glass bottle containing tequila is not exempt from displaying the "Difficult for Recycling" grade based on the Ministry of Environment Notice, Packaging Materials/Structure Grade Display Standards, because tequila is not classified as fruit wine or whiskey. In accordance with the Notice, however, if the Minister of Environment acknowledges that the grade may not be marked after review by the Packaging Materials and Structure Review Committee composed of qualified experts, the duty to label the grade may be waived. The Notice enumerates the examples of packaging materials that are exempt from the labelling duty such as the paper packs with aluminium foil along with the wine bottles, and whiskey bottles. In order to be recognized as a packaging material subject to exemption, the packaging material manufacturer or importer needs to submit the document needed to the Korean Ministry of Environment to prove that the material is difficult to be changed due to concerns over potential

functional failure of the product. Afterwards, the Packaging Materials and Structure Review Committee operated by the Ministry of Environment will review the matters and decide whether or not to waive the duty of labelling.

2.328. Wine bottles are the packaging materials that are recognized as the items to be exempt from labelling duty due to concerns about product malfunctions when the packaging material or structure is changed. Please note that this labelling duty exemption does not correspond to the exemption of their "Difficult for Recycling" grade itself. We could find that the quality of olive oil can be affected when the bottle is colourless according to the documents EU sent. However, clear evidence or relevant data could not be identified as to whether the use of green and brown glass bottles specified in the above notification can affect the quality of olive oil. Some wine bottles with green or brown colour have been rated "Excellent for Recycling", so it is necessary to review whether olive oil bottles can be packed in green or brown glass bottles. Therefore, if an olive oil manufacturer or importer requests an exemption from labelling of its products, the "Packaging Materials and Structure Review Committee" will decide whether to exempt them by reviewing alternative materials and fairness among items. The regular meetings of the "Packaging Materials and Structure Review Committee" are held biannually, and occasional meetings are held under the convocation of the Minister of Environment, if necessary. The most recent meeting was held in July of last year, and the schedule for the next meeting has not been set yet. Once the next meeting is scheduled, we will inform the EU delegation embassy with the timeline and required documents. Also, other requests that give us today will be delivered to the relevant ministries.

2.1.3.38 European Union - Concerns on regulations with regard to eco-design requirements for various products in EU, [G/TBT/N/EU/615](#) (ID 592⁷⁰)

2.329. The representative of [China](#) provided the following statement. We suggest that: (i) the EU clarify whether washing machines without heating function are applicable to this regulation. The draft regulation requires that the washing process of household washing machines should include an "ECO 40-60" washing cycle, 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; and (ii) the EU cancel the requirement for spare parts delivery time. We believe that the delivery time for spare parts is a business practice and should not be stipulated and implemented as a regulation, and this measure is not feasible especially during the COVID-19 pandemic.

2.330. In response, the representative of the [European Union](#) provided the following statement. The Ecodesign 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 declared by the manufacturer, importer or authorised 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 ecodesign 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 Ecodesign 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 for encouraging customers to have their appliances repaired. As indicated in Annex II to the Ecodesign 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 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.

2.1.3.39 Qatar - Ministry of Public Health Circular regarding shelf life for cheese (ID 602⁷¹)

2.331. The representative of the [European Union](#) provided the following statement. The European Union would like 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

⁷⁰ For previous statements follow the thread under [ID 592](#).

⁷¹ For previous statements follow the thread under [ID 602](#).

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 Agreement. The implementation of these rules continues to cause serious disruptions to EU exporters as compliance with these requirements is not feasible for certain cheeses and milk products. As a consequence, EU products covered by the measure cannot be exported to Qatar anymore. The EU would like to recall that this measure is now in place for nearly two years without any clarity provided by Qatar on when this measure will be lifted. 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 work constructively with Qatar to resolve this important issue.

2.332. The representative of the United States provided the following statement. The United States remains concerned over disruptions to trade as a result of Qatar's Ministry of Public Health's (MPH) dairy products regulation, published in May 2019, which restricts the reconstitution of milk and shelf life of cheeses. Qatar adopted this measure without notifying it to the WTO, providing a comment period, or providing a reasonable implementation period. This measure appears to have been issued as a final measure. No comments were taken into account, and the measure has caused significant disruptions to trade since its implementation on 1 June 2019. Despite the United States participating in many bilateral discussions with Qatar, US exports 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 urge Qatar to suspend implementation of this measure until Qatar fulfils its WTO TBT transparency obligations, including notification of the measure to the WTO TBT Committee so that Members may review and provide comments, and so Qatar can take comments into account.

2.333. The representative of Canada provided the following statement. Canada joins the United States and the European Union to reiterate its concerns with Qatar's new shelf-life requirements for identified milk and cheese products established by the Qatar Ministry of Public Health on 30 May 2019. In its response at the last TBT Committee Meeting, Qatar stated that it has taken note of Member's concerns. However, despite efforts to obtain additional clarifications, both through several Meetings of this Committee and through Qatar's Enquiry Point, Canada's questions remain unanswered. Qatar has provided assurances that the relevant measures would apply equally to domestic and imported products. However, the overly restrictive shelf-life requirements and the lengthy ocean transit (50-55 days) from Canada to Qatar make it impossible for Canadian exporters of paneer cheese to fulfil contracts with Qatar importers and comply with the new 45-day shelf-life requirements. As Canada has previously stated, these logistical limitations could effectively lead to favouring domestic or close proximity sourcing of these products, which potentially leads to the discriminatory treatment of imported products. In light of Qatar's stated objective of ensuring the safety and quality of products sold in its market, Canada once again encourages Qatar to notify this measure to the WTO, pursuant to the WTO's transparency obligations, and suspend its implementation to ensure that Member comments and concerns have been taken into account. Canada looks forward to receiving the requested clarifications and information from Qatar, which are detailed in Canada's intervention from the last TBT Committee Meeting, and we will continue to follow these discussions closely.

2.334. 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.

2.1.3.40 Republic of Korea - Ballast Water Management Act (ID 606⁷²)

2.335. 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. Despite numerous reports and clarifications being submitted to the Korea Institute of Ocean Science and Technology (KIOST) in order to obtain the certification, KIOST continues to request even more additional information. This is despite the fact that the tests that have already been submitted are issued by a globally-recognized classification society (DNV GL) and certification body (DHI Group), which are sufficient for certification by many flag states. For example, in Denmark, there is an automatic certification when the testing is carried out by an approved Recognised Organisation (RO), such as DNV GL; other member States require three weeks to three months approximately; and third countries take up to eight months. The certification process has taken more than two years in South Korea and the certificate has still not been issued. This does not appear consistent with Article 5.2.3 of the TBT Agreement. 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 remain under review.

2.336. In response, the representative of the Republic of Korea provided the following statement. Korea would like to thank EU for its interest to this regulation, and would like to deliver official announcement from the competent authority. As explained at various meetings such as the WTO and FTA meetings, this delegation would like to say that Korea's Ballast Water Management Act has already stipulated that foreign and Korean products shall be treated equally in terms of the conditions for type approval. So, we would like to reiterate that Korea has no technical or institutional barriers to foreign products in the type approval procedure of the Ballast Water Management System. In the case of a European company that is undergoing the type approval process in Korea, the deliberation process was completed on 4 January 2021, and the Ministry of Oceans and Fisheries notified the company of the deliberation results. The company was exempted from the readiness evaluation and environmental test, meaning that it is required to conduct only two seawater tests for the land-based test, and validity verification for the shipboard test. It can obtain a type approval certificate if it passes these tests, but it has not yet conducted them. On the other hand, in the case of a Korean company that applied for a foreign type approval at around the same time, the company immediately carried out the tests it was notified to conduct even though the deliberation results called for more demanding requirements compared to the case of the European company, such as the requirement to conduct four times seawater tests for the land-based test, and validity verification for the shipboard test. So, Korea would like to inform you once again that Korea is affording equal treatment to domestic and foreign companies without imposing any technical or institutional barriers in terms of the type approval of the Ballast Water Management System. In addition, this delegation would like to inform you that any comments or enquiries will be received by the Ministry of Oceans and Fisheries, which is the competent authority of Korea.

2.1.3.41 India - Air Conditioner and its related Parts (Quality Control) Order, 2019, G/TBT/N/IND/131, G/TBT/N/IND/143 (ID 598⁷³)

2.337. The representative of China provided the following statement. Firstly, China would like to suggest India change the testing and factory audit method. At present, the factory audit or inspection to be conducted by the Bureau of Indian Standards (BIS) cannot be carried out in other Members due to the COVID-19 pandemic. In this regard, China would like to suggest India conduct remote factory inspection or audit to maintain robust accredited certification. To respond to extraordinary

⁷² For previous statements follow the thread under [ID 606](#).

⁷³ For previous statements follow the thread under [ID 598](#).

circumstances, the general mechanism established by IAF ID3 Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs, and Certified Organizations, and IAF ID4 Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes, instructs the IAF Member ABs and accredited Conformity Assessment Bodies on how to use information and communication technologies to support and maintain the integrity of the audit or assessment process. In addition, many Members' experience has shown that remote auditing with ICT can achieve the audit objectives. We also welcome India to accept the third-party laboratory test or the third-party certification body of other Members.

2.338. Secondly, we suggest India to further extend the transitional period of the implementation of the regulation. Taking into account the current progress of testing and certification and the difference between the parts and the whole machine certification, we suggest that India postpone the certification of air conditioning parts (two devices, electronic control) to 1 January 2022, and postpone the certification of the whole machine to 1 July 2022. Thirdly, we suggest India use ISO9001 quality management system instead. According to our understanding, the BIS certification of India includes factory system approval and product (parts) approval. For factory system approval: at present, it can only be carried out after the on-site factory audit and it can only be arranged according to the schedule of BIS officials. We hope factory audit can accept the equivalent effect of the international general management system, such as the ISO9001 quality management system, which is also the recognition certificate for the production capacity of the factory. For product (component) approval: at present, samples must be sent to India for testing. From the perspective of standard differences, it is suggested that India can accept, for example, European Union product certification (CE) or International Electrical Commission product certification.

2.339. In response, the representative of India provided the following statement. The QCO on AC was notified in December 2019 with implementation date 1 June 2020 and this was extended and the new date of implementation is 1 January 2021.

2.1.3.42 Kingdom of Saudi Arabia - Saber Conformity Assessment Online Platform / Saleem Product Safety Program (ID 615⁷⁴)

2.340. 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. The sector of 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 notified bodies authorized by Saudi Standards, Metrology and Quality Organisation (SASO). In particular, EU exporters report that such notified bodies continue to find new ways to increase costs when carrying out conformity assessment procedures. The European Union would like to raise the following points. Manufacturers report that despite the latest GSO Guidance specifying test reports are only required for one representative item from a product group, Notified Bodies (NBs) frequently request physical samples of all products in a group, and not only of the representative items. This neutralises the benefit of only having an additional assessment for GCTS, based on a representative item. A physical inspection of all items in a product group is still very burdensome and costly.

2.341. There is misunderstanding related to which test reports are required. GSO has created a "toy categorization document" published in June 2020, which includes EN 71-9. This testing is not a useful method when companies have full control of the substances used in toys. This is exactly the objective of chemical control processes and the chemical safety assessment that is a requirement for both the European Union Toy Safety Directive and the GCTS documentation review. Misalignment between scope of Technical regulation for toys (products that require the GCTS), HTS codes and SABER. The latter requires GCTS for all imports under the toy and games HTS codes (9503 and

⁷⁴ For previous statements follow the thread under [ID 615](#).

9504). Some toy and game products are age graded 14+ and therefore officially do not fall under the Toys Technical Regulation, but are still tested against these requirements. However, Notified Bodies do not accept these products for GCTS registration, based on the older age grade of 14+ and therefore not falling under the Toy Technical Regulation. In these cases, SABER cannot process the item because of not having a GCTS code. Changing HTS codes for import is not allowed for the Gulf region – so companies cannot receive GCTS and cannot change the HTS code neither. Therefore, these products currently cannot be imported into Saudi Arabia. The ceramic sector is also very affected. Ever since its establishment, the Saudi Quality Mark procedure has been non-transparent to applicants and still today, after 1.5 years since its entry into force, there are no official guidelines issued by SASO for the audit process, leaving the interpretation of the Technical Regulation to the discretion of the Accredited Certification Bodies (CBs). Obtaining the Saudi Quality Mark for EU producers of ceramic tiles is expensive, burdensome, time-consuming and unpredictable sometimes.

2.342. The European Union would like to raise the following points, which represent a major concern. *Audits are disproportionate and exceed the requirements set out in ISO standards.* To obtain the SQM, applicants are requested to prove compliance with SASO ISO 13006, which is supposedly based on the International Standard ISO 13006 (for specific characteristics of ceramic tiles). However, the SQM audits requires to conduct all the tests for rectified and non-rectified tiles, which seems to be unnecessary and arbitrarily requested by SASO in addition to the official ISO parameters. *High Costs.* According to the data available, this certification is not only one of the most expensive certifications in the world but it is also discriminatory towards SMEs. While the previous system applied in Saudi Arabia was based on different fees commensurate with the shipment value, the current SQM has a (very high) fixed price that is prohibitive for SMEs, which are simply not able to invest this amount of money for limited volumes exported each year. This has *de facto* excluded many EU producers from the market, as most of them are SMEs. *Limited number of Certification Bodies.* The limited number of Certification Bodies accredited by SASO in Europe creates bottlenecks as applicants are faced with long waiting times before being assigned a date for the audit. This delay results in foregone business for EU companies. *Unclear audit procedures.* SASO has never published a list of documentation required for the audit; hence, there is no standardized procedure and there can be discrepancies in the audit requirements set out by different Certification Bodies. As a result, the SQM procedures are unpredictable and applicants are subject to different conditions based on the Certification Body they utilize. *Yearly Surveillance Audits.* The yearly renewal of the SQM should entail less requirements due to its surveillance nature. However, companies have reported that the yearly surveillance includes the same level of detail as the first SQM audit – which is completely disproportionate to its purpose. 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. The European Union is available to discuss this issue with the Saudi authorities bilaterally.

2.343. The representative of the United States provided the following statement. The United States reiterates its concerns regarding the conformity assessment procedures required under the Saleem Saudi Product Safety program using the Saber system. Stakeholders continue to have a number of questions and concerns regarding this programme, most significantly the lack of documentation. Can you provide copies of all relevant regulations instituting the program and the outlining the scope of product coverage? To address at least some of the concerns from stakeholders, the United States requests that the Kingdom of Saudi Arabia simplify the registration and certification process and implement clear and transparent guidelines.

2.344. The representative of Switzerland provided the following statement. Switzerland maintains its concerns over the potential impact of the Saber Conformity Assessment Online Platform on bilateral trade with the Kingdom of Saudi Arabia in a range of products, including textiles and machineries. The registration and certification process remains costly, complex and time-consuming for our exporters. Manufacturers continue to report that recognized bodies require disproportionate fees when carrying out conformity assessment procedures. Depending on the sector, strict conformity assessment procedures apply for products considered in their majority to be low-risk products. Furthermore, additional third party certification is required for low-risk products that already have been certified and registered in the system. In particular for companies exporting quality products in small quantities, the registration and certification process leads to disproportionate costs and documentation requirements which is prohibitive to enter the market. Switzerland reiterates its call 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. Switzerland would further appreciate the

publishing of all relevant regulations instituting the programme and outlining the scope of products coverage. 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 applicable 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.

2.345. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia thanks the European Union, United States and Switzerland for their interest in this matter. We want to clarify that SALEEM program works through the development of an integrated systems of regulations and standards that conform to internationally recognized professional practices by developing a highly efficient system for measuring product safety indicator in the market through mechanisms and procedures that comply with the technical regulations of each product, especially essential requirements for health of human and animals, environment protection, and ensure the effectiveness of the services provided by legislative and regulatory bodies to achieve safety by conformity of those products to SASO Standards. The main purpose of Saber is to improve the import experience and obtain the certificates of conformity and shipment by using one platform integrated with other entities. Saber has reduced the time to one to seven working days compared to 7-15 working days previously. In addition, Saber is linked directly to Saudi customs, which allows products clearance within 24 hours. Moreover, Saber is implementing UX design project to improve the experience for the importer in registering their product and applying for their required certifications. Please note that registration and applying for certification is done by the importer in Saudi and the local manufactories. We advise visiting the website below to find the requirement for each HS-code and note that you can search by using the first six digits since it is matching the international HS-code.⁷⁵

2.346. The validity of the certificate is one year for the certificate of conformity and three years for the Saudi quality mark as well as the G-Mark. However, the test report can be valid for three to five years if nothing has been changed in the production line or the composite of the product. In Saber platform, clients can search by six digits select from the results for the nearest description of their product. 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. We strongly advise all toys industries to contact the notified bodies according to the GSO Technical Regulation for Toys scheme (listed in Saber platform) for detailed explanations regarding the test report and GCTS requirements. The conformity assessment procedure is based on the technical regulations published by SASO. These technical regulations were developed to protect consumer from high/medium risk products based on international best practices. The technical regulations can be found in the official website of SASO via the link below.⁷⁶ Please note that the Saudi Customs is the authority responsible for the HS-code, and all HS-codes can be found on their website. Therefore, we recommend viewing their website to find the right HS-code that matches the product description.

2.347. SASO is committed to reviewing some details of these procedures of conformity assessment to extend the validity of test reports used in issuing the product conformity certificate. The technical regulations for the acceptance of conformity assessment bodies in accordance with the international standard ISO/IEC 17065 set this requirement to ensure the efficiency of test reports issued by laboratories and that they are issued by a laboratory accredited by a full member accreditation centre in ILAC. The laboratory (in addition to being an accredited entity) must be registered by SASO in order to be able to issue test reports for energy efficiency products. The conformity assessment procedures done by the manufacture differ from those done by an importer. This is explained in Article 18 of the GSO Toys regulation and detailed in appendix 4 and 5 of the regulation. Therefore, the certificate and GCTS (GSO Conformity Tracking Symbol) must be issued through GSO. Once the GCTS has been obtained from GSO, it can easily issue the shipment certificates through the Saber platform. We advise the US toys industry stakeholders to contact the notified bodies in GSO Technical Regulation for Toys in Saber platform for detailed explanations regarding the test report and GCTS. SASO audits the conformity assessment procedures and requirement to ensure fair trade. Therefore, we encourage all interested parties that if they have any concerns regarding notified bodies, they contact SASO immediately via email.⁷⁷

⁷⁵ <https://saber.sa/home/hscodes>

⁷⁶ http://www.saso.gov.sa/en/laws-and-regulations/technical_regulations/pages/default.aspx

⁷⁷ info@saso.gov.sa

2.1.3.43 Mongolia - Mandatory Requirement for Enrichment of Agricultural Products with Vitamins (ID 616⁷⁸)

2.348. The representative of the Russian Federation provided the following statement. The Russian Federation would like to reiterate its statements made during the previous meetings of the Committee on TBT and the Council for Trade in Goods with respect to the requirements on the mandatory fortification of wheat flour applied in Mongolia. Although Russia raised this issue multiple times, Mongolia has not provided clarification with regard to the international standard that was used for the development of Mongolian standard on wheat flour fortification MNS 6812:2019 of 30 December 2019. In particular, it remains unclear to Russia the reasons of deviation from the WHO recommendation as well as the scientific basis for establishing the dosage of vitamins. Other areas of concern are implementation and enforcement of these mandatory requirements in Mongolia. The fact that domestic non-enriched wheat flour is present on retail shelves in Mongolia while foreign producers have to comply with fortification requirements accords less favourable treatment to imported flour. Also, Russia requests Mongolia to provide the information on accredited laboratories, which examine wheat flour on compliance with the fortification requirements. Taking into account all the above, the Russian Federation is looking forward to getting further clarifications regarding the issues reiterated in our statement today. We will continue to monitor the implementation of this measure. We again urge Mongolia to intensify bilateral dialogue on these issues.

2.349. In response, the representative of Mongolia provided the following statement. We thank again the Russian Federation for the statement. We also thank Russia for the bilateral meeting that was held in Moscow on the matter on 11 February 2021. The Mongolian Government Resolution No.336 of 2018 approved the list of products necessary for enrichment and the volume of enriching ingredient. The Mongolian Agency of Standardization and Measurement has approved the technical requirements for enriched wheat flour MNS 6812:2019 and the technical requirements for enriching ingredient for wheat flour MNS 6811:2019. These requirements were adopted based on international standards CAC152:1995; CAC/GL09-1987, CACRCP1:2003 as well as the recommendations of the World Health Organization. They are available online. Technical requirements for enriched wheat flour MNS 6812:2019 apply to both domestically produced and imported wheat flour. The National Laboratory for Food Safety (NLFS) is working to be accredited to certify enriched food and enriching ingredients. We would like to inform that our statistics show imports of wheat flour from Russia both in 2019 and 2020. Mongolia will continue working with the Russian Federation on this matter.

2.1.3.44 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/468](#) y [G/TBT/GEN/302](#) (ID 608⁷⁹)

2.350. The representative of Costa Rica provided the following statement. Costa Rica wishes to support the trade concern raised by Chile, 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. Costa Rica would like to 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 of the standard in question, and to provide relevant justification for the use of the front-of-pack warning sign as supplementary nutrition information, the scientific basis for setting classification parameters, according to which a product is considered to contain excessive calories, sugar, saturated fats, trans fats or sodium, given that they are not Codex-based.

2.351. 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

⁷⁸ For previous statements follow the thread under [ID 616](#).

⁷⁹ For previous statements follow the thread under [ID 608](#).

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. Costa Rica maintains its view in this Committee 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, constitutes a challenge that hampers global economic recovery efforts, especially in developing countries that are reliant on international trade, such as Costa Rica. This is without prejudice to the power that Members have to adopt them if considered necessary. Costa Rica would be grateful if the Mexican delegation could inform it about the progress of this draft amendment.

2.352. The representative of the United States provided the following statement. We refer to previous interventions, and support extending the use of stickering in order to meet the requirements of the Mexican regulation.

2.353. The representative of Chile provided the following statement. Chile wishes to highlight, and express its appreciation to Mexico for, the outcome of a bilateral meeting, according to which, as we understand it, the permanent use of stickers to incorporate warnings on front-of-pack labels would provide a solution.

2.354. The representative of Guatemala provided the following statement. The new Mexican Official Standard (NOM) for the labelling of pre-packaged food and non-alcoholic beverages (NOM-051-SCFI/SSA1-2010), in force since 1 October 2020, aims to establish the commercial and health information that must be contained on the labelling of the pre-packaged domestic or foreign products marketed in the national territory, as well as to determine the characteristics of such information and to establish a system of front-of-pack labelling for the general population, in order to inform the consumers clearly and truthfully of the content of critical nutrients presenting health risks in excessive consumption. As has been stated at previous meetings, we appreciate Mexico's efforts to protect human health and provide consumer information. Nevertheless, we reiterate that, pursuant to Article 2.2 of the TBT Agreement, measures must not be more trade-restrictive than necessary to fulfil that objective. We have raised this matter during discussions at previous meetings, and our position remains unchanged.

2.355. With regard to the use of adhesive labels and stickers, the following reference is made to Mexico's publications and notifications: The transitional articles of Mexican Official Standard NOM-051-SCFI/SSA1-2010, notified in document [G/TBT/N/MEX/178/Add.9](#), establish that the alternative provided for in one of transitional articles contained in the Standard can only be used until 31 March 2021. The transitional articles of the Amendment to the Agreement under which the Ministry of the Economy issues general rules and criteria in respect of foreign trade, published on 1 October 2020 and notified in document [G/TBT/GEN/302](#), also indicate that, until 31 March 2021, goods with adhesive transfers or stickers affixed to product labels may be presented for customs clearance. We thank the Mexican Government for the flexibility in the interpretation issued in the Criteria for the Application of Mexican Official Standards by the Under-Secretariat of Industry, Trade and Competitiveness, on the application of inputs not intended for the final consumer, bulk goods, and raw materials, all of which are dated 26 October 2020. However, to date, there has been no provision in Mexico's legal framework which clarifies the possibility of using adhesive labels or stickers after 1 April 2021 for imported products. CODEX CXS 1-1985, General Standard for the Labelling of Pre-packaged Foods, authorizes the use of a supplementary label which fully and accurately reflects the information contained on the original label. We therefore reiterate that the current standard deviates from the international reference standard, thus creating an unnecessary barrier to trade. Guatemala allows the use of supplementary labelling for Mexican products marketed in Guatemala and therefore requests reciprocity treatment in line with international standards. 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 limit trade.

2.356. The representative of Paraguay provided the following statement. Paraguay refers to its most recent statement and, given that its position remains unchanged, requests that its statement at the previous meeting of the Committee be reflected in the minutes of this current meeting. 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.

2.357. 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 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 4 of the TBT/WTO Agreement on Technical Barriers to Trade. The standard may stigmatize certain foods based on non-technical classifications and criteria because they refer to systems that are not clear or precise, causing confusion among consumers. Regarding the use of adhesive labels, we understand that the Mexican standard provides that this alternative may only be used until 31 March 2021. This situation will incur high costs for enterprises, which will henceforth have to reflect the labelling requirements in printed form on packaging from the market of origin. This situation particularly affects small and medium-sized enterprises, which find it too costly to design and use different packaging for each export market. On this matter, we invite consideration of the Codex Standard CXS 1-1985, which provides that a supplementary label should be allowed, fully and accurately reflecting the information appearing on the original label. We therefore respectfully request Mexico to extend the application of the rule allowing the indefinite use of adhesive labels or stickers with warning icons and messages on food packaging.

2.358. 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". Lastly, 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. We 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.

2.359. 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.

2.360. 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.

2.361. In response, the representative of [Mexico](#) provided the following statement. The delegation of Mexico welcomes the comments submitted by the delegations of Guatemala and Costa Rica via the eAgenda, as well as the comments submitted today by the United States of America and Chile. Regarding the questions on the proportionality of the measure, its purpose and conformity with international standards, we invite those concerned to consult the information that was provided in previous Committee discussions and reflected in the minutes contained in documents [G/TBT/M/80](#), [G/TBT/M/81](#) and [G/TBT/M/82](#). Regarding the use of stickers, it is important to indicate the publication, on 10 July 2020, of an Agreement allowing the use of adhesive materials on imported products in order to comply fully with the commercial and health information requirements established in the amendment to Mexican Official Standard NOM-051, which will enter into force on 1 April 2021 for the marketing of products to the final consumer. The necessary stickers should therefore be used before 1 April 2021 in order to comply with this technical regulation in time. There is no expiry date as this is a permanent mechanism.

2.362. Furthermore, the NOM Annex provides for four possibilities for importers to verify the compliance of their products with the Mexican Official Standards on commercial information, in short: *Option 1*: It is not necessary to submit the inspection certificate issued by a third party (inspection unit). The label must be placed on the product in the country of origin and comply with the requirements of Mexican Official Standard NOM-051. *Option 2*: It is necessary to submit the inspection certificate issued together with the labelling of the goods to be imported. In this case, the products must be labelled in the country of origin. Unlike option 1, in this case, the certificate is prepared prior to importation and is included at the time of importation. *Option 3*: If the product to be imported does not have a label, the labelling may be carried out in a general bonded warehouse in the national territory. Where the general bonded warehouse has been authorized as an inspection unit, it may carry out the inspection and thus issue the certificate of compliance. *Option 4* (similar to option 3): If the product to be imported does not have a label, the labelling may be carried out at a private home in the national territory, where an inspection unit may be employed to carry out the inspection and thus issue a certificate of compliance. The delegation of Mexico reiterates its willingness to clarify any doubts that the Members of this Committee may have on the implementation of this measure. Such concerns may be sent in writing via the WTO contact point.

2.1.3.45 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](#)) (ID 632⁸⁰)

2.363. 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 on multiple occasions during bilateral talks with India and at previous WTO TBT Committee meetings of February, May and October 2020. So far, the EU

⁸⁰ For previous statements follow the thread under [ID 632](#).

is not aware of any response of India to our concerns. The EU would like to reiterate in particular the concerns related to the certification requirements recently introduced by the Bureau of Indian Standards (BIS). As of 1 January 2021, date when the regulatory order entered into force, all toy imports, including premium toys produced by European manufacturers which already comply with the highest standards of safety and quality, have come to standstill. The order mandates that only toys with BIS marking may enter the country as of 1 January 2021. Factory audits by BIS auditors are a precondition to obtain the necessary BIS marking. While domestic toy producers have had the opportunity to comply with regulatory order and BIS auditors have audited domestic facilities. The same cannot be said for plants in third countries. EU companies already adhere to the strictest quality and safety standards, they have nonetheless committed to comply with Indian regulation. Consequently, EU companies have submitted the necessary applications well in time that furnish the Indian authorities with the necessary information to enable factory audits by BIS auditors.

2.364. However, as a result of the prevailing pandemic related travel restrictions, BIS auditors have not responded to applications and requests from EU companies for in-person audits. EU companies therefore find themselves in a challenging situation. Firstly, despite fulfilling the highest international standards of quality and safety for toys their exports to India are at a standstill. Secondly, despite fulfilling the requirements laid out by the QCO (Quality Control Order) there is no way for them to comply, as exports to India require in-person audits by BIS, which are not possible in current context. At this stage, there is no clarity as to when travel will return to normal in India and in third countries, as the pandemic continues to affect a large part of the world. It is difficult to envisage BIS auditors travelling to foreign plants in these conditions. The EU would therefore request India to allow third-party or virtual audits of third country factories (especially as such flexibility is allowed for domestic manufacturers) and in the meanwhile allow imports of toys, under the continued enforcement of the DGFT system (in place until 31 December 2020) with Customs continuing testing imports for conformity with applicable Indian Standards by NABL accredited labs (as per DGFT Notification 33/2015-20). Without these alternatives, EU companies do not have a fair chance of being able to satisfy their existing consumer base in India, and their investments to date to grow the Indian market for premium quality toys are affected. The European Union would be grateful if India could respond directly to the concerns mentioned in the previous EU written comments, as well as to the concerns reiterated today.

2.365. 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 requirement, India has made it more difficult for exporters to successfully bring safe toys to market. We support the Indian Government's objective to improve the quality of toys on the market. US toy companies produce high-quality toys made to the highest international standards and the health and safety of children is a key priority for all of us. However, India's 1 January 2021 implementation of the Toys (Quality Control) Order, 2020 (QCO) has made it impossible for international toy companies to comply with the order given the apparent inability of the Bureau of Indian Standards (BIS) to conduct in-person audits of foreign manufacturing facilities during the COVID-19 pandemic. We understand that US firms submitted applications for the required certification of their manufacturing plants, including overseas facilities, soon after the August 2020 BIS release of the QCO Product Manual. However, US industry reports that, although BIS authorities are currently auditing domestic manufacturing facilities, they have yet to start audits of overseas manufacturing plants. To date, companies with manufacturing facilities outside of India report that India has not provided any information about scheduling audits by BIS inspectors. We understand that COVID-19-related restrictions will likely prevent BIS inspectors from traveling internationally to conduct these audits for the foreseeable future. Consequently, it appears the QCO disproportionately impacts toys originating outside of India. The licensing process required to obtain a BIS mark is lengthy and US firms estimate it may take an additional four to six months after scheduled factory audits to complete the QCO requirements. According to industry, as a result of auditing delays, foreign manufacturers are unlikely to bring new toys to the Indian market in 2021. Will India consider alternative solutions, such as virtual audits or the use of recognized third-party certification companies in the country of manufacturing, in lieu of in-person audits by BIS inspectors?

2.366. The representative of China provided the following statement. The current Toy Import Policy and the certification rules in the Quality Control Order (QCO) impose repeated testing and charges on the same type of imported toys, which increases the economic burden and Customs clearance time of foreign manufacturers. According to the test price stipulated by the Bureau of Indian Standards BIS, sample testing (per sample) is charged about US\$150, which means that the testing cost of a toy exported to India by a foreign toy manufacturer is about US\$300. According to Article

5.1.2 of the TBT Agreement, China kindly requests India to delete the repeated testing and charging requirements in the QCO and DGFT Notification No. 33/2015-20, simplify customs clearance procedures and shorten customs clearance time. Considering the huge workload caused by the dual testing requirement of toy certification testing and import testing in a short time, it is suggested that India exempts imported toys from testing, enlarges the lists of third-party labs and accepts their testing results. Both the QCO and Import Policy require samples to be sent to NABL-accredited labs for testing or sampling. Among the 29 labs accredited by NABL at present, no more than ten labs can meet IS 9873 and IS15644 standards at the same time and operate normally, which is difficult to meet the huge dual testing requirements. According to Article 5.2.1 of the TBT Agreement, it is suggested that India exempt the import toys with the Standard Mark from testing in a certain period of time, and enlarge the lists of third-party labs in Schedule-II of Indian Bureau of Standards (Conformity Assessment) Regulations 2018 which is stipulated in Article 3 of the QCO, to include NABL accredited labs and all ILAC-accredited labs, and accept the results of foreign labs accredited by ILAC. It is recommended that India cancels the factory's testing facilities requirements for all items such as electrical toys testing ones. As these testing facilities are relatively expensive and highly technically demanding, making it difficult for small and medium-sized enterprises. Besides these tests are usually completed by third-party labs outside. Requiring the factory of toys to set up such facilities is unnecessary and unreasonable. It is recommended that India withdraws the factory testing facilities requirements for all items such as electrical toys, etc.

2.367. The representative of Canada provided the following statement. Canada would like to reiterate its support for regulations of toys that are developed and implemented by WTO Members to protect the health and safety of children. Canada shared comments to India on the Quality Control Order for Toys on 6 April 2020, and we have yet to receive a response. Canada further outlined its concerns with the measure during the May 2020 TBT Committee written procedure (statement recorded in paragraph 1.84 of [G/TBT/M/81](#)). At the October 2020 TBT Committee meeting, Canada joined other WTO Members in seeking a further delay for the implementation of the Order beyond 1 January 2021. It is Canada's understanding that the Order did come into force on 1 January 2021, including its requirement that Indian officials conduct inspections of toy factories in exporting countries, at the exporters cost. In the context of the global COVID-19 pandemic, with several countries – including Canada – maintaining travel restrictions and quarantine requirements, it is our understanding that it has become impossible for these inspections to occur and, consequently, imports of toy India have basically stopped. Further, India is not allowing foreign exporters to sell any stocks of toys that were already in India, because those toys do not have the certification. In order to provide a level playing field for imported toys and address what has clearly become a barrier to the trade in toys to India, Canada urges India to cease implementation of the Quality Control Order at least until the inspection of foreign toy production facilities can resume normally and be completed on a basis equivalent to inspections taking place in India. In addition, Canada reiterates its request that India respond to the comments it provided to India on 6 April 2020, through the Indian Enquiry Point.

2.368. In response, the representative of India provided the following statement. Four months extension beyond 1 September 2020 was accepted to clear the inventories and get a licence from BIS. As per the packing and marking requirements of the Scheme of Inspection and Testing, Standard Mark shall be marked legibly and indelibly either on the primary package or on the toy itself. The material used for the marking should also conform to the specifications. The packing, marking, labelling, including warnings and other instructions shall be done as per the provisions of the Indian Standard. Besides, the model number and the following shall be incorporated on each package: (i) BIS Licence Number CM/L and (ii) BIS website details- Foreign inspection visits are on hold due to the prevalent restrictions on international travel due to COVID-19. Factory visits and inspections will be resumed once the restrictions are lifted. BIS has recognized a number of laboratories for carrying out toy testing as per various parts of IS 9873 and IS 15644 (Safety of Electrical Toys). All of these laboratories are currently running normally. The IS-wise list of recognized laboratories is dynamically updated and is available on the BIS website at the link below.⁸¹

⁸¹ http://164.100.105.198:8096/bis_access/iswise_v2.html

2.1.3.46 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](#) (ID 633)⁸²

2.369. 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.

2.370. 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 with other Members 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. 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.

2.371. In response, the representative of India provided the following statement. The provision of the use of non-animal rennet in the manufacture of cheese is not newly introduced. This provision has been existing in our Food Safety and Standards Regulations (FSSR) notified in 2011 and the erstwhile Prevention of Food Adulteration Rules as well. During a recent revision of the milk and milk product standards in FSSR, these provisions were retained as such and continue to be a specified requirement regulation therein. The veterinary certificate for dairy products is primarily mandated by the Department of Animal Husbandry and Dairying, Government of India. The Department has recently aligned the certification with our FSSR in respect of the prohibition on the use of animal rennet which otherwise was in contradiction to the provisions in FSSR and needed to be corrected. Further, FSSAI has been lately asking importers of milk and milk products in India to furnish a copy of the veterinary certificate, already mandated by the Department of Animal Husbandry and Dairying, and hence it is not a new requirement introduced by FSSAI.

2.1.3.47 India - Order related to requirement of Non-GM cum GM free certificate accompanied with imported food consignment, [G/TBT/N/IND/168](#) (ID 651)⁸³

2.372. The representative of the European Union provided the following statement. On 21 August 2020 India issued an Order relating to the requirement of non-GM cum GM free certificate accompanied with imported food consignment, notified on 2 September 2020. This order originally should have entered into force on 1 January 2021 and has been postponed to 1 March 2021. The EU would like to highlight the following concerns. The basis for the list of 24 food crops in Annexure 1 is not clear. The EU invites India to explain the rationale behind this list. Non-GM origin cum GM-

⁸² For previous statements follow the thread under [ID 633](#).

⁸³ For previous statements follow the thread under [ID 651](#).

free certification per consignment should not be required, at least for the listed crops for which no GMOs are authorized in the exporting country for food use. For the EU, this applies to 19 out of the 24 crops listed in Annexure I. For these 19 crops, there is no authorization for GMOs in the EU. To avoid imposing an unnecessary administrative burden, the exporting country could provide a general non-GM origin statement to India on such crops. For listed crops for which GM varieties are authorized in the exporting country (for the EU, this applies to maize, soybean, cotton, Argentine canola, and sugar beet) a requirement to produce a certificate for every consignment is not justified. Such a burdensome and expensive measure should only be imposed where recurrent non-compliance has been established by official controls. To date, we have not received any information from India indicating that there have been identified instances of non-compliance with GM requirements by the EU.

2.373. India should explain why they consider it necessary to impose such a burden on trading partners with a high prevalence of non-GM food on their domestic market and a robust regulatory regime governing the use of GMOs. The EU underlines that in addition to the fact that only a limited number of the food crops referred to in the annexure are authorized to contain GMOs, there are very strict traceability and labelling requirements applicable to food that is GM. This allows a strict and effective separation between non-GM and GM production. According to EU legislation, there is zero tolerance for unauthorized GM material in food. GM food authorized in the EU must be labelled as such, with the exception of authorized GM food in a proportion less than 0.9%, provided the presence is adventitious or technically unavoidable. The EU as well as India are both parties to the Cartagena Protocol on biosafety to the Convention on Biological Diversity. To ensure coherent implementation of the Protocol, the EU adopted Regulation 1946/2006 on transboundary movements of genetically modified organisms. According to Article 12(2) of this regulation, exporters of GMOs intended for direct use as food or feed or for processing must accompany their exports with a document stating that the export contains or consists of GMOs. This obligation for accompanying documentation of GMOs provides the necessary reassurance to the importers and to the authorities. Therefore, we consider that the additional certification of non-GM food is not needed and is unjustified. In conclusion, the Indian proposal, imposing non-GM origin cum GM free certification for all consignments of the listed crops, puts an additional burden and therefore costs on EU exporters (and their related food operators in the underlying supply chain). Given that the necessary assurances can be provided to the Indian authorities on the basis of existing documentation, these measures go beyond what is necessary to achieve the stated objective. Therefore, the EU considers the notified Order to be disproportionate and creating unjustified barriers to trade. The EU would be grateful if the above-mentioned comments could be taken into account and replied to. The EU also invites India to take immediate action to avoid any trade disruption and allow for a reasonable transitional period of at least one year since the entry into force of the new order.

2.374. The representative of the United States provided the following statement. The United States continues to have serious concerns with India's 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 March 2021. While we appreciate India's notification of this measure to the TBT Committee and an extension of the entry into force date, 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. 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. 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 urge India to withdraw this measure to consider alternative approaches consistent with those of other Members to avoid creating unnecessary obstacles to international trade. If India is unable to withdraw this measure, we request that India significantly delay implementation to allow for coordination with trade partners to develop less burdensome alternatives to the certificate requirement.

2.375. The representative of Brazil provided the following statement. Since India has not provided any explanation on the points raised by Members regarding STC 651 in the last Committee meeting, Brazil would like to reiterate its remarks. Brazil strongly supports the Indian commitment to ensuring high standards of health and safety for its population. However, 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 GMOs, differing from obligations set under Article 5.12 of the TBT Agreement. Said regulation might be already impacting Brazilian exporters. 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 the TBT Agreement and about its willingness to actually take into account timely submitted comments. Brazil urges India to reply to our timely submitted comments as soon as possible. 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 relevant international studies it relied upon in order to draft this regulation?

2.376. The representative of [Australia](#) provided the following statement. Australia thanks India for their ongoing engagement and cooperation regarding the use of Non-GM cum GM free certificates. Australia welcomed India's additional clarification provided by the Food Safety and Standards Authority of India (FSSAI) on 12 October 2020, that the Order ([G/TBT/N/IND/168](#)) relates to food crops only, and not to processed food products. Australia recognizes the right of the Indian Government to take measures necessary to ensure the safety and wholesomeness of food imported into India. However, Australia continues 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 looks forward to India's continued engagement on this issue.

2.377. The representative of [Canada](#) provided the following statement. Canada would like to reiterate concerns raised at the October 2020 TBT Committee Meeting regarding India's non-GM import certification requirement which will come into effect on 1 March 2021. While we understand India's commitment to ensuring the health and safety of its population, it is unclear how India's non-GM certification requirement will fulfil its intended objective given the lack of available scientific information and/or justification to support its implementation. As previously stated, robust, science-based regulatory frameworks have been developed in countries around the world, including in Canada, to assess the risks of GM food products prior to their approval and commercialization. These products are authorized for commercialization only once they have received appropriate safety approvals. We remain concerned that the imminent implementation of India's Order will disproportionately impact the ability of GM-producing countries to export to India and unnecessarily restrict international trade. To minimize potential trade disruptions, Canada respectfully requests that India delay the imminent implementation of this measure to further engage with Members and take their concerns into account. In addition, we strongly encourage India to consider the scientific and technical information in its approach to support a transparent, predictable and fair trading environment. Lastly, we look forward to the responses to Canada's questions submitted through India's Enquiry Point in October 2020.

2.378. 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 remains 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 again 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? New Zealand looks forward to receiving a response to the written submission made by New Zealand on India's notification [G/TBT/N/IND/168](#).

2.379. The representative of [Japan](#) provided the following statement. Japan shares the concerns on India's proposed measure requiring "non-GM origin and GM free certificates" for 24 agricultural products imported to India, which 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 scientific 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 the crops whose detection methods on GMOs have not been established and how to inspect such products at the border of India. Japan also would like India to clarify the necessity of the non-GM certificate if the production and importation of such GM crops are effectively prohibited in the exporting countries. Japan would like India to address the concerns raised by Member countries and reconsider the implementation of the proposed measures.

2.380. The representative of [Chile](#) provided the following statement. Chile thanks India for its notification on the "Order related to requirement of Non-GM cum GM free certificate accompanied with imported food consignment", communicated to the World Trade Organization through Notification [G/TBT/N/IND/168](#), and circulated on 2 September 2020. Chile reiterates its concern about the upcoming entry into force of the measure, and states that it looks forward to receiving a response to the comments submitted through the WTO TBT Enquiry Point, which were made last October.

2.381. The representative of [Argentina](#) provided the following statement. Argentina would like to reiterate 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. We stress once again that scientific evidence shows that GM 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. Hence, there is no scientific justification for discriminating between one or the other. We hope that India will amend the notified Order so as not to create unnecessary barriers to international trade. We recall that we have already submitted more detailed comments and specific questions through India's TBT Focal Point and hope that they will be reviewed by the Indian authorities in order to safeguard the normal flow of trade in agri-food products.

2.382. 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 reiterate our concern about this measure, which we consider could limit exports of certain fresh fruits and vegetables to that market. From the information provided by India, there is no clarity with respect to the legitimate objective pursued by India, its scope, products covered or the requirements for market access. Similarly, the scientific evidence on which these new requirements would be based is also not known. Account should be taken of the fact that 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".

2.383. Although we have learned that the entry into force of this regulation was postponed from January 2021 to 1 March this year, we would like to reiterate that Article 2.12 of the TBT Agreement provides that, "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, a situation that generates uncertainty and possible significant disruptions to trade. Such a situation creates uncertainty and possible major disruptions to trade. We request India to revise this regulation, extend implementation times and consider alternative ways to avoid the creation of unnecessary obstacles to international trade.

2.384. The representative of Paraguay provided the following statement. Paraguay wishes to support the trade concern raised by the European Union, the United States, Brazil, Australia, Canada, New Zealand and Japan regarding the 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](#). The entry into force of this Order was originally planned for 1 January 2021, but has been postponed until 1 March 2021. This regulation applies to 24 crops, for which an official certificate must be submitted attesting that the imported products have not been genetically modified. In this connection, and taking into account the statements and concerns of other Members, we have been unable to identify the criteria used by India to select these 24 crops and further clarification is therefore required. We also agree with other Members' comments regarding the fact that India has not submitted or identified any regulatory impact assessment, scientific evidence or risk analysis on which the measure is based. Furthermore, we have not found any technical justification providing the reason for which a certificate is to be submitted for each consignment. This would place costly additional burdens on exporting firms.

2.385. Paraguay is of the view that India's measure could affect Paraguayan producers' potential trade, since the Order lays down unnecessarily cumbersome requirements. In this regard, it should be highlighted that the measure to be imposed by India is inconsistent with Article 2.2 of the TBT Agreement, which specifies 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. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products". Moreover, international standards established under the Codex Alimentarius Commission lay down guidelines to support the conducting of food safety assessments for GM products and allow for the growing and trading of GM products that, once authorized, are considered equally as safe and nutritional as their conventional counterparts.

2.386. We are also concerned that this measure may create the unjustified assumption that GM food products are inherently less safe than non-GM food products, despite the fact that GM products have been assessed and authorized through sound regulatory processes and have undergone rigorous scientific safety assessments in accordance with international standards, guidelines and recommendations, in order to ensure that they are considered equally as safe as their conventional counterparts. In January, Paraguay, together with other Members, sent a note outlining the above-mentioned concerns to the Government of India. We look forward to an examination of and response on the matter. In light of the above, Paraguay is of the view that the regulation notified in [G/TBT/N/IND/168](#) could be more trade-restrictive than necessary to fulfil any legitimate objective under the TBT Agreement and therefore requests that India reconsider the measure.

2.387. The representative of Uruguay provided the following statement. Uruguay would like to thank the delegations of the United States of America, Brazil and the European Union for including this concern on the Committee's agenda. As recalled by the delegations of Argentina and Paraguay, there is consensus internationally that genetically modified products, approved by exporting countries on the basis of Codex recommendations, in relation to the risk assessment methodology, are equivalent to their conventional counterparts. Uruguay therefore considers that there is no apparent technical justification for the implementation of the certification measure proposed by India, taking into account the legitimate objective, cited in the Order in question, of ensuring the safety and wholesomeness of imported food. While we note the extension of the proposed date of entry into force of the measure until 1 March, we wish to stress the importance for Members to establish measures based on scientific principles, and particularly to ensure that such measures are applied with the objective of minimizing negative trade effects, in line with the provisions of the TBT and SPS Agreements. We remain attentive to the comments made by the delegation of India in response to Members' concerns.

2.388. In response, the representative of India provided the following statement. It may be noted, the Genetic Engineering Appraisal Committee (GEAC) is a statutory body under the "Rules for the Manufacture, Use /Import /Export and Storage of Hazardous Microorganisms/Genetically Engineering Organisms or Cells, 1989" notified under the Environment (Protection) Act, 1986. This Committee is empowered to approve proposals relating to the release of genetically engineered organisms and products into the environment. The Committee has so far not approved any of the crop varieties of Genetically Modified/Engineered origin listed in the above-mentioned Order. In pursuance of the above, FSSAI is only seeking a certificate from exporting country to ascertain the GM-free status of listed crops. Further, FSSAI has clarified the non-applicability of this requirement for the import of processed food vide letter dated 12 October 2020 (Q 37 of TPR).

2.1.3.48 Russian Federation - Federal Law n° 468 on wine making and wine growing in the Russian Federation (ID 650⁸⁴)

2.389. The representative of the European Union provided the following statement. Russia has adopted a measure "Federal Law N° 468 of 27 December 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. Amendments to the law (the so-called Bakharev proposal) are being considered by the Duma where the discussion appears to be delayed. This Federal law contains several provisions that amount to obstacles for the importation of wine and wine-based products into the Russian Federation territory - regarding wine based products; Geographical indications; discrepancies between the Law and OIV provisions and the differences with EAEU Technical Regulation. The EU is very concerned that the Law will have a strong impact on import of foreign wines. In this context, the EU would like to ensure that enriching wine with concentrated grape must or rectified concentrated grape must or sucrose to attain a higher alcohol content level is an authorised (oenological) practice for imported 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. The EU has been informed by three EU member States (France, Italy, Spain) that they recently received a letter from Rosselkhoz nadzor asking to provide extraordinary detailed information on every wine production facility exporting to Russia. In addition, the same letter refers to the legal right to carry out inspection missions. The EU sees this new measure with concern and would like to request clarification on a series of issues raised by this letter and would be grateful if Russia could answer the following questions.

2.390. What is the rationale for requesting the amount of information requested in the letter? Could Russia explain the rationale for carrying out inspections of producing facilities? The EU would like to underline that wine is not a risky product as regard sanitary hazards and to invite Russia to adopt a balanced approach in terms of inspections systems to avoid unnecessary disruption of international trade. In addition, wine is produced in the EU under a very comprehensive legislation which is to a large extent harmonized at EU level and which is compliant with the international standards from the International Organisation of Vine and Wine and the Codex Alimentarius. Has Russia the intention to notify to the World Trade Organization any new measure having an impact on international food trade? Also important is to highlight that this kind of request should also be sent to the relevant EU institutions. 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 TR on safety of alcohol products, contributing to regulatory uncertainty. We understand that the date of implementation of the TR has been postponed by one year to allow some additional harmonisation work with the Russian Law, while amendments to the Russian Law are being considered at the Duma. This harmonisation phase would also be a good opportunity to correct also divergences with the international standards produced by OIV. 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 TRIPS. The EU invites Russia to notify the new wine measure, under the TBT Agreement as well as under the TRIPS Agreement. Meanwhile, the European Union would like to ask Russia to take these comments into consideration during the ongoing amendments' procedure.

2.391. The representative of the United States provided the following statement. The United States supports the request for Russia to notify implementing measures to the WTO TBT Committee, provide at least 60 days for interested stakeholders to comment on the measure, and take submitted

⁸⁴ For previous statements follow the thread under [ID 650](#).

comments into account before finalizing the measures. The United States also seeks a response to our comments on Federal Law n° 468 submitted to Russia's WTO TBT Enquiry Point in August 2020.

2.392. The representative of Australia provided the following statement. Australia understands Russia has adopted "Federal Law N° 468 of 27 December 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 International Organisation of Vine and Wine (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.

2.393. 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 Trade-related Aspects of Intellectual Property Rights (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 N° 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.

2.394. The representative of Argentina provided the following statement. Argentina would like to highlight its concern regarding the implementation of Federal Law No. 468 on wine making and wine growing in the Russian Federation. We are particularly concerned about possible restrictions that the new Law could impose on imports of "bulk wine", as, although such imports are permitted, "bulk wine" is considered "wine material" and the product cannot be called "wine" once it has been divided up and packaged, even if it is only packaged and does not undergo any other organic process or procedure and is not blended with other beverages or substances. We trust that through constructive dialogue with stakeholders, appropriate amendments can be made to the standard in order to avoid unnecessary trade disruption.

2.395. In response, the representative of the Russian Federation provided the following statement. Russia took note of the statements made by the delegations of the EU, the US and Australia. For the time being, in response we would like to state the following. The Federal Law on winemaking and winegrowing entered into force on 26 June 2020. The Law is aimed to develop and improve Russian internal market, it sets requirements both for domestic and foreign winemakers irrespective of their origin. The provisions of the Federal Law are elaborated taking into account the obligations of the Russian Federation in the WTO and other international organizations. Preliminary available results of the year show that entry into force of the Law did not lead to substantial decline in imports. Specifically, wine import value for 11 months of 2020 as compared to the same period of 2019 from Australia increased by 4%, from the EU decreased by 5%, from the United States increased by 22%. This is quite good performance in the pandemic year. To put these numbers into context, import value to Russia of all products for the same period from the world fell by 6%, from the European Union by 8%, from Australia by 4%, from the US by 1%. As for the TRIPS Agreement, we stress that this Law does not cover intellectual property rights (IPR) and does not set the legal environment for protection of IPR. In the Russian Federation intellectual property rights are registered and protected under the Civil Code of Russia that is based, *inter alia*, on Russia's obligations under the TRIPS Agreement.

2.1.3.49 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 (ID 662⁸⁵)

2.396. The representative of the United States provided the following statement. • The United States thanks Panama for delaying implementation of its potato measure for another six months. Additionally, we thank Panama for allowing U.S. onion exporters to show letters from their packers as evidence of compliance with the harvest date requirement. Under the US-Panama Trade Promotion Agreement, Panama has grown into an important market for US onion exporters. Unfortunately, Panama's storage criteria, harvest date requirements, and sprouting limits continue to harm US onion exports and will soon harm US potato exports. The United States is frustrated by Panama's lack of transparency around these two measures. We submitted comments to both of Panama's notifications, but Panama has yet to reply to our comments, provide scientific or technical justification for its measures, or provide a follow-up response to our concerns raised in our intervention at the October 2020 TBT Committee. Onions and potatoes produced in the United States can be marketed for close to a year after harvest due to quality seed, variety selection, good supply chain practices, cold storage, and other technologies. The relevant Codex standard specifically excludes fruits and vegetables from "use-by date" or "best-before date" labelling requirements and Panama has not provided a justification for its deviation from Codex standards. Regarding the zero-sprouting tolerance, we again note that this requirement is unnecessary and is not commercially viable. Industry standards provide consumers with high-quality produce, and consumers ultimately choose whether they want to purchase any individual onion or potato. Importantly, there are also no demonstrated food safety concerns regarding sprouting. We also note Panama appears to be applying stem and bulb nematode testing to protect plant health and, as such, we request that Panama notify this measure to the SPS Committee. Given the above, we request that Panama suspend implementation of both measures indefinitely and work with trading partners, including the United States, to address its TBT and SPS concerns in a manner that facilitates safe trade.

2.397. The representative of the European Union provided the following statement. We join the trade concerns voiced by the US. Our EU exporters are also facing similar difficulties in agricultural trade with Panama. The European Union would like to stress the importance of speedy, consistent and transparent SPS procedures carried out by independent authorities and the need to avoid unnecessary barriers to trade. The EU is prepared to work bilaterally with Panama to find a satisfactory solution.

2.398. In response, the representative of Panama provided the following statement. The delegation of Panama thanks the United States of America and the European Union for their comments. It is our understanding that our capitals are working bilaterally to address this trade concern, and we hope that we will soon find a solution that we will be able to share with this Committee. We welcome your comments, which we will forward to our authorities.

2.1.3.50 European Union - Wine labelling requirements – listing of importers for multiple destinations (ID 659⁸⁶)

2.399. The representative of Australia provided the following statement. Australia understands that, following the end of the Brexit transition period, the UK has rolled over existing EU wine laws and regulations. As the EU would be aware, this means that from 1 January 2021, wine imported into the UK, either in bulk or in bottles, and sold in the UK now requires the name and address of a UK-based importer on the label. We understand that this was the same as the requirement that previously applied, 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 to give details of both EU and UK importers on a single label to ensure trade can continue uninterrupted and without additional expense to wine producers. Under EU regulation, we understand that an indication of the "importer" is compulsory 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.

⁸⁵ For previous statements follow the thread under [ID 662](#).

⁸⁶ For previous statements follow the thread under [ID 659](#).

2.400. However, we are seeking assurance from the EU that its labelling requirements are no more trade restrictive than necessary to achieve their 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:". We are also seeking clarity from the EU on whether it is possible to list importers for multiple destinations on the same wine bottle label under current EU Regulation. Further guidance and clarity are important to provide certainty to traders and ensure no interruptions to trade occur. We look forward to working closely with the EU on this issue to ensure a mutually satisfactory outcome as we continue similar discussions with the UK to resolve this issue for wine imported into the UK.

2.401. In response, the representative of the European Union provided the following statement. As explained in the previous TBT Committee, 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).

2.1.3.51 European Union - Waste Framework Directive, [G/TBT/N/EU/778](#) (ID 658⁸⁷)

2.402. The representative of India provided the following statement. New obligations (with cost implications) for Indian exporters to meet the extended database requirements for SCIP under Waste Framework Directive. This STC was raised in the last TBT meeting with a request to defer the measure for a year. But the EU has rolled out the measure. Brief background: the EU revised its Waste Framework Directive (WFD) in July 2018. This revision was in alliance with the EU's principle of the circular economy. It enables EU to recycle and reuse the materials, thereby gradually decreasing the imports of raw materials. As per the amendment to the WFD, the ECHA is mandated to establish a new database on the list of hazardous chemicals present in articles by 2019. Such a database will serve as a source of information for waste treatment operators and consumers. The range/degree of hazardous nature of chemical substances listed in the database would enable the waste treatment operators to treat and recycle waste materials accordingly. This system is designed to make the information available throughout the chemical substances' lifecycle to manage and navigate the risk nature of chemical substances during waste collection, recycling, and reuse. This database would also enable the consumers to make an informed decision in their purchase of various products. In other words, through this measure, the EU is intending to exert pressure on the use of hazardous chemical substances and move towards substituting them with non-toxic substances.

2.403. SCIP Database: SCIP stands for Substances of Concern In articles or complex objects (Products). It is a database of articles (products) containing substances of very high concern (SVHCs) from the Candidate List (to be noted, this candidate list is maintained under the REACH). It has information on articles that includes Candidate List substances in quantities of more than 0.1% of their weight. As per the WFD requirement for the database, the business operators (producers, assemblers, distributors, retailers and importers) must submit the details on the products, including company data, Candidate List substance data, article description and safe use instructions of the Article to the ECHA. The EU mentions that such information is already submitted by the business operators under the REACH. Since REACH regulation's applicability covers multiple sectors covering chemicals, textile, electrical, electronic, leather, plastics, packaging, paints, dyes, varnishes, etc., such sectors are required to become a part of this database. The ECHA has established a database on 5 January 2020, and the operators must submit information from 5 January 2021. As a result, the business operators must submit data from 2021 concerning information on articles, the name, concentration range, and location of SVHC in the Article, and other information on the safe use of the Article. The business operators must mention such details only if their products contain chemical substances listed in the Candidate List. ECHA reports that it is working to reduce the industry's administrative burden in submitting such details. The database was launched on 28 October 2020.

2.404. Concerns: a) *Waste Directive 2018 and REACH*: Obligation: REACH defines the recipient of an article as "an industrial or professional user, or a distributor, being supplied with an article but

⁸⁷ For previous statements follow the thread under [ID 658](#).

does not include consumers". Therefore, Article 33(1) of REACH imposes an obligation to communicate certain information about the substances of very high concern (SVHC) in the article to the recipient entity in the supply chain. The Waste Directive 2018, Article 9 now requires this same information to be notified to the ECHA as well. Impact/Analysis: It may be noted that REACH Article 7(2) already has an existing duty for producers and importers of articles containing Candidate List substances to notify the ECHA, but only if they are present in articles above one tonne per legal entity per year. However, as per the new directive, manufacturers and importers who are placing less than 1-tonne quantity of the article in the EU market are also obligated to notify ECHA information regarding SVHC.

2.405. *b) The Obligations under the Waste Directive 2018:* Obligation: The obligation to notify the requested information about SVHC under Waste Directive 2018 is on "suppliers of an article". REACH allows direct submissions and notification to the ECHA only by EU-based producers, importers, etc. Non-EU producers, distributors, and other suppliers must appoint an "only representative or OR" responsible for communicating information to the ECHA. Impact/Analysis: Article 7(2) of the REACH already requires all manufacturers and importers of articles (in quantities greater than 1 tonne annually) containing SVHCs to notify information about the Article to the ECHA through ORs. Therefore, all such manufacturers and exporters of articles who are not based in the EU will already have contracted with ORs based in the EU for liaising with the ECHA. Thus the obligation to engage new ORs will fall only on non-EU (a) manufacturers and importers who are placing less than 1-tonne quantity of the Article in the EU market, and (b) other suppliers such as wholesale distributors of the articles. The new directive imposes notification obligation on other entities in the supply chain, such as distributors and other actors. This will create duplicity of obligations as manufacturers may have already provided such information via their ORs to ECHA. Requiring distributors to repeat such a process will add to the costs and administrative burden. 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. Apart from adding to the costs, this requirement also acts as a barrier to trade for non-EU countries. This measure became too cost-intensive in case export quantities of SVHCs are less than one tonne per annum.

2.406. *c) Confidential Business Information:* As per Article 9 of the WFD, the ECHA may provide access to the database to the consumers upon request other than the waste operators. Regarding data confidentiality, as it concerns business information, there is no specific mention in the WFD. Hence, consumers' accessibility for information under this clause is a concern to business operators. However, the ECHA has mentioned that it will ensure protection in cases where it is justifiable. If the links are established between parties in the supply chain, such information may not be available to the public. But, there is no mention of protection of such information from being available between businesses. *d) Implementation Concerns:* The WFD does not elaborate on how the Article and 0.1% will be evaluated, whether as a percent of the entire product or the component. We seek clarification from the EU on this. Testing / extracting a representative sample may be very difficult, especially when the SVHC is in the coating, surface treatment, paint, etc. In such cases, one can end up with an overestimation of the SVHC contents. Last TBT Committee meeting: This issue was raised in the last TBT Committee meeting in November 2020 by India and was supported by Canada and the US. China had also raised a similar issue on the SCIP database. India has requested EU to notify the measure to WTO and defer the implementation of the regulation until the comments are received and taken into consideration. The EU though notified its amended measure on Waste Directive at the WTO via [G/TBT/N/EU/778](#) dated 3 February 2021 but did not wait to receive the comments. EU has implemented the database. China, the US, and Canada requested to delay the database's implementation by one year. The database was rolled out on 28 October 2020, giving the industry very little time to assess, prepare, and input the information in the SCIP Database. Conclusion: In view of the above, the EU is requested to hold back the implementation of the measure till it receives comments from the stakeholders. Further: (i) EU is requested to share the risk assessment for removing the quantity barrier; (ii) how EU proposes to protect access to data between businesses; (iii) request EU to clarify the implementation issues raised.

2.407. In response, the representative of the European Union provided the following statement. The EU would like to thank India for the continued interest in the SCIP database for information on Substances of Concern In articles or in Products, established under the Waste Framework Directive (WFD). The European Union would like to inform WTO Members that the obligations with regard to the information on substances of very high concern in articles and products to be provided to the

European Chemical Agency through the SCIP database entered into application on 5 January 2021. The European Union notified the final text of the Waste Framework Directive under the TBT Agreement, for transparency purposes, under reference [G/TBT/N/EU/778](#). Regarding the question from India about the protection of commercial interests, the EU would like to note that the information in the SCIP database will be public and therefore readily available to consumers and to waste operators to bridge the current gap in the information flow from supply chains to these operators when articles and products reach the waste stage. The information in the SCIP database covers only articles containing substances of very high concern (SVHCs) on the Candidate List and not all components of a product (or complex object). Such information must already be communicated down the supply chain under REACH Article 33(1) and to consumers upon request under REACH Article 33(2) in order to ensure the safe use of articles placed on the EU market. The SCIP database therefore complements the existing communication and notification obligations for Candidate List substances in articles under Articles 33 and 7(2) of REACH, and should reinforce compliance with them.

2.408. ECHA has implemented several measures to ensure the protection of the commercial interests of submitters for the information submitted to ECHA in SCIP notifications, in particular information that could reveal links between actors in the supply chain. Those measures focused both on the information requested to be submitted (information requirements) and on the public dissemination of the data submitted to ECHA. The information requirements for SCIP notifications include some measures to avoid the submission of information that could undermine commercial interests, for example, no details are requested concerning the chemical composition of articles. It is only required to provide the identification of the main material the article is made of and the Candidate List substance present in that article, as well as its concentration range in the article. Concerning the identification of the article, it is only required to provide its identification as it appears, for instance, in labels and catalogues and by identifying the function or use of the article (article category) by selecting an article category from pre-defined list based on the Combined Nomenclature (CN) and TARIC lists. ECHA has also provided advice on "grouping" quasi-identical articles and complex objects (products), as well as on simplifying the "hierarchy" of components and subcomponents in a notified product to allow the determination of the "location" of the article containing a Candidate List substance within the product.

2.409. Concerning the dissemination of data to be made publicly available, in order to avoid the establishment of links between actors in the supply chain by any means from that data, the following information is not made available: the identity of the submitters (duty holders); specific names (e.g. brand, model) or (alphanumeric or numeric) identifiers of components in complex objects (or products). All other information submitted to ECHA is published as received on the ECHA website. We invite you to consult "Dissemination and confidentiality in the SCIP Database" document which further elaborates these aspects. The quality and accuracy of the submitted data always remains under the responsibility of each submitter, as well as the responsibility of not submitting any data that may be considered to undermine their commercial interests. On this regard, ECHA strongly encourages submitters to simplify their SCIP notifications by submitting only relevant data in a clear and understandable manner for waste operators and consumers by following the recommendations included in the user manual "Requirements for SCIP Notifications" and in the "Key tips for successful SCIP notifications".

2.410. In conclusion, the measures implemented by ECHA to ensure the protection of the commercial interests of submitters addresses the information available to consumers, waste operators and between businesses. With regard to the question about the relationship between the notification under REACH Article 7(2) and the SCIP notification, the EU recalls that these notifications have different objectives. The former aims at providing ECHA and the member State competent authorities with information which may be used to identify a need for initiating regulatory risk management procedure under REACH (authorization and restriction) or under other EU legislation, while the latter aims at the availability of information on articles containing Candidate List substances throughout the whole lifecycle of products and materials, including at the waste stage. The REACH Article 7(2) tonnage threshold (one tonne per legal entity per year) covers all articles containing a specific Candidate List substance in a concentration above 0.1% within the portfolio of a producer and/or importer. The notification obligation under that provision has also two important specific exemptions (REACH Art. 7(3) and 7(6)). Furthermore, the information required (REACH Art. 7(4)) to be submitted to ECHA under REACH Art. 7(2) is not intended to achieve the same objectives as the SCIP notifications. Therefore, these information obligations are complementary. The European Union would like to refer to the statement from the October 2020 TBT Committee for more

information and remains available to provide replies with regard to the SCIP database to interested Members.

2.1.3.52 France - New legislative requirements about index of reparability of electrical and electronic equipment, [G/TBT/N/FRA/195](#), [G/TBT/N/FRA/196](#), [G/TBT/N/FRA/197](#), [G/TBT/N/FRA/198](#), [G/TBT/N/FRA/199](#), [G/TBT/N/FRA/200](#), [G/TBT/N/FRA/201](#), [G/TBT/N/FRA/202](#), [G/TBT/N/FRA/203](#) (ID 657⁸⁸)

2.411. The representative of [China](#) provided the following statement. According to Articles 2.2 and 2.12 of the TBT Agreement, it is proposed to postpone the implementation of article L541-9-2 of environmental law to 2022. The reasons are as follows: (a) These requirements for the establishment and mandatory display of reparability index of electrical and electronic equipment are the first in the world, and there is no previous experience for reference. In addition, there are only two days between the date of entry into force and the final date for comments. It is too short for most enterprises, including Chinese enterprises to carry out implementation works. (b) Compared with traditional CE and energy efficiency labels, the evaluation of the reparability index mostly depends on the commitment of enterprises. The commitment requests the cooperation between departments to re-evaluate the enterprise's ability, potential risks, as well as to modify and print the corresponding documents afterward. A complex assessment process with communication and cooperation between departments requests more time to achieve compliance. (c) For many companies, especially a large number of small and medium-sized manufacturers outside of France, the implementation of the new regulations requests reshaping after-sales channels. Both self-built after-sales channels and professional repairers pointed as after-sales partners cost much time. Especially at present, the impact of COVID-19 has caused global supply chains and logistics chains to be blocked. So, the manufacturers face difficulties in compliance rectifications with the new decree.

2.412. It is proposed to add supplementary clauses on the date of entry into force of each category of equipment. At present, only orders relating to the criteria, sub-criteria, and scoring system for reparability index calculation and display of washing machines, smartphones, laptops, televisions, and electric lawn mowers (batteries, cables, and robots) have been released. The requirements for other electrical and electronic equipment products are still not clear. This causes great compliance difficulties for manufacturers. It is not consistent with Article 2.12 of the TBT Agreement. It is recommended to add a supplementary clause: "The date of entry into force of each category of equipment is determined by its specific 'criteria, sub-criteria and scoring system for the reparability index calculation and display.'" China suggests France amend Article 1 R. 544-3 to be consistent with other laws and regulations. To be specific, the new decree would apply to products placed on the market after the decree entry into force, rather than products already on sale. China suggests France clarify the relevant law enforcement entities and responsibilities, as well as the customs clearance and market supervision of products in France before the penalty clause entries into force on 1 January 2022. It is proposed to refine the conformity assessment method and market supervision scheme as soon as possible, and issue relevant guidelines.

2.413. In response, the representative of the [European Union](#) provided the following statement. Thank you to the delegation of China for its comments on new legislative requirements about index of reparability of electrical and electronic equipment of France. 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. 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. As according to the law, the reparability index entered into force on 1 January 2021 starting with the following products: front-loading washing machines, smartphones, laptops, TV monitors, electric lawn mowers (three types: with electric cable, with battery, robot). 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. You can find more information on

⁸⁸ For previous statements follow the thread under [ID 657](#).

the website of the Ministry for ecological transition⁸⁹ (the following documents are also available in English: manual, calculation grid, and the graphic charter).

2.1.3.53 Chile - Technical specifications for the design of energy efficiency labels for washing machines, [G/TBT/N/CHL/297](#), [G/TBT/N/CHL/325](#) (ID 654⁹⁰)

2.414. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of Chile to protect the environment and Korean companies are fully committed to complying with the regulations of Chile. At the time of notification in 2015, there was no need to submit opinions, but as the Korean companies are having difficulties complying with Chilean washing machine energy-efficiency label regulations, Korea would like to make some comments regarding this regulation as follow. At the 3rd WTO TBT Committee in 2020, the Chilean delegation replied that the comments of the Korean delegation on tolerance of energy efficiency labels for washing machine would be delivered to the Chilean Ministry of Energy in order to provide a proper reply. However, since there has not been a reply yet, Korea would like to enquire about whether the comments of Korea have been delivered to and under review process by the Ministry of Energy. If the review has not yet been conducted, Korea would like to kindly request that our comments be delivered to the Chilean Ministry of Energy again for review and proper reply.

2.415. In response, the representative of Chile provided the following statement. Chile thanks the Republic of Korea for its submission to this Committee regarding notifications [G/TBT/N/CHL/297](#) and [G/TBT/N/CHL/325](#). Chile wishes to report that Law No. 21.305 on energy efficiency was published on 13 February 2021, on which the Ministry of Energy worked closely with the National Congress and other ministries recently involved in regulations. The implementation of energy efficiency measures is an important public policy for Chile, given the many benefits it provides: it leads to reduced household energy spending, global and local pollutant emissions and international market energy dependency, limits land use for energy infrastructure, and increases the country's productivity by reducing production costs associated with energy consumption, which is also reflected in an increase in national energy security. The Chilean Ministry of Energy has prioritized its work on the recently established Regulation, and would like to inform the Korean delegation that it hopes to be able to respond in the near future to the requests about the energy efficiency of washing machines, which would require amendments. Stakeholders should be invited to participate in a national and international public consultation process on this matter soon.

2.1.3.54 Republic of Korea - Revision of Safety Conformation Criteria for Textile Products for Infants, [G/TBT/N/KOR/678](#) (ID 652⁹¹)

2.416. 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 the extra testing is more trade restrictive than necessary to fulfil a legitimate objective thus not in line with Article 2.2 of the TBT Agreement. 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. Consequently, testing and certification costs have increased substantially for European producers. As an example, the total testing costs for infant clothing of an EU producer increased by 287% in 2018 compared to 2017 whilst the sales of children's clothing in Korea increased by only 1.5% over this period. Similarly, the testing costs in 2019 were 284% higher than 2017 whereas sales increased by only 12% over this period. The main issue is that Korea's testing procedure requires a huge amount of samples to be sent to Korea for testing. To our knowledge, Korea is the only country that requires in-country lab testing for these products. Other countries either recognize international standards or allow the testing to be performed by an internationally accredited laboratory that carries out tests according to specific standards. In an effort to facilitate the customs procedures, EU industry has submitted applications for their recognition as a "best practice company" to the Korea Customs Service (KCS). However, at the end of 2020, EU industry was informed by KCS that their applications could not be completed due to a lack of input from the KATS. We would appreciate an update in this regard. The EU has had

⁸⁹ <https://www.ecologie.gouv.fr/indice-reparabilite>

⁹⁰ For previous statements follow the thread under [ID 654](#).

⁹¹ For previous statements follow the thread under [ID 652](#).

multiple meetings with the relevant Korean authorities to address these issues and would therefore kindly request that the Korean authorities take the necessary steps to remove this trade barrier.

2.417. In response, the representative of the Republic of Korea provided the following statement. Korea would like to take this opportunity to respond to the issue regarding South Korea's requirements for Textile Products for Infants, which was raised by the EU at this TBT committee. The EU has raised concerns regarding specific textile products used by or for infants under 36 months of age. Specifically, the EU believes that infant clothing is not a hazardous product, and that the requirements are therefore too strict. However, a risk assessment on textile products for infants in Korea found that such a risk was in fact very high for infants, especially due to injuries caused by strings, cords, harmful substances, and others. In this vein, the safety of infant clothing products must be verified through product inspections with a view to protecting infants from harm in Korea. In addition, we would like to ask for the EU's understanding that Korea has one of the lowest birth rates in the world, and thus makes every effort possible to ensure the safety of infants. We also note that Article 2.2 of the TBT Agreement does not apply to the legitimate objective of protecting human health or safety.

2.418. Regarding the EU's concerns about a substantial increase in testing and certification costs for European manufacturers in 2018 due to the amended requirements for Textile Products for Infants, we found that during the relevant period specific EU manufacturers were faced with an increase in testing costs on a single occasion only, which was in line with enforced supervision and controls by the Korea Customs Service. Furthermore, the role of the Korea Customs Service is prescribed by the Customs Act. Regarding the claims from specific EU manufacturers that their sales-volume in the Korean market (only a 12% increase in sales) is insufficient compared to their increased expenditure for testing (284%), we have not found any basis for this claim nor any direct connection between testing costs and sales volume during the relevant short period. The 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", unequivocally ensures equal treatment between domestic and foreign manufactures with respect to national treatment in the context of goods and manufacturers. We also note that on no other occasion have any other countries made a similar complaint in this respect. Korea very much hopes to resolve the EU's concerns at this TBT Committee in a mutually beneficial manner.

2.1.3.55 Mexico - Various State Measures Restricting Sale of Food and Drink Products to Minors (ID 648⁹²)

2.419. The representative of the United States provided the following statement. The United States continues to be concerned about Mexico's prohibition of sales of "high-calorie" foods and beverages to minors, including already passed state-level bans in Oaxaca and Tabasco, a proposed federal ban, and additional state-level bans under consideration. We request that Mexico notify Oaxaca and Tabasco's state-level measures to the WTO and postpone finalization and implementation until Members have an opportunity to review and comment. We requested notification on 18 August 2020, through the US WTO TBT Enquiry Point, and at the October 2020 TBT Committee meeting. In the United States' view, these measures form part of a larger national approach to nutrition and public health, in conjunction with federal-level technical regulations, and therefore should be notified to the WTO. Furthermore, any measures that have a significant effect on trade may be raised in the TBT Committee, irrespective of the measure being introduced at the federal- or state-level. In particular, these measures classify foods as "high-calorie" based on nutrient thresholds established in a corresponding federal technical regulation, Official Mexican Standard NOM-051 SCFI/SSA1-2010 "Labeling for prepackaged food and non-alcoholic beverages – Commercial and Health Information." While the United States continues to support initiatives that advance the goal of promoting healthy dietary choices and lifestyles to children, our understanding is that the measures will impact a large number of products. We urge Mexico to ensure that its measures are no more trade restrictive than necessary to achieve its legitimate objectives. We ask that Mexico please provide an update on the current status of this issue, and, again, to please notify these measures to the TBT Committee.

2.420. The representative of Colombia provided the following statement. Colombia shares this trade concern and indicates its interest in the matter, given it is closely related to other items reviewed on the Committee's agenda. As noted by other Members, we consider that these measures that are being taken at the subnational level must be notified to the Committee and be in line with the

⁹² For previous statements follow the thread under [ID 648](#).

provisions of the WTO TBT Agreement. We urge Mexico to take account of the relevant international standards and adopt the least trade-restrictive measures to fulfil legitimate public policy objectives

2.421. In response, the representative of Mexico provided the following statement. As mentioned in the statement made during the Committee meeting in October 2020⁹³, these state measures are part of a national strategy aimed at combatting public health problems in the country such as obesity and overweight, in both adults and minors. The Government of Mexico has analysed these legislative amendments and, on the basis of this analysis, we reiterate that the amendments do not fulfil the assumptions that would make them verifiable as a technical regulation in the light of the definition contained in the WTO Agreement on Technical Barriers to Trade and, therefore, no notification of these amendments to this Committee is foreseen. I wish to reiterate that the relationship between these state measures and Mexican Official Standard NOM-051 concerns only the scope of application, and that state measures do not elaborate on additional conditions and do not contain any TBT requirements. To date, besides Oaxaca and Tabasco, no amendments have been approved in other Mexican states.

2.1.3.56 India - Phase II of the Mandatory Testing and Certification of Telecommunications Equipment (MTCTE), implementing the Indian Telegraph Amendment, [G/TBT/N/IND/66](#), [G/TBT/N/IND/158](#), [G/TBT/N/IND/159](#), [G/TBT/N/IND/160](#), [G/TBT/N/IND/161](#), [G/TBT/N/IND/162](#), [G/TBT/N/IND/163](#), [G/TBT/N/IND/164](#), [G/TBT/N/IND/165](#), [G/TBT/N/IND/166](#) (ID 646⁹⁴)

2.422. The representative of the United States provided the following statement. The United States understands that a 24 June 2020 addendum to India's Mandatory Testing and Certification of Telecom Equipment (MTCTE) procedures extended recognition of test results from laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories to 30 September 2020. According to US industry, India further extended recognition of technical parameter test results from ILAC-accredited laboratories until June 2021. However, US industry reports that this extended recognition does not apply to electromagnetic interference and electromagnetic capability (EMI/EMC) test results from ILAC-accredited laboratories. The United States requests that India recognize all relevant test results, including EMI/EMC results, from ILAC-accredited laboratories, for at least one year from the date of publication of any future phases of this measure. This extended period of recognition will help alleviate concerns regarding potential testing backlogs and will allow time for manufacturers to perform in-country testing for noncertified products, including new models. The United States appreciates India's floor response during the October 2020 TBT Committee meeting, which noted that to maintain business continuity and ensure existing business supply chains remain undisturbed, India would provide a six-month exemption for the labelling requirement for MTCTE-certified products from the date on which testing and certification become mandatory for such products. However, considering the scope of test requirements under the MTCTE, the technical complexity involved, as well as disruptions to product testing and certification timelines caused by the COVID-19 pandemic, the United States respectfully requests that India provide a one-year exemption period, rather than six months, from in-country testing and certification requirements from the date of publication of any future MTCTE phase notifications.

2.423. The representative of Canada provided the following statement. Canada understands that, according to a 13 November 2020, Addendum from the Technical Engineering Centre (TEC), acceptance of test results and reports from labs accredited by ILAC signatories in the context of the implementation of Phase 2 of the Mandatory Testing and Certification of Telecommunications Equipment (MTCTE) has been extended to 30 June 2021. While Canada welcomes this development, Canada continues to be concerned with India's movement away from accepting testing in ILAC-accredited labs outside India for telecommunications equipment. Accepting foreign test results, in appropriately accredited labs, is the least trade-restrictive manner of achieving legitimate safety and security objectives. Canada wishes to further note the high cost that the measure imposes on foreign suppliers, which must produce the product for testing, ship it to India and then wait for the product to be tested before being able to put it on the market. Operators need at least a year to undertake this process. This is why Canada requests that India provides firms with at least one year to comply with any future phases of the measure. We understand that Phase III of the MTCTE could be

⁹³ [G/TBT/M/82](#), paras. 2.56-2.57.

⁹⁴ For previous statements follow the thread under [ID 646](#).

implemented by the end of 2021; can India provide any information on Phase III, including potential timelines for implementation?

2.424. In response, the representative of India provided the following statement. Mandatory Testing and Certification of Telecom Products (MTCTE) scheme provides for acceptance of test results from TEC designated Conformance Assessment Bodies (CABs) or test labs from MRA partner countries. Acceptance of test results from laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories is by way of relaxation until sufficient test capability exists in the country. Testing capability 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 International Laboratory Accreditation Cooperation (ILAC) signatories ceased from 31 March 2020. For technical parameters, acceptance of test results from laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories is available up to 30 June 2021. Regarding the need for relaxation for products to be covered under future phases of MTCTE, they will be looked into at the time of launch of notification for such products. Moreover, the MRA agreement with India shall facilitate OEMs to test in MRA partner country which may lessen the burden in terms of cost and time. In order to maintain business continuity and to ensure existing business supply chains remain undisturbed, the date of enforcement for the products covered under future phases of MTCTE is likely to be from six to eight months from the date of notification. Considering a relaxation for six months for the labelling requirement for MTCTE-certified products from the date on which testing and certification become mandatory, the OEMs will get a period of more than one year to comply with the labelling requirement of MTCTE for such products. The request of Canada to provide firms with at least one year to comply with any future phases of the MTCTE shall be considered at the time of launch of future phases of MTCTE.

2.1.3.57 India - Notification of 2018 draft cosmetic rules, amending provisions of the India Drug and Cosmetics Act of 1940, [G/TBT/N/IND/101](#) (ID 586⁹⁵)

2.425. The representative of the United States provided the following statement. We understand that on 15 December 2020, India's Ministry of Health and Family Welfare published the Cosmetics Rules, 2020 (as final), in the Gazette. While we thank India for notifying a previous draft of the Rules to the WTO in June 2019, as the final version has been partially changed or amended, we ask that India notify the final Rules as an addendum to its original notification, provide a public comment period of at least 60 days, and delay implementation of the final Rules until such comments may be taken into account. We understand that India adopted and implemented the final Rules on the same date as the Gazette notification. To allow sufficient time for manufacturers to adapt their products or methods of production to the new requirements, we also ask that India provide a 12-month transition period for new product registrations from the date the final Rules are notified to the WTO. Will India consider US cosmetics already on the market in the United States as conforming with India's requirements? Can India please clarify per Article 39 if imported products must comply with the Bureau of Indian Standards (BIS) standards listed in Schedule Nine, or if India will allow other means by which imports can establish conformity? While the US FDA does not require animal testing and encourages the use of alternative methods, we note that some foreign jurisdictions still require animal testing for cosmetics, even when alternatives exist. We therefore ask that India consider amending Article 18.4 of the final Rules to exempt cosmetic products and ingredients subject to animal testing when such tests were conducted pursuant to the requirements of foreign jurisdictions. We ask that in Article 34, India consider adopting the US FDA Cosmetics Labelling Guide on use of the term, "may contain," for labelling of cosmetic products that have colour additives that are not found in all shared formulations of that product.⁹⁶

2.426. In response, the representative of India provided the following statement. A draft of Cosmetic Rule 2018 had been published by the Government of India in the official Gazette via G.S.R 1153(E) dated 29 November 2018 for inviting public comments within the period of 45 days from the date on which copies of the Gazette of India containing these draft rules are made available to the public. On request, additional 60 days were provided for comments before finalization of the draft rules. Finally, Cosmetics Rules, 2020 has been published by Ministry of Health and Family

⁹⁵ For previous statements follow the thread under [ID 586](#).

⁹⁶ More information on the US FDA labelling guide and requirements are available at <https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide> and <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=701.3>

Welfare, Government of India via Gazette notification G.S.R 763(E) dated 15 December 2020, and which come into force on 15 December 2020. In response to the question "Will India consider US cosmetics already on the market in the United States as conforming with India's requirements?" Yes, if cosmetics products comply with provisions of Cosmetics Rules, 2020 (with respect to products already in the market). These rules have not put any embargo on the cosmetics products to be imported from the US or any other country.

2.427. As per Rule 39 of Cosmetic Rule 2020, no cosmetic shall be imported or manufactured unless it complies with the specifications prescribed under the Ninth Schedule or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case the cosmetic is not included under the Ninth Schedule, it shall meet the requirements under these rules and specifications and standards applicable to it in the country of origin. As per rule 135-B, Drugs and Cosmetics Rules 1945, no cosmetic that has been tested on animals after the 12th day of November 2014 shall be imported into the country. The same provision has been retained (Rule 18(4)) under Cosmetics Rules 2020. As per Rule. 39 (3) of Cosmetics Rules 2020, no cosmetic shall be imported or manufactured which contains dyes, colours and pigments other than the one specified by the Bureau of Indian Standards (IS: 4707 Part I or IS: 4707 Part 2 as amended) and included in the Tenth Schedule. Further, as per Rule 34 (7), Manner of labelling, in all cases, the list of ingredients, present in concentration of more than 1%, shall be listed in the descending order of weight or volume at the time they are added, followed by those in concentration or less than or equal to 1%, in any order, and preceded by the words 'INGREDIENTS'. It is provided that this statement need not appear for packs of less than or equal to 60 ml of liquid and 30 gm of solid and semi-solids.

2.1.3.58 Brazil - Draft Technical Resolution nº 69, 9 September 2014, Regarding the Requirement of Describing the Chemical Composition, in Portuguese, in the Label of Personal Hygiene Products, Cosmetics and Perfumes, [G/TBT/N/BRA/608](#), [G/TBT/N/BRA/608/Add.1](#) (ID 443⁹⁷)

2.428. The representative of Mexico provided the following statement. The delegation of Mexico thanks Brazil for the bilateral meeting and looks forward to continuing discussions on this subject. Mexico refers to Resolution RDC No. 432 of the Brazilian National Health Surveillance Agency (ANVISA), notified as a final measure by the Brazilian Ministry of Health to the Members of this Committee on 26 November 2020 in document [G/TBT/N/BRA/608/Add.1](#). Article 2 of the Resolution states that "the personal hygiene products, cosmetics and perfumes marketed in Brazil must have their chemical composition written in Portuguese on their labels, without prejudice to the other requirements established in the regulations in force". Furthermore, Article 2.1 of the Resolution states that the requirement to include the International Nomenclature of Cosmetic Ingredients (INCI) remains mandatory for the labelling of the products mentioned above. These are two requirements that focus on the same objective, which is, to provide information on the composition of the product. Given the requirement contained in the Resolution for the inclusion of the chemical composition in Portuguese, and the mandatory inclusion of the INCI nomenclature, the measure is considered more restrictive for international trade than necessary and contrary to the principle of proportionality provided for in Article 2.2 of the WTO TBT Agreement. It also represents two procedures for the same purpose, and an additional and more burdensome process for the industry exporting these products to Brazil. In this context, it is important to emphasize that the use of the INCI nomenclature is an international practice that has allowed regulatory convergence in this area not only between Mexico and Brazil, but also among industries worldwide, and its creation seeks to provide accurate and standardized information about the ingredients on the labels of cosmetics, personal hygiene products and perfumes. It is therefore considered that the application of the INCI nomenclature is sufficient to achieve the desired objective. In light of the above and recognizing the importance of keeping consumers informed, we request the Government of Brazil to re-evaluate this requirement in order to prevent these products from creating unnecessary restrictions on trade.

2.429. The representative of the European Union provided the following statement. The European Union would like to thank Brazil for a very constructive and useful bilateral meeting on this subject held earlier this week and for the willingness to explore trade-facilitating solutions, including a postponement of the implementation date. Nevertheless, the EU would like to recall that the main source of our concern remains the fact that from the international trade perspective, the new labelling rules may set a wrong regulatory precedent. The translation of scientifically and internationally recognized INCI names into national languages will cause unnecessary administrative

⁹⁷ For previous statements follow the thread under [ID 443](#).

and economic burdens to cosmetic manufacturers and ultimately lead to confusion, misidentification, or the loss of essential information for consumers. The EU maintains its interest in finding a mutually acceptable solution.

2.430. The representative of Colombia provided the following statement. Colombia would like to raise its concern regarding various elements of Brazil's notification [G/TBT/N/BRA/608/Add.1](#). Colombia's comments were sent through the contact point. The main concern is that ANVISA Resolution - RDC No. 432 of 2020 stipulates that the list of ingredients of personal hygiene products, cosmetics and perfumes must be included in Portuguese. However, at the international level, the declaration of ingredients for these products is made through a single universally recognized nomenclature known as the INCI (International Nomenclature of Cosmetic Ingredients). For our industry, the mandatory translation into Portuguese of such a globally-recognized nomenclature is an additional process and a one-off requirement, which has never been registered at the international level. The situation therefore poses technical, logistical and economic challenges for the marketing of products in this sector in Brazil. Account should be taken of the fact that the use of the international nomenclature INCI for the declaration of ingredients has not created any sanitary or problematic risk to the protection of human health and safety. It is therefore considered that there are no health grounds to justify the measure. Thus, this measure may be more trade restrictive than necessary, whereas the INCI nomenclature is an equal and less burdensome alternative to fulfil the legitimate objective identified.

2.431. In response, the representative of Brazil provided the following statement. RDC 432/2020 establishes that personal hygiene products, cosmetics and perfumes marketed in Brazil must have their chemical composition written in Portuguese in their labels. The regulatory process for the issuance of said regulation took place to ensure compliance with a final judicial decision from an appellate court in Brazil, against which no appeal can be filed. According to the decision, the National Health Agency (Anvisa) was obliged to edit a regulation that foresees mandatory description of the ingredients in Portuguese for the labelling of personal hygiene products, cosmetics and perfumes. The judge asserted that the Brazilian Consumer Code requires that all product information must be presented in Portuguese, which was not observed in personal hygiene products, cosmetics and perfumes. Thus, the absence of components in Portuguese would be a violation to the Code. It is worth noting that such judicial process has been evolving since 2014 when a trial court first decided on the merit of the regulation notified as [G/TBT/N/BRA/608](#). Since then, as a party to the process, Anvisa presented technical elements stressing that it is not necessary to include the description of the ingredients in Portuguese. As a member of the International Cooperation on Cosmetics Regulation (ICCR), it presented technical grounds to support a harmonized nomenclature that provides greater transparency to customers, producers, and health professionals. Anvisa is aware that INCI is a nomenclature specially conceived for the substances and ingredients used in the production of cosmetic products, through a system based on scientific names and other Latin or English words, depending on their origin. It represents a code that covers the need to designate, in a clear, unique, and unequivocal way the labelling of cosmetic ingredients without distinguishing between language or characters. Despite its efforts, Anvisa can no longer reverse the decision that motivated RDC 432. However, the agency is evaluating the possibility of delaying its entry into force to 5 November 2023. Anvisa is also studying alternatives such as the use of QR codes to describe the composition in Portuguese, in order to minimize the costs of implementing the new labelling requirements.

2.1.3.59 India - Mandatory Certification for Steel Products, [G/TBT/N/IND/32](#), [G/TBT/N/IND/32/Add.1](#), [G/TBT/N/IND/32/Add.2](#) (ID 224⁹⁸)

2.432. The representative of Japan provided the following statement. Regarding implementing of IS for steel products, Japan has requested that India should ensure proper implementation through discussions in the TBT Committee from 2008-2013. However, it is taking a very long time to get approval of conformity assessment, and it has become normal that no response is given to Japanese steel companies even after a year has passed, especially for new projects. The Government of India cannot proceed in application and scheduling factory audits because of COVID-19, therefore Japan has requested the Ministry of Steel and BIS to implement appropriate alternative measures and postpone the enforcement of new standards. If nothing is done, it may become a substantial import restriction measure, so we would like to request the implementation of appropriate alternative measures and the postponement of the introduction of new compulsory standards. In addition, the

⁹⁸ For previous statements follow the thread under [ID 224](#).

Government of India requested that Japanese companies submit future plans for indigenous development or to switch to local procurement from Indian companies which is not related to the application of conformity assessment. These requirements are not required to be submitted in the original procedure. Japan would like to request strongly for immediate improvement in these issues. Finally, Japan would like to request that the implementation of these mandatory standards should be done consistently with the TBT Agreement and that it would be no more trade-restrictive than necessary to achieve its legitimate objectives.

2.433. In response, the representative of India provided the following statement. Mandatory BIS Certification for Steel Products is enforced through notification of QCOs to ensure that the quality of steel being manufactured by domestic producers or imported in the country is as per the Indian Standards. It may be noted that WTO recognizes the Member's right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety, or protection of the environment. The Technical Regulations/QCOs on steel and steel products have also been issued based on the same policy objectives such as protection of human, animal or plant health, safety of the environment, or prevention of unfair trade practices, or national security. QCOs notified by Government are not trade-restrictive but a necessity to fulfil a legitimate objective of ensuring a level playing field for the domestic as well as the foreign suppliers and also save the Indian consumers and common citizens from the dumping of spurious and defected steel and steel products. India is a developing economy and steel is one of the critical elements enumerated in the development of infrastructure in the country. Ensuring the quality of steel and steel products used in the housing and infrastructure and other critical end-use sectors of the economy, through the implementation of Technical Regulations, is a necessity for the country. Technical Regulations on the Indian Steel provide an impetus towards the "Zero Effect and Zero Defect" objective of the Indian Government and also lead to a quality steel products regime. India has adopted the method of implementation of Technical Regulations based on the Indian Standards. The Indian Standards are well documented and aligned to the world standards. All the TRs issued by the Ministry of Steel along with the details of adoption or application of technical regulations are WTO compliant and had been submitted through the WTO Secretariat and uploaded on the WTO website for the examination, analysis and comments of all the WTO Members.

2.1.3.60 European Union - Chlorothalonil (pesticide active substance), [G/TBT/N/EU/625](#), [G/SPS/N/EU/394](#), [G/SPS/N/EU/394/Add.1](#) (ID 579⁹⁹)

2.434. 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's concern has been raised during previous meetings of this Committee and is based on the lack of conclusive scientific evidence and the application of a precautionary approach in the processes to renew the marketing approvals, which then affect the establishment of MRLs. This has happened in the case of 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, and 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 and 2021, including the non-renewal of the active substance chlorothalonil.

2.435. 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 ingredient chlorothalonil. Despite the many technical and scientific comments submitted within the consultation deadlines, and requests for a longer transition period to adapt production processes, which in the agricultural sector are particularly complex, the regulation under which the marketing approval of the active ingredient chlorothalonil is not renewed entered into force in May. In addition, through European Commission Regulation (EU) 2019/677 of 9 February 2021, it was decided to set the MRL at 0.01 mg/kg, or the minimum level of detection, which will enter into force on 2 September 2021. These decisions have been taken without the EU taking into account the concerns raised by various members in this

⁹⁹ For previous statements follow the thread under [ID 579](#).

Organization and in other settings, and without responding to the calls for dialogue made on a number of occasions. As we have already stated, beyond this particular case, the EU has been taking measures under which approval for the use or marketing of plant protection products is not renewed. Subsequently added to these measures was the reduction of the MRLs to the minimum detection level, further hindering sales of certain agricultural products. An example is the case we are dealing with in this specific trade concern with the substance chlorothalonil.

2.436. These measures are being taken without any sound scientific evidence or proof that they effectively constitute less trade-restrictive measures to ensure an appropriate level of protection for consumers. 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. In our view, the European Commission (DG SANTE) is interpreting these opinions taking a precautionary approach rather than an approach based on real risk and, as a result, is not renewing 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.

2.437. 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. 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. Chlorothalonil is used in particular for banana crops, to control Black Sigatoka, a fungus that can devastate this crop. Moreover, the situation arising from the COVID-19 global health emergency has forced the health and scientific authorities of all countries, and the productive sector, to focus attention on that crisis. In line with the statement made in communication [G/TBT/GEN/296/Rev.3](#), 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 ingredient chlorothalonil.

2.438. 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 European Food Safety Agency (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 is particularly harmful towards Brazil's producers of banana, coffee, citrus fruits, papaya, watermelon, among others.

2.439. The representative of [Guatemala](#) provided the following statement. Guatemala wishes to express its support for the concern, particularly because there is no information on the scientific evidence of the damage to human health arising from the consumption of fruits and vegetables, in particular those produced in Latin America, and for this reason, it is important to conduct 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.

2.440. 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, 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). 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.

2.441. The representative of Paraguay provided the following statement. Paraguay refers to its previous statements. Like other Members, we are concerned by the EU's decision to base measures on a hazard-based approach without a proper risk analysis and without complying with scientific principles. This has resulted in the reduction of MRLs and the non-renewal of substances such as mancozeb, chlorothalonil and picoxystrobin, which will cause significant damage to Paraguay's export sector. As we have previously stated, 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. We urge the EU to consider less trade-restrictive alternatives and base its measures on conclusive scientific evidence.

2.442. 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 approval of the active substance chlorothalonil and document SANTE/10186/2018 Rev 1, through which the EU confirms the non-renewal of the approval of the substance. The full statement will be uploaded to eAgenda; however, I would like to touch upon the main issues raised therein. Chlorothalonil is the main tool for controlling Black Sigatoka (*Mycosphaerella fijiensis*) 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. Controlling Black Sigatoka is the main challenge for banana production in Latin America. To control the disease, strategies of rotating fungicides with different modes of action have been pursued to avoid fungal resistance to these compounds. A limited variety of molecules is available for rotation in spraying schedules. Restricting the use of chlorothalonil will further complicate efforts to prevent pest resistance. Our concern stems from the fact that the non-renewal of approval of chlorothalonil has resulted in the notification of document [G/SPS/N/EU/394/Add.1](#), on 12 February 2021, pursuant to which new MRLs came into force for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine. In this case, tolerance for chlorothalonil in bananas is reduced from 15 ppm to 0,01 ppm. Implementing the MRL at default level will affect banana production in Ecuador. Reducing the MRL for chlorothalonil could have a very significant economic impact on small-, medium- and large-scale producers in our country, as well as on consumers in the EU, because the supply of our products would be affected. Moreover, no substitute or similar phytosanitary products with the same environmental or toxicological profile are currently available, since the alternatives to chlorothalonil (mancozeb,

metiram) are already under reviews by the EU. 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. 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.

2.443. Ecuador is also focused on the implementation and certification of Good Agricultural Practices (GAP), having established a public standard for that purpose, which meet the same standards as international certifications, such as GLOBAL GAP, since they are based on the following pillars: (i) *innocuousness*: to deliver to the consumer a healthy, nutritious and innocuous product, without the risk that it would affect their health; (ii) *worker health care*: safeguard and care for the health of farmworkers on the premises; (iii) *environmental protection*: to preserve and care for the natural resources of the agricultural production unit, beneficial insects, natural barriers within the farm, among other things; and (iv) *animal welfare*: refers to the animal's condition and how it copes with the conditions in which it lives. Ecuador requests that the European Commission review this decision, as well as the broader entry into force of new MRLs, and that it take into account 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 relevant scientific information emanating from international specialized agencies recognized by the WTO, such as the Codex Alimentarius, which has relevant information on this substance and, in the specific case of bananas, has established an MRL of 15 ppm. This statement is underpinned by the provisions of the WTO SPS Agreement, which stipulates that, when determining the appropriate level of sanitary or phytosanitary protection, Members should minimize negative trade effects and that sanitary and phytosanitary measures should be scientifically and technically justified, be based on risk assessment and not constitute unjustified barriers to trade.

2.444. In response, the representative of the European Union provided the following statement. As explained at previous meetings, the EU proposed not to renew the approval of chlorothalonil through Implementing Regulation (EU) No 2019/677¹⁰⁰, adopted on 29 April 2019 and previously notified to the TBT Committee. Chlorothalonil was evaluated in accordance with Regulation (EC) No 1107/2009 on the placing of plant protection products on the market.¹⁰¹ The conclusion¹⁰² by the European Food Safety Authority (EFSA) on this substance was published in January 2018. During the peer review process, the approval criteria 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 Maximum Residue Limits (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 lowered all MRLs for chlorothalonil at the relevant limits of quantification through Regulation (EU) 2021/155 of 9 February 2021¹⁰³. The new values will apply to all food products as of 2 September 2021, since the Regulation provides for a transitional period of six months for application. On that date, also food products produced beforehand must comply with the new MRLs. Import tolerance requests, which need to be supported by substantial new data addressing the concerns, remain possible and will be assessed on a case-by-case basis by the "rapporteur" member State and the EFSA.

2.1.3.61 United Kingdom - Wine labelling and documentation requirements at the end of the Brexit transition period (ID 663¹⁰⁴)

2.445. 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 following the 21-month grace period that the UK has implemented. Our wine industry is concerned with the current lack of clarity around the requirements. Australia understands that, following the UK's exit from the European Union, the UK has rolled over existing EU wine laws

¹⁰⁰ OJ L 114, 30.4.2019, p. 15.

¹⁰¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1489747880535&uri=CELEX:32009R1107>

¹⁰² EFSA 2018 Conclusion on the peer review of the pesticide risk assessment of the active substance chlorothalonil. EFSA Journal 2018;16(1):5126: <https://www.efsa.europa.eu/en/efsajournal/pub/5126>

¹⁰³ OJ L 46, 10.2.2021, p. 5.

¹⁰⁴ For previous statements follow the thread under [ID 663](#).

and regulations and has implemented a 21-month grace period for which we are grateful. However, it is still not clear what labelling requirements will apply to agri-food products including wine exported through the UK to the EU, 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 seeking flexibility to allow the listing of importers on the label of wine bottles imported into the UK and for multiple destinations. We believe it is possible to include a UK importer and importers in other third countries and still meet regulatory objectives. 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. It isn't clear whether a VI-1 form, or its equivalent, is required to import into the UK, and then whether a separate, additional, VI-1 form is required 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 re-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.

2.446. The representative of Uruguay provided the following statement. Uruguay would like to thank the delegation of Australia for once again bringing this item to the attention of the Members of the Committee. My delegation thanks the United Kingdom for the clarifications provided at the last meeting in October and the guidelines on the import and export of wine, published by the Department for Environment, Food and Rural Affairs (DEFRA) on 31 December 2020¹⁰⁵, with respect to the conservation and incorporation of European Union regulations in this area, and the 21-month grace period for labelling. Considering that the United Kingdom has been the main destination for Uruguayan wine exports to the European Common Market in recent years, our delegation reiterates its interest in being informed of the regulatory requirements and conditions that will apply to the importation of wine into the Member's market from 1 October 2022, in particular with respect to documentation and labelling, and that such requirements will be the least trade-restrictive possible.

2.447. 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.¹⁰⁶ We would also like to thank Australia for the constructive engagement we have had on this topic bilaterally. From 1 January 2021, the Common Organisation of the Markets in Agricultural Products (Miscellaneous Amendments) (EU Exit) (No. 2) Regulations 2020¹⁰⁷ allows for either a European Union or a United Kingdom importer's details to be shown on the label of wine products marketed in Great Britain until 1 October 2022. After that date, only wine products bearing a United Kingdom importer's details will be able to be marketed in Great Britain. From 1 January 2021 and after 1 October 2022, additional details may be included on the label provided they do not appear in combination with the words "imported by" or "importer", and that additional details do not confuse consumers with regards to the importer responsible for bringing wine into Great Britain.

2.448. Under this regulation, the United Kingdom will continue to accept wine import certificates (VI-1) issued by the European Union for wine entering the United Kingdom from non-European Union countries.¹⁰⁸ Provisions relating to the operation of United Kingdom VI-1 arrangements are contained in the retained Regulation 2018/273¹⁰⁹ as amended by the Agricultural Products, Food and Drink

¹⁰⁵ <https://www.gov.uk/guidance/importing-and-exporting-wine#contents> (DEFRA, 2020).

¹⁰⁶ As per the United Kingdom's statement of 26 February 2020 under Article 15.2 of the TBT Agreement (contained in document [G/TBT/2/Add.128](https://www.wto.org/gatt/tbt/2/Add.128)), the United Kingdom ceased to be a member State of the European Union on 31 January 2020. The following transition period ended on 31 December 2020. At the end of the transition period, the European Union (Withdrawal) Act 2018 incorporated the European Union Regulations that applied in the United Kingdom at the end of that transition period into our domestic law as retained Regulations. This included European Union Regulations relating to wine documentation and labelling. Some minor amendments have been, and are being, made to those retained Regulations to make them operable within our national context.

¹⁰⁷ SI 2020/1453: <https://www.legislation.gov.uk/ukxi/2020/1453/contents/made> For further guidance, see <https://www.gov.uk/guidance/importing-and-exporting-wine>

¹⁰⁸ These arrangements are set out in the Common Organisation of the Markets in Agricultural Products and Common Agricultural Policy (Miscellaneous Amendments) (EU Exit) Regulations 2019 (2019 No. 828).

¹⁰⁹ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32018R0273>

(Amendment etc.) (EU Exit) Regulations 2020.¹¹⁰ Further details of the labelling and certification measures that apply are available on the UK Government website.¹¹¹ Arrangements relating to imports, exports and movement of wine between Australia and Great Britain will be subject to simplified procedures as set out in the United Kingdom/Australia Agreement on Trade in Wine. Australian wine bottled in the United Kingdom and re-exported to the European Union will continue to be subject to European Union rules when imported into the European Union from Great Britain. 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 develop a streamlined and user-friendly system, with a view to ensuring that any labelling and documentation requirements are no more trade restrictive than necessary. The United Kingdom welcomes further bilateral engagement with Australia on this matter and invites bilateral engagement with Uruguay.

2.1.4 Reported progress on STCs

2.449. The representative of the United States reported on the resolution of a specific trade concern with regard to Brazil's Ordinance 259 of 27 May 2019. This measure corrected and updated conformity assessment requirements to medical devices and had been originally notified in [G/TBT/N/BRA/605](#) and its addenda.¹¹² The United States noted that the measure now aligned medical device conformity assessment requirements with international practices, including by removing the requirements to retest medical devices every two or four years and by removing the requirements to recertify medical devices every five years. Also, other requirements, unique to Brazil, had been made. These changes had addressed the concerns raised by the United States.

2.450. The representative of Brazil valued the cooperation with the United States and confirmed the resolution of the trade concern.

2.1.5 Trade Concerns Database – Beta version

2.451. The Secretariat reported on an information session introducing the Trade Concerns database (beta version) on 24 February, which took place over Zoom. It was noted that the Trade Concerns database is a first step in the process of replacing the aging TBT-IMS, which had originally been launched in 2009, in line with instructions of the TBT Committee. The database integrates information on TBT and SPS specific trade concerns. It aims at improving access to the information on STCs already available to Members and the public through the TBT- and SPS-IMS. The Trade Concerns database is a work in progress, and there may be glitches or missing information. At the moment, information contained in the database is only complete in English. Spanish and French data were in the process of being added. The purpose of the information session was to demonstrate the database, and Members were encouraged to provide their feedback to the Secretariat.

2.2 Exchange of Experiences

2.2.1 Transparency

2.452. The Chair recalled that the Committee had held a thematic session on Transparency on 4 February 2021. He referred delegations to his report on the session, circulated in [JOB/TBT/402](#) – as well as the Secretariat's note on "Using ePing to Disseminate Comments and Replies on Notifications" ([JOB/TBT/396](#)). He noted that, regarding other matters, there were no further updates regarding statements from Members under Article 15.2. He reminded Members that the Annual Review ([G/TBT/45](#)) contains more details on Members' statements of implementation. In addition, the Secretariat had held an ePing information session on 22 February and for any further queries regarding ePing, Members were invited to contact the Secretariat directly.

¹¹⁰ SI 2020/1637, <https://www.legislation.gov.uk/ukdsi/2020/9780348214109/contents>

¹¹¹ <https://www.gov.uk/guidance/importing-and-exporting-wine>

¹¹² Brazil - Ordinance 259, on 27 May 2019, which makes corrections and updates to the Conformity Assessment Requirements for Medical Devices Subject to the Health Surveillance System in Ordinance 54, from 1 February 2016 ([ID 604](#))

2.2.2 Standards

2.453. The representative of Canada presented the moderator's report of the Committee's 8 December 2020 Workshop on the Role of Gender in the Development of Standards. The full report, provided by Ambassador De Boer of Canada, is contained in [G/TBT/GEN/309](#).

2.2.3 Conformity assessment procedures

2.454. The Chair recalled that, since its last meeting, the Committee had received a new submission from China, contained in document [JOB/TBT/391](#). A total of six submissions had now been tabled (the others being from: 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](#)). It was recalled that at the informal meeting of 8 December, the Committee had had a productive exchange of views on the development of guidelines on Conformity Assessment – the most recent discussion had been summarized in document [JOB/TBT/273/Rev.7](#).

2.455. The representative of China introduced his delegation's proposal. The main purpose of China's proposal ([JOB/TBT/391](#)), he stressed, was to support the WTO in implementing a quality infrastructure system as a fully integrated system. An example of what China had done to implement a national quality infrastructure was presented. This system, it was noted, was essential for supporting regulators when selecting and developing conformity assessment procedures, as well as enforcing them. For the guidelines, it was also important to consider risk assessment and the use of risk-based decision making (e.g., different procedures for low- and high-risk products). Market supervision was also important – there was a need to shift from pre-market control to post-market control. China also stressed the importance of inclusiveness, including the use of international standards and respecting the differences across Members (laws, practices, policies and regulatory objectives) and appropriate flexibilities.¹¹³ In conclusion, China stressed his delegation's willingness to engage in discussions on the topic of conformity assessment procedures.

2.456. The representative of the United States thanked China for the proposal and noted that her delegation would be reviewing the paper and the presentation.

2.457. The representative of New Zealand expressed her delegation's support for ongoing work on the development of non-prescriptive guidelines on conformity assessment procedures in the context of the 9th Triennial Review. She thanked Members for their efforts and acknowledged the contributions on the table. New Zealand wished to make a few remarks for the Committee's consideration. Building on what Australia had shared earlier, her delegation believed that the guidelines would need to emphasize the principles of transparency and good regulatory practice for conformity assessment procedures as significant contributors of the reduction of trade barriers. They needed to be trade facilitating and promote the use of relevant international guides, recommendations and standards when adopting regulatory texts for conformity assessment procedures, so as to avoid unnecessary duplication. The guidelines would also need to allow for sufficient flexibility for regulators and policy makers to innovate and be able to select the conformity assessment procedure most aligned with their particular need and circumstances, and regulatory policy objectives. There was considerable value, she said, to promoting dialogue on regulatory cooperation and coordination with a view to delivering confidence in regulatory convergence outcomes.

2.458. The representative of Paraguay stressed the importance of flexibility and the need to take into account the realities of different countries as the development of conformity assessment procedures was a major challenge for developing countries. It was important to leave room for innovation so that countries could find the right balance, appropriate and tailored to their own circumstances and policy objectives.

2.459. The Chair encouraged Members to come forward with additional submissions to help the Committee advance its work. He also noted that one of the proposals on the table for the 9th Triennial Review was also on the topic of conformity assessment procedures. The Chair stressed that anything that was achieved in the work flowing from the 8th Triennial Review, could be rolled into the 9th

¹¹³ The full presentation of the proposal is contained in [JOB/TBT/403](#) and [JOB/TBT/403/Corr.1](#)

Triennial Review. He stressed that continued engagement was important to enable the Committee to advance on this mandate.

2.3 Report on Informal Meeting of 8 December on Conformity Assessment Procedures, COVID-19 Information Sharing and Workshop on the Role of Gender in the Development Of Standards

2.460. The Chairman reported on the informal meeting of the TBT Committee, held on 8 December 2020 to discuss conformity assessment procedures (CAP) and COVID-19 information sharing. The full report is contained in [JOB/TBT/395](#), dated 22 January 2021. This report also contains a reference to the report on the workshop on the Role of Gender in the Development of Standards (mentioned above and contain in separately in [G/TBT/GEN/309](#)).

3 NINTH TRIENNIAL REVIEW

3.1. The Chair introduced his report on the Committee's informal meeting held on 23 February 2021 on the 9th Triennial Review. An advance copy was provided in the room at the time of the meeting. Subsequently, the final version was circulated in [JOB/TBT/404](#), on 9 March 2021.

4 TWENTY-SIXTH ANNUAL REVIEW

4.1. The Secretariat introduced the Twenty-Sixth Annual Review of the Implementation and Operation of the TBT Agreement under Article 15.3, contained in [G/TBT/45](#). The Committee took note of this report.

5 TECHNICAL COOPERATION ACTIVITIES

5.1. The representative of the United States highlighted its ongoing efforts to support the implementation of the TBT Agreement. She spoke of a public-private programme between the US Agency for International Development (USAID) and the American National Standards Institute (ANSI), which coordinated aid in developing countries, and LDCs, to prioritize needs for technical assistance. The Standards Alliance had been established in 2012 with a focus on implementation of the TBT Agreement in 10 countries; it was later expanded. The original Standards Alliance would come to a close in 2021 but the programme had been renewed for a second phase in 2019. Based on lessons learned in the first phase, targeted technical assistance would be provided to developing countries, including the support of development of national quality infrastructure, and good regulatory practices that are rooted in the principles of the TBT Agreement. To date, the Standards Alliance had completed over 100 trainings and workshops with more than 4,500 participants. It had helped increase capacity in partner countries in several specific areas. More detailed is contained in the full report available in [G/TBT/GEN/311](#).

5.2. The Secretariat introduced the Third Edition of the WTO Agreements Series Technical Barriers to Trade Handbook, available on the WTO Website.¹¹⁴

6 OBSERVERS

6.1 Updates

6.1. The representative of the OECD shared information with the Committee on the "Global Partnership to Implement the GHS" (Globally Harmonized System for the Classification and Labelling of Chemicals). The full presentation is contained in document [G/TBT/GEN/313](#). The Chair drew the Committee's attention to information provided by other observers ([BIPM](#), [IEC](#) and [ISO](#) ([G/TBT/GEN/314](#))).

6.2 Pending Requests

6.2. Regarding pending requests for observer status, the Chair recalled that the list of observers, including pending requests, is contained in document [G/TBT/GEN/2/Rev.15](#) circulated on 22 February 2021. He drew delegations' attention to a recent request for observer status received

¹¹⁴ https://www.wto.org/english/res_e/booksp_e/tbt3rd_e.pdf

from the Arab Industrial Development, Standardization and Mining Organization (AIDSMO). In addition, he said, document [RD/TBT/1/Rev.7](#) provides a compilation of the original communications received by the WTO from the various bodies that have sought observer status in the TBT Committee and whose requests are still pending. Both these documents were currently up to date (no further requests have been received to date). Regarding previous requests, the Chair said that he had no new information that would lead him to believe that the situation had changed from where the Committee stood at the last meeting. He therefore suggested that the Committee revert to this matter when Members had had the time to further consult among themselves.

6.3. The representative of Turkey expressed her delegation's support for the request from the Standards and Metrology Institute for Islamic Countries (SMIIC). She noted that the process for evaluating the applications observer status requests needed to be reviewed in light of the growing list of pending requests, some of them dating back several years.

6.4. The representative of the United States reiterated that her delegation could not accept SMIIC as an observer in the TBT Committee. The BIPM was the relevant inter-governmental organization that had been granted observer status; this organization cooperated with Members on the topic of measurement science, and measurement standards. Moreover, OILM had been granted observer status as an inter-governmental treaty organization for legal metrology. These two organizations represented the globally recognized framework for metrology that underpinned quality infrastructure. Also, there were *international* organizations with pending requests that needed to be given priority before regional bodies were considered, such as ILAC and IAF.

6.5. The Chair encouraged Members to consult on this matter to reach a more satisfactory outcome. He reiterated his willingness, as Chair, to facilitate consultations.

7 ELECTION OF CHAIRPERSON

7.1. The Chair noted that, at the time of the meeting, Members had not yet finalized the selection process for the Chairpersons of the Committee on Trade in Goods and its subsidiary bodies, including the TBT Committee. This meant that the current agenda item would be suspended, and that the Committee would revert to it at the next formal Committee meeting, when a new Chair may be nominated and agreed for this seat.

8 DATE OF NEXT MEETING

8.1. The Chair recalled that the next regular meeting of the Committee is scheduled to take place on 2-4 June 2021 and will be preceded with an informal meeting on the Triennial Review on 1 June.
