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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 2-4 JUNE AND 9 JUNE 2021

CHAIR: MR LAURENCE SANDRAL

Note by the Secretariat[1]

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in WTO/AIR/TBT/20.

2 ELECTION OF CHAIRPERSON

2.1. 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.

3 NINTH TRIENNIAL REVIEW

3.1. The Chair's report on the 1 June 2021 informal meeting on the 9th Triennial Review is contained in document JOB/TBT/404/Rev.3, circulated on 23 July 2021.

[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.

4 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

4.1 Specific Trade Concerns

4.1.1 Withdrawn concerns

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 The Chair reported that the following STCs had been withdrawn from the agenda at the request of the concerned Member:

- Republic of Korea - Amendments to the Act on the Promotion of Saving and Recycling of Resources
- European Union - Directive 2008/98/EC of the European Parliament and of the Council on waste
- Japan - 100% inspection system for sports goods and toys and non-acceptance of test reports from Indian test houses
- 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)
- India - Testing and Certification of telegraph (The Indian telegraph (Amendment) Rules, 2017) (ID 558)

4.1.2 New Specific Trade Concerns

4.1.2.1 European Union - Draft EU Batteries Regulation (implementation of the European Green Deal), G/TBT/N/EU/775 (ID 685[2])

4.2. The representative of the Russian Federation provided the following statement. The Russian Federation acknowledges the right of all WTO Members to regulate to achieve legitimate environmental objectives. However, we would like to raise concern on the draft EU Regulation on batteries and waste batteries that is developed in order to implement the European Green Deal. The draft Regulation was notified in document G/TBT/N/EU/775. It sets out product requirements for new batteries as a condition for access to the EU market as well as material recovery targets for waste batteries. For new batteries the draft Regulation specifically sets requirements on the maximum level of carbon footprint over the life cycle of batteries and minimum level of recycled materials such as cobalt, lithium and nickel. Apparently, the requirements for the minimum level of recycled materials in batteries are aimed to reduce use of primary metals in the EU for the purpose of battery manufacturing. It is no secret that the EU does not have sufficient capacities of primary non-ferrous metals in its territory in order to meet internal demand. By introducing provision that discriminates imported primary materials vis-à-vis domestically remanufactured, the draft Regulation is aiming to substitute imported primary metals for the like domestically recycled ones. This is a protectionist aim which we reject as a legitimate one.

4.3. Article 2.2 of the Agreement on TBT requires Member to ensure that technical regulations are not developed, adopted and implemented in a manner more trade restrictive than necessary to fulfill legitimate objectives. The article also requires that technical regulations do not create unnecessary obstacles to international trade. In this regard, we are wondering if the European Union considered less trade-restrictive measures to stimulate recycling of nickel, lithium, cobalt, and lead rather than such administrative measure as minimum level of recycled materials in the battery. If yes, please name the measures that the EU has considered and reasons why these measures have not been employed or proposed for implementation. The current draft Regulation provisions on recycling efficiencies and the minimum requirement of recycled materials targets five metals – cobalt, copper, lead, lithium and nickel. We are wondering what criteria have been used by the European Commission to choose these particular five metals.

[2] For previous statements follow the thread under ID 685.

4.4. As far as the requirement on the maximum level of carbon footprint over the life cycle of batteries is concerned, there is no comprehensive methodology to calculate this parameter. Moreover, the draft Regulation does not specify the ways for the stakeholders from outside the EU to submit their data and calculations made under internationally recognized protocols, which are likely to be different from the EU standards. As a result, the lack of methodological clarity as well as the unresolved recognition issue unfairly penalizes non-EU battery value chain economic operators and constitutes a technical barrier to trade. Finally, the current approach of the EU concerning the recycling efficiencies and recycled content target-setting may result in market distortions and supply risks and consequently affect the global battery value chains. The EU proposes certain *ad hoc* due diligence requirements that are limited to a number of raw materials only. The introduction of new specific due diligence requirements additional to the existing ones would significantly increase the number of audits and reporting requirements for the upstream parts of the supply chains, as well as divert resources from proper and efficient risk management.

4.5. The representative of China provided the following statement. We suggest that the EU considers the following comments and provides necessary basis or scientific explanation. (i) In accordance with Article 7 and Annex II, the carbon footprint of rechargeable industrial batteries and electric vehicle batteries with internal storage and capacity above 2 kWh is required. However, there is no unified international calculation criteria or basis for the carbon footprint of such products, and the equitable and scientific assessment is hard to carry out. Besides, as industrial batteries are widely used, and of various types, it is difficult to make a unified footprint calculation. Therefore, China thinks it is not the right time to carry out those works. (ii) Regarding the recycled content in active materials from batteries in Article 8, it is suggested to cancel the "Minimum share of recycled content" in current stage, and to be considered after methodology of the calculation and verification is set up. For industrial batteries, electric vehicle batteries and automobile batteries, the regulations set the minimum share of cobalt, lead, lithium, or nickel recycled from waste present in active materials by 2030 and 2035, but the methodology for the calculation and verification of the recycled materials will not be set out until the end of 2025. In addition, companies in China also considered that the recycled proportion of cobalt is relatively high.

4.6. (iii) Regarding Article 13 and Annex VI on "Labelling of batteries", according to section 38.3 of the UN Manual of Tests and Criteria (UN Transportation Testing), lithium batteries need to be marked/labelled with energy (Wh) information on the shell, therefore we recommend that the energy (Wh) information shall be added to the information on the label of batteries; considering environmental protection, we recommend that the CE label and the symbol for separate collection of batteries shall be integrated into the QR code; as the appearance of some battery products would be black, if the QR code of the product is uniformly required to be 100% black, it may cause the QR code to be difficult to read or confused with other information. Therefore, we recommend that the requirements of QR code shall change to: clearly visible, indelible, colour-unified, and easy to identify. (iv) It is suggested that the EU could cancel the disclosure of the technical documents containing commercial secrets of enterprises on the premise that regulatory purpose has already been met. Article 7, article 8 and appendix 2, appendix 13 require to provide the technical information, but the technical information about the battery content, the material and processing process involves some core secrets, such as the content of cobalt, nickel, lithium contained in batteries, and data about carbon emissions of materials in the process of production, which increases the risk of disclosure.

4.7. (v) In accordance with Article 15, Article 48, Article 55 and Annex VI, the targets of collection rates of waste portable batteries are given, however, the achievement of the target mainly depends on consumers' willingness to participate. Therefore, referring to the manufacturers' and importers' collection obligations of the WEEE Directive, we recommend to cancel collection rate, and replace it with: manufacturer or importer should establish an effective waste collection management system. (vi) In accordance with Article 56, Article 57 Annex XII, the recycling efficiency and material recovery targets requirements are given. However, there is currently no sufficient scientific basis to support the rationality of these requirements in the world. Also, the requirements of waste materials may increase costs of manufacturers and sales enterprises and cause reliability risks. Therefore, we recommend that the limitation requirements shall be cancelled, if not, a scientific and reasonable explanation shall be provided, in order to avoid unnecessary trade barriers. (vii) In accordance with Chapter VIII and Annex XIII "By 1 January 2026, the Commission shall set up the electronic exchange system for battery information", however, the adaptation period is not specifically indicated. In accordance with Article 2.12 of Agreement on Technical Barriers to Trade that "Except in those urgent circumstances referred to in paragraph 10, 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", we recommend that at least two years adaptation period after setting up of the electronic exchange system shall be given.

4.8. (viii) In accordance with Article 39, Article 72 and Annex X "Obligation for economic operators that place rechargeable industrial batteries and electric vehicle batteries with internal storage and a capacity above 2 kWh on the market to establish supply chain due diligence policies". Considering the fact that the raw material procurement due diligence involves a long list of materials, long and multiple-layers supply chain, 12 months is not long enough to provide a complete and qualified due diligence. Therefore we recommend extending the time of provision of the due diligence to at least 24 months. Besides, China suggests documents concerning unreasonable mining in the origin which would cause environmental damage are added, and appropriately to optimize the list of raw materials based on the results of the actual risk assessment.

4.9. The representative of India provided the following statement. India expresses support for this STC.

4.10. The representative of Canada provided the following statement. Canada welcomes this opportunity to voice its interest to work with the European Union throughout the development and implementation of this measure to ensure that international trade considerations are fully accounted for and provide for an approach that allows for effective and sustainable global battery value chains given their key role in advancing our decarbonisation efforts. Recognizing and strongly supporting Members' right to regulate, we find common ground with the EU's desire to contribute to sustainable development, green mobility, and clean energy. On that basis, Canada signals its intention to monitor the development of the proposed regulation, and its possible relationship with other Members' domestic initiatives on sustainability. Canada looks forward to continuing to engage and collaborate with the EU on its Batteries Regulation as its Implementing and Delegated Acts are developed.

4.11. In response, the representative of the European Union provided the following statement. The EU would like to thank the delegations of China and Russia for their comments on the Proposal for a Regulation of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (the Batteries Regulation). The EU would like to recall that the Batteries Regulation proposal was presented on 10 December 2020 and notified to the TBT Committee on 26 January 2021 with a commenting period of 90 days. Batteries are an important source of energy and one of the key enablers for sustainable development, green mobility, clean energy and climate neutrality. In order for the EU's product policies to contribute to these objectives, it needs to be ensured that batteries marketed and sold in the EU are sourced and manufactured in a sustainable manner. Batteries that are more sustainable throughout their life cycle are key for the goals of the European Green Deal and contribute to the zero pollution ambition set in it. Addressing the entire life cycle of batteries placed on the EU market requires the setting up of harmonized product and marketing requirements, including conformity assessment procedures. The proposal addresses the social, economic and environmental issues related to all types of batteries. Batteries placed on the EU market should become sustainable, high-performing and safe all along their entire life cycle. This means batteries that are produced with low environmental impact, using materials obtained in full respect of human rights as well as social and ecological standards. Batteries have to be long-lasting and safe, and at the end of their life, they should be repurposed, remanufactured or recycled, feeding valuable materials back into the economy.

4.12. The EU would like to reassure that there will be sufficient time to consider the feedback on the Batteries Regulation proposal. Implementing and delegated acts that will be developed under the proposal will involve consultation of stakeholders, though the exact way in which this will be done is to be determined in each case separately. Their drafts will be notified to the TBT Committee. The application dates for some of the provisions in the proposal are relatively soon. This is because significant developments in the battery sector are taking place in the near future. However, the EU would like to clarify that the indicated application dates are provisional, because it will depend on the time needed for the regulatory process to adopt this regulation. The EU currently expects that the proposal will be adopted by the Council and the European Parliament during 2022. In conclusion, the EU stresses that the notified measure seeks to fulfill objectives such as protection of human

health and safety and prevention of deceptive practices, which are legitimate policy objectives under Article 2.2 of the TBT Agreement. For the reasons specified above, the EU considers that the notified proposal is not more trade-restrictive than necessary to fulfill its legitimate policy objectives, also taking account of the risks that non-fulfillment would create. It therefore fully complies with the provisions of the TBT Agreement.

4.1.2.2 Egypt - Regulatory Guidelines for the Circulation of Cosmetics Products in Egypt (ID 686[3])

4.13. The representative of the European Union provided the following statement. The EU would like to refer to draft Regulatory Guidelines for the Circulation of Cosmetics Products in Egypt, a non-notified measure, and to remind Egypt that according to Article 2.9.2 of the TBT Agreement, the proposed technical regulations should be notified at an early appropriate stage, when amendments can still be introduced and comments taken into account. The EU welcomes the Egyptian decision to harmonize its cosmetics regulation with global regulatory best practices, and to base it, *inter alia*, on the EU system. However, the non-notified draft Regulatory Guidelines maintain burdensome pre-market approval and customs clearance processes, while also instituting new, burdensome in-market enforcement procedures on all products, regardless of risk. As a result, the business environment cosmetics producers risk important disruptions in the Egyptian market. In particular, the EU would like to ask Egypt to consider eliminating the pre-approval process (registration), and to allow products to go directly to market once the manufacturer submits adequate product information (notification before placing on the market) to enable efficient in-market controls. The pre-market approvals are burdensome for the Authority without safeguarding the consumer as the submitted documentation may not reflect actual products on the market, and illegitimate actors may bypass the registration process. Furthermore, pre-market approvals add unnecessary costs and cause significant delays in placing a product on the market. This is further exacerbated by the high volume of products being registered. As fast-moving consumer goods, cosmetics are dependent on seasonal sales and fashion trends; this necessitates the ability to immediately place products on the market. Control system based on approvals is an inefficient use of government resources as they create bureaucratic burdens for companies that are most likely to comply with regulations and do not address counterfeit and/or unsafe products on the market.

4.14. In the EU regulatory system, consumer safety is ensured by in-market controls based on risk: the product information provided must be adequate to demonstrate product safety and for the authority to perform in-market control. Given that a burdensome registration process creates administrative costs that may result in legitimate products being comparatively more costly to illegitimate, counterfeit and unsafe ones, the EU would like to ask Egypt to limit the information required to be provided to EDA to what is essentially needed to perform in-market control. In addition, according to the EU, testing requirements as a condition for pre-market approval are unreasonable and should be revised. The EU would also like to ask Egypt to replace the proposed customs clearance process with release at port and a risk-based approach to inspections for all products, not only those that may be sold in designated third countries. The current requirements add a significant cost and cause delays, as many shipments must be stored at a bonded warehouse for one week at the importer's expense awaiting visual inspection. Such practice increases cost and comparatively favours illegitimate products. Furthermore, the delays affect the ability to supply the market promptly. The EU would like to note that industry experience globally has shown that customs inspections are best performed on a risk-based approach, i.e., in a targeted fashion towards non-compliant actors and higher risk products.

4.15. The EU would also like to ask Egypt to remove the requirement for the notification number to be placed on the packaging. According to the EU, the product name and the address of the person responsible for the product safety are sufficient to identify a product and perform in-market control, in particular by requesting technical documentation on the product safety from the responsible person. Requiring the notification number to be annotated on the packaging creates additional steps in the supply chain. It also results in unnecessary fragmentation of the international supply chain by requiring a unique packaging for Egypt only. International practices give preference to over labelling instead of direct annotation of country-specific labelling requirements on the packaging. Finally, the European Union would like to ask Egypt to limit the requirement to report only serious adverse events to the authorities. The vast majority of adverse experiences with cosmetic products experience relate to minor, temporary skin irritations that are resolved without a need for medical

[3] For previous statements follow the thread under ID 686.

treatment. Cosmetics companies perform cosmetovigilance to understand and improve consumer experiences. Reporting all adverse events will result in significant efforts and cost in monitoring for both the authorities and industry. The EU would like to suggest a requirement to report only serious adverse events to allow for more efficient in-market controls and safeguard of public health. The European Union calls on Egypt to notify the draft Regulatory Guidelines for the Circulation of Cosmetics Products in Egypt in line with the provisions of the TBT Agreement, and to give Members sufficient time to submit comments.

4.16. The representative of the United States provided the following statement. We understand that the Egyptian Drug Authority published a revised draft of its Regulatory Guidelines for the Circulation of Cosmetics Products in Egypt. We note that this draft regulation was not notified to the WTO TBT Committee and we have made a request Egypt notify the measure on April 26. We welcome an update from Egypt on the status of the draft and when it intends to notify the most recent draft to the WTO TBT Committee.

4.17. In response, the representative of Egypt provided the following statement. Egypt takes note of comments and will revert to the delegations in due course with feedback.

4.1.2.3 Russian Federation - On Safety of Wheeled Vehicles (TR CU 018/2011), G/TBT/N/RUS/100 (ID 687[4])

4.18. The representative of the Republic of Korea provided the following statement. Korea respects the EAEU Council's efforts to protect consumer safety through revision of vehicle regulations. Furthermore, Korean companies are fully committed to complying with the regulations of EAEU. Regarding the EAEU's regulation of "TR CU 018/2011: On Safety of Wheeled Vehicles" notified to the WTO on 20 March 2020 as G/TBT/N/RUS/100, Korea submitted comments in December 2020, February 2021, and May 2021, via the EAEU TBT Enquiry Point. Since Korea has not yet received any response from the EAEU, we would like to reiterate the comments at this meeting. Firstly, Korea requests the EAEU for regulatory improvements for requirements that fall under the e-Call System category, stipulated in Clause 16. The requirements are in regard to Mandatory e-Call Installation, Error from Standard Time, User Information Support Mode, PSAP Information while Driving, Transmission of Surroundings Information, System Operation Signal, and Transmission Protocol, respectively. Specifically, Korea asks if each EAEU member State could regulate the e-Call installation requirement under its own domestic law as they see fit because the lack of infrastructure in some EAEU member States would hinder the regulation's entry into force. Additionally, apart from the current e-Call system meeting the System Operation Signal requirement, Korea asks to clarify if the System Operation Signal requirement is mandatory for PSAP (Public Safety Answering Points) function as well. If so, Korea requests the EAEU to grant an exemption from its application or a grace period of three years before enforcement for vehicles already placed on the EAEU's markets.

4.19. Secondly, regarding the Safety Declaration of Advanced Autonomous Driving Function, Korea requests to reflect the UN ECE regulations' ALKS (Automated Lane Keeping Systems) function on Annex 2 of EAEU regulation. And as for other advanced autonomous functions (over SAE level 3), Korea requests to recognize certificates if they meet the relevant UN ECE regulations currently under revision. Thirdly, regarding the installation of tachometers and additional safety requirements for cold/subarctic region, Korea requests to stipulate the interpretations of the requirements, provided by the EAEU representatives at the Korea-EAEU briefing session on 11 September 2020, to promote consistency in implementation. Fourthly, regarding the fuel tank and rear side collision, Korea requests to consider revising the requirements to be consistent with the scope of the relevant amended international standards (UN R-34.03). Fifthly, since the local manufacturers are having difficulties in producing parts that meet the requirements, Korea requests an exemption (reflecting the exception clause in Annex 20) of the regulation on four heavy metal contents (lead, mercury, cadmium, hexavalent chromium) in motor vehicle parts. Lastly, regarding the maximum speed measurement, the UN ECE R-68 adopted in this regulation has not been used by countries other than Russia due to the need of technical development and financial burden imposed by the addition of actual test driving. Therefore, Korea requests the EAEU to retract the requirements. If not, we ask for an exemption for the vehicles placed on EAEU markets. All details for these six subjects are included in our comments submitted to EAEU TBT Enquiry Point on 7 May 2021. We would be grateful

[4] For previous statements follow the thread under ID 687.

if the EAEU would review them again and take into positive consideration and reply to Korea in writing.

4.20. In response, the representative of the Russian Federation provided the following statement. We appreciate Korea's interest in the Russian Federation's regulatory policy. The draft amendments to the Technical Regulation "On safety of wheeled vehicles" that are being discussed in the Committee were notified to the WTO on 20 March 2020 in accordance with Article 2.9 of the Agreement on Technical Barriers to Trade. 60-day comment period was provided and expired on 20 May 2020. Currently, the amendments in question have not been adopted yet. We acknowledge receipt of comments by Korea noting that they came with long delay. Russia is open to work on this and other issues bilaterally both with Korea and other WTO Members.

4.1.2.4 Viet Nam - The List of products and goods with unsafe capability under management responsibility of Ministry of Information and Communications, G/TBT/N/VNM/186 (ID 688[5])

4.21. The representative of the Republic of Korea provided the following statement. Korea respects and supports the efforts of Vietnam to ensure the safety of its people. Furthermore, Korean companies are fully committed to complying with the regulations of Vietnam. However, Korea would like to make the following comments reflecting concerns raised by Korean companies regarding the amended regulation of "Products and goods with unsafe capability under management responsibility of Ministry of Information and Communications, Circular 11/2021/TT-BTTTT." Korea requests Vietnam to consider removing the performance tests requirement from the amended regulation. Under the existing regulation of 'Circular 11/2020/TT-BTTTT,' Appendix II No. 6.1 specifies that lithium batteries used for laptops, notebooks, mobile phones, and tablets are only required to meet the safety standard tests based on QCVN 101:2016/BTTTT. On the contrary, the amended regulation requires companies to submit reports on performance tests as well as safety tests. The amended regulation would cause a new burden on most companies in terms of cost and time. Many countries, including the EU, China and Japan, require only safety test reports. As an alternative, Korea requests Vietnam to provide a transitional period of at least six months after the publication of the final rule. If the regulation enters into force on 1 July 2021, as stipulated in the notification, Korean companies exporting goods to Vietnam would encounter difficulties complying with the regulation because more than three months will be required to submit performance test reports.

4.22. In response, the representative of Viet Nam provided the following statement. Vietnam would like to thank Korea for comments submitted to the Ministry of Information and Communications. The draft Circular providing amendments for the Annexes of Circular No.11/2020/TT-BTTTT dated 14 May 2020 specifying the List of products and goods with unsafe capability under management responsibility of Ministry of Information and Communications was notified in G/TBT/N/VNM/186 with 60 days provided for comments. After this period, all comments received from WTO Members and other stakeholders had been fully taken into considerations. Accordingly, the performance test requirement has been removed in the final version of the above-mentioned draft Circular, which has been promulgated as Circular No. 01/2021/TT-BTTTT on 14 May 2021.

4.1.2.5 Ecuador - Sanitary Technical Regulation on processed foods, processing plants, establishments for the distribution, marketing, and transportation of processed foods, and mass catering establishments, G/TBT/N/ECU/490 (ID 689[6])

4.23. The representative of the United States provided the following statement. The United States appreciates the opportunity to discuss Ecuador's draft sanitary technical regulation, establishing registration and certification requirements for processed retail food, notified as G/TBT/N/ECU/490. We thank Ecuador for their response in February 2021 to the US Government's comments. On 24 March 2021, the United States requested a Spanish version of Ecuador's response to US comments. Could Ecuador provide the response in Spanish for a clearer interpretation? The United States observes that Ecuador shall require US manufacturers to provide a health certificate for all processed foods. The United States would like to note that some processed foods are especially highly processed, shelf-stable products that pose relatively minimal food safety risks. Therefore, please explain its scientific rationale for requiring a health certificate for all processed food products.

[5] For previous statements follow the thread under ID 688.
[6] For previous statements follow the thread under ID 689.

4.24. The United States would like to note that a Certificate to a Foreign Government, issued by the US Food and Drug Administration (FDA), indicates that exported foods meet US regulatory requirements, including processing according to Good Manufacturing Practice regulations. Can Ecuador please confirm that a US FDA-issued Certificate to a Foreign Government would satisfy Ecuador's health and good manufacturing practice requirements? The measure states the Good Manufacturing Practice certification are carried out by an inspection body accredited by the Ecuadorian Accreditation Service (SAE). Could Ecuador confirm that the FDA Certificate to a Foreign Government, which is issued by a competent authority, is sufficient and does not require accreditation? Please clarify the implementation timeline for this draft regulation. The United States looks forward to continuing the dialogue with Ecuador about developing regulations in a manner that addresses Ecuador's health concerns while continuing to facilitate trade. Our regulators and technical experts are available to share more information on our regulatory approach. Would Ecuador be interested in having a technical exchange in this area?

4.25. In response, the representative of Ecuador provided the following statement. The replies to the United States' concerns were transmitted to the US delegation this morning. I would, however, like to make the following comments. The draft "Substitute Sanitary Technical Regulation on processed foods, processing plants, establishments for the distribution, marketing and transportation of processed foods, and mass catering establishments" is still being drawn up and analysed at the technical level. Our National Agency for Sanitary Regulation, Control and Surveillance has provided detailed replies to the comments sent by the United States, in Spanish and English. The information provided indicates the time frame for the implementation of this draft regulation, which takes into account public consultation periods in accordance with the Agreement on Technical Barriers to Trade. Our regulators and technical experts are available to provide further information on our regulatory approach. My country welcomes the opportunity to learn about the regulatory approach of the United States. Therefore, in order to arrange a technical exchange regarding registration and certification and to address the concerns raised by the United States, our capital will facilitate a meeting between our technical authorities and the technical authorities of the United States.

4.1.2.6 European Union - Chemical strategy for sustainability (implementation of the European Green Deal) (ID 690[7])

4.26. The representative of the Russian Federation provided the following statement. On 14 October 2020, the European Union published Chemicals Strategy for Sustainability. The Strategy is part of the European Green Deal. Implementation of Strategy can have significant worldwide trade-distorting effect in a wide range of economic sectors. Although the Strategy is a non-binding document, it is a strong political commitment which involves plans to tighten even further current regulation of chemical substances and mixtures under the CLP/Reach Regulations as well as other product specific regulations. The Russian Federation would like to raise the following concerns in respect of this Strategy and its implications for foreign trade. First, the EU's legislation, specifically REACH/CLP, employs precautionary principle which implies strict classification decisions without available laboratory or epidemiological data. One recent example of this practice is cobalt classification under the 14th Adaptation to Technical and Scientific Progress of the EU Classification, Labelling and Packaging Regulation. The Strategy implies banning the use of the "most harmful chemicals", classified under this category in the CLP Regulation. This situation will entail restrictions and prohibitions of safe substances classified unjustifiably strictly using precautionary principle. The EU sticks to the position that once relevant scientific data is available the classification decision can be revised. However, such revision will have little practical implications since manufacturers of prohibited products would stop production, revise technological processes or even go out of business.

4.27. In this context, we request that the EU answer the following questions. Could the EU explain how described situation is supposed to be mitigated? Could the EU elaborate how such an approach complies with the provisions of the Agreement on TBT bearing in mind the requirements of scientific justification in Article 2.2 of this Agreement? Will the EU ban substances only in case of their use leading to actual risks? Second, the Strategy introduces the new categories of chemicals, i.e. most harmful chemicals and substances of concern while category of substances of very high concern is already incorporated in the REACH regulation. Could the EU elaborate on the differences between these three categories? Could the EU explain why the current version of the CLP/REACH legislation is not sufficient to fulfill protection of human health objective? Third, the Strategy implies the plans

[7] For previous statements follow the thread under ID 690.

to introduce new information requirements to the REACH (for example, for endocrine disruption, immunotoxicity, neurotoxicity, carcinogenicity at all tonnage levels, etc.). Could the EU explain why these new requirements are not more trade restrictive than necessary? Finally, could the EU inform if legal acts implementing Strategy have already been developed?

4.28. The representative of the United States provided the following statement. The United States continues to closely follow the EU's proposed Chemicals Strategy for Sustainability (CSS). While the US supports the EU's intent to better protect human health and the environment, we remain concerned about the potential trade implications of the CSS. We note the establishment of the "High-Level Roundtable Group" and continue to encourage the Commission to conduct meaningful stakeholder engagement, including with third countries, on the Strategy. We also ask the Commission to perform thorough impact assessments to understand the economic and trade implications in advance of all actions proposed in the Strategy. Finally, we ask the Commission to keep stakeholders updated with regards to the consultation and implementation timetable for the Strategy.

4.29. The representative of India provided the following statement. We appreciate and understand the intent of the EU Green Deal and the chemical strategy for sustainability. Having said that, we are also concerned about the trade implications and hence we thank the Russian Federation for raising this concern and we remain interested in the development and answers that the European Union has to give to the concerns raised.

4.30. In response, the representative of the European Union provided the following statement. The European Union would like to recall that the EU Chemicals Strategy for Sustainability was adopted on 14 October 2020. The Strategy is the first step towards a zero pollution ambition for a toxic-free environment announced in the European Green Deal. The objective of the Strategy is thus to boost innovation for safe and sustainable chemicals, and increase protection of human health and the environment against hazardous chemicals. This includes prohibiting the use of the most harmful chemicals in several consumer products such as toys, cosmetics and textiles, unless proven essential for society, and ensuring that all chemicals are used more safely and sustainably. The Chemicals Strategy aims at an increased protection of consumers and vulnerable groups by not allowing the most hazardous chemicals in consumer products, childcare articles and for professional uses, except for essential uses. This is a generic approach to risk management, which recognizes that exposure to chemicals in those products and uses cannot be easily controlled.

4.31. The European Union would like to clarify that the generic approach to risk management is not a new approach in the EU chemicals legislation, and is consistent with WTO rules as it is based on risk considerations, including the available scientific and technical information on the properties of the concerned substances and the intended end-uses of products. This approach is already in use in consumer products for chemicals that cause cancer or that are toxic for our reproductive system. The Strategy only proposes to extend this approach to other hazard classes, such as endocrine disruptions, to further protect consumers and children as well as the environment. The way this approach will be extended and the associated impacts will be assessed under the revisions of the relevant pieces of legislation, in particular REACH and other product-specific pieces of legislation (e.g. legislation on food contact materials). Those assessments will follow the European Commission's Better Regulation guidelines and will be based on updated scientific information and on the feedback of all relevant stakeholders. Moreover, regarding the Regulation on Classification, Labelling and Packaging (CLP), the European Commission will propose a targeted revision in order to achieve the objectives of the Chemicals Strategy and in particular to ensure that the CLP regulation fully fulfills its main objective: appropriate classification of the hazardous properties of substances according to the best scientific knowledge and available data. To this goal, the European Commission will propose new hazard classes and criteria in particular on endocrine disruptors and to fully address environmental toxicity, persistency, mobility and bioaccumulation. However, the way the classified substances or mixtures are dealt with will depend on other pieces of legislation (in particular, REACH and specific products legislation); this will be designed and assessed within specific sectorial impact assessments, according to the European Commission's Better Regulation guidelines.

4.32. The European Union would also like to recall that the CLP Regulation already includes a possibility to review an adopted classification. Economic operators who have new information which may lead to a change of the harmonized classification and labelling can in fact submit a revision proposal to a competent authority in one of the member States. The authority can then decide to

officially submit a proposal to reassess the classification. The European Union would further like to clarify that the Chemicals Strategy does not introduce a new category for "most harmful substances". However, the following hazard categories of substances have been found from recent policy evaluations and scientific evidence to be the most harmful, in particular for consumers: chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative, chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ. Substances of concern are defined in the Strategy as those substances having a chronic effect for human health or the environment (as for Candidate list in REACH and Annex VI to the CLP Regulation) but also those which hamper recycling for safe and high quality secondary raw materials. The category of Substances of Very High Concern (SVHC) is a specific category under REACH (not applied in other pieces of EU chemicals legislation) to list those substances whose use is proposed to be subject to authorization. The European Commission will propose to introduce endocrine disruptors, persistent, mobile and toxic and very persistent and very mobile substances as categories of substances of very high concern, as part of its proposal for the revision of REACH. Also, the Strategy has announced that the European Commission will assess options to improve the overall authorization and restriction processes under REACH.

4.33. The Strategy aims to consolidate and strengthen the current EU legal framework on chemicals, not to establish new approaches. In particular, the European Commission's proposals aim to speed up the regulatory management of the most harmful substances, as the current approaches have been found too slow to protect consumers, professional users and the environment against risks from those substances. Furthermore, the European Commission will propose to revise information requirements in REACH in order to ensure sufficient information for the scientific assessment of those substances, in line with the objectives set in the Chemicals Strategy. This will affect equally manufacturers located in the EU and importers of substances from outside the EU; thus the same rules will apply. The exact proposal and its impacts will be assessed during the impact assessment for the revision of REACH, according to the European Commission's Better Regulation guidelines. Finally, the European Union would like to clarify that the European Commission is currently implementing the Strategy and in preparing the necessary legal proposals. Those will concern mostly the revision of chemicals legislation already in place. The only new piece of legislation proposed will be a founding regulation for the European Chemicals Agency (ECHA). In May 2021, two Inception Impact Assessments were published, or so-called roadmaps, one on the revision of the EU CLP Regulation and one on the revision of the EU REACH Regulation. These roadmaps were open for stakeholder feedback until 1 June 2021. Both roadmaps provide overall descriptions of the problems that need to be solved, possible options for how changing the two pieces of legislation may help to solve these problems as well as initial assessments of the potential impacts of such changes. The feedback on both roadmaps will be used to further develop and fine-tune each initiative. After assessing the responses to the roadmaps, another round of public consultations will be launched to gather more specific and more in-depth feedback. The open public consultations for three months for the revision of the CLP Regulation is expected to be launched in Q4 2021, and for the REACH Regulation late 2021 and running into 2022. They will be available on the "Have-your-say" portal and will also be referred to on the Commission's webpage for the Chemical Strategy for Sustainability. In terms of engagement with stakeholders and WTO Members, the European Union would recommend to provide feedback during the foreseen public consultations. Moreover, the European Union would like to reiterate that any legislative proposal put forward in the context of the EU Chemicals Strategy for Sustainability, including the proposals for the revision of the CLP and REACH Regulations, will be notified in accordance with the TBT Agreement.

4.1.2.7 Republic of Korea - Amendment of particular requirements for appliances for heating liquids (KC 60335-2-15), G/TBT/N/KOR/939 (ID 691[8])

4.34. The representative of China provided the following statement. We suggest that pot with rubber sealing ring meets IEC safety standards and can be designed as a pressure safety device. It is suggested that KC 60335-2-15 be consistent with IEC 60335-2-15.

4.35. In response, the representative of the Republic of Korea provided the following statement. Korea would like to deliver the official response from the regulatory authority. This WTO TBT notification (G/TBT/N/KOR/939) is in regard to the revision of "particular requirements for appliances for heating liquids (KC 60335-2-15)" such as rice cookers. Korea would like to respond to China's request for the requirement in Clause 22.107 "rubber packing is not considered a pressure safety

[8] For previous statements follow the thread under ID 691.

device" to be harmonized with the international standards (IEC 60335-2-15). This requirement applies only to domestic standards in Korea, and was introduced following incidents of electric rice cooker explosion in Korea in 2004. Furthermore, the requirement was made by taking into consideration consumer safety in Korea, a country in which an electric rice cooker is present in almost every household. Against this backdrop, this requirement entered into effect upon the revision of the KC60335-2-15 Safety Standards on 2 August 2004. However, this phrase has thus far been omitted due to the amended requirement during the KS standard matching work on 23 September 2015. However, consumers can easily buy and replace rubber packing, which is a consumable item that may harden during use. In addition, we have reached the conclusion that rubber packing cannot be considered an appropriate pressure device based on opinions gathered from related industries, test and certification bodies that long-term use leads to a greater risk of reduced safety. Therefore, we would like to inform China that as a result of the inclusion of this phrase, this revision will in fact strengthen domestic safety standards for consumer safety.

4.1.2.8 Canada - Concentration of Nicotine in Vaping Products Regulation, G/TBT/N/CAN/633 (ID 692[9])

4.36. The representative of Japan provided the following statement. Regarding Canada's proposed regulations on concentration of nicotine in vaping products, notified on 5 January 2021, while Japan respects their policy objectives, Japan has a concern whether Canada will allow a "reasonable interval" between the publication of the regulations and their entry into force in accordance with Article 2.12 of the TBT Agreement. Canada currently proposes "15 days" as the interval. However, Japan considers it is difficult for some producers and distributors of vaping products to remove newly-regulated products from their global supply chains in such a short period of time, and it could lead to disruptions in the Canadian market. Furthermore, we are strongly concerned that such a short interval would become the standard in the Canadian rulemaking process even though Doha Ministerial Decision, WT/MIN(01)/17, describes "reasonable interval" as normally "not less than 6 months". For these reasons, Japan would like Canada to fully consider concerns from stakeholders and respect WTO rules in the process of finalizing the regulations to the extent possible.

4.37. In response, the representative of Canada provided the following statement. We would like to thank the delegation of Japan for their intervention. Canada believes that, with respect to the present measure, Canada respected its international obligations under the TBT Agreement and was able to strike the appropriate balance between pursuing a legitimate public policy objective – which is the protection of public health, and in this case, the health of young Canadians – and providing producers in exporting countries time to adapt to requirements of the measure. Canada appreciated Japan's openness to meet bilaterally with Canada, which allowed for a positive exchange of views and information on the measure concerned. Canada remains available for further bilateral engagement with Japan on this issue.

4.1.2.9 Chile - Amendment to the general regulation of the compulsory system for livestock classification and the grading, marking and marketing of beef, G/TBT/N/CHL/544 (ID 693[10])

4.38. The representative of Brazil provided the following statement. Brazil would like to express its concerns regarding Chilean draft regulation G/TBT/N/CHL/544, which aims to amend the general regulation of the compulsory system for livestock classification and the grading, marking and marketing of beef. This proposal provides for the application of a compulsory stamp to be used exclusively for meat from animals born, reared, and slaughtered in Chile, and two voluntary stamps that may only be used on meat that already has the compulsory stamp. Brazil understands that the use of quality stamps that are exclusive to national producers may create discriminatory marketing conditions in favour of Chilean producers. The measure also seems to be more trade restrictive than necessary to pursue Chilean legitimate policy objectives. If this draft is adopted as a final regulation, meat produced abroad with the same amount of fat content or other similar characteristics compared to Chilean meat will be denied the possibility of receiving both mandatory and voluntary stamps, which will give rise to discrepancies in consumers' quality perception. Chilean regulation could also constitute a violation to Article 2.1 of the Agreement on Technical Barriers to Trade, which states that "Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like

[9] For previous statements follow the thread under ID 692.
[10] For previous statements follow the thread under ID 693.

products of national origin and to like products originating in any other country". In light of the above, we kindly ask Chile to explain what legitimate objectives it is willing to safeguard with said regulation, as well as the link between these objectives and the proposed measure. Also, we encourage Chile to present other less trade-restrictive alternatives it considered prior to proposing the draft regulation.

4.39. In response, the representative of Chile provided the following statement. Chile thanks the Federative Republic of Brazil for its submission regarding notification G/TBT/N/CHL/544. The Chilean Ministry of Agriculture is indeed amending Decree No. 239 on the general regulation of the compulsory system for livestock classification and the grading, marking and marketing of beef, in respect of which comments were received from Brazil and other countries, with work underway to duly address these comments.

4.1.2.10 European Union - Withdrawal of the approval of the active substance alpha-cypermethrin, G/TBT/N/EU/770 (ID 694[11])

4.40. The representative of Brazil provided the following statement. Brazil would like to express its concerns related to notification G/TBT/N/EU/770 regarding the Commission Implementing Regulation proposal to withdraw the approval of the active substance alpha-cypermethrin. Alpha-cypermethrin is registered in Brazil as an insecticide against important pests that damage a variety of crops, including soy, cotton, corn, citrus, watermelon, peanut, coffee, among other products exported to the European Union. In relation to these crops, our national health agency has set MRLs for alpha-cypermethrin of 0.05mg/kg, 0.15mg/kg, 0.05mg/kg, 0.3mg/kg, 0.05mg/kg, 0.05mg/kg and 0.3mg/kg, respectively. If the register of said substance is withdrawn and MRLs are automatically reduced, it would significantly affect the income of Brazilian farmers, especially citrus producers, since the substance is essential to control greening, a disease affecting citrus orchards worldwide. Greening has been recognized by EFSA itself as a priority pest for control, according to the Commission Delegated Regulation (EU) 2019/1702. The Brazilian citrus industry plays an important role in generating jobs in the countryside. Export of orange juices to the European market represented almost USD 1 billion of exports in the 2019-2020 marketing year. Alpha-cypermethrin is also an important component to conduct integrated pest management, once it may be combined with other insecticides to contribute to increase their useful life, ensuring efficient pest control and maintaining the sustainability of crop production. In light of the above, in case the register of the substance is withdrawn, Brazil would like to kindly encourage the EU to adopt MRLs for imported products in accordance with the limits set by Codex Alimentarius.

4.41. The representative of Paraguay provided the following statement. Paraguay appreciates the opportunity to comment on notification G/TBT/N/EU/770 (draft Commission Implementing Regulation withdrawing the approval of the active substance alpha-cypermethrin in accordance with Regulation (EC) No. 1107/2009) and supports the concern expressed by Brazil on this draft Regulation. It should be noted that, in 2020, Paraguay imported approximately 80,000 kilograms of the substance alpha-cypermethrin, which is duly registered as a systemic insecticide with the competent authority, the National Plant and Seed Quality and Health Service (SENAVE), and is used to control pests that attack crops of great economic importance. Pests controlled by the affected substance include: *Spodoptera frugiperda* in maize and soybean crops, *Anticarsia gemmatalis* (velvetbean caterpillar), *Loxostege bifidalis* (green caterpillar), *Epinotia aporema* (bud borer) in soybean crops, *Horcias nobilellus* (cotton bug), *Alabama argillacea* (cotton leafworm) and *Porosagrotis gypaetina* (brown cutworm) among other Lepidoptera, Hemiptera and insects that attack crops such as cotton, maize and sunflower. In this regard, these insects pose a real problem for the development of a number of crops, and it is therefore important to possess duly controlled and authorized substances that have met the technical and scientific requirements for use and have proven both effective in controlling these pests and vital for the rotation of active ingredients, thereby preventing insect resistance as part of the integrated management of pests.

4.42. Paraguay considers that the withdrawal of this substance by the European Union could significantly restrict local producers in terms of the technological substances available for the proper management of their crops, thus having a direct impact on the national economy. Our concern therefore is founded on the negative impacts that this measure would have on Paraguayan producers, bearing in mind the importance of the crops on which alpha-cypermethrin is used and its impact on the domestic exports on which it is used. While it is recognized that Members have the

[11] For previous statements follow the thread under ID 694.

right to determine the appropriate level of sanitary or phytosanitary protection necessary to protect human, animal or plant life or health, we are of the view that this measure is inconsistent with Article 2.2 of the TBT Agreement as it generates unnecessary trade restrictions. Paraguay insists that 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. It is important to adopt a science- and risk-based approach for regulating plant protection products and we consider that the European approach to limit the use of pesticides is more trade-restrictive than necessary to fulfill its legitimate objectives under the TBT Agreement.

4.43. The representative of Colombia provided the following statement. We would like to register our interest in this STC and thank Brazil for raising this issue. We note particularly the concern that this EU standard creates in the use of this substance in citrus crops in Colombia as well as its insecticide quality which allows it to be used on a broad range of products. It is noteworthy that tropical climate countries such as Colombia rely heavily on these substances to ensure there is effective control of pests and insects in their crops.

4.44. In response, the representative of the European Union provided the following statement. The approval of alpha-cypermethrin had to be withdrawn, as the Commission Implementing Regulation that renewed its approval in 2019 included the condition that the applicant had to submit confirmatory information as regards the toxicological profile of certain metabolites by 30 October 2020. In addition, confirmatory information had been required for three other points by other deadlines. However, in October 2020, the applicant informed the Commission that it would not submit any confirmatory data. Therefore, as the information required in accordance with Article 6(f) of Regulation (EC) No 1107/2009 on plant protection products was not submitted and the applicant had clearly stated that he will not fulfill his regulatory obligations, the approval for alpha-cypermethrin had to be withdrawn according to Article 21(3) of Regulation (EC) No 1107/2009. Following the withdrawal decision, the EU will prepare a draft Regulation to lower the existing Maximum Residue Limits (MRLs) for alpha-cypermethrin to the limit of quantification, and will notify it to the WTO/SPS Committee. The procedure for the lowering of the current EU MRLs will not commence before expiry of the grace periods for use of products containing alpha-cypermethrin. Whether MRLs currently established based on earlier import tolerance requests or based on Codex MRLs will remain unchanged, will depend on the outcome of the forthcoming MRL review of the group of cypermethrins by the European Food Safety Authority (EFSA), planned to be launched in 2021. If Brazil and other Members consider it necessary to ensure that MRLs for alpha-cypermethrin on relevant crops remain or should be newly set at higher/different levels, they may wish to submit an application for setting import tolerances according to Article 6 of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin. If submitted early enough, the application will be thoroughly assessed by EFSA at the same time as the review of the group of cypermethrins mentioned above and, if the data provided are complete and there is no risk for consumers, such an import tolerance can be established. The EU would like to invite Brazil to contact the relevant authorities in Belgium, the rapporteur member State, and to ensure that the necessary information will be available in due time for the evaluation by the rapporteur member State and EFSA.

4.1.2.11 Colombia – Biofuels Decree – Resolution No. 40111 of 9 April 2021 (ID 695[12])

4.45. The representative of the European Union provided the following statement. The EU would like to present its remarks pertaining to the non-notified measure, the Regulation No. 40111 of 9 April 2021, establishing maximum content of fuel alcohol – ethanol in the mixture with regular and extra gasoline at national level and the maximum biofuel content in the mixture with fossil diesel fuel at the national level. The EU would like to recall that according to Article 2.9.2 of the TBT Agreement, the proposed technical regulations should be notified at an early appropriate stage, when amendments can still be introduced and comments taken into account. Given that Colombia adopted the measure in question, failing to comply with its TBT obligation of notification at draft stage, the EU calls on Colombia to suspend the measure and to notify it, respecting the provisions of the TBT Agreement, and providing WTO Members sufficient time to submit comments. In any case, the EU would like to take this opportunity to indicate to Colombia that blends higher than B7 may render it impossible to meet high emission standards such as euro 6 or euro 7, as well as euro VI and euro VII. In some cases, such blends can also reduce the duration of the after-treatment

[12] For previous statements follow the thread under ID 695.

systems, thereby increasing the actual emissions from the vehicles. If the combination of fuels available and mandatory emission limits in Colombia would require a specific vehicle production for Colombia, this would result in a reduced availability of vehicle models at higher prices in Colombia.

4.46. The European Union would like to invite Colombia to share with the EU the tests and studies performed to ensure that the vehicles will be able to meet the envisaged emissions limits without damaging their power and after-treatment systems. The EU would also like to ask Colombia to significantly delay the entry into force of the Regulation in order to allow the necessary time for vehicle producers to adapt to new requirements. The EU would like to suggest that for several years Colombia continues offering B7 biodiesel for the existing car park. The European Union calls on Colombia to notify the Regulation in line with the provisions of the TBT Agreement, and to give Members sufficient time to submit comments.

4.47. In response, the representative of Colombia provided the following statement. The delegation of Colombia thanks the European Union (EU) for sharing its observations and submits the following comments. Resolution 40111 of 2021 is based on the *Política Nacional de Producción de Biocombustibles* (National Biofuels Production Policy), and the basic premises underpinning it. In CONPES document No. 3510 of 31 March 2008 on the "Policy guidelines for promoting the sustainable production of biofuels in Colombia", the following was one of the specific objectives on promoting biofuels production: "To diversify the country's energy mix through the efficient production of biofuels, making use of current and future technologies". Article 1.2 of Decree No. 4892 of 2011, compiled in article 2.2.1.1.2.2.3.111 of Decree No. 1073 of 2015, provided that the Ministry of Mines and Energy and the Ministry of the Environment and Sustainable Development, after consultation with the Intersectoral Commission on Biofuels, may set mandatory percentages above 10% for biofuels for use in diesel engines. In light of the above, in 2018 the Office of the President gave the impetus to go ahead with increasing the blend of diesel with biodiesel in the country. Working groups met under the auspices of the Intersectoral Commission on Biofuels, in compliance with the provisions of the above-mentioned decree. These round tables concluded that, based on the national study on biofuel supply, in addition to the air-pollutant-reducing effects of the use of biodiesel for a 12% blend level under sustainable practices in the life cycle, it is feasible to regulate a mandatory maximum blend level of 12% of biodiesel with fossil diesel for Colombia. As a result, in order to address the concerns raised by the EU, a meeting between our technical authorities and the EU technical authorities would be facilitated from our capital.

4.1.2.12 Argentina - Requirement of affidavit along with the product certification from a certified body for export of boards derived from wood (ID 696[13])

4.48. The representative of India provided the following statement. Argentina has notified the requirement of an affidavit in addition to a product certification from a certified body for the export of boards derived from wood. India thanks Argentina for its notification G/TBT/N/ARG/342/Add.6 dated 22 February 2021 on the proposed draft Resolution "Technical quality and safety requirements applicable to boards derived from wood". As per Article 2 of the Draft Resolution, besides product certification, an affidavit from a certified body indicating compliance to the requirements is required. India has submitted its queries to Argentina's enquiry point seeking relevance of an affidavit indicating a product's compliance, mainly when a certification requirement is already in place. India believes that the additional requirement of an affidavit will add both to the cost and procedural burden for exporters, thereby adversely affecting the competitiveness of the product in Argentina. Further, no risk assessment for the additional requirement of an affidavit is shared by Argentina.

4.49. As per Article 2.2 of the TBT Agreement: "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 fulfill a legitimate objective, taking account of the risks non-fulfillment would create". Further, as per Article 2.3 of the TBT Agreement: "Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner". Hence, *prima facie* Argentina's requirement of an affidavit in addition to certification requirement appears to be trade restrictive. It is also not known what other less trade-restrictive or alternative measures were considered by Argentina before deciding on the present measure. Given the above, Argentina is requested not to impose the additional affidavit requirements, to respond to the queries submitted

[13] For previous statements follow the thread under ID 696.

by India to its enquiry point and if it cannot do away with the additional affidavit requirements, share the risk assessment done in arriving at the imposing such a trade-restrictive measure.

4.50. In response, the representative of Argentina provided the following statement. Argentina thanks the delegation of India for its questions and comments with regard to Argentina's notification in document G/TBT/N/ARG/342/Add.6 of 22 February 2021 concerning the "Technical quality and safety requirements for wood-based boards" and other provisions. In this connection, we wish to point out that Secretariat of Domestic Trade (SCI) Resolution No. 240/2019 and the amendment thereto, and SCI Resolution No. 428/2021 establish three distinct and non-overlapping stages for the fulfillment of the technical requirements that they lay down and that seek to ensure compliance with the appropriate quality and safety standards deriving from a number of specific standards of the Argentine Standards and Certification Institute (IRAM). In the first stage, both domestic manufacturers and importers must prepare an affidavit that demonstrates compliance with the requirements of these reference standards, and provide laboratory test reports as supporting documentation. In the second stage, proof of initiation of the certification process is needed. Lastly, a certificate issued by a certification body is required from the third stage. As I previously stated, these stages do not overlap. In other words, the affidavit stage ends once the certification stage takes effect and the submission of this affidavit will no longer be accepted. In conclusion, I wish to inform the distinguished delegation of India that the Argentine Focal Point has no record of India's question. As a result, on 31 May, we asked the Indian Focal Point to resend the comments submitted. We hope that these clarifications are useful to the Indian delegation and remain open to any other questions.

4.1.2.13 Colombia – Good manufacturing practices of overseas production establishments, G/TBT/N/COL/242 (ID 697[14])

4.51. The representative of the European Union provided the following statement. The European Union would like to thank Colombia for its reply of November 2020 to the EU written comments and for the extensive bilateral discussions and hopes that the Decree no 162 published on 16 February 2021 will not create unnecessary burdensome requirements for EU exporters of wines and spirits. The European Union notes that Article 3 of the adopted decree refers to the possibility to present alternatives to the Good Manufacturing Practices certificate upon import to Colombia. EU exporters of wines and spirit drinks already comply with the existing obligation to submit Free Sales Certificates for sanitary register. The Free Sales Certificates state that the product is compliant with the EU legislative requirements, which encompass Good Manufacturing Practices. The European Union therefore considers that Free Sale Certificates issued by EU member States would comply with the Colombian requirement to provide Good Manufacturing Practices certificate upon import. The European Union would, therefore, like to ask Colombia to confirm this interpretation. The European Union is prepared to continue the bilateral work should there be any need for additional clarifications.

4.52. In response, the representative of Colombia provided the following statement. Colombia thanks the EU for bilateral discussions. Decree No. 162 of 2021 was issued because there was a need to move forward in optimizing the existing regulation in order to establish conformity with good manufacturing practices (GMP) certification for manufacturers located outside the national territory, given that Decree No. 1686 of 2012 already established certification for domestic manufacturers but did not provide importers with the option of such conformity, and thereby ensure equal conditions for both parties. In this regard, Article 3.2 of the decree in question provided that establishments located outside the national territory where alcoholic beverages are produced and imported into the country must comply with GMP, a requirement that must be supported by one of the following documents: "(a) Certificate of good manufacturing practices (GMP), from the manufacturing and/or packaging establishment, issued by the relevant authority of the country of origin, by the accredited certification body or by the authorized third party in the country of origin. (b) Hazard Analysis and Critical Control Point (HACCP) System certificate or document supporting its implementation, issued by the relevant authority of the country of origin, by the accredited certification body or by the authorized third party in the country of origin of the product. (c) Certification issued by the relevant authority, by the accredited certification body or by the authorized third party in the country of origin of the product, stating that the alcoholic beverage and the producer should comply with the technical standards, processes or procedures or are subject to monitoring and inspection. (d) Certificate of good manufacturing practices of the manufacturing and/or packaging establishment, issued by the

[14] For previous statements follow the thread under ID 697.

Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA (National Food and Drug Surveillance Institute)."

4.53. Stakeholders should evaluate each of the above options and apply one of them in order to comply. In this regard, the *Certificado de Libre Venta*, CVL (Certificate of Free Sale) may still be used, as long as it states that the alcoholic beverage and the producer comply with the technical standards, processes or procedures established in the country of origin. Taking the above into account, the Ministry of Health and Social Welfare, together with INVIMA, have undertaken working sessions with EU representatives with the aim of providing guidance on the compliance options described in Decree No. 162 of 2021. Colombia will continue to facilitate these bilateral technical meetings to clarify aspects of the content of the regulation. Lastly, it must be mentioned that the establishments producing alcoholic beverages located inside and outside the national territory will have until 14 February 2023 to comply with the good manufacturing practices certification as per Article 3, bearing in mind that the validity of the certificates already granted by the INVIMA will be extended for two (2) more years.

4.1.2.14 Kingdom of Saudi Arabia - Technical Regulation for Building Materials – Part 4: Bricks, Tiles, Ceramics, Sanitary Appliances, and related products (published on the official gazette on 22/03/2019), G/TBT/N/SAU/993, G/TBT/N/SAU/993/Rev.1 (ID 698[15])

4.54. The representative of the European Union provided the following statement. The European Union is strongly concerned by the difficulties related to the implementation of the Technical Regulation for Building Materials and in particular the Saudi Quality Mark (SQM). Since the establishment of the SQM, the European companies are facing important challenges that have resulted in a de facto quantitative restriction to imports. The European Union would like to reiterate 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 require 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.

4.55. *High Costs*. According to the data available, this certification is not only one of the most expensive certification 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 procedures 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 utilise. *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 invite the Kingdom of Saudi Arabia to ensure that the Saudi Quality Mark will not constitute a barrier to trade. The European Union remains available to discuss this issue with the Saudi authorities also bilaterally.

4.56. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia would like to express its appreciation for the concerns addressed by the EU, and for their valuable comments on Technical Regulation for Building Materials – Part 4: Bricks, Tiles, Ceramics, Sanitary Appliances, and related products, and we would like to provide the European side with clarification regarding the points mentioned in their above statement as follows. The audits process is carried out in accordance with the international standard ISO 17067 (type 5), which requires compliance with all SASO ISO 13006 (adopted identically from ISO standard) standard items. Due to the difference in the size of dimensions and tolerance mentioned in the

[15] For previous statements follow the thread under ID 698.

Standard ISO 13006 for rectified and non-rectified ceramic tiles, a test report requires to state the compliance with the standard limits. The costs of obtaining the quality mark are based on international practices, and the same equal fees are applied for all companies without any discrimination. SASO has expanded the acceptance of authorized bodies in Europe in the field of ceramic tiles in order to facilitate the SQM process; the number of authorized bodies is five conformity assessment bodies listed as below: (i) SGS Societe General de Surveillance; (ii) TUV Austria Services GMBH; (iii) TÜV Rheinland LGA Products GmbH; (iv) UL International DEMKO A/S; (v) Intertek. The auditing requirements are clarified in the grant procedure for the ceramic tile product that is available in the certification system, and conducted by all authorized bodies in the same manner. All technical requirements are published for free on the SASO website. In yearly Surveillance audits, the requirements are less than requirements in initial and renewal audits. Requirements are fixed for grants or renewals audits.

4.1.2.15 European Union - The specific test procedures and technical requirements for the type-approval of motor vehicles with regard to the driver drowsiness and attention warning systems, G/TBT/N/EU/771 (ID 699[16])

4.57. The representative of China provided the following statement. We suggest that the EU: (i) add technical requirements of various technical routes in the regulation to better meet the needs of industrial technology development at this stage; (ii) increase the requirements and methods of systematic objective evaluation so as to quantify the events that cause driver distraction from a safety perspective. The detailed suggestions are listed as follows. *Part 1*: Regarding 2.3.1 "The DDAW system shall function in normal operation mode without the use of biometric information, including facial recognition, of any vehicle occupants", the definition of "facial recognition" is too broad. The DDAW based on facial recognition will monitor the facial information to determine whether the driver is tired or not. It is suggested to determine which information cannot be used; does "the use of biometric information" mean to store or detect; and are blinking and yawning included in facial recognition. Regarding 3.1.4 "The DDAW system shall be automatically activated above the speed of 70 km/h", the activation speed shall be at least 70km/h, however, some commercial vehicles driving on non-highway usually can't reach speed. Hence, we suggest to lower the activation speed properly to make sure the monitoring can be realized in most driving courses.

4.58. Regarding 3.3.1 "The DDAW system shall provide a warning to the driver at a level of drowsiness which is equivalent to 8 or above on the reference sleepiness scale set out in the Appendix (Karolinska Sleepiness Scale, hereinafter referred to as "KSS")." The DDAW system may provide a warning to the driver at a level of drowsiness which is equivalent to level 7 on KSS. In addition, the manufacturer may implement an information strategy on the HMI prior to the warning." Firstly, using KSS level as the fatigue analysis is subjective and the alarm interval is ambiguous. Secondly, please explain the meaning and differences of the two concepts "information strategy" and "warning", or give examples to illustrate what they contain. In 3.3.2 "a reduction in the number of micro-corrections within driver steering, paired with an increase in the number of large and fast corrections", there is no definition of the degree of reductions. The control strategies of each manufacturer will lead to a large difference in the time to determine fatigue. It is recommended to specify the amount of change, such as the percentage reduction of fine-tuning times. At the same time, there are no quantitative indicators for fine-tuning and rapid large-scale adjustment. We suggest to make it clear. Regarding "An alternative manner of measuring driver performance through vehicle systems analysis ("metrics") may be used, provided that it is an accurate and robust measure of driver drowsiness", visual recognition of driver distraction is widely used in China. On the basis of safety, requirements such as increasing driver's eyes closed for more than 2 seconds, head deflection exceeding the normal forward vision range for more than 3 seconds are given. When the driver's sight deflection exceeds the above threshold, an alarm should be issued. It is suggested that the European Union can refer to this quantitative indicator to put forward driver's distraction and fatigue requirements.

4.59. Regarding 3.4.1.1 "Visual, auditory and any other warning used by the DDAW system to alert the driver shall be presented as soon as possible after the occurrence of the trigger behaviour and may cascade and intensify until acknowledgment thereof by the driver", the requirement of "as soon as possible" is too subjective. The regulation shall clearly define that the alert shall be presented within how many seconds after the drowsiness occurs since the alert in time is a key indicator to assure the safety of the system. The "Reference sleepiness scale for DDAW system (Karolinska

[16] For previous statements follow the thread under ID 699.

Sleepiness Scale)" in Appendix to PART 1 is too subjective and has no objective evaluation indicator. Also, the whole part has no content of the scale of distraction. Distraction of attention involves fatigue. But drivers can be distracted for a long time (for example, they look left and right for a long time) without fatigue, which is also at greater risk.

4.60. Part 2 Regarding 2.1 and 2.2, DDAW is different from other systems. The use of human participants on real road tests is very dangerous since people might be injured. We suggest the highly dangerous test on the real roads to be done in a closed testing area with relatively long tracks and a controllable environment. Regarding 2.2, the operation of safety backup is difficult. As the method used to evaluate fatigue in this regulation is too subjective, it is possible that there may be a difference between the two drivers' perceptions. If the driver is drowsy and the backup driver intervenes, the possibility of not reaching the system warning threshold may occur. If the intervention is only done with the warning presented, severe traffic accidents may already happen. Our general opinion for the 2nd point of PART 2 is to add a highly repeatable, highly consistent, and high safety validation scheme. Regarding the 3rd point of PART 2, due to the lack of objective comment of driver drowsiness, it is quite difficult to accurately evaluate the number of real events. Regarding "two raters and an inter-rater reliability test shall be conducted", the methods of raters are too subjective to guarantee the consistency of ratings.

4.61. In response, the representative of the European Union provided the following statement. The EU notes that China has also submitted detailed written comments to the EU TBT Enquiry Point on 16 March 2021. In this regard, the EU would like to reassure China that a reply will be sent in due course. Since the EU has not received any additional comments ahead of the Committee meeting, the EU hopes that our future written reply will sufficiently clarify China's comments. Therefore, the EU is confident that our continued dialogue can continue in writing.

4.1.2.16 European Union - Uniform procedures and technical specifications for the type-approval of motor vehicles with regard to their emergency lane keeping system (ELKS), G/TBT/N/EU/767 (ID 700[17])

4.62. The representative of China provided the following statement. We suggest that the following points be adjusted and explained in detail and that certain transitional periods be provided. Regarding 1.4 "changes to the steering angle of one or more wheels and/or braking of individual wheels may result from the automatic evaluation of signals initiated on-board the vehicle optionally enriched by data provided off-board the vehicle", it defines the technical solution for lane maintenance by changing the steering angle of one or more wheels and/or the braking of a single wheel in order to correct lane deviation. It is suggested to change to "control the lateral movement of the vehicle" because the purpose of ELKS is to keep and control the lane and the regulations shall not specify the technology used. Regarding 3.1.1.1 "There shall not be an appreciable time interval between each ELKS self-check (an integrated function that checks for a system failure on a continuous basis at least while the system is active), and subsequently there shall not be a delay in illuminating the warning signal, in the case of an electrically detectable failure", the ELKS is specifically required to perform two self-tests. We suggest that article 3.1.1.1 self-check requirement should be modified as "When turned on, the system should be capable of self-check, which means the system can check if the main electric components and sensors relevant to the system work normally". The purpose of self-check is to make sure if the system can satisfy the fundamental running conditions and the number of self-checks can be defined by the enterprise itself.

4.63. Regarding 3.1.1.2 "Upon detection of any non-electrical failure condition (e.g. sensor misalignment), the warning signal as defined in point 3.1.1 shall be activated", the "Non-electrical failure condition" is contradicted with "e.g. sensor misalignment", since the sensor bias might be caused by electrical failure. Regarding 3.2.1.2 "The manual deactivation of the full ELKS shall not be possible with less than two deliberate actions, e.g. press and hold on a button, or select and confirm on menu option.", it specifies how to manually deactivate the system. While we suggest the behaviour manner of manually stopping the system should not be limited. As long as the purpose of lane keeping and controlling is achieved, the specific technology should not be restricted. Regarding 3.6.2 "In the absence of conditions leading to deactivation or suppression of the system, the CDCF shall be able to prevent lane departure by crossing of visible lane markings in the scenarios shown in the following table by more than a DTLM of -0.3 m", the requirement of lane departure by 0.3m is too high and different requirements should be provided respectively for passenger car and

[17] For previous statements follow the thread under ID 700.

commercial vehicle. Based on the research conclusion of Chinese LKA system standard, the suggested lane departure should be 0.4m for M1 and N1 vehicles and 0.75m for vehicles of other categories. Besides, only relevant requirements for ELKS system in straightway scenarios are specified in the regulation. We suggest relevant ELKS requirements for curve lane should be added by referring to the relevant parts in Chinese LKS standards for passenger cars and commercial vehicles.

4.64. 3.6.2(a) The definition of "for lateral departure velocities in the range of the 0.2 m/s to 0.5 m/s for vehicle speeds up 100 km/h and for lateral departure velocities in the range of 0.2 m/s to 0.3 m/s for vehicle speeds greater than 100 km/h and up to 130 km/h (or the maximum vehicle speed if it is below 130km/h)" is unreasonable since the system in the activated status should always keep the vehicle within the lane and do not need to differentiate other conditions. 3.6.2(e) The requirement "in all illumination conditions without blinding of the sensors" is too strict. Quantitative requirement should be raised such as 500lx. Regarding 3.6.3.1 "The steering control effort necessary to override the directional control provided by the system shall not exceed 50 N. Significant loss of steering support once overridden shall not happen suddenly", we suggest the requirements of steering control effort be deleted. As long as the purpose and requirements of control are achieved, the OEMs should be allowed to calibrate the steering torque according to the realizing strategy. 3.6.4 The requirements of CDCF warning guidance are too detailed. We think the warning conditions alone are enough, requirements could be changed to "warning signal should be given when the system intervention action enters and exits, electronic or electric malfunction occurs during the system self-check and running, and the driver actively (manually) turns off the system and that signal shall be acoustic, tactile or optical signal (at least one of those three aforementioned)". 4 and 5: only relevant requirements for ELKS system in straightway scenarios are specified in the regulation. We suggest the curve lane testing scenario be added by referring to the relevant parts in Chinese LKS standards for passenger car and commercial vehicle. 4.2(b) and 5.2(b): the requirement of environment illumination condition, 2000lx, is too high and we suggest the number should be 500lx. Regarding 4.2(c) and 5.2(c) "In ambient air temperatures between 5°C and 45°C", the environment temperature condition doesn't consider low temperature and we suggest the temperature range be modified from 5℃~45℃ to -20℃~40℃.

4.65. 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 7 February 2021 was submitted via the TBT Enquiry Point on 13 April 2021. As stated in the reply, the EU would like to clarify that the manufacturer has to demonstrate to the Technical Services that the requirements under the draft Regulation are fulfilled for whole range of speed and lateral departure velocity. The Technical Service can request the manufacturer to provide the respective documentation and can carry out, if needed, its own tests under these different conditions. In addition, where it is recognized that the performance required may not be fully achieved in other conditions than those listed in points 3.5 and 3.6 of the draft Regulation (e.g. different environmental conditions), the manufacturer should ensure that the system does not unreasonably switch the control strategy under these other conditions and should demonstrate this to the satisfaction of the Technical Service. In that respect, the EU also observes that if being switched off manually, the ELKS shall be switched on automatically upon each activation of the vehicle master control switch. The AEBS and the ESC are covered by other Regulations independently. For example, in accordance with UNECE Regulation No 152 on AEBS that will apply in the EU on a compulsory basis from July 2022, the AEBS shall also be automatically switched on at the initiation of each new ignition cycle. In addition, when the automatic deactivation of the AEBS function is a consequence of the driver manually switching off the ESC function of the vehicle, this deactivation shall require at least two deliberate actions by the driver.

4.1.2.17 Kingdom of Saudi Arabia - Order on Standards for Import Products (ID 701[18])

4.66. The representative of India provided the following statement. India recognizes the right of Saudi Arabia to regulate products it imports within the commitments of the WTO. Apart from conforming to Saudi Arabia's SASO (Saudi Standards), all consignments to Saudi must carry the Certificate of Conformity. Indian Exporters are already adhering to the SASO requirements by obtaining certifications from accredited laboratories based on product testing. However, insisting on such certification even for regular consumer products that do not endanger the health and safety of humans makes the trade burdensome and restrictive. Hence Saudi Arabia is requested to remove the SASO requirement for everyday consumer items like leather products and footwear. Article 5.1.2

[18] For previous statements follow the thread under ID 701.

of the TBT Agreement requires that Members shall ensure that CAPs are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. CAPs shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create. In view of the above, Saudi Arabia is requested to remove the CoC requirements to regular consumer products; if not, it may clarify the rationale for extending the requirement of SASO to regular consumer products that are not a threat to human life or health.

4.67. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia would like to express its appreciation on the concerns addressed by India. Saudi Arabia is aiming at protecting human health and safety, and the environment, by regulating and ensuring that such products are complying with safety requirements and relevant standards in consumer products. Saudi Arabia does not mandate all products to obtain a certificate of conformity and considers supplier's declaration of conformity as sufficient for risk-free products, however, the Kingdom issues technical regulations for medium and high-risk products, which requires issuing a certificate of conformity. As for the conformity assessment procedures, SASO has chosen to apply the international standard ISO/IEC 17067 for granting certificates of conformity to products issued by Notified Conformity Assessment Bodies in response to the pressing health problems posed by non-conforming products detected by National Surveillance Authorities. In regard to leather products, it contains a number of risks to the health and safety of the consumer and the environment, therefore, Saudi Arabia was keen to mandate a certificate of conformity as well as number of requirements related to harmful substances in the technical regulation for leather products, and the most important of these harmful substances, which must be adhered to the permissible limits of the relevant standards, are: Chromium (VI); Formaldehyde; Chlorinated phenols.

4.1.2.18 United Arab Emirates - Requirement of G-mark for every toy (ID 702[19])

4.68. The representative of India provided the following statement. India is deeply concerned about the UAE's G-mark requirement for all children's toys exported to the UAE and it can be issued only by the agencies authorised by the GCC Standardisation Organisation. This requirement of G-mark makes Indian products uncompetitive in the UAE as no agency is authorized to issue G-mark in India. To get G-mark certified products, Indian exporters have to send the entire consignment to the place where it can be G-mark certified. As per the extant regulation, the G-mark needs to be obtained for each and every toy. This process involves additional procedural requirements; it is also cost-intensive and makes the Indian product uncompetitive when placed in the UAE market. Further, the G-mark Notified Bodies (NBs) during the conformity assessment frequently request physical samples of all products in a group, and not only of the representative item. This is despite the latest GSO guidance specifying test reports are required only for one representative item from a product group. A physical inspection of all items in a product group is burdensome, costly and inconsistent with Article 5.1.2 of the TBT Agreement. Hence, the UAE is requested to consider that when the G-mark is obtained for each and every toy, then the physical sampling should not be insisted by the NBs for all the products in the group. Such insistence is trade restrictive and renders high costs and difficulties. Besides, it also inconsistent with Article 5.1.2 of the TBT Agreement.

4.69. In response, the representative of the United Arab Emirates provided the following statement. We have already forwarded the concerns of India to the capital. We will get back to the delegation of India as soon as we receive a response from the concerned authority.

4.1.2.19 EU - Phosmet, G/TBT/N/EU/790 (ID 703[20])

4.70. The representative of Chile provided the following statement. Chile appreciates the opportunity to comment in this Committee on the European Union's notification submitted on 25 March 2021 to the WTO Committee on Technical Barriers to Trade in document G/TBT/N/EU/790, which concerns the non-renewal of the approval of the pesticide active substance phosmet under Regulation (EU) No. 1107/2009, as well as on the measures that shall likely be notified to the WTO Committee on Sanitary and Phytosanitary Measures relating to the reduction or definitive elimination of the maximum residue levels (MRLs) for this substance in food. The Chilean Fruit Exporters

[19] For previous statements follow the thread under ID 702.
[20] For previous statements follow the thread under ID 703.

Association is a non-profit, private trade association, the various programmes of which bring together over 350 fresh fruit producer-exporter companies, accounting for around 90% of Chile's fresh fruit exports and 63.1% of the area under fruit cultivation nationally. In such activities, phosmet has for many years been an irreplaceable tool for implementing plant protection programmes and strategies to control a broad spectrum of pests of productive significance, such as, *inter alia*, *Lobesia botrana*, *Pseudococcus* spp. and *Drosophila suzukii*. Furthermore, phosmet possesses a range of technical characteristics that are associated with strong levels of pest control and crop protection periods, convenient withholding or safety periods, large tolerances and a very good cost/benefit ratio. A reduction in European Union countries of the current MRLs for phosmet in various fruits would cause a serious problem for our producers and exporting companies, since there are no alternatives possessing all the strengths described above for this insecticide.

4.71. We have received information from the firm Gowan Company, which is a manufacturer of this product. The firm submitted a range of data from the record in January 2016 as part of the European Union's active substance renewal process (AIR), with the intention of securing the renewal of the inclusion of this insecticide in Annex I to Directive 91/414/EEC. The rapporteur member State, Spain, submitted an assessment report in December 2017 containing a recommendation for the renewal of this substance in Annex I. The European Food Safety Authority's (EFSA) peer-review experts meetings in June 2019 and February 2020 concluded that there are no effective substitutes for phosmet, that it is not persistent in the environment and that it does not cause endocrine disruption problems. However, the EFSA decided to lower by between ten and twenty times the thresholds for assessing both the effects of the substance in mammals and its ecotoxicological effects, meaning that the toxicity and ecotoxicological aspects of the molecule would not have been appropriately reviewed. Chile considers that the elimination of MRLs, rather than their reasonable reduction, will lead to serious problems for domestic and international fruit-farming, encouraging the use of less effective products that will result in smaller yields and, consequently, in an increased use of substitute products, which subsequently runs the major risk of the permitted levels being exceeded, among other considerations. In summary, we ask the European Commission to take into account the above considerations in order to ensure an appropriate assessment of the MRLs for phosmet in the products and by-products that our country and others export to this economic area.

4.72. The representative of Brazil provided the following statement. Brazil would like to support the STC raised by Chile against the European Union regarding the Draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance phosmet, notified as G/TBT/N/EU/790. Phosmet is registered in Brazil as an active substance for insecticide and acaricides used on citrus, apple and peach. It is recognized as an important crop protection tool used by Brazilian citrus growers to treat citrus fruit borer, fruit flies and citrus psyllid pests. Regarding the control of the citrus psyllid, combined with other several non-chemical measures, it is rather important since this insect transmits the greening disease, recognized by EFSA itself as a priority pest for control, according to the Commission Delegated Regulation (EU) 20-19/17-02. The non-renewal of the approval of this active substance, coupled with the following reduction of its MRL, will have a significant impact on trade and will be particularly harmful towards the citrus industry in Brazil, where citrus is the main source of income to thousands of farmers living in the countryside. The European Union is the top destination of Brazilian citrus products with over USD 1.13 billion of export value in the 2019-2020 marketing year. Brazil regrets having to urge once again the European Union to also notify measures related to registration of active substances to the SPS Committee. The EU had already committed to notifying such measures to both committees, so the fact that this draft regulation was notified only to the TBT Committee is seen as a worrisome setback. Brazil would also like to kindly ask the EU to adopt new MLRs that are in line with the limits defined by the Codex Alimentarius.

4.73. In response, the representative of the European Union provided the following statement. The European Union confirms that it has received comments from the Chilean Fruit Exporters Association (Asociación de Exportadores de Frutas de Chile A.G., Asoex) that were forwarded by the Ministry of Foreign Affairs. The European Union is currently preparing an official reply to those comments. At this stage, we can inform you that the Commission has proposed not to renew the approval of phosmet. Following a comprehensive and transparent assessment of the information submitted by the applicants by the designated rapporteur member State, and after being peer-reviewed by all other member States and the European Food Safety Authority (EFSA), serious risks and concerns in relation to human health and the environment have been identified. It is therefore considered that the applicants have not demonstrated that plant protection products containing phosmet can be used safely.

4.1.3 Previously raised concerns

4.1.3.1 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 294[21])

4.74. 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.

4.75. The representative of Japan provided the following statement. Japan continues to have concerns regarding the 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 February 2021. At the last TBT Committee, China explained that they would release the regulations for public consultation. We recognize that the public consultation had done until 19 September 2020. Japan would like to request that China provide relevant information regarding the current revision process and that the regulations would be implemented transparently.

4.76. In response, the representative of China provided the following statement. With regard to the management of commercial encryption products, China has, from 1 January 2020, cancelled the approval of varieties and models of commercial encryption products in accordance with the law, and established a unified national certification scheme for commercial cryptography. The management of commercial encryption products fully reflects the principles of non-discrimination and fair competition. It treats domestic and foreign products as well as companies equally. China implements mandatory testing and certification on commercial encryption products which is related to national security, national economy, people's livelihood, and public interest, and implements voluntary testing and certification on other commercial encryption products. Regarding the MLPS, with technology development, in response to more complicated cybersecurity circumstances, information security multi-level protection scheme needs to be improved. Based on experience in past years and responding to new development, Cybersecurity Law stipulates that China will carry out the cybersecurity MLPS, which is based on information security MLPS. To fulfill the requirements in Cybersecurity Law, 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.

4.1.3.2 European Union - Hazard-based approach to plant protection products and setting of import tolerances (ID 393[22])

4.77. The representative of Costa Rica provided the following statement. As on previous occasions, Costa Rica reiterates its support for the trade concern raised by 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.

4.78. The representative of Australia provided the following statement. Australia would like to thank the EU for clarifying that requests for import tolerances for substances not authorized within the EU will be conducted in line with risk assessment principles on a case-by-case basis and for hosting seminars with stakeholders providing details on related policy changes currently being considered by the European Commission. Australia notes that the EU is considering taking into account

[21] For previous statements follow the thread under ID 294.
[22] For previous statements follow the thread under ID 393.

environmental effects when assessing requests for import tolerances for active substances no longer approved in the EU. Australia rejects this approach as it assumes the EU is better placed to assess the environmental impacts of active substances in third countries than the chemical regulators of those countries. Australia has a robust regulatory framework for agricultural and veterinary chemicals providing Australian farmers with safe access to the pesticides they need to maintain productivity and profitability while looking after Australia's unique environment. Australia requests that the EU respects the conclusions of trading partners' regulators on the environmental impact of chemical substances and limits its assessment of requests for import tolerances to the consideration of dietary risks. Departing from this approach will result in significant trade disruption. We remain available to discuss our approach to pesticide regulation with the EU and look forward to continued constructive engagement on this issue.

4.79. The representative of Colombia provided the following statement. Colombia once again shares this concern regarding the approach taken by the EU for identifying plant protection substances. As we have stated in various fora 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 phytosanitary 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.

4.80. The representative of Paraguay provided the following statement. Paraguay reiterates its position and refers to its statement made at the previous meeting. Paraguay stresses 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. While the European Union has noted the concerns expressed by a number of Members, we hope that it takes into consideration the relevant information on pesticides provided by specialized agencies recognized by the WTO, such as the Codex Alimentarius; reconsiders its approach; bases its decisions on conclusive scientific evidence and real risk weights, in accordance with the relevant international principles and standards; ensures import tolerances and, where necessary, provides adequate transitional periods.

4.81. The representative of Brazil provided the following statement. Brazil would like to refer to its previous statements regarding STC 393. 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 LMRs. Brazil believes that the European approach to limit the use of pesticides is more trade-restrictive than necessary to fulfill 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.

4.82. The representative of Canada provided the following statement. Canada would like to take this opportunity to once again echo the concerns raised by many other Members regarding the EU's hazard-based regulation for active substances in plant protection products. Canada does not favour or promote the use of any one production method over another. Instead, we support producers having access to the widest choice of safe production methods based on their own assessment of growing conditions, market demand and other factors. Plant protection products are registered for use in Canada only after rigorous scientific evaluations confirm that they do not pose unacceptable risks and have value. As such, these products have a role in supporting a variety of production methods and enable the sector to supply the vast array of differing products demanded by Canadian and international consumers. We encourage the EU not to limit or discourage the use of these agricultural tools, and base its regulatory decision-making on both hazard and risk for all active substances.

4.83. The clarifications provided by the EU regarding 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, have been welcome. Canada also notes the EU's intents to conduct risk assessments for all import tolerance requests, including those for active substances that meet the EU's hazard-based criteria, in accordance with internationally-accepted risk assessment principles and EU legislation. To eliminate the need for import tolerance requests for some substances and minimize disruptions to trade, Canada once again requests that the EU consider maintaining MRLs for substances that do not pose unacceptable dietary risks. We recognize that a dietary risk assessment as part of the re-authorization process would likely be needed, regardless of the results of the hazard screen. We welcome further engagement with the EU on this issue. We also invite the EU to share any relevant information on upcoming regulatory or policy changes to ensure that unnecessary trade barriers are minimized and that measures are consistent with international trade obligations.

4.84. The representative of Guatemala provided the following statement. 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 are assessed and there is growing scientific uncertainty. We would like to emphasize the importance of using risk analysis for import tolerances, particularly for tropical developing countries, where climatic conditions differ from those in the EU because we do not have a harsh winter to help control pests. In addition, geographical location, namely the distance and time needed to export a product to the EU, is another factor that should be taken into consideration to avoid applying measures that unnecessarily restrict trade.

4.85. The representative of Uruguay provided the following statement. We 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 Regulation No. 1107/2009. We again emphasize 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, while contributing little or nothing to the cited aim of protecting public health. Like other Members, we would like to be given further details on the way in which the European Union plans to take environmental effects into account when assessing requests for import tolerances for active substances no longer approved in its territory. 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 socio-economic consequences that this may have for other Members, in particular developing and least developed countries, for which the European Union is a key market.

4.86. The representative of Chile provided the following statement. Chile is grateful for the opportunity to reiterate to the European Union the concern regarding the bloc's Regulation, as raised by the delegations that took the floor before me. These measures will have far-reaching trade effects for Chile's export sector.

4.87. The representative of Ecuador provided the following statement. 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 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 practices, 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 upon the EU to ensure that, in cases where there is a lack of scientific information, EFSA does not make a recommendation on the 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.

4.88. 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 further developments.

4.1.3.3 China - Cyberspace Administration of China – Draft implementing measures for the Cybersecurity Review of Network Products and Services (ID 533[23])

4.89. 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 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.

4.90. The representative of Japan provided the following statement. Japan has its interest in and concern with regard to the Cyber Security Review and would like to refer to the previous statement we made at the last TBT committee in February 2021. 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.

4.91. The representative of Canada provided the following statement. Canada echoes the concerns raised by the EU and Japan. With respect to this STC, Canada continues to seek defined criteria that operators of Critical Information Infrastructure are to use in assessing a security threat; and a clear commitment to National Treatment, MFN treatment and the use of international standards. Canada appreciated the recent opportunity to provide comments on the 2nd draft of China's Data Security Law, as follows: The law sets requirements for entities processing "important data" and transferring it across borders. With a view to better understanding the legitimate objectives of the Law and the risks of non-fulfillment, Canada requests that China clarify the meaning of "important data"; Canada also seeks China's clarification of how the inclusion of language on reciprocal Chinese actions, to address other countries' discriminatory actions, is consistent with the TBT Agreement's obligations. In order to provide clarity and predictability, we also reiterate our request for a clear definition of "Critical Information Infrastructure", which is referenced in both the draft cybersecurity measure

[23] For previous statements follow the thread under ID 533.

and the draft Data Security Law. Canada looks forward to receiving China's feedback on the Data Security Law and seeks China's agreement to notify it to the TBT Committee.

4.92. In response, the representative of China provided the following statement. In April 2020, CAC and 12 other authorities jointly issued Cyber Security Review Measures. Focusing on national security risks associated with the procurement of network products and services by critical information infrastructure operators. Through the cybersecurity review, the risks and hazards brought by the purchase of products and services to the operation of critical information infrastructure could be found earlier and avoided, ensuring the security of the supply chain of critical information and infrastructure, and safeguarding national security. The Measures came into effect on 1 June 2020, and the former Cybersecurity Review of Network Products and Services (for Trial Implementation) issued in May 2017 was repealed at the same time.

4.1.3.4 Russian Federation - Law No. 425 - on Amending Article 4 of Russian Federation Law "On Protecting Consumer Rights" (ID 612[24])

4.93. The representative of the United States provided the following statement. We continue to raise 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 implementation deadline was 1 April 2021. Despite the passing of this deadline we remain unclear on the status of the final implementing guidance for the amendment and whether the measure has been revised in response to our concerns. We presented our concerns to Russia in writing in March 2020 and raised them again during each subsequent meeting 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.

4.94. 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 explain why they believe Russian software developers are being denied access to these electronic devices, and why such a requirement is necessary. We also ask Russia to explain how the requirement is not more trade restrictive than necessary and does not create unnecessary obstacles to trade. We have urged 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. With the passing of the implementation deadline, we remind Russia of these requests and also urge Russia to notify the implementing rules as soon as they are available.

4.95. 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 receive the answers to the questions raised by the US delegation.

4.96. 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

[24] For previous statements follow the thread under ID 612.

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.

4.97. The representative of Canada provided the following statement. Canada supports the statements made by the United States, Japan and the European Union.

4.98. In response, the representative of the Russian Federation provided the following statement. We appreciate interest of the US and other delegations in the Russian Federation's regulatory policy. As stated previously on numerous occasions, Russia maintains its position that the measure in question does not fall under the scope of the Agreement on Technical Barriers to Trade and cannot be considered as a technical regulation. The amendments to the Federal Law "On Consumer Rights Protection" do not set requirements for product characteristics or production methods. Thus, requirement on pre-installation of certain Russian software products on technically complex products does not correspond to the definition of technical regulation set forth in Annex I to the Agreement on Technical Barriers to Trade. Moreover, the measure in question cannot be considered as discriminative since it does not mandate replacement or de-installation of the foreign software programs. Russia is open to bilateral discussions.

4.1.3.5 Colombia - Food Prioritized for its Sodium Content, Certification Requirements, G/TBT/N/COL/238, G/TBT/N/COL/238/Add.1 (ID 609[25])

4.99. 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 again 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.

4.100. In response, the representative of Colombia provided the following statement. The following are some considerations and information on Colombian regulations. Resolution No. 2013 of 2020 is the result of a public health measure and is part of a comprehensive strategy called the National Strategy for the Reduction of Sodium/Salt Consumption 2012–2021, which covers not only sodium content in processed foods, but also other sources of sodium, such as the salt added to preparations in restaurants, at home and in institutions. The strategy seeks to reduce mortality attributable to high blood pressure and cardiovascular disease by gradually reducing salt consumption from food sources until the WHO recommendation for 2021 has been achieved: 5 grams of salt or 2 grams of sodium per person per day. With regard to concerns about the technical and functional role of sodium in the production of prioritized foods, Colombia wishes to reiterate that this was analysed at all of the technical meetings for the 12 categories of food, involving industry, academic and government representatives, leading to an agreement and dissemination of the draft regulations. The following are documents produced by the Ministry of Health and Social Welfare providing technical support for the measures taken through Resolution No. 2013 of 2020 on the maximum sodium content for processed foods. National Strategy for the Reduction of Sodium/Salt Consumption 2012–2021.[26] Regulatory impact analysis of the draft resolution defining the maximum sodium content in

[25] For previous statements follow the thread under ID 609.

[26] Available at https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/PP/SNA/Estrategia-reduccion-sal-2012-2021.pdf

prioritized foods.[27] Document explaining the methodology for prioritization and setting targets for the 59 foods and summarizing the report of the regulatory impact analysis report (Annex 1).

4.1.3.6 India - Quality Control Orders for Chemical and Petrochemical Substances, 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/116, G/TBT/N/IND/121, G/TBT/N/IND/122, G/TBT/N/IND/123, G/TBT/N/IND/124, G/TBT/N/IND/125, G/TBT/N/IND/126, G/TBT/N/IND/127, G/TBT/N/IND/128, G/TBT/N/IND/129, G/TBT/N/IND/130, G/TBT/N/IND/132, G/TBT/N/IND/133, G/TBT/N/IND/134, G/TBT/N/IND/135, G/TBT/N/IND/136, G/TBT/N/IND/137, G/TBT/N/IND/138, G/TBT/N/IND/139, G/TBT/N/IND/140, G/TBT/N/IND/141, G/TBT/N/IND/142, G/TBT/N/IND/144, G/TBT/N/IND/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/191, G/TBT/N/IND/193, G/TBT/N/IND/199 (ID 630[28])

4.101. 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, phthalic anhydride, n-butyl acrylate and terephthalic acid (notified by G/TBT/N/IND/69, G/TBT/N/IND/116, G/TBT/N/IND/123 and G/TBT/N/IND/124). Firstly, we would like to thank India for postponing the enforcement date on n-butyl acrylate for another 180 days, which were announced on 26 April 2021. In the view of the persistent impact of COVID-19, we suggest that India consider postponing the implementation of the other drafts of Chemical and Petrochemical Orders, at least, for another 180 days. Secondly, we have been following closely the above-mentioned drafts since last year. We still have the following concerns to seek India's clarifications. The reason and risk assessment of changing the current voluntary system to a compulsory certification system, especially for terephthalic acid. The necessity of annual "on-site" factory inspection. The reasonable validity period of licence for both domestic and foreign applicants on a non-discriminatory basis. Accepting conformity assessment results from testing laboratories and inspection bodies outside India.

4.102. Thirdly, since the pandemic will not likely end in the short term, we understand the difficulty of conducting regular conformity assessment procedures under the current situation. We still suggest that India implement alternative measures during the pandemic, such as temporary factory audit exemption for a limited period or remote factory inspection, to address the difficulties of physical inspection resulted from international travel restrictions. Finally, we would like to express our concern on the Caustic Soda Quality Control Order, which entered into force in April 2018. We respect the efforts of India to introduce the Order for the health and safety of Indian people. Our manufacturers submitted their applications and ensured compliance of their products with the specifications stated in IS 252. However, their applications have been pending for more than a year even after payment of fees and completion of testing as well as on-site factory audit. We urge India to accelerate procedures for granting approval of our companies. In this regard, we noted recently that a policy was adopted by the Department of Chemicals and Petrochemicals of India to stop granting BIS licences to all foreign applications for caustic soda because of the sufficient installed capacity in India. As this policy will also apply to foreign applications for other chemicals, we seek confirmation from India on this policy and urge India to observe the principle of non-discrimination as stated in Article 2.1 of the TBT Agreement. We would be grateful if the above-mentioned comments could be taken into account and look forward to a written response.

4.103. The representative of the European Union provided the following statement. The European Union would like to refer to its previous statements on this matter. The EU remains concerned 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. The EU welcomes India's recent decision to defer the implementation of some QCOs pertaining to chemical products by 180 days to 3 February 2022 and 13 March 2022. However, the European Union would like to seek clarifications from India, explaining the reasons for establishing India-specific Quality Control Orders when these chemical products

[27] Available at: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/PP/SNA/analisis-impacto-normativo-sodio.pdf

[28] For previous statements follow the thread under ID 630.

already comply with internationally recognised standards. The EU would like to remind the authorities of India that in accordance with the TBT Agreement, standards are considered voluntary, whereas mandatory standards are considered as technical regulations. The EU would like to recall Article 2.2 of the TBT Agreement, according to which Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. The EU would like to encourage India to align the BIS standards with international approaches.

4.104. The representative of the United States provided the following statement. As of May 2021, India's Ministry of Chemicals and Fertilizers (MoCF) notified 43 Quality Control Orders (QCO) to the WTO TBT Committee. Each QCO appears to identify substances that correspond to or fall under the 72 identified chemicals and petrochemicals for which India intends to mandate compliance to standards set by the Bureau of Indian Standards (BIS). We also understand that on 15 April 2021, MoCF published final versions of 7 of the notified QCOs in the Gazette, with the measures set to enter into force on 15 October 2021. We appreciate India's efforts to notify these QCOs to the WTO TBT Committee and to provide stakeholders with the opportunity to submit comments. Given the impact on trade and the difficulty in accessing the referenced standards, we kindly reiterate our request that for the 43 notified QCOs and any future QCO notifications, India provide website links to and/or copies of the BIS proposed standard. With respect to the previously notified QCOs, we would recommend that such links and/or copies be notified as addenda. Without access to the BIS standards, interested parties will be unable to become fully acquainted with the QCOs or to provide meaningful comments.

4.105. With respect to the QCO for polyethylene material used for molding and extrusion (Polyethylene QCO), notified as IND/191, we note that US industry has expressed concerns regarding inclusion of a labelling requirement that involves the marking of individual unit packages of polyethylene product with a new "designation code" that includes an array of technical information (e.g. a product's melting point, density, and destination use). US industry has indicated that these labelling requirements will pose challenges since many polyethylene products are used as intermediate inputs that undergo further transformation, thereby making it difficult to identify all of the destination uses. The "designation code" would have limited utility to end users considering the numerous physical properties and applications that a category of polyethylene product might have. Several US industry members have recommended alternative methods to meet the Polyethylene QCO's mandatory labelling requirements. US industry has also noted that the Polyethylene QCO may disrupt Indian imports of, and access to, essential materials used by Indian health care, pharmaceutical, and other Indian export-critical sectors such as the automotive sector. Would India consider exempting polyethylene products used as intermediate inputs from the labelling requirements set forth in the Polyethylene QCO?

4.106. The representative of Canada provided the following statement. In previous Committee meetings, Canada raised concerns over the approach taken by India to make mandatory the use of Indian Standards on the regulation of a series of chemical substances. Canada remains of the view that the notification process followed by India to inform interested parties of its "Quality Control Orders" (QCO) is problematic and could benefit from adjustments to improve the sharing of information with interested Parties. For example, the 1-page document notified by India to explain its QCO could provide a link to additional background information on the science and deliberations having led to the propose measure. The current scarcity of readily available supporting documentation in the notifications makes it difficult to assess and comment on the measures. At the February 2021 TBT Committee, India stated having carried out a review of the existing standard and conducted consultations with various leading manufacturers to ensure to reflect new testing methods. Canada would suggest that such information – when available – be added to the TBT notifications as basic background information for interested Parties seeking to understand the objective and rationale behind the Indian measure.

4.107. To further facilitate stakeholders' access to any related information on the BIS, Canada would also suggest that India includes an hyperlink to the latest official version of the standards in the notifications. India shared such a link with WTO Members at the last TBT Committee meeting. If interested parties and stakeholders are not provided somewhat intuitive access to the relevant information that led to the regulatory proposal, they can hardly provide substantive comments and information that could inform India's decision-making process. Canada recognizes and strongly supports Members' right to regulate. However, Members must ensure that such actions follow internationally agreed-upon rules and processes to ensure a level playing field for all interested

parties. It is in this view that Canada is sharing suggestions on potential adjustments to the future Quality Control Orders notifications of India. We believe these improvements could have a genuine positive impact for stakeholders, and go a long way to support the transparency obligations of the TBT Agreement.

4.108. The representative of Singapore provided the following statement. Singapore echoes the concerns raised by other Members, and would like to express our concerns regarding India's Quality Control Orders (QCOs) on a growing number of chemical and petrochemical products. There remain many operational issues, and we would like to outline a few key examples. Regarding India's QCO on polyethylene (PE) materials used for molding and extrusion, notified under document G/TBT/N/IND/191, the labelling requirements pose challenges for industry, as they involve the inclusion of complex designation codes. Specifically: PE products can have multiple physical properties and applications, which could result in the overcrowding of product labels, while providing limited utility to end users; and PE products can also involve an array of potential destination uses, which manufacturers may not have sight of, particularly if there are intermediaries involved in the sales and/or production process. Given the above, it is also operationally challenging to apply the labelling requirement at the smallest packaging level. Hence, we would like to request India to positively consider alternatives, that have been proposed by industry to meet the information requirements of the QCO on PE products, such that the mandatory labelling requirements are not too onerous and challenging for the industry to comply with.

4.109. Regarding India's QCOs on ethylene glycol, and styrene monomer, we understand that India is looking to allow virtual inspections as part of the certification process. Given the fluid COVID-19 situation globally, we thank India for this facilitative approach. For the industry to better prepare, we would be grateful if India could direct us to the relevant resources to initiate the virtual inspections as soon as possible, so as to allow the industry to proceed with the certification process, ahead of the impending entry-into-force of the measures. For any new additional QCOs, Singapore would like to request for India to provide specific website links and/or copies of the proposed BIS standards together with the notification to the WTO in a timely manner, so that interested parties can acquaint themselves with the new requirements, and provide meaningful comments to India. We understand India's desire to protect human health and the environment, and we respectfully urge India, as per its obligations under the TBT Agreement, to give full consideration to the use of international standards to achieve the same legitimate objectives, and to ensure that measures imposed are not more trade-restrictive than necessary, or create unnecessary obstacles to international trade.

4.110. In response, the representative of India provided the following statement. The measure is in line with international practices. India issuing Quality Control Order for chemicals and petrochemicals of HS chapters 28 and 29 as mandatory is in line with the international practices. India has formulated individual standards for specific chemicals indicating discreet and separate numbers under the BIS Act, giving technical characteristics and testing methods. Since each chemical has a different BIS standard number, possesses different features and different testing methods, India has not preferred to file a single comprehensive mandatory notification. DCPC (Department of Chemicals and Petrochemicals) has notified the draft Quality Control Orders on chemicals and petrochemicals under the provisions of BIS Act 2016 and Rules and Regulations framed thereunder, which envisages conformity assessment Scheme-1 of BIS Regulations 2018. As per draft 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 to India. Under the provisions of the BIS Act 2016, no person shall manufacture, import, distribute, sell, hire, lease, store, or exhibit for sale chemicals and petrochemicals notified in the QCO without a standard mark, except for a valid licence. For persons selling these chemicals without a requisite certificate (licence), penal provisions of the BIS Act 2016 shall be applicable. The violators shall be prosecuted as per the Act and punishable with a fine or with imprisonment. The requirement for using Standard Mark as per Scheme-1 is given in BIS (Conformity Assessment) Regulations 2018. A copy of the same is available on the BIS website (www.bis.gov.in).

4.111. Under the provisions of Scheme-1 of BIS (Conformity Assessment) Regulation 2018, the licence can be granted for a minimum of one but up to two years and subsequently can be renewed for a period of a minimum of one, but up to five years. Under these provisions, BIS grants a licence to the manufacturer based on a 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 in India or testing in the manufacturing premises or a combination of both. Under Scheme-1 of BIS (Conformity Assessment) Regulation 2018, there is no provision 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 DCPC notified were reviewed by BIS, and due consideration was given to international standards like ISO/ASTM, wherever available. As per Article 2.2 of the TBT Agreement, Members can formulate technical regulations to fulfill 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 an opportunity to the Members to comment within 60 days.

4.112. These standards are made mandatory to protect human health and the environment. Even if other countries have not formulated TR's for such chemicals, the fact is that number of TRs of chemicals and petrochemicals in India are less as compared to other nations. For a long time, the Indian standards of chemicals and petrochemicals were voluntary in nature. The trade of chemicals and petrochemicals usually occurs as per the specifications settled between the manufacturer and buyer irrespective of the specifications stipulated in the BIS standard, which sometimes resulted in dumping poor quality chemicals into India. Many chemicals are toxic and hazardous. The impurities such as heavy metals, cyanides, isocyanates, halides etc., enter the human and plant chain, harming human and animal life. 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 a review of existing standard and following stakeholder 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 the foreign manufacturer to penetrate and reach into Indian chemical market. There would be no delay on the Indian regulator in the clearance of import consignments, provided the supplier satisfies the conditions stipulated in the QCO.

4.113. Regarding the scope of the QCOs, there is no discrimination as they apply to domestic and foreign manufacturers. The BIS formulate the standards by studying all available international standards. Finally, standards are aligned with international standards. Presently India is in the process of formulating Chemicals (Management and Safety) Rules. The aspect of unnecessary animal testing and the element of Mutual Acceptance of Data will be looked into. As regards the links for the information of the QCO, the BIS standards are available at the link below.[29]

4.1.3.7 Bangladesh - Hazardous Waste (E-waste) Management Rules, 2019, G/TBT/N/BGD/3, G/TBT/N/BGD/3/Add.1 (ID 620[30])

4.114. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of Bangladesh to introduce waste management rules to protect the environment and facilitate resource recycling. Furthermore, Korean companies are fully committed to complying with the regulations of Bangladesh. However, Korean companies have raised concerns regarding the Electronic Waste Management Rules. And because Bangladesh has not yet sent a letter of reply regarding the date of enforcement and the restricted chemicals designated in Schedule-3, Korea would like to reiterate the following comments already stated at the 24-26 February 2021 TBT Committee Meetings. Firstly, no specific enforcement date has been provided for these proposed rules. Although the schedule had been stipulated as within 2020, complying with these rules may be difficult if they suddenly enter into force without any prior notice. Therefore, Korea requests Bangladesh to provide an interval of more than six months between the publication of regulations and their entry into force. Korea would also like to ask Bangladesh to provide a specific schedule of enforcement if there is one. Secondly, in Schedule-3, nine chemicals such as Polyvinyl Chloride, Liquid Crystals, etc, are designated as hazardous substances. These nine chemicals are internationally unrestricted and virtually irreplaceable. Korea requests Bangladesh to consider retracting them from Schedule-3 as the designations deviate from the international practices. If not, Korea requests Bangladesh to kindly provide scientific evidence for limiting the use of them. Thirdly,

[29] https://standardsbis.bsbedge.com/
[30] For previous statements follow the thread under ID 620.

for compounds of certain hazardous substances designated in Schedule-3, the standards of threshold limits are not clear. Korea requests Bangladesh to clarify whether the standard of threshold limit is applied to the respective amount or to the total amount of the individual substances within a compound. We would be grateful if Bangladesh provides quick answers to our concerns.

4.115. 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.

4.116. 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. 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?

4.117. The representative of Canada provided the following statement. In its initial comments submitted to Bangladesh's Enquiry Point on 16 April 2020, Canada requested that Bangladesh share the full regulatory text of the Management Rules with WTO Members. While Canada trusts that Bangladesh is currently giving due consideration to Canada's comments, we nevertheless use this opportunity to again highlight some of our questions and concerns regarding the Management Rules. Canadian stakeholders have voiced various concerns regarding the lack of clarity of the proposed Management Rules and have requested that Bangladesh provide additional supportive documentation on the new measure. Additional explanations would be beneficial on the scope of the measure, the selection criteria for the substances identified as "hazardous", and the rationale behind the determination of the threshold limits for each of them. Canada has further requested that Bangladesh clarify specific aspects of the Management Rules, notably regarding the method and rationale Bangladesh has followed to elaborate the grouping in Schedule-3. Some of these groups contain a broad range of substances, each with their own level of risks and hazard profiles. Some of these may not require to be grouped under the same threshold limit, or be included in Schedule-3 altogether. This includes, for example, the broad group of "Mineral Wool" or the joint entry for "Nickel and Cadmium/Cadmium oxide/ Cadmium Sulphide".

4.118. We also understand that some substances serve a specific purpose in the design of electronic products, like the flame retardant Tetrabromobisphenol-A, and would like to understand better the rationale for their inclusion in Schedule-3. Canada would also appreciate additional information on how Bangladesh will be approaching enforcement of the Management Rules. Furthermore, Canada would strongly encourage Bangladesh to give due consideration to any additional inputs or scientific evidence provided by stakeholders to ensure that the Management Rules are not more trade restrictive than necessary to meet its objectives, specifically with regards to the categories and threshold limits of Schedule-3. This would help ensure that the new measure does not generate unnecessary complexity and uncertainty in global trade. Canada thanks Bangladesh for its engagement on this STC, and we look forward to reviewing the full text of the Management Rules. Canada would appreciate if Bangladesh could provide Members with a notional timeline on when the full text of the Management Rules, along with its supportive documentation, will be shared with interested Parties.

4.119. 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.

4.120. In response, the representative of Bangladesh provided the following statement. Bangladesh thanks the Republic of Korea, the US, Canada, Russia, Japan, India and others for their interest in Hazardous Waste (E-waste) Management Rules, 2019. Most of the concerns raised by different WTO members have been addressed and hopefully responses will be notified in due course.[31]

4.1.3.8 China - Commercial Cryptography Administrative Regulations (ID 644[32])

4.121. 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) last 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 organizations. The EU urges the SCA to address these concerns in the further development of the draft regulations in order to ensure that legal and regulatory requirements are 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 China to notify the draft regulations to the WTO.

4.122. The representative of the United States provided the following statement. The United States has concerns regarding China's draft Commercial Cryptography Administrative Regulations, issued by the State Cryptography Administration on 20 August 2020 and we submitted comments to China in September 2020. The United States is concerned that this draft measure would impose potentially far-reaching, highly trade-restrictive cryptography-related constraints on foreign 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 imports and exports of commercial cryptography in instances where "social and public interests" are concerned. Can China explain how it plans to implement this scheme in line with its national treatment commitments? What steps is China taking to ensure the scheme will be not operated as an unnecessary obstacle to trade?

4.123. 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

[31] Document G/TBT/W/759 was subsequently circulated.
[32] For previous statements follow the thread under ID 644.

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.

4.124. The representative of Canada provided the following statement. In September 2020, Canada provided China with written comments on a draft of the regulation by China's State Cryptography Administration and continues to look forward to a response. At the last TBT Committee in February, China indicated that the revision of the Regulation is still being researched and will be open for public comments in due course.[33] Could China please indicate when the regulation will be opened for public comments again and if China plans to notify the measure to the WTO TBT Committee? As we noted in previous meetings of the Committee, 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 technical regulations regarding commercial cryptography; (iii) supporting the creation of equitable standards by indicating that all stakeholders can participate in the creation of commercial cryptography 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. Canada would also like to reiterate its ongoing concerns with China's Cryptography Law and requests 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.

4.125. In response, the representative of China provided the following statement. In order to implement the requirements of the State to promote 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 law-based, democratic and scientific principles. And it will be open, transparent, and on a scientific basis. China will solicit opinions widely and ensure that stakeholders participate in legislative activities through legal means. Now, the revision is still under study. We will solicit public opinions when it is appropriate.

4.1.3.9 India - Indian standards and import restrictions in the automotive sector (Quality Control Orders): wheel rims, safety glass, helmets, G/TBT/N/IND/118, G/TBT/N/IND/147, G/TBT/N/IND/167 (ID 649[34])

4.126. The representative of the European Union provided the following statement. The EU would like to refer to its previous statements on this issue. India has adopted a number of measures in the automotive sector that raise important concerns across the EU industry. The EU would like to underline that the measures in question have protectionist orientation and are sending 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. Furthermore, the implementation of the QCOs for foreign companies who have their production facilities located outside India is impossible in the context of travel restrictions due to the ongoing pandemic. In this context, the European Union appreciates the decision to postpone the introduction of the mandatory Indian Standards Institution (ISI) marking for automotive Safety Glasses to 1 April 2022. According to the new Quality Control Order, as of April 2022, the automotive glass not mounted in vehicles (loose or spare parts) sold in India will have to obtain a new national licence and marking.

4.127. Although the postponed entry into force by a year to 1 April 2022 should be sufficient for the industry to comply with this new requirement as the industry has so far made the necessary applications, the current conditions in India and elsewhere, due to COVID-19 pandemic, do not allow for the implementation of this QCO. Its entry into force as planned would result in production lines coming to a standstill due to the lack of supply of safety glass compliant with Indian QCO. We are hopeful that the overall health situation in India will not further affect the industry preparations for the new certification system. Should this be the case, we would suggest that India considers further postponement of the entry into force of this new requirement, with a view to ensuring the continuity of imports of safety glass into India. Besides safety glass, EU companies are also facing concerns

[33] G/TBT/M/83, para. 2.103.
[34] For previous statements follow the thread under ID 649.

related to other QCOs in the automotive sector. The draft Quality Control Order (QCO) for wheel rims 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 is 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 welcomes recent decision to defer the implementation of the Automotive Wheel Rim Component (Quality Control) Order 2020 to 21 March 2022. Like the safety glass QCO, this Quality Control Order mandates an in-person audit by auditors from BIS on the basis of cumbersome application process requiring local presence. The EU companies have complied with this requirement and made the necessary applications. However, the prohibition to travel from and to India due to the COVID-19 restrictions continue to make physical audits difficult to envisage in the foreseeable future. EU companies require a timeline of 4 months from the completion of the audit to ensure the certified product on the factory floor.

4.128. The EU therefore asks India to reconsider the introduction of this QCO. The EU would like to suggest as a minimum a meaningful delay of the entry into force of this measure that takes into account the gravity of the pandemic and the implications on international travel and financial vulnerabilities of businesses. This would allow the EU companies to meet the new requirements and to continue supplying customers in India. The EU would also like to urge India to consider virtual audits or audits performed by recognized third-party certification experts in the location of the manufacturing plants. Furthermore, the EU would like to recall its suggestion to keep the BIS marking as optional for components, which are already in compliance with the current marking requirements. 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. However, 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 motor cycles and mopeds. The European Union finds these measures to be disproportionate and causing obstacles to international 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.

4.129. The representative of Indonesia provided the following statement. Indonesia thanks and supports the European Union for raising concern on Indian Standards and Import Restrictions in the Automotive Sector (Quality Control) Order. Indonesia thanks India for notifying the draft of Automobile Wheel Rims (Quality Control), Order 2020 on 25 May 2020 to WTO Members through G/TBT/N/IND/147. Under these measures, wheel rims product shall conform to the IS 16192 and shall bear India Standard Marking under the licence form the Bureau of Indian Standard (BIS). Indonesia also appreciates India for the discussion in the virtual bilateral meeting on February. However, Indonesia is yet to receive substantive responses from India on our concern. According to the notification, this order shall come into force with effect from 1 October 2020, yet India has not made any addendum to the notification regarding the stipulation of the regulation. Indonesia seeks clarification regarding the status of the implementation of the regulation. Indonesia is of the view that the regulation has impacted and become trade barrier for the exporters as there are no clarity regarding the mechanism of the regulation. Therefore, Indonesia requests India to postpone or provide sufficient transition time to allow industries to comply with the regulation.

4.130. Indonesia remains concerned that the conformity assessment procedure as required in the document is more restrictive than necessary. The procedure includes that audit and certification can only be carried out by BIS and requires factory visit as part of scheme. Indonesia regrets that India has not taken into account the current pandemic situation that made factory visits impossible due to the travel ban and social distancing policy. Therefore, Indonesia urges India to consider the use of remote assessment in conducting factory visit or any relaxation policy as a means to facilitate trade and minimize technical barriers to trade, particularly in this difficult time. Indonesia also encourages India to recognize and accept conformity assessment results performed by accredited conformity assessment bodies outside India under the framework of IAF and ILAC signatory. Indonesia is also aware that before the mandatory implementation of IS 16192, India requires all manufactures of automobile wheel rims to implement ICAT (International Center for Automotive Technology) Standard prior to entering India's market. Therefore, we would like to ask clarification from India regarding the implementation of the ICAT standards once this regulation comes into force. Indonesia remains concerned about the potential duplicative conformity assessment

procedure. Hence, Indonesia requesst India to harmonize both requirements with a single conformity assessment procedure.

4.131. In response, the representative of India provided the following statement. Wheel Rims: The testing and certification system in India is in line with the global regime. Component certification is an essential prerequisite of Whole Vehicle Type Approval, and the two are complementary. This practice is well established worldwide and quite harmonised 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 wheel rim is recognized as one of the critical safety components 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 influencing driving safety. These Indian standards have been prepared to ensure quality, reliability and consistency required, keeping in view human safety and consumer protection. These standards prescribe wheel rims' general and performance requirements intended for use on two, three and four-wheeled motor vehicles. The Quality Control Order (automotive wheel rims) is non-discriminatory, both at the original fitment level of automobiles and after sales/repair service, to ensure supply of only quality product in the Indian market duly certified approved by the Indian implementing agency. The QCO also provides for market surveillance to check the 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.

4.132. Safety Glass: Implementation of safety glass QCO has been again extended by one year beyond 1 April 2021, i.e. new implementation date is 1 April 2022. Foreign inspection visits are on hold due to the prevalent restrictions on international travel given the ongoing COVID-19 pandemic. As soon as the situation of COVID-19 improves and the restriction lifted, India will plan the inspections (factory visit). Helmets: India is the largest two-wheelers market in the world. Around 15 million two-wheelers are sold in the country every year. The Government and the Apex Court, i.e. Supreme Court, are focussing hard on policies and measures to make people wear proper helmets while riding two-wheelers. In this regard, there was a move to reduce the maximum weight of the helmets so that people should use helmets, and BIS had issued the notification in this regard which prescribed for the maximum weight of helmets to 1200 grams from earlier 1500 grams. But due to the demand from the foreign helmet importers the cap on weight from 1200 was extended to 1500 grams. Now there is a proposal for including the helmet in the compulsory certification regime. This will ensure that the helmets are manufactured or imported only with the specifications of BIS standard and ensure good quality helmets, ensuring proper protection and reducing fatalities. The BIS provides a mechanism for foreign manufacturers to obtain BIS certification, enabling them to sell in India. Considering the road safety scenario in India as above, which is quite different from any European countries, the requirements for certified helmets is a high priority.

4.1.3.10 Kingdom of Saudi Arabia, Kingdom of Bahrain, State of Kuwait, Oman, Qatar, Yemen, United Arab Emirates - Halal Feedstuff, G/TBT/N/SAU/1134, G/TBT/N/ARE/474, G/TBT/N/BHR/574, G/TBT/N/KWT/532, G/TBT/N/OMN/407, G/TBT/N/YEM/176, G/TBT/N/QAT/570 (ID 643[35])

4.133. 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 refer to its written comments of 12 June 2020. The European Union would also like to thank to the Kingdom of Saudi Arabia for the reply to the EU written comments. The European Union would like to reiterate that the condition of the use of Halal feedstuff for imports of animal products for human consumption certified and labelled as halal would require a significant alteration to the feeding regime for food producing animals in the EU and would negatively affect EU exports to GCC countries. The European Union would like to ask GCC countries and Yemen to reconsider this requirement for animals reared in non-GCC countries and Yemen. 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.

[35] For previous statements follow the thread under ID 643.

4.134. In response, the representative of the Kingdom of Bahrain provided the following statement. On behalf of the member States of the Gulf Cooperation Council: We would like to thank European Union for their interest and is pleased to clarify the following. The "Halal Feedstuff" regulation covers the requirements to be followed during the production, preparation, handling, transport and storage of Halal feed for food-producing animals. The GCC member states would like to invite interested Members to discuss this matter bilaterally.

4.1.3.11 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 678[36])

4.135. The representative of the United States provided the following statement. On 5 May 2020, Mexico notified the World Trade Organization (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 August 14 and September 11, including providing expert presentations on standards of identity for cheese by the US Agricultural Marketing Service and the Food and Drug Administration. The US Department of Agriculture was also a regular participant. The opportunity to provide comments to the Mexican regulatory process and participate in the working group are greatly valued and we took 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.

4.136. In its notification, Mexico listed the objective of the conformity assessment procedures as the 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 in relevant scientific and technical information and incidence of non-compliant products to justify this onerous certification scheme for the objective of preserving the quality of cheese in the market? The July 2020 United States comments on the draft NOM-223 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 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 Mexican consumers. We also made suggested less trade-restrictive suggestions alternatives 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 could further force consumer substitutions for lower-quality products.

4.137. 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. We recommended and requested Mexico continue the use of international standards and test methods, and to 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

[36] For previous statements follow the thread under ID 678.

and accept testing from conformity assessment bodies located outside of Mexico, to ensure testing could be performed at the point of production.

4.138. Despite participating in early 2018 drafting, providing comments to CONAMER in 2018, providing comments in response to WTO TBT notification in July 2020, and 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. 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 typically 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 fulfill the legitimate objective of the regulation. We request 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.

4.139. Further, this would be an entirely new certification scheme that has never existed in any other country previously for cheese. If this certification scheme 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. 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 factory 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, and purchase of adulterated and unregulated cheese could increase. The United States exported USD 428 million in cheese to Mexico in 2020. We again request Mexico suspend the final measure, keep drafting with trading partners and stakeholders, 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.

4.140. 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 to 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.

4.141. The representative of the European Union provided the following statement. The European Union would like to join again 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.

4.142. In response, the representative of Mexico provided the following statement. The characteristics of Official Mexican Standard NOM-223-SCFI/SAGARPA-2018, Cheese Names,

specifications, commercial information and test methods, mean that it meets the requirements of a Technical Regulation according to the provisions of the Agreement on Technical Barriers to Trade of the World Trade Organization. It sets out four major components to which products must conform to be named as "cheese" in order to be marketed in Mexican territory. These are: physico-chemical specifications for each type of cheese (water content, protein and fat); the product is made only from milk and includes no more than 2% of caseinates; replacing milk fat by vegetable fat is not permitted; and commercial information is provided on the specific label for this product. The failure to comply with any of the above components would mean that effective compliance with this Technical Regulation cannot be demonstrated. Work is therefore ongoing internally with the relevant authorities in Mexico on a conformity assessment procedure to provide certainty of compliance with the requirements of NOM 223, adhering to Mexico's international commitments, including equal treatment of infrastructure or conformity assessment bodies nationally and in foreign countries, as well as non-discriminatory treatment between domestic and foreign producers. The Government of Mexico reiterates its commitment to the Members of this Committee to keeping them informed about the development of this procedure; we will be reporting on this as soon as the internal work under way with the relevant authorities tasked with drafting this CAP has been completed. We thank the European Union for its interest in discussing bilaterally and invite the EU to get in touch.

4.1.3.12 Thailand - Ministerial Regulation Prescribing Description, Production, and Method of Displaying of Standard Marks on the Industrial Products, G/TBT/N/THA/577 (ID 672[37])

4.143. The representative of the United States provided the following statement. The United States appreciates Thailand extending the date of enforcement of its Ministerial Regulation prescribing the description, production, and method of displaying of Standard Marks on its Industrial Products to 20 July 2021. 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. However, the United States does have continued concerns regarding the QR code requirements. We encourage Thailand to consider other approaches that may meet consumer protection goals in a less burdensome manner. In particular, a voluntary e-labelling approach in line with international best practices and standards should be considered. An e-labelling programme can help consumers discover important information without unnecessarily raising compliance costs and slowing time to market. We also request that the Thai Industrial Standards Institute (TISI) kindly provide clarification on the paperwork factory inspection process and the fee for each shipment. We understand that TISI indicated that a paperwork factory inspection is only valid for one shipment. We encourage Thailand to reconsider this duplicative and burdensome approach which would require a new inspection and fee for each shipment without improving the safety or quality of the products.

4.144. We further understand that the price of a paperwork factory inspection is almost three times higher than the usual onsite factory inspection price. Can TISI please provide more information about this cost structure and explain the difference in scope and objectives between these two inspection processes? We appreciate TISI's flexibility regarding the labelling requirement for small batteries. However, we also request that TISI simplify the requirements for the TISI logo and QR code for use on small AV products. We also request TISI remove the requirement for the importer's name to be imprinted on the power cord. If this requirement is maintained, efforts should be made to minimize the impact of this requirement, such as simplifying the requirements for the importer's name to be listed on a paper tag rather than molded or labelled on the power cord. The United States requests that Thailand continue to examine the regulation and consider less burdensome conformity assessment and labelling requirements to meet the legitimate objective of consumer protection.

4.145. 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) and the paper work factory inspection process and fee. For the Ministerial Regulation Prescribing Description, Production and Method of Displaying of Standard Marks on the Industrial Products B.E.2563 (2020), we reiterate it is necessary that the regulation be promulgated to fulfill legitimate objective under the scope of the TBT Agreement, Article 2.2, whose purpose is to prevent deceptive practices and consumer protection. The ministerial regulation stipulates that the

[37] For previous statements follow the thread under ID 672.

electronic information shall be displayed clearly visible, prominently and indelible on industrial products. In case where the electronic information cannot be displayed on the industrial products, the regulation is allowed to display on a package, a container, wrapper or binder in order to facilitate the manufacturing process. The date of enforcement is extended for 180 days which will be entered into force on 20 July 2021. As you may know, the spread of COVID-19 has been affected to factory inspection abroad. Import licensing, type 1b according to ISO/IEC 17067, widely accepted, has been applied during this hard period of time and product testing result of each batch shipment shall be submitted instead of visiting the production site. Finally, we would like to propose a constructive dialogue with the United States for our better understanding.

4.1.3.13 India - Refrigerating Appliances (Quality Control) Order, 2020, G/TBT/N/IND/173 (ID 671[38])

4.146. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of India to protect consumers and Korean companies are fully committed to complying with the regulations of India. Korea would like to make some comments regarding the "Refrigerating Appliances (Quality Control) Order, 2020" as follows. On 28 January 2021, via the Indian WTO TBT Enquiry point, Korea submitted comments in regard to Clause 14.8 of the Indian standard IS 1476(Part1):2000 and Clause 19.8 of IS 15750:2006. In the letter, Korea asked India to consider revising the High Voltage Test Time to one second in accordance with the international standard (IEC 60335-1). Since then, Korea has received two responses from India. On 2 February, India replied that India's BIS was working on revising its standard and would consider changing the High Voltage Test time from two seconds to one second. However, at the 24 February 2021 TBT Committee Meeting, India stated that India's standards and testings on refrigerating appliances have been established after collecting opinions from relevant stakeholders and manufacturers, and the regulations would not hamper foreign companies from entering the Indian market. These two responses from India do not seem unambiguous on whether the standard in question is under revision or it is set to be implemented without any further revision. Therefore, Korea asks India to clarify India's current position on this matter of revising the standard of the High Voltage Test and requests India once again to harmonize its standard with the relevant international one. In addition, Korea requests India to implement the "Refrigerating Appliances (Quality Control) Order, 2020" after the relevant Indian standard revision is completed and a sufficient transition period has been provided.

4.147. In response, the representative of India provided the following statement. The standard has been chosen after due stakeholder consultation including industry associations. As per the note in QCO notified in gazette, "the latest version of Indian Standards including the amendments issued thereof, as notified by the Bureau of Indian Standards from time to time, shall apply from the date as notified by the Bureau" QCO was notified on 10 December 2020 with implementation date of 1 January 2022 thus providing sufficient time for the industry to prepare. Since Korea mentioned about confusion between the two responses it received in the past, we hope this reply provided the required clarification.

4.1.3.14 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 668[39])

4.148. The representative of the Republic of Korea provided the following statement. Korea respects the efforts of the Kingdom of Saudi Arabia to protect the environment and Korean companies are fully committed to complying with the regulations of Saudi Arabia. At the February 2021 TBT Committee Meeting, regarding the Saudi Arabian regulation on "Air conditioners' Energy-Efficiency, notified as G/TBT/N/SAU/1167, Korea requested Saudi Arabia to reconsider the newly added Clause 7.4., which requires the disclosure of additional information on "AC setting for partial load operation". Also, Korea asked to ease the requirement of energy efficiency certification renewal for products with specifications identical to the existing products already certified. This relaxation can be achieved by either granting an exemption to relevant certification renewal or allowing companies to apply for the renewal with the existing test report used for initial certification. The Kingdom of Saudi Arabia responded that it would reply to Korea's comments via the WTO TBT Enquiry Point after reviewing the current status on Saudi air conditioners energy-efficiency regulations' standards. However, we

[38] For previous statements follow the thread under ID 671.
[39] For previous statements follow the thread under ID 668.

have not received any reply yet. Therefore, Korea requests Saudi Arabia to provide quick answers to our concerns.

4.149. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia would like to thank the Republic of Korea for addressing this concern. We would like to clarify that Saudi Arabia changed the requirements of submitting the additional documents to be only submitted electronically via the SASO website. Thus, the exposure of intellectual property of technologies from manufacturers will be secured and will not be exposed to the public. Regarding the renewal process, a team is currently working on studying the increasing validity period of test reports, and it will be announced once the study is completed.

4.1.3.15 Indonesia - Halal Product Assurance Law No. 33 of 2014 and its implementing regulations, G/TBT/N/IDN/123, G/TBT/N/IDN/131, G/TBT/N/IDN/131/Add.1 (ID 502[40])

4.150. 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 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 thanks Indonesia for its notification to the TBT Committee in February of its Government Regulation 39/2021 on The Organization of Halal Product Assurance (G/TBT/N/IDN/131), and subsequent addendum in May regarding the measure's entry into force (G/TBT/N/IDN/131/Add.1). Australia appreciated the opportunity to provide formal comments of the regulation and looks forward to Indonesia's response to our submission. Australia welcomes further dialogue on the Halal Law to ensure its implementation is no more trade restrictive than necessary.

4.151. The representative of the United States provided the following statement. The United States supports Indonesia's goal to provide reliable, relevant information regarding the halal integrity of certain products to consumers and we have sought to work with Indonesia over the last seven years to ensure that objective is achieved without creating any unnecessary barriers to trade. However, we were disappointed to learn that the draft implementing regulation had been finalized and published as Government Regulation 39 of 2021 (GR 39/2021) on 2 February 2021, prior to its notification to this Committee on 12 February 2021 as G/TBT/N/IDN/131. The addendum notification also noted entry into force began 2 April 2021, before the end of the sixty-day comment period. As you know, the recommended comment period for proposed regulations is 60 to 90 days and the reasonable interval for implementation is six months. We respectfully remind Indonesia of its WTO obligation to notify draft measures to the Committee, allow a reasonable time for stakeholder comments, and take such comments into account before draft measures are adopted and implemented. We request that Indonesia clarify the scope of the products and services covered by GR 39/2021. Article 2 states that all goods and/or services relating to food, beverage, medication, cosmetics, chemical products, biological products, genetically engineered products, or useful goods must undergo mandatory halal certification. This conflicts with the scope outlined in Decree 464.

4.152. Does Indonesia intend to develop implementing regulations or guidelines for each listed product category? What is the envisioned timeline for this development and will Indonesia conduct stakeholder consultations prior to issuing such implementing regulations or guidelines? Concerning the requirement for a government-to-government MOU to continue recognition of foreign halal certifiers, the United States Government does not have oversight on halal products as Indonesia does. We understand Indonesia intends to continue to accredit overseas halal certifiers and that these organizations will be permitted to assess the conformity of products intended for export to the country. Can Indonesia provide an update on BPJPH's process and timeline for renewing existing accreditations and adding new US-based halal certifiers? Will Indonesia consider renewing these accreditations in the absence of a government-to-government MOU to prevent trade disruptions? We request that Indonesia continue to accept goods imported from countries without a government-to-government MOU? Can Indonesia also assure the United States that goods coming from a non-MOU country will not be treated less favourably than goods from those countries with an MOU? We understand this measure also contains labelling and colour-coding requirements for non-halal products. We note that this new non-halal labelling scheme will significantly increase compliance

[40] For previous statements follow the thread under ID 502.

costs and we question its utility, as halal products are labelled. Would Indonesia consider removing this non-halal labelling requirement?

4.153. The United States is also highly concerned that the measure mandates halal and non-halal product separation at every stage with regards to the location, areas, and equipment for the slaughtering, processing, storage, packaging, distribution, sales, and presentation of all products. The United States requests that Indonesia refrain from implementing the supply-chain and product segregation requirements contained within GR 39/2021 and/or consider their applicability by sector. These requirements are unclear and a burden to trade. Industries have means across their respective supply chains to maintain the integrity of halal products. Can Indonesia open public consultations on this requirement? It also appears that GR 39/2021 requires that each business operator must employ a halal supervisor. To the best of our knowledge, no other country, international organization, or international standard requires each individual business operator to employ a halal supervisor and such an overly burdensome requirement would constitute a significant obstacle to trade. Given the uncertainty and potential trade-restrictiveness of this measure, we request Indonesia to suspend this measure and the implementation schedule until Members' comments have been taken into account. We urge Indonesia to consider Members' comments, revise and renotify the measure, and reset the phase-in schedule for all projects covered by the revised measure.

4.154. 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 again its concerns about the draft of Government Regulation Regarding Implementation of Halal Product Assurance. The requirement that non-halal products must include information about non-halal ingredients on the labelling is unnecessary and overly burdensome for the manufacturers of non-halal products. In our view, products that do not display a halal certification will not cause confusion with halal products. Please re-consider the necessity of this labelling requirement. In addition, the need for a government-to-government mutual recognition arrangement as a pre-condition for recognition of foreign halal certificates represents an excessive burden for Members who have no governmental body to administer halal affairs. We would appreciate Indonesia showing flexibility on this issue, such as allowing cooperation on halal accreditation between the BPJPH and foreign halal accreditation organizations. We hope our comments can be taken into consideration as the regulation approaches finalization.

4.155. The representative of the European Union provided the following statement. Thank you to Indonesia for the bilateral discussions. 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, resulting in significant obstacles to 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. The EU thanks Indonesia for its reply of 18 March 2021 to comments on Implementing Regulation 26/2019 on the Facilitation of Halal Product Assurance. However, we kindly invite Indonesia to reply to EU comments of 12 May 2020 on Regulation 31/2018 on Processed Food Labelling, as well as to EU comments of 20 April 2021 on the draft Government Regulation (RPP) 39/2021 on Halal Product Assurance implementing the Omnibus Bill on Job Creation (Law 11/2020), submitted on 20 April 2021. More broadly, the EU encourages Indonesia to provide comprehensive information to Members on the status of implementing provisions. The EU stresses the excessive restrictive impact on trade of the measures in question and invites Indonesia to consider less restrictive alternatives.

4.156. The main issues of concern for the EU in the current measures are, among others, the "non-Halal" information requested for non-Halal products or the extension of Halal requirements to products other than food and beverages. Furthermore, in order to ensure the workability of the system for foreign operators, there is a need for more clarity and a pragmatic approach as regards the requirements for recognition by Indonesia of foreign Halal certificates. In particular, we consider that the pre-condition of a government-to-government mutual recognition arrangement for recognition of foreign Halal certificates represents an excessive burden for economic operators and does not allow for smooth trade relations. The additional registration requirement for Halal certifications of certain products by foreign bodies also appears to be an unjustified, costly and duplicative request. The EU urges Indonesia to review these measures with a view at adopting a more trade-friendly approach. Notably, the EU firmly calls upon Indonesia to: (i) keep Halal certification and labelling voluntary, in order to pursue the legitimate objective of ensuring reliable information without unduly hindering trade flows; and (ii) accept 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 reiterates its willingness to further discuss and cooperate on Halal issues with Indonesia, with the aim of finding a practical way forward and solve trade concerns.

4.157. 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 thank Indonesia for notifying G/TBT/N/IDN/131 Draft of Government Regulation Regarding Implementation of Halal Product Assurance, to which we have submitted a number of questions and comments. We look forward to receiving Indonesia's comments on this in due course. We also seek clarity regarding the recent notification of Government Regulation Number 39 of 2021 (G/TBT/N/IDN/131/Add.1). This Regulation was originally notified by Indonesia on 12 February as a draft in G/TBT/N/IDN/131 seeking comments from Members by 13 April 2021. However, notification G/TBT/N/IDN/131/Add.1 indicates that Government Regulation Number 39 of 2021 was adopted on 2 February 2021 and entered into force on 2 April 2021. We respectfully remind Indonesia of its obligation to notify its regulations at an early appropriate stage so that amendments can still be introduced and comments from other Members taken into account, as well as its obligation to provide a reasonable period of time between adoption of a measure and its entry into force.

4.158. The representative of Canada provided the following statement. While Canada appreciates Indonesia's transparency in notifying this measure, we would like to remind Indonesia of its WTO transparency obligations to provide trading partners with adequate time to comment on a given measure and have those comments taken into consideration prior to that measure being finalized. Canada was concerned to see that the draft implementing regulation had been finalized 2 February 2021, prior to its notification to this Committee on 12 February and during the allowed comment period – during which Canada sent comments to Indonesia. The addendum notification of 12 May 2021 also noted entry into force on 2 April 2021, before the end of the comment period. In its comments, Canada signalled some remaining concerns on the draft implementing regulation. For example, it is still unclear on how foreign halal certification bodies will be recognized under Indonesia's law, particularly in countries such as Canada where the government does not provide oversight for halal certification. Some of the requirements necessary to obtain accreditation, such as the requirement that halal auditors hold Indonesia citizenship, would appear to be inappropriate for foreign certification bodies. Clarity around anticipated/expected timelines for the accreditation of foreign bodies would also be useful.

4.159. While Canada supports Indonesia's right to ensure the integrity of products that are certified as Halal, some requirements, including that separate facilities be used to store cleaning equipment for halal and non-halal slaughter, are neither financially or technically feasible for Canadian food producers and could impede their ability to export to Indonesia. Canada would like to explore Indonesia's openness to consider feasible alternative solutions that would achieve the same results (halal certified food products). There is also a lack of clarity around whether foreign halal certifying logos will be permitted in the Indonesian market. Could Indonesia inform if it will accept equivalent or alternative logos for imported products? Does Indonesia intend to develop implementing regulations specifically for acceptable logos, labels and other packaging requirements? In addition, concerns still remain with some of the proposed requirements including that non-halal products are required to display non-halal information on products, whether non-halal products can be imported and what constitutes "processing". Canada takes this opportunity to remind Indonesia that as per WTO transparency obligations, a six-month period between the notification of the final measure and its entry into force is considered a reasonable amount of time to provide industry time to adapt to the new requirements. We appreciate Indonesia's willingness to discuss these issues bilaterally and we look forward to having a more in-depth discussion in a bilateral context.

4.160. In response, the representative of Indonesia provided the following statement. Indonesia would like to refer to its statement on the previous TBT meeting on February. Indonesia is mindful of its transparency obligations as mandated in the TBT Agreement. Thus, Indonesia has notified the Government Regulation Number 39 of 2021 on Implementation of Halal Product Assurances through addendum notification G/TBT/N/IDN/131/Add.1. In this regard, we would like to thank all Members who have provided comments and inputs to the draft regulation. Indonesia reconfirms the regulation revoke the Government Regulation Number 31 of 2019 in order to implement the mandate of Indonesia Omnibus Law. We would also like to reiterate that there are phases or stages to implement mandatory halal certification such as for food and beverage products will be effective on 17 October 2024; while for non-food and beverage products will be effective on 17 October 2026. Furthermore, Indonesia provides a transitory provision as mentioned in Article 169 to accommodate stakeholder and industry that obtained halal certification based on previous mechanisms, as follows: all forms of cooperation with foreign halal certification body and accreditation agencies in other countries that were carried out before this government regulation is made, remain in effect until the period of cooperation ends; foreign Halal Certificate recognized by MUI before this Government Regulation is made, remains valid until the expiration of the validity period of the foreign Halal Certificate. Indonesia would like to reiterate its openness to international cooperation on Halal Assurance System based on the principle of mutual recognition and mutual acceptance in accordance with international regulations and practices.

4.1.3.16 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, G/TBT/N/CHN/1524, G/TBT/N/CHN/1525, G/TBT/N/CHN/1526, G/TBT/N/CHN/1527, G/TBT/N/CHN/1539 (ID 576[41])

4.161. The representative of the Republic of Korea provided the following statement. Korea thanks China for responding to Korea's comments regarding the Specifications for Cosmetic Efficacy Claim Evaluation, the Specifications for Registration and Filing of New Cosmetic Ingredients, and the Specifications for Cosmetic Registration and Filing. However, the reply from China did not give direct answers to Korea's enquiries but only gave a general explanation on the implementation of measures. As our concerns were not duly addressed in the finalized version of the Specifications for Cosmetic Efficacy Claim Evaluation and the Specifications for Cosmetic Registration and Filing and so on, we would like to raise this STC once again. First, according to the Regulation, exporters to China are required to specify the sources and quality data of all ingredients in the application, which demands more information than what is required in other countries. Such information contains a number of trade secrets that are critical to businesses, and the requirement is more rigorous than necessary to fulfill a legitimate objective of guaranteeing product safety and consistent market norms. Therefore, Korea would like to request China to provide an evidence-based explanation for such requirement. Furthermore, according to Appendix 12-16, businesses are required to submit documents that specify manufacturing processes and corporate standards regarding ingredient safety and product standards, which include detailed information on the processes and procedures of product manufacture.

4.162. Second, the Regulations stipulate that the test results required for the registration of cosmetic products must be issued by testing laboratories that have obtained China Metrology Accreditation (CMA) in compliance with the regulation. However, only laboratories in China are known to have obtained CMA. Thus, Korea would like to request China to offer flexibility to foreign laboratories in granting CMA and to recognize test results issued by foreign laboratories or internationally recognized laboratories, including Good Clinical Practice (GCP) or Good Laboratory Practice (GLP). Third, pursuant to Article 13 of New Cosmetic Ingredients Authorization and Registration Regulation, in case of using alternative test methods, exporting companies are required to provide equivalence evidence which proves their test results are equivalent to the results of *in vivo* toxicity testing method, or animal testing. However, we would like to request that the OECD-approved and internationally recognized alternative test methods also be recognized without having to provide equivalence evidence. Fourth, regarding "the administrative Measures on Cosmetic Labelling", Korea would like to request that China assure that the labelling requirement follow the internationally recognized practice so as not to be more trade restrictive than necessary. Especially, with respect to the labelling requirement of all ingredients in cosmetics, Korea invites China to maintain its current regulation on the declaration of the ingredient list in cosmetics on the labels. In

[41] For previous statements follow the thread under ID 576.

most countries, the declaration of ingredient list is applied to substances at a 1% or higher concentration. According to China's draft regulation, however, the declaration of ingredients for the substances at a 0.1% or higher concentration is required, and the substances at a lower than 0.1% concentration are declared as "other ingredients in small amounts." This requirement goes against the harmonization of international regulations.

4.163. As the "Administrative Measures on Cosmetic Labelling" will cause great change, reasonable transition time is necessary to ensure business entity. Korea would like to request that China provides an adequate grace period, in order to adapt to a new cosmetic labelling regulation. Fifth, under the Specifications for Cosmetic Efficacy Claim Evaluation, China still 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. 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.

4.164. The representative of the United States provided the following statement. The United States unfortunately must reiterate our concerns with China's development of the implementing measures for the Cosmetics Supervision and Administration Regulation (CSAR). CSAR's final implementing measures, as published, will pose significant risks to companies' intellectual property, are not proportionate to cosmetics' low risk compared to medical products, and may result in less favourable treatment of imports than that accorded to like products of national origin. Both the draft measures and those published as final appear to continue to require extensive disclosures of trade secrets and confidential business information (CBI) that may not be limited to what is necessary to assess conformity and fulfill CSAR's regulatory objectives. The United States and other WTO Members asked that China consider how CSAR could be made more similar with the approaches taken by regulators in other major cosmetics markets, in which cosmetics companies maintain responsibility for their products, making their data and other documentation available to regulators as needed upon request. This allows companies to safeguard their information. We are disappointed that NMPA has not pared back its extensive disclosure requirements to the information necessary to assess conformity, and we urge NMPA to do so. As regards current draft measures, we have the following concerns and questions: we are concerned that the draft Standards of Information File for Toothpaste (1539), may not distinguish how cosmetic toothpaste is tested compared to other types of general and special cosmetics, despite differing uses.

4.165. Regarding China's draft Administrative Measures on Cosmetic Labelling (1515), the United States is concerned that the proposed regulation regarding foreign language text and use of trademarks or suggestive words, graphics or symbols, would create an unnecessary obstacle to trade. We ask China to clarify that the foreign language labelling is not required to match the Chinese label exactly so long as the required Chinese label and the foreign labelling do not conflict. We also ask that China not require companies to disclose the product manufacturer on the product label, as the label already requires the name of the responsible person and their contact information. Product manufacturer information is proprietary and available to NMPA via the product filing. Given the extensive comments provided by WTO Members and industry, can China advise if it intends to renotify an updated version of the Administrative Measures on Cosmetic Labelling (CHN 1515), before it is finalized? Can China clarify if this measure is mandatory? If it is mandatory, we are then unclear as to why China has yet to notify its draft standard for Good Manufacturing Practices for Cosmetics (cGMP). We ask that China notify the draft standard and clarify how relevant international cGMP standards such as ISO 22716 are used as a reference for the standard, or alternatively, why these relevant international standards, or relevant parts of them, are inappropriate for the fulfillment of China's regulatory goals.

4.166. In addition to the above concerns on the draft measures, despite extensive engagement from the United States, US industry, and other stakeholders, significant concerns remain over CSAR's recently finalized implementing measures. For example, we, as well as other WTO Members, continue to urge that China not require cosmetics rightsholders to publicly disclose CBI used to verify their product claims, as specified in Annex 4 of the Standards for Cosmetics Efficacy Claim Evaluation (Standards) (a draft of which was notified as 1526). Rather, companies should be allowed to limit public disclosures to a non-proprietary summary of the product, validation methods and outcomes

used to validate claims. We ask NMPA to confirm that companies, not NMPA, will be allowed to compile the product abstract published on NMPA's website. We are also disappointed that these finalized Standards may require testing that may be more trade restrictive than necessary, if duplicative, of what is available from the use and testing of the product in other markets. We urge China to recognize test reports from foreign labs that do not have Chinese Metrological Accreditation, if they follow Good Laboratory Practices or Good Clinical Practices, per the ICH Guidelines, and are in conformity with China's requirements. Will China consider alternative means of validating these claims, not included in the Claims Guidelines, if the means are in conformity with China's requirements? The United States acknowledges the new language on intellectual property (IP) protections in Article 55 of the Administrative Measures on Cosmetics Registration and Notification (a draft of which was notified as 1454), stating that authorities shall not disclose trade secrets and CBI, subject to exceptions for national security or major social public interests. The United States remains concerned, however, that China's disclosure exceptions as provided in the Administrative Measures (1454) and the Regulation on the Disclosure of Government Information will undermine protections for trade secrets and CBI.

4.167. We heard that China may, in response to prior comments from the United States and other WTO Members, develop an explicit mechanism for companies to indicate to NMPA when information submitted in line with the CSAR, its regulations, measures, specifications and standards, should be marked as trade secrets or CBI. We ask that this mechanism provide a means by which protections from unauthorized disclosures can be monitored and legally enforced within China. We are disappointed that China has not taken into account the concerns raised by several Members of the WTO TBT Committee, that the Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers (draft of which was notified as 1525) may have the effect of requiring importers to animal test their products if they cannot provide a regulator-issued Good Manufacturing Practices (GMP) certificate. The United States has explained that the US Food and Drug Administration does not issue these GMP certificates. We note that several other WTO Members including the European Union, Australia and New Zealand have noted that such certificates are not relevant in terms of how they regulate cosmetics, and they have similarly asked China to consider other means to establish GMP conformity that are not trade restrictive. For example, in the United States, trade associations and other third parties can issue certifications in line with the international GMP standard ISO 22716, which the US FDA and regulators in other major cosmetics markets reference. So as to avoid creating disparate treatment of imports or requiring unnecessary animal testing, we ask that China consider how it can be flexible and transparent in determining which GMP certificates and/or production licences, it will accept as conforming to its requirements. To date, neither China's WTO TBT Committee delegation nor NMPA has responded to US Government or US industry enquiries for additional clarification. The United States appreciates China's most recent notifications of CSAR implementing measures and the opportunity to provide comment, however, we are deeply concerned by China's 1 May date for adoption of many of the final measures. We request that China delay finalization of additional measures until these serious trade concerns expressed by the United States and many other WTO Members are addressed.

4.168. 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. 1. "Management Rules for Testing required for Cosmetic Product Registration and Notification", which was promulgated on 12 September 2019, stipulates 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 appreciates that China took Japan's repeated request into a certain level of consideration regarding "Specifications for Registration and Filing of New Cosmetic Ingredients", which was promulgated on 4 March 2021, stipulates that physical, chemical and microbiological testing reports relevant to new cosmetic ingredients registration and filing may be issued by the registrants or filers themselves or by entrusting a testing institution with corresponding testing capabilities. Japan would like to request, relevant to cosmetics registration and filing, 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" stipulates that test methods including test items other than those stated above, can 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.

4.169. 2. 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 favourably than products produced in China. In addition, regarding China's draft of the "Administrative Measures on Cosmetic Labelling", Japan would like to express its following four concerns. 3. Article 5 stipulates 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 fulfill legitimate objectives. 4. Regarding Article 6, Japan has concerns that multiple company names and addresses on the label may cause misunderstandings on the part of the consumer rather than achieving the aims of this article to inform consumers of the persons responsible for product quality and efficacy. 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.

4.170. 5. 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 stipulates that only ingredients with a compounding amount of 0.1% or less are allowed to be listed in no particular order. It also stipulates that ingredients with a compounding amount between more than 0.1% and 1% are to be listed in descending 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. 6. Article 19 stipulates that the indication "evaluated and verified efficacy" can be included on product labelling only if the efficacy is confirmed by the qualified testing laboratory in China. However, "Specifications for Cosmetic Efficacy Claim Evaluation", which was promulgated on 9 April 2021, stipulates 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", not limited to the one confirmed by the qualified testing laboratory in China. Moreover, the "Provisions for Cosmetics Registration" stipulate that overseas inspections are to be conducted in accordance with relevant regulations 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.

4.171. 7. 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. 8. 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 stipulates equal treatment for both domestic and overseas companies. 9. Japan requests that China ensures that confidential information will not be disclosed to persons other than those who are necessary for the legitimate purpose of the inspection, since production sites also contain a large amount of confidential corporate information. Furthermore, Japan has the following concerns on other implementing regulations.

4.172. 10. In "Specifications for Registration and Filing of New Cosmetic Ingredients", there are specific requirements for nano ingredients and Annex 5 stipulates the definition of such ingredients. Article 29 of "Specifications for Cosmetics Registration and Filing" stipulates 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)" stipulates 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. 11. Regarding article 33 (II) (Exemption from submitting toxicological testing documents) of "Specifications for Cosmetics Registration and Filing", 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. 12. Regarding the test of freckle-removing/whitening products, Japan would like to request that China adopt the approach of Read-Across that was stipulated 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 process from application to permission.

4.173. 13. Japan would like to request clarification so that filers of toothpaste products can use new toothpaste ingredients only when registrants/ filers of new ingredients have confirmed their use in advance during the three-year safety monitoring period after their registration/ filing of new ingredients, in the same manner as article 29 of "Specifications for Cosmetics Registration and Filing", which stipulates the handling of new cosmetic ingredients. 14. Article 32 of "Standards of Information File for Toothpaste Notification (Draft for Comments)" stipulates that the abstract of an efficacy evaluation report shall be submitted during the filing process. The "Cosmetics Supervision and Administration Regulation" stipulates that "cosmetics registrants or filers" are the persons responsible for efficacy of cosmetic products, however, its implementing regulations do not require submission of the abstract of an efficacy evaluation report. Japan would like to know the reason for the requirement of submitting the abstract of an efficacy evaluation for toothpaste. 15. Article 36 of "Specifications for Cosmetics Registration and Filing" newly requires that their registrants/ filers retain samples of each batch of cosmetics produced for future inspection. It also stipulates that the number of retained samples shall be able to meet the requirements for conducting registration and filing tests. Retaining such samples from all lots requires prohibitive amounts of space and imposes substantial burdens. Japan would like to request that China stipulate detailed rules allowing for flexible operation, such as setting the storage period up to each sample's expiration date since overdue samples from their expiration data is unable to use as samples. 16. Finally, as the "Cosmetics Supervision and Administration Regulation" and its implementing regulations will cause great changes, reasonable time for transition is necessary to ensure business continuity. Japan would like to request that China provide an adequate grace period of 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.

4.174. The representative of Australia provided the following statement. Australia thanks China for providing a written response to Australia's previous comments on China's Cosmetics Supervision and Administration Regulation (CSAR). We appreciate China taking the time to provide this reply, which does help answer some of our questions in relation to the CSAR and some of its implementing regulations, including those notified in 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; G/TBT/N/CHN/1524; G/TBT/N/CHN/1525; G/TBT/N/CHN/1526; G/TBT/N/CHN/1527; and G/TBT/N/CHN/1539. We understand that this new regulatory system was to enter into force from 1 May 2021. Could China clarify whether the CSAR and all the relevant implementing regulations are being implemented? We would also request an update on how implementation is progressing and whether any cosmetics have been imported to China under the new regulatory system. Does China intend to notify the WTO of the final versions of each implementation regulation? We understand China has notified only drafts of many of these regulations to date. Australia still has questions and concerns about how the CSAR and its various implementing regulations are to be implemented.

4.175. While Australia is pleased that China appears to have addressed the need for an alternative 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. In this respect, a key concern is the requirement for government involvement in certifying quality (e.g. via Good Management Practice (GMP)) of cosmetics production facilities and the requirements to register

and certify low-risk cosmetic products even when these include approved ingredients. Exporters are also concerned about requirements to provide information on their production processes and other aspects of their intellectual property. The Australian Government would welcome the opportunity to work with China and discuss the CSAR in more detail to exchange information on our respective health regulatory systems, including our respective systems for cosmetics regulation and GMP certification.

4.176. The representative of New Zealand provided the following statement. New Zealand welcomes China's endeavours to modernize its regulatory system for cosmetics and also welcomes the opportunity to comment on specific elements of China's Cosmetic Supervision and Administration Regulations. 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 implementation of the regulations. New Zealand notes that under the measures, non-animal tested cosmetics are able to enter China's market only on the basis that regulator-issued GMP certification is provided. Non-special use cosmetics are considered to be low-risk products in many countries, including New Zealand, and for this reason are not subject to regulator-issued GMP certification. While we welcome the introduction of alternatives to mandatory animal testing for imported products, like others, New Zealand is disappointed that the measures do not provide for non-regulator issued GMP certification or other trade facilitative mechanisms for providing product assurances. This appears to mean that animal testing requirements will still apply for Members who cannot offer regulator-issued GMP certification for cosmetics imported into China and as such will act as a significant and unnecessary barrier to trade for imported cosmetics products. New Zealand would like to better understand what consideration China has accorded to less trade-restrictive alternatives. We encourage China to engage directly with New Zealand and other affected Members to identify a trade-facilitative mechanism to demonstrate GMP conformity, without imposing animal-testing requirements.

4.177. New Zealand further requests that China also provide flexibility in respect of product testing requirements. In particular, we encourage China to accept test reports from accredited laboratories situated outside of China. If test reports from internationally accredited bodies outside of China are not accepted, then this will create burdensome and unnecessary 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. New Zealand also holds concerns, that we note are shared by a number of Members, around the issue of China requiring more detailed disclosure of product 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 CSAR measures and welcomes China's response to the concerns raised by New Zealand and other Members.

4.178. The representative of the European Union provided the following statement. The EU would like to support the delegations of Australia, the United States, Korea, Japan, 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 they 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 in pre-market registration or filing dossier is not necessary to ensure consumer safety and traceability of the ingredients used in cosmetics.

4.179. Companies' registration and notification documentation may be accessible to a number of people including the pharmaceutical supervisory and administrative department, professional technical institutions and their staff, and personnel participating in the review. Could China confirm

that all institutions and individuals that may have access to the submitted data will be subject to non-disclosure requirements? Have specific procedures and enforcement measures been developed to ensure the non-disclosure of submitted data? 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.

4.180. In response, the representative of China provided the following statement. Requiring a registration applicant and the filing applicant to submit safety-related information is a common practice of other Members for the safety review of health-related products. In China's cosmetics regulations, the procedures and data requirements for the registration and filing and new raw materials are focused and clear. The brief description of the production process, raw material production process, and other registration and filing materials required in the regulations and submitted by enterprises are not the contents of government information disclosure. Government information disclosure is a measure for the government authorities to accept social supervision and protect the public's right to know. According to the Regulations on the Disclosure of Government Information, authorities are prohibited from disclosing information involving trade secrets and personal privacy that may harm the legitimate rights and interests of third parties. Therefore, trade secrets and intellectual property rights will not be damaged in this regard. China attaches great importance to the protection of trade secrets and IP of enterprises. Article 47, Article 56 of the Regulations on the Supervision and Administration of Cosmetics, as well as the Measures for the Administration of Registration and Filing of Cosmetics issued on 7 January 2021 all stipulate that the commercial secrets of the parties shall be kept confidential. Besides, in relevant technical requirements, only a summary of the efficacy claim basis rather than the full text is required in evaluation data of cosmetics efficacy claim. The technical requirements of new raw materials for disclosure only include some basic information, not complete technical information. The authorities will also strictly abide by the principle of protecting business secrets in the management of cosmetics registration and filing.

4.181. Strengthening the supervision of cosmetics production is a necessary means to ensure product quality and safety. It is also a common practice internationally. Based on the non-discrimination principle of WTO, the Provisions on the Administration of Cosmetics Registration and Filing Data put forward exactly the same requirements on imported and domestic cosmetics for an alternative program of animal tests for safety evaluation. For the quality management system certification issued by the government agency, it is non-discriminate to domestic and imported products, for the purpose to ensure the quality and safety of the products. *On the submission of information related to the safety of cosmetics raw materials*. As product safety is closely related to the safety of the raw materials, it is important to require the registration applicant and the filing applicant to clarify the information related to raw material safety when applying for registration and filing, so as to ensure product safety. 4. In the aspect of cosmetics registration and notification inspections, to protect the legitimate rights and interests of Chinese consumers, ensure the accuracy of test results, etc., National Medical Products Administration (NMPA) requires testing the efficacy of 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.

4.182. As a matter of fact, the Administrative Measures for Cosmetic Labelling (Draft for Comments) does not require that all contents of the Chinese sticker and original label should correspond to each other, but only requires that the content of product safety and efficacy claims indicated in the Chinese sticker should correspond to those of original label. Labelling of information of manufacturers is an important measure to protect consumers' right to know, and also an important means to promote social co-governance and combat counterfeiting. The imported products can be labelled according to the requirements of relevant regulations, and there is no situation that it is in conflict with the information of manufacturers. In fact, the declared efficacy of products is closely related to the efficacy of cosmetic ingredients. In general, there is a positive dose-effect relationship between the efficacy of the ingredients and the amount added in the formulation. Therefore, in order

to prevent the "conceptual addition" of cosmetic ingredients, the proposed draft measures, based on the scientific supervision concept, propose that ingredients with formula content not exceeding 0.1% (w/w) should be labelled with "other trace ingredients" as guide words. "Other trace ingredients" does not equal to "ineffective ingredients", the ingredients which are of very low amount but still have some efficacy, and could be declared in the labelling for efficacy declaration on the premises that the regulation requirements could be satisfied. *On the transitional period for the implementation of regulations*. On 29 June 2020, China has issued a new revision of the regulations on the supervision and administration of cosmetics, and come into effect on 1 January 2021. For other regulations on cosmetics, reasonable transition periods have been or will be provided as well.

4.1.3.17 European Union - Transitional periods for MRLs and international consultations (ID 580[42])

4.183. 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 because of 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 are already having a direct impact on fruit producers in Colombia. They 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 particular crisis. In line with the statements made in document 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.

4.184. 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 the 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 EU to state that, as soon as the European Food Safety Authority (EFSA) recommendation and the Standing Committee on Plants, Animals and Food and Feed (PAFF) 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. Colombia once again welcomes the opportunity to express its concerns on this issue and looks forward to a response from the European Union.

4.185. 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 and Colombia, 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 agricultural

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

production in 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 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 global 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.

4.186. The representative of the United States provided the following statement. We continue to raise our concern about the European Union's (EU) transitional 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 what the impact of non-renewal decisions will be on future maximum residue levels (MRLs). In addition, we reiterate our concern about import tolerance applications, which remain active. The review of additional data is often only considered after the EU notifies its intent to issue a non-renewal notice. 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. We also again request that imported products' MRLs be considered on the EU market at the time of production, the same as for European products.

4.187. The representative of Ecuador provided the following statement. Ecuador is extremely concerned about the "transition periods" granted by the EU for implementing its measures relating to the non-renewal of the use of substances and the reduction of tolerances. In order to establish reasonable transition periods, it is necessary to consider harvesting periods and the times when agrochemicals are applied. Farmers need more time to adapt to MRL requirements, as it takes 36 months on average to develop or register a new phytosanitary pest-control product. We therefore urge the EU to consider a period of at least 36 months, which will allow enough time to make the necessary adjustments to production and ensure that developing countries meet the new requirements established in the European regulations. The extension for applying the measures has also been requested given that their implementation makes it necessary to find alternative measures that do not affect the price of agricultural products, and because of the need to minimize the impact of the reduction of agricultural production in the country, as it is important to bear in mind that according to data in the study carried out by the United States (USITC - Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels), it is estimated that the strategies applied by the EU, in a middle-of-the-road scenario, would lead to the prices of agricultural products increasing by around 50% and a 4% decline in global agricultural production, which would have a huge impact on the country's economy.

4.188. It is clear that the regulations on the prohibition of the use and the withdrawal of the molecules are of an internal nature for EU member countries; however, bearing in mind that the next step is to review and modify the MRLs for these molecules and in some cases involves reduction to the level of detection, this would mean that the restriction on their use would also be reflected in exporting countries. Ecuador is aware that the EU allows its farmers to request emergency authorizations so that, in certain special situations, they can use active substances that have already been banned in the European market. For Ecuador, it is important to know whether, where emergency authorizations are issued for the use of such substances, EU member countries have notified and justified the application of MRLs that differ from those established in the EU's existing MRL regulations. We would also like to know how the EU monitors whether the member State that has received an emergency authorization for the use of prohibited substances is complying with the existing MRL regulations and how it verifies, in the case of non-compliance with the MRL regulations, that the products containing the prohibited substances have not been marketed in other EU member States.

4.189. The representative of Paraguay provided the following statement. Paraguay reiterates its concern and asks for the statements made at previous meetings to be recorded in the minutes. We support Colombia's comments regarding the immediate publication of measures at the end of the comment period and the apparent failure to consider these comments. We have asked the EU to provide concrete examples of when comments have been taken into account, without receiving a response that identifies such cases. We once again ask to be granted an appropriate period of time to adapt, reflecting the realities of the production processes and geographical locations, including the distances, of the EU's trading partners. The six-month period is insufficient for adapting productive systems.

4.190. 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 our previous statements regarding STC 580. We respectfully bring to the attention of the EU its obligations under Article 2.12 of the TBT Agreement, which relate to the establishment of a reasonable interval between the publication of technical regulations and their entry into force, except in cases of urgent problems of safety, health, environmental protection or national security. It is of utmost importance 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.

4.191. The representative of Canada provided the following statement. Canada would like to reiterate its concern with the EU's approach to transition periods for maximum residue limits. In our view, the sudden deletion of MRLs and import tolerances seem disproportionate to the level of risk to human health and is more trade-restrictive than necessary. Moreover, transition periods are not granted to third countries, making it very difficult for our domestic 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 that the EU will allow more reasonable transition periods for MRLs where the risks of dietary exposure are acceptable. Transition periods will allow trade to continue uninterrupted, while providing sufficient time for producers and exporters to adapt to the new EU requirements. At a time when ensuring food security is paramount, Canada urges the EU to extend transition periods for MRLs to third countries, taking into account the need for exporters to adapt to new requirements, as it has done so for its domestic producers.

4.192. The representative of Panama provided the following statement. Like the delegations that have already taken the floor, Panama wishes to reiterate its concern regarding the transitional periods established by the European Union. Time is needed to adapt agricultural production to the standards and doing so within a six-month period is impossible. We refer to our previous statements on this matter and invite the European Union to promote open dialogue with stakeholders, transparency and the minimizing of market distortions.

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

4.194. The representative of Chile provided the following statement. Chile associates itself with the statements by Colombia, Costa Rica, the United States and the other delegations that took the floor on maximum residue levels.

4.195. The representative of Uruguay provided the following statement. 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 to 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.

4.196. The representative of El Salvador provided the following statement. El Salvador also shares the concerns expressed by other delegations in relation to the different draft technical regulations of the European Union for MRLs. We would urge that these be based on scientific evidence and not constitute unnecessary obstacles to trade.

4.197. 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 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. On the contrary, all measures concerning non-approval or restriction of active substances used in plant protection products in the EU are notified to the TBT Committee. These measures do not have direct consequences on SPS-related matters. However, in the interest of transparency and, further to requests by some Members, when notifying these measures under the WTO/TBT notification system, the EU additionally informs the SPS Committee of the submission of those notifications on pesticide active substances. In practice, both Committees are informed about draft acts on the non-approval or restriction of approval of an active substance in the EU. However, comments should only submitted via the TBT notification system. The European Union would like to point out in this context that the commenting deadlines are always respected and that the comments received within those deadlines are duly taken into account in the EU's decision-making process.

4.198. 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. As regards the joint Request for the suspension of the processes and entry into force of reduction of Maximum Residue Levels (MRLs) of plant protection products in light of the COVID-19 pandemic in documents G/SPS/GEN/1778 and G/TBT/GEN/296 and subsequent revisions, the EU has informed WTO Members of its position in the last three WTO/SPS Committees (respectively, on 25-26 June 2020 - G/SPS/R/99, 5-6 November 2020 – G/SPS/R/100 and 25-26 March 2021 – G/SPS/R/101). In addition, the EU position is included in document G/SPS/GEN/1814/Rev.1 of 6 November 2020.

4.1.3.18 European Union - Chlorothalonil (pesticide active substance) (ID 579[43])

4.199. 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, the regulation under which the marketing approval of the active ingredient chlorothalonil is not renewed entered into force in May 2020. This decision is already beginning to have implications and consequences for banana producers in Colombia and has repercussions for a broad chain of domestic agricultural production. 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. In this case, the EU has also failed to take into consideration the technical comments submitted and the requests for a longer transition period to adapt production processes, which in the agricultural sector are particularly complex. These decisions have been taken without the EU taking into account the concerns raised by various members in this

[43] 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. We recall in particular that in document G/TBT/GEN/296/Rev.3 Colombia and a large group of Members request the EU to temporarily suspend review processes of market approvals for plant protection substances, and the entry into force of regulations in this area, planned for 2020, including the non-renewal of the active substance chlorothalonil. This request was made in the context of the current health crisis, which has demanded the full attention of the health authorities, which do not have the capacity to deal with issues related to plant protection substances at this time.

4.200. 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. 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. The foregoing constitutes a violation of Article 2.2 of the TBT Agreement, which stipulates that technical regulations should 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 or on the environment has not been clearly determined. 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.

4.201. The representative of Costa Rica provided the following statement. Costa Rica once again 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 expressed in previous meetings of this Committee and is based on the lack of conclusive scientific evidence and the application of a precautionary approach to 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 marketing 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.

4.202. 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. Chlorothalonil is one of the main tools for controlling Black Sigatoka in bananas due to its effectiveness, low cost and multisite mode of action, meaning that the risk of resistance is low. It is available in a wide range of products, through many suppliers, and is widely available in the country. Controlling Black Sigatoka (*Mycosphaerella fijiensis*) 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 the approval of chlorothalonil also resulted in the notification of document G/SPS/N/EU/394/Add.1 dated 12 February 2021, pursuant to which new MRLs came into force for the active substances 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 Ecuador, as well as on consumers in the EU, since 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 review by the EU.

4.203. We ask that consideration be given to the fact that the 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. Ecuador is also focused on the implementation and certification of Good Agricultural Practices (GAP), having established a public standard for that purpose, and these meet the same standards as international certifications such as GLOBAL GAP, since they are based on the following pillars: 1. Innocuousness: to deliver to the consumer a healthy, nutritious and innocuous product, without the risk that it would affect their health. 2. Worker health care: to safeguard and care for the health of farmworkers on the premises. 3. Environmental protection: to preserve and care for the natural resources of the agricultural production unit, beneficial insects, natural barriers within the farm, etc. 4. 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 definitive 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. Furthermore, Ecuador would like to ask the EU if, where emergency authorizations have been issued for the use of this substance, EU member countries have notified and justified the application of MRLs that differ from those established in the EU's existing MRL regulations. If so, which MRL is being applied by member countries and how is compliance with that MRL being monitored in intra-European trade?

4.204. The representative of Paraguay provided the following statement. Paraguay refers to its previous statements. Like other Members, we remain concerned by the EU's decision to base measures on a hazard-based approach without a proper risk analysis and without sound scientific evidence, which results in the non-renewal of substances such as chlorothalonil and the subsequent reduction of their MRLs. This would cause significant damage to Paraguay's export sector since, as we demonstrated previously, this substance and others are used as the main or complementary tool in fighting pests in Paraguay, which is a country with climatic conditions and thus pest-pressure levels that 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.

4.205. 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.

4.206. The representative of Guatemala provided the following statement. Guatemala maintains its position on this concern, especially because there is no information on scientific evidence of the possible damage to human health caused by consuming fruits and vegetables, particularly those produced in Latin America. We therefore reiterate the importance of conducting a risk analysis. Chlorothalonil is used in the production of bananas, snow peas, sugar snap peas, French beans and coffee; this active substance is 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.

4.207. 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, creating around 20,000 jobs. Guatemala's banana exports account for 30% of total exports of traditional products from the customs territory. The banana is the world's most consumed and exported fruit. Banana production has directly and indirectly created over 280,000 jobs, and any changes to the production cycle resulting from an increase in disease due to a lack of alternative substances would affect over 1,120,000 Guatemalans (*Asociación de Productores Independientes de Banano*, APIB (Independent Banana Producers' Association)).

4.208. 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 Alimentarius. Accordingly, Guatemala requests it to: (i) consider the risk assessment approach and scientific evidence; (ii) 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 because it 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 (iii) provide scientifically based information showing that vegetables and fruit exported from Guatemala or third countries are harmful to the health of European consumers.

4.209. The representative of Chile provided the following statement. Chile wishes to echo the comments made by Costa Rica, Colombia and the delegations that took the floor before me. We would like to express our ongoing concern and will continue to follow up on this matter, especially given the impact that it will have on the agricultural sector.

4.210. 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 2019/677[44], 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.[45] The conclusion[46] 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 2021.[47] The new values will apply to all food products as of 2 September 2021, since the Regulation provides for a transitional period of 6 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. As regards the joint request for the suspension of the

[44] OJ L 114, 30.4.2019, p. 15.
[45] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1489747880535&uri=CELEX:32009R1107.
[46] 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 .
[47] OJ L 46, 10.2.2021, p. 5.

processes and entry into force of reduction of Maximum Residue Levels (MRLs) of plant protection products in light of the COVID-19 pandemic in documents G/SPS/GEN/1778 and G/TBT/GEN/296 and subsequent revisions, the EU has informed WTO Members of its position in the last three WTO/SPS Committees (respectively, on 25-26 June 2020 - G/SPS/R/99, 5-6 November 2020 – G/SPS/R/100 and 25-26 March 2021 – G/SPS/R/101). In addition, the EU position is included in document G/SPS/GEN/1814/Rev.1 of 6 November 2020.

4.1.3.19 Republic of Korea - Amendments to the Act on the Promotion of Saving and Recycling of Resources, G/TBT/N/KOR/843, G/TBT/N/KOR/844, G/TBT/N/KOR/857, G/TBT/KOR/918, G/TBT/KOR/919, G/TBT/KOR/937 (ID 588[48])

4.211. 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.

4.212. 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. Specifically concerning the draft notified under G/TBT/N/KOR/919, please clarify to what the "standards" refer in Article 9 para.1(1). Additionally, please clarify if the "evaluation result document number" should also be indicated on the label. If so, please explain how this information would be relevant for consumers. The EU would also like to know why there are different entry into force dates for G/TBT/N/KOR/918 and G/TBT/N/KOR/919. Regarding G/TBT/N/KOR/937, the EU would appreciate receiving information about the exact scope of the notified draft, as well as on the justification for the measure, especially since the "Act on the Promotion of Saving and Recycling of Resources" already defines packaging rules that companies have to follow and requires administrative authorities to regularly perform post-market audits on packaging standards compliance. The new obligations appear to be quite burdensome and costly for the affected industries, and given the turnover of product portfolios, this may reduce product innovation. Hence, the EU would be grateful if the Korean authorities could share information from any study or analysis that they have commissioned on this topic.

4.213. The EU also notes that there could be space issues to accommodate the required information on small products and would like to enquire if such products could be exempted from the notified requirements. Additionally, there may be a business risk with potentially confidential product information, such as innovative product packaging, being disclosed to competitors during pre-launch inspections. Given the objective of reducing waste and use of resources, the EU is of the view that the amendment should be implemented with enough transition time to avoid a massive change of the packaging of existing products, which could inadvertently cause a waste of materials and resources. A differentiated approach would be needed between new products and products already placed on the market.

4.214. The representative of the United States provided the following statement. As we noted at the last meeting, the United States recognizes the importance for Korea to work towards reducing waste and appreciates Korea's January 2021 notification of the draft partial amendment of the Act on the Promotion of Saving and Recycling of Resources (G/TBT/N/KOR/937). We remain interested in responses to the questions raised at the February Committee meeting. In particular, we welcome an update from Korea regarding the status of the amendment and any implementing guidance, the timeline for entry into force, and further information regarding grace periods upon entry into force. We would also welcome a copy of the most recent version of the amendment and look forward to the opportunity to provide comments on any draft implementing guidance as soon as it becomes available. We also would ask that Korea, in developing new and proposed amendments to the Act, not lose sight of the potential for some materials to be recycled via exports rather than in Korea. The packaging criteria and labelling should allow for packaging classifications to be updated based on new recycling technologies, which are advancing rapidly. In its response to US industry comments

[48] For previous statements follow the thread under ID 588.

on G/TBT/N/KOR/918 and G/TBT/N/KOR/919, the Ministry of Environment (MOE) suggests that "simplified methods" such as QR codes may be allowed for more flexibility for small-capacity products. Does MOE intend to release implementing guidance? We appreciate the opportunity to provide comments on any draft implementing guidance as soon as it becomes available.

4.215. 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. Is there an update on the timeline for adoption and implementation of G/TBT/N/KOR/937? MOE states in its 29 December 2020 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." When will that three-year grace period begin? 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?

4.216. The representative of Chile provided the following statement. Chile, as indicated at previous meetings of this Committee, recognizes the right of the Republic of Korea to implement regulations that promote waste reduction and the production of easily recyclable packaging materials. The Chilean Ministry of the Environment 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, is what this measure will create.

4.217. 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.

4.218. The representative of Mexico provided the following statement. Mexico wishes to reiterate its concern with regard to the amendments to the implementing regulations of the Act on the Promotion of Saving and Recycling of Resources, notified by Korea. The doubts and comments expressed during the February meeting remain. Thus, in the interest of time, we request Korea to: provide clarification on the procedure to be followed to request the exemption of certain products from this requirement, which in this particular case, would be an exemption for tequila; and share the most recent information on the date of entry into force envisaged and the latest version of the measure, preferably in English. We thank Korea for its replies, which we will examine in detail.

4.219. In response, the representative of the Republic of Korea provided the following statement. Korea appreciates the interest of the Members in Korea's Act on the Promotion of Saving and Recycling of Resources. Korea would like to deliver the official response from the regulatory authority. Wine bottles, in accordance with the Subparagraph 3(B) of Article 5 of the Packaging Materials/Structure Grade Display Standards (Ministry of Environment Notice No. 2020-39), are 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. Korea would like to clarify that the recycling contribution (environmental) fee will be paid according to the

recycling obligation of manufacturers or importers, regardless of whether or not the labelling obligation is exempt. Therefore, wine importers are not required to mark the recyclability grades on their wine bottles, but they are required to pay the recycling contribution fee based on their duty to facilitate recycling, with additional charges when their bottles are graded "Difficult to Recycle". Korea will proceed subordinate statutes legislation for labelling guideline regarding labelling method such as exemption from labelling obligation for small sized products and QR code application, and notify the TBT Committee so as to allow for comments when the legislation is adopted. Korea will allow self-test to check packing regulation compliance according to the guideline by Ministry of Environment as well as the inspection by certified test agencies designated by MOE, which will settle the matters such as product launch delay, higher cost and information leaks that you are concerning. It is planned to grant one year of grace period to newly released products and three-year grace period to existing products considering the adaptation period of concerned business when the legislation is adopted. Korea has reviewed the comments regarding notifications G/TBT/N/KOR/918, G/TBT/N/KOR/919 and G/TBT/N/KOR/937 from the WTO Members, and we are discussing legislation amendment with the National Assembly to implement and settle the legislation regarding the pre-test and labelling of packaging. We will notify TBT the revised legislation again when the legislation is confirmed.

4.1.3.20 China - Draft Administrative Measures for Registration of Overseas Producers of Imported Foods, G/TBT/N/CHN/1522, G/SPS/N/CHN/1191 (ID 611[49])

4.220. The representative of Australia provided the following statement. Australia recognizes the right of governments to take measures necessary to protect public health, including food safety and hygiene measures. However, we remain concerned that aspects of China's "Decree 248 Regulation of the People's Republic of China on the Registration and Administration of Overseas Producers of Imported Food" (notified in G/TBT/N/CHN/1522) are more trade-restrictive than necessary to fulfill China's food safety objectives. Australia thanks China for its reply to Australia's comments to TBT notification G/TBT/N/CHN/1522. Whilst we appreciate the response received, it did not completely address Australia's concerns. Australia would still like to understand the specific food safety health concern that China seeks to address through this Regulation and China's Food Safety Law as well as the scientific justification for its application across all foods regardless of their food safety risk. Australia would like to again request that 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 would also be grateful for China to advise how Australia's and other Members' comments on its notification have been taken into account in finalising the regulation as Decree 248. Australia will carefully consider China's response to Australia's comments in detail and provide further written comments to China regarding our remaining concerns.

4.221. Australia requests that China implement this Regulation in a risk-based and proportionate manner that minimises the regulatory burden on China and other WTO Members, in accordance with China's WTO obligations. It is unclear if the new registration requirements are intended to apply equally to foreign food facilities and China-based facilities that manufacture for China's domestic market. Australia reminds China that its regulations must not be used to discriminate against imported goods and must be WTO-consistent. We are concerned that the Regulation 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. Requiring foreign food facility registration for all imported foods does not accord with a food safety risk-based approach to managing imported food. Australia does not consider this measure to be appropriate, proportionate or necessary for low risk foods. For example, Australia considers that highly processed shelf-stable foods and food storage facilities should be exempt from registration requirements, given their low food safety risk. The Regulation specifies that China must first consider the food safety management system of the exporting country as equivalent to China's before accepting any applications for registration of facilities. This would be a significant administrative burden for both China and the exporting country. Where China does recognize another WTO Member's national food control system as equivalent, it would be duplicative and unnecessary to also require individual food facilities to provide commercial documentation and inspection and audit reports. Conversely, where food facilities are already being individually registered with China, it would seem excessive and

[49] For previous statements follow the thread under ID 611.

trade-restrictive to also require recognition of food safety system equivalence. Australia again requests that China reconsider these additional administrative requirements.

4.222. Given the short timeframe leading up to the date of implementation on 1 January 2022, Australia asks that China publish any draft implementation procedures or regulations as soon as possible to enable other WTO Members to comment on the drafts, to take those comments into account and to allow businesses sufficient time to adjust to any new measures – thus ensuring minimal disruption to trade. We note that China has indicated it will provide a transition period before entry into force of Decree 248. Given the significance of the new measures outlined in Decree 248, Australia requests that China consider extending the implementation date to at least 1 July 2022 to allow time for WTO Members and food facilities to make arrangements to meet China's requirements. Australia has an established and successful history of trade in food products with China and seeks to continue this strong bilateral trading relationship. We would welcome an opportunity to engage with the competent authority of China to meet the objectives of the proposed measures while safeguarding trade.

4.223. The representative of the United States provided the following statement. The United States notes that China has published the final version of this measure as Decree 248 on 12 April 2021, with an implementation date of 1 January 2022. We remain concerned with such a trade-restrictive regulation, which does not have clear food safety and public health benefits. The measure appears to apply to all food products, regardless of risk or whether foods are already subject to additional import certification requirements. We anticipate that the measure, when implemented, will likely create major trade disruptions for the United States and every country that exports food and agricultural products to China. The United States urges China to reconsider implementation of this measure. We suggest that China utilize a risk-based approach to determine which procedures may be required for individual product groups to meet China's appropriate level of consumer protection. We request that China identify and explain which food safety risks its procedures will mitigate that are not already addressed by China's prior legislation. Furthermore, any measure of this magnitude requires far more than nine months to be implemented. Given these various concerns, we ask that China suspend or delay implementation of these measures. This measure appears to overlap with other similar measures, notably Decree 177 on the import/export of grain, and the "Administrative Measures on Import and Export Food Safety" notified to the WTO SPS Committee as G/SPS/N/CHN/1191, and recently published by China as Decree 249. How does Decree 248 relate to these other measures?

4.224. 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 notifying the draft regulation on Registration and Administration of Overseas Manufacturers of Imported Food (G/TBT/N/CHN/1522 on 16 November 2020). As this proposed measure will be affecting a wide range of our food-related industry, we expressed our concerns at the previous TBT Committee Meeting on 24-26 February 2021. In addition, detailed comments were sent to seek confirmation and clarification on 6 April 2021. Up to this date, we have not received response from China. We remain concerned with the significant impact of this measure and would appreciate an update on the status of the measure. We look forward to receiving a written response to our comments and further information on the future implementation of the measure.

4.225. The representative of the European Union provided the following statement. The EU has been following the development and consolidation of these measures carefully and commented on draft texts before and after they were notified to WTO under G/TBT/N/CHN/1522 and G/SPS/N/CHN/1191. The EU finds it regrettable that Decrees 248 and 249 were published by the General Administration of Customs of the People's Republic of China (GACC) without consideration of our comments or any reaction. China and the EU trade high volumes of food products and beverages through tens of thousands of enterprises, some big, many small. While the EU shares China's commitment to ensuring the safety and legality of trade, the administration of business registrations should support trade and avoid cumbersome procedures, where possible. Clear guidance, standardized template forms and realistic transition periods are indispensable in order to minimize disruptions to economic relationships between enterprises on both sides. Accordingly, the EU urges GACC to: develop detailed guidelines, implementing rules and template forms in cooperation with stakeholders and notify these elements through WTO channels for comment; clearly define the product categories by their HS numbers that must register under the "registration with recommendation" procedure under Article 7 of Decree 248; define the types of operations that must register. It is the EU's understanding that the exporter of consumer products must register,

i.e., the entity that is liable for guaranteeing conformity of the product with food safety standards; it is also our understanding that products shipped in bulk from business to business – such as dairy powders – are not required to register; provide for realistic and practicable implementation and transition periods of at least 18 months after detailed guidance is available. Enterprises that are already registered and listed by GACC today should be exempt from the immediate implementation of the measures. For example, enterprises approved in 2018 should remain approved for five years; ensure that once registrations are approved and registration numbers are allocated, provisions related to labelling under Article 15 be implemented with adequate transition periods. In particular, products with a long shelf life, such as spirits, may be in retail stocks for many months and must be protected by transition periods of at least 36 months.

4.226. The representative of the Philippines provided the following statement. The Philippines refers to China's proposed "Administrative Measures for Registration of Overseas Producers of Imported Foods" (Decree 248). In this regard, we have submitted comments and asked clarifications to China, first on 2 February 2021, and then again on 11 May 2021 because China had neither acknowledged receipt of those comments and questions, nor replied to them. We look forward to receiving China's response to the comments and clarifications submitted through its enquiry point. Our request is one of bare, minimum transparency so that we can understand the rationale and assess better the relevant procedures foreseen in the proposed measure. The Philippines joins other WTO Members in asking China to abide by the clear rules of the TBT Agreement and ensure that its regulations do not create unnecessary obstacles to trade and are not more trade-restrictive than necessary to fulfill its legitimate objectives. We respect China's right to regulate in order to ensure food safety. Every WTO Member has that right, but every WTO Member, including China, must also abide by its obligations in the TBT and other applicable WTO agreements. The Philippines thus asks China to explain the health and safety objectives that China seeks to achieve through the proposed measure. Does it take into account Codex risk analysis principles? Would such Codex guidance not achieve the objectives that China seeks? What are the scientific underpinnings of the comprehensive registration system that China is proposing?

4.227. We would also like to be assured that the proposed measure is intended to be enforced in an even-handed manner on both imports and domestic food producers. Non-discrimination is a core obligation in the WTO. The proposed measure must not be a disguised means to protect the domestic industry. The proposed measure will have a negative impact on food trade between China and other WTO Members. The product scope is comprehensive, and the additional administrative requirements will certainly be a burden on all exporters as well as on the competent authorities. Furthermore, the competent authority can have capacity constraints, as it will be in our case. The proposed mandatory registration will require our competent authority to vouch for all food exporters through a registration system envisioned by China, and yet its own General Administration of Customs of China, or GACC, as we understand, will undertake the same process again. It is, thus, duplicative and costly. The inefficiency is amplified if the required registration is on top of current arrangements in existing bilateral agreements that have worked well.

4.228. The Philippines' representation to the WTO in China coordinates with our commercial representations around the world. Our trade promotion offices in China informed us about the China International Import Exposition (or CIIE) and requested that the following statement be made at this meeting. The Philippines has been actively promoting trade for food products at the Philippine Pavilion at the China International Import Exposition (CIIE) in Shanghai, ever since its inaugural edition in 2018. As we were made to understand, the CIIE's primary objective was to lend credence to China's announcement that it is ready to open its market to the world and be a pillar in economic cooperation. In fact, it is the only exposition in the world that is an "import" exposition, where Chinese companies are not allowed to join as exhibitors. The government in China has fully supported and promoted the CIIE, stating that China's imports will exceed USD 5 trillion in the coming years, and that as China's new economic strategy promotes the so called "dual circulation" model, the building up of a powerful, consumption-driven domestic market will open opportunities further for trade and investments. The CIIE has helped tremendously in boosting food exports and tapping China's mainstream markets. In 2020, our booked orders for food alone at the CIIE, despite the pandemic, was close to half a billion US dollars. The hope is that the proposed changes due to China's announcement of Administrative Measures for Registration of Overseas Producers of Imported Foods will not nullify the gains made in international trade cooperation initiated by China itself through major projects such as the CIIE.

4.229. The representative of Mexico provided the following statement. The Mexican Government reiterates the concerns raised during the February meeting, which refer to the lack of clarity with respect to the products covered by the measure, additional administrative procedures for the competent authority of the country of origin, as well as information on the risk analysis that will determine the method of application for registration and documentation to be requested from each enterprise. In light of the above, the Mexican delegation once again kindly requests the delegation of China to: clarify the scope of the products covered by the Regulation, and confirm whether alcoholic beverages are included in this list of products; explain how the measures contained in the Regulation are effective and proportionate in terms of meeting China's legitimate food safety objective; share technical and scientific information, as well as 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.

4.230. The representative of Japan provided the following statement. It is highly regrettable that the regulations have been published without any responses from China to Japan's comments on TBT notification, G/TBT/N/CHN/1522. We are seriously concerned that the regulation would impose additional burdens on overseas manufacturing, processing and storage facilities and foreign competent authorities, and the implementation of the regulations would create unnecessary trade barriers and negative impact on food trade between China and WTO Members. Japan would like to underline the four points of our concerns at present. Firstly, the scope is specified in product name but not in HS code, so what food items would be affected by the new regulations have not been clarified. For example, soy sauce is mainly used as seasoning but it does not fall into China's HS code of "seasoning", 2103909000. We do not know whether soy sauce is subject to the regulation or not. Japan requests China to specify not only the product name but also the HS codes of the affected products. In addition, "foodstuffs" stated in Article 9 should be also specified in HS code. Secondly, the scope of overseas manufacturing, processing and storage companies subject to the registration of Article 2 is not clearly defined. Japan would like China to clearly state which business categories defined in the Chinese Food Safety law will be subject to the registration. Thirdly, according to the China's response to the Japan's comments, Japan understands that registration of the overseas manufacturers that have been registered before the publication and implementation of the Administrative Regulations will be valid after the implementation during their validity period. However the expiration date of the registration of manufactures is not clear. The validity period should be clarified.

4.231. Finally, it is published that the regulations will be enforced on 1 January 2022, but there is no information on the specific procedures and timeline of the registration of business operators, such as when the competent authorities of foreign countries should submit the list of business operators to China, and when China will complete registration of business operators in the submitted list and provide the registered numbers, when China will publish the name of the registered company and the registration number on the official website. Without such basic information, it is difficult for foreign competent authorities to establish domestic system and prepare to comply with the regulations. In order that the regulations do not make a negative impact on the trades between China and WTO Members, we would like China to take into consideration the comments and concerns from the WTO Members and reconsider the implementation date of the regulations. Japan would like to request China to provide sufficient transition period after providing WTO Members with necessary information on the regulation.

4.232. The representative of Brazil provided the following statement. Brazil appreciates the public consultation notified under G/TBT/N/CHN/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. The new measure 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.

4.233. 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. Brazil kindly asks China to clarify how registration for the importation of high-risk products will take place, including whether other requirements such as annual reports or inspections will be demanded. We urge China to provide reasonable transitional periods for said products and to allow for the possibility of adequate adjustment to its new regulation. We also ask China to further detail any information related to inspections and annual reports. 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 commit to also 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?

4.234. 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 seek more clarifications with regard to the product categories (by their HS codes) and the types of operations that will need to be registered. Switzerland invites China to foresee realistic and practicable implementation and transition periods as well as to adopt more detailed guidelines, implementing rules and template forms.

4.235. The representative of the Republic of Korea provided the following statement. Korea shares the concerns raised by the delegations of Australia, the EU, the United States, Chinese Taipei, the Philippines, Mexico, Japan and Brazil regarding China's "Administrative Measures for Registration of Overseas Producers of Imported Foods" (in short, the Administrative Measures). Korea believes the objective of promoting food safety is well reflected in the Administrative Measures. However, the Measures, which China has promulgated on 12 April 2021, still include the provisions of the Draft Measures notified in 2019, on which Korea and other countries have raised concerns. Therefore, Korea would like to once again ask China to address the following concerns on the Measures. (i) We ask China to provide scientific evidence that underpins its decision to expand the scope of products subject to preliminary review and registration recommendation of the exporting country's government, to include agricultural foods, special dietary foods, dietary supplements and condiments. Such requirement would impose a significant administrative burden and incur excessive time and cost on both importing and exporting authorities, resulting in unnecessary barrier to trade. Korea therefore calls on China to revise the scope and allow processed food products, which are lower in risks, to be registered via document review. (ii) According to the Administrative Measures, exporting competent authorities are required to report to the Chinese government and suspend export if hazards associated with food safety are found in food products. This measure would place an undue burden on governments of exporting countries, which merits more reflection in the implementation. 3) Last but not least, it is imperative that China clarify the relevant guidelines such as those on competent authorities' evaluation standards on exporters' food safety management system as well as on the interval of GACC's foreign manufacturer registration. Korea also calls on China to allow reasonable time for businesses to adapt to the new Regulation (G/TBT/N/CHN/1522) under Article 2.12 of the TBT Agreement. Korea looks forward to China's feedback on the comments and concerns of Korea and other Members, and reconsideration of the above-mentioned provisions in the Measures.

4.236. The representative of Canada provided the following statement. Canada would like to thank all the Members raising this specific trade concern regarding China's administrative measures for registration of overseas manufacturers of imported food. While Canada welcomes and appreciates the information provided by China on 24 May 2021 in response to comments submitted in January

2021, further clarifications are still needed on a number of elements contained in the draft regulations. This information is necessary to ensure that industry stakeholders and foreign competent authorities understand and are able to comply with the requirements. As such, Canada remains concerned that the administrative measures being implemented by China are overly burdensome and unjustified as they go beyond the extent necessary to protect against food safety risks. The new measures under Decree 248, which outline additional oversight, establishment and product registration requirements, appear to be more trade restrictive than necessary by creating unnecessary administrative delays which could impact resources throughout the supply chain. In Canada's view, if these measures are implemented as they are currently published, they will negatively impact trade and restrict food exports to China. We strongly encourage China to have open and transparent discussions with trading partners to further clarify the requirements under the new Decree and consider the impact the new measures may have on trade prior to its implementation. To further minimize any disruptions to trade, Canada would invite China to provide trading partners with information on measures, including those that are currently in place or under development, that are put in place by China to strengthening registration and supervision in a timely manner to avoid any trade disruption. 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. In light of these concerns, Canada respectfully requests that China delays implementation of the new measures for 18 months to provide a reasonable timeframe for trading partners to adjust and avoid unnecessary trade disruptions. Finally, Canada notes that our technical experts remain available to pursue further discussions on this issue in a bilateral setting.

4.237. In response, the representative of China provided the following statement. It is a clear requirement of the Food Safety Law of the People's Republic of China to improve further the administration of overseas manufacturers of imported food. Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufactures of Imported Food was published on 12 April 2021, and will come into force on 1 January 2022. This regulation optimizes the registration procedures, clarifies the duties of overseas manufactures and regulators, and improves the operation of the regulation with more relevant details, so as to facilitate the registration. It is noted that this regulation will not affect the implementation of the agreements which have already been signed with other Members by Chinese authorities, and will promote the stable trade development. On 16 November 2020, China notified the WTO the revised draft of Regulations (G/TBT/N/CHN/1522) and gave 60 days commenting period for Members. China has also given written replies to the comments from EU, USA, Canada, Philippines, Japan, Korea and Australia.

4.1.3.21 Peru - Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA (ID 618[50])

4.238. The representative of Costa Rica provided the following statement. Costa Rica wishes to thank Peru for keeping it informed about progress made in 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 previously stated, 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 March 2022. 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. The food industry has informed us about 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.

[50] For previous statements follow the thread under ID 618.

4.239. 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. At the national level, Peruvian food products sent to the Costa Rican market are able to comply with domestic labelling requirements through the use of supplementary adhesive labels, instead of having to affix permanent labels in the country of origin, exclusively for the Costa Rican market. This undoubtedly fosters trade and is proportionate to the level of protection sought. We therefore ask for reciprocity of treatment. Moreover, we note that other Peruvian instruments, such as Supreme Decree No. 007-98-SA adopting the regulations on sanitary surveillance and control of food and beverages, permit the use of stickers to meet labelling requirements, given that this is an appropriate means for the fulfillment 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 fulfill 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. In view of the above, we respectfully restate Costa Rica's wish that the Peruvian authorities remove the proposal to prohibit the use of stickers and maintain the possibility of permitting their permanent use.

4.240. 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). However, the EU importers are increasingly concerned because this deadline is now quickly approaching. EU recognize that reliable information to the Peruvian consumer is a legitimate objective. Nevertheless, the obligation to print information on the product package before the product is shipped to Peru is trade restrictive and represents a disproportionate burden for foreign producers, in particular SMEs. 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 urgent invitation to Peru to provide for a permanent possibility to use stickers. We are committed to working with Peru bilaterally on this issue.

4.241. 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 these regulations, the deadline was set for to 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 on 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 the Law on Healthy Eating, given that the warnings presented through stickers 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. Such a specific technical measure on labelling constitutes a barrier to trade, particularly for small and medium-sized enterprises. It should be recalled that most Colombian 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 one country in particular.

4.242. Furthermore, this type of measure runs counter to international labelling practice and the Codex Alimentarius approach, such as Article 8 on Presentation of Mandatory Information, 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. We welcome the bilateral talks that have taken place at different levels, and the progress reported. We request further information from the Peruvian authorities on the status of these regulations, taking into consideration that the deadline for the use of stickers is drawing near. Colombia once again

requests Peru to agree to the application of the rule allowing the indefinite use of adhesive labels or stickers with warning icons and messages on food packaging.

4.243. 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). 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. Brazil shares Peru's endeavour to ensure the highest health standards through technical regulations that help better inform consumers. Despite Peruvian legitimate concerns with deceptive practices, advances in labelling technologies allow for their safe affixation. 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.

4.244. The representative of Guatemala provided the following statement. We reiterate the recognition of Peru's right to protect people's health and to provide consumer information on foods. In accordance with the Agreement on Technical Barriers to Trade, relevant international standards where they exist will be used to avoid unnecessary obstacles to international trade. As raised in previous meetings, CODEX CXS 1-1985, General Standard for the Labelling of Pre-packaged Foods, states that a supplementary label may be used on imported products that do not comply with Peruvian regulations, which must accurately reflect the information on the original label. Peru is again requested to reconsider the use of a supplementary label, given that its use is widely recognized internationally, as it fulfills the same public health protection and consumer information purposes. Regarding the points made to Peru at previous meetings on Supreme Decree No. 015-2019-SA, Guatemala's position remains the same.

4.245. The representative of Paraguay provided the following statement. Paraguay has received comments from its industries through the Chamber of Paraguayan Food Businesses, which highlight the negative effects that could be generated by the limitations on the use of supplementary labels to be adopted by this measure. As other Members pointed out at the previous meeting, the use of supplementary labels is widely recognized at the international level and is a valid option for industries to adjust to the specific requirements of different markets, bearing in mind the main objective of these labels, which is to provide consumers with clear information and meet regulators' requirements. Paraguay supports Peru's objective of protecting public health and considers that the provision of information to consumers through the label is an appropriate strategy. However, we share and support the concerns expressed by other Members with regard to the time limit established for the use of supplementary labels, since this may be more trade-restrictive than necessary, and we therefore urge Peru to reconsider this measure and bear in mind the provisions of Article 2.2 of the TBT Agreement, which specify: "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 fulfill a legitimate objective, taking account of the risks non-fulfillment 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." We thank Peru for the information received regarding a further extension of the grace period and while we appreciate this decision, it shall not solve the underlying problems that our exporters will face. We therefore request that Peru review this measure.

4.246. 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 the country's international trade commitments in this domain. In this connection, Peru is seeking to ensure that the information contained in the Manual

of Advertising Warnings (MAP) 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, 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 MAP under Law No. 30021 on the promotion of healthy eating among children and adolescents, is permitted until 30 June 2021. However, in the light of the concerns expressed by some Members, Peru is currently making the relevant final arrangements in order to further extend the period during which the use of adhesive labels is permitted. 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.

4.1.3.22 European Union - Non-renewal of the approval of the active substance mancozeb (ID 627[51])

4.247. 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. We have already referred to the importance of this substance in plant protection on previous occasions. On this occasion, we would like to ask the EU to provide clarification on the relationship between the notification in document G/TBT/N/EU/712 on mancozeb and the notification in document G/TBT/N/EU/797 regarding the REACH regulation, with respect to carcinogenic, mutagenic and toxic for reproduction substances. We would also like to recall that, 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.

4.248. 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". The information available indicates that 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. 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.

4.249. The representative of Costa Rica provided the following statement. Costa Rica wishes to express its support for the concern raised by Paraguay, Brazil, Australia 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 and 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.

[51] For previous statements follow the thread under ID 627.

4.250. 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 maximum residue levels (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 a alternative substance so that Costa Rican farmers can continue to grow bananas and export the volumes required to meet the EU market demand.

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

4.252. The representative of Paraguay provided the following statement. Paraguay refers to its past 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 conclusive scientific evidence, which resulted in the reduction of the MRL for and the non-renewal of mancozeb. The loss of mancozeb as a plant protection tool would cause significant damage to Paraguay's export sector. As we have stated, 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, which is a country with climatic conditions and thus pest-pressure levels that 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.

4.253. 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. 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 will significantly impact the income of Brazilian farmers. 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 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 align MRLs with limits established under the framework of Codex Alimentarius and to less trade-restrictive alternatives that would also safeguard its legitimate policy objective.

4.254. The representative of Ecuador provided the following statement. We thank Australia 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 throughout the world for a wide range of strategic crops, many of which are produced by Ecuador and imported into the European Union (EU), e.g. bananas, cocoa, broccoli, pineapples, pitahayas, mangoes and cape gooseberries. This compound is crucial for pest management because, due to the tropical climate in countries like Ecuador, pest behaviour follows patterns that are very different from those prevailing in countries with four seasons such as those in the EU, meaning that chemical pesticides for agricultural use with the active ingredient mancozeb are vital for agricultural production. Prohibiting the use of mancozeb could have a very significant economic impact on small-, medium-, and large-scale producers in Ecuador, as well as on consumers in the EU, because the supply of our products would be affected. Due to the way in which this substance is applied in banana production, the use of mancozeb is the most effective and environmentally friendly phytosanitary control method for Black Sigatoka. Black Sigatoka is considered to be the most destructive foliar disease for banana and plantain crops; it is thought to pose the highest economic risk for such crops and can cause yield losses of up to 50%. There are currently no approved and properly registered alternatives to this substance that are as effective as mancozeb.

4.255. In Ecuador's view, it is vital that studies concerning the renewal of active substances be based on scientific evidence and conclusive data, and not only on the precautionary principle. Ecuador refers to Article 2.2 of the WTO TBT Agreement, which states that "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. […] 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". 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 information relating to this substance.

4.256. EFSA decided not to approve the renewal of the use of the active ingredient mancozeb, classifying it in "toxic for reproduction" category 1B, and considers it to be an endocrine disruptor in humans and non-target species; however, given the reproductive toxicity hazard profile of mancozeb, it would be more appropriate to classify it in "toxic for reproduction" category 2, or even to refrain from classifying it. The toxicity classification of mancozeb must be decided on the basis of the active ingredient, and the studies to be taken into account must comply with the analytical and procedural rigour required by European regulations. Moreover, mancozeb does not produce adverse effects in experimental species of mammals or humans in doses/concentrations lower than those at which it might be expected to see effects as a result of systemic toxicity. Mancozeb has an effect on the thyroid hormonal system in a number of mammal species; however, thresholds and reversibility have been demonstrated. On the basis of the foregoing, mancozeb should be classified as "toxic for reproduction" category 2, and it is not a significant endocrine disruptor in humans. Ecuador requests the EU to renew its approval of the use of mancozeb and to maintain its maximum residue levels (MRLs) as a risk management measure to ensure and protect the health of consumers in the EU and avoid possible effects on trade. The ban on mancozeb and the subsequent reduction of MRLs for this substance in the EU, would leave farmers in countries such as Ecuador without any phytosanitary tools for programmes aimed at managing and controlling Black Sigatoka (a pest of economic importance) and would prevent resistance, which would have very unfortunate consequences for the environment and the economic sustainability of banana crops, as well as social implications, bearing in mind that in Ecuador this sector generates between 2 million and 2.5 million jobs for workers at various stages of the value chain.

4.257. Ecuador also wishes to express its concern about the lack of effective alternative pest-control substances, which would exponentially affect to an even greater degree the country's agricultural exports, especially given the impact of the current world health situation (COVID-19). We should remind the EU that Ecuador was part of a group of 39 WTO Members that, in 2020, called upon the EU to temporarily suspend processes related to the review of authorizations for the marketing and use of plant protection substances, and their entry into force, in the context of COVID-19, a disease that continues to claim thousands of lives throughout the world. For these reasons, Ecuador calls upon the EU to consider alternative measures that are less trade-restrictive, to identify substitute substances that enable existing trade to continue, to base its measures on conclusive studies, not only the precautionary principle, and to establish transition periods of at least 36 months for the

registration of alternative substances, in view of the current shortage of tools available to control pests.

4.258. The representative of Panama provided the following statement. The delegation of Panama reiterates its concern regarding the non-renewal of mancozeb. The active substance mancozeb is vitally important for the country's main crops. Its specific mode of action means that it is irreplaceable in the control of black sigatoka, which is the main pest in tropical crops. I would like to reiterate that there are no other active ingredients available to replace mancozeb, leaving the industry without any phytosanitary tools and thereby having a severe impact on Panama's exports to the European Union. Panama recognizes the right of Members to determine the appropriate level of sanitary or phytosanitary protection necessary to protect human, animal or plant life or health, yet such measures must be science-based and should not create unnecessary barriers to trade. In the light of the foregoing, Panama once again requests that the EU postpone the non-renewal process for the MRL for mancozeb.

4.259. The representative of Guatemala provided the following statement. Guatemala maintains its position on this concern because there is no information on scientific evidence of the damage to human health that might be caused by consuming fruits and vegetables, particularly those produced in Latin America. The European Union has mentioned on previous occasions that it has identified potentially negative effects on health, without bringing scientific evidence to the discussion table. It has failed to provide countries 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 maximum residue levels, which will have a direct impact on agricultural exports from countries with tropical climates 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 (including bananas and plantains) and vegetables, which would affect other Latin American countries. 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.

4.260. 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 a negative social and economic 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 crops provide over 280,000 direct and indirect jobs, thereby affecting more than 1,120,000 Guatemalans. Banana exports for Guatemala account for 30% of total exports of traditional products 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 European Union to maintain the current maximum residue levels for mancozeb so as to avoid affecting the production and exports of Guatemala and other Latin American countries, particularly given the economic and social impact that this type of measure will have on developing countries. We reiterate the request set out in documents G/SPS/GEN/1778 and G/TBT/GEN/296, especially given the ongoing COVID-19 situation.

4.261. The representative of Chile provided the following statement. Chile appreciates the opportunity to once again point out to the EU that the notified measure, as indicated by previous delegations, will create an unnecessary obstacle to the trade of our agricultural export sector.

4.262. The representative of Uruguay provided the following statement. Mancozeb is an active substance that is authorized and widely used in a safe manner in Uruguay for the control of diseases and pests in various national fruit and vegetable sector products, including apples, pears and citrus fruits. It is particularly important for the control of apple and pear scab, which is the main disease affecting apple and pear production and is caused by fungus of the genus *Venturia* spp. In this connection, we support the concerns and requests raised by other delegations, particularly with respect to the possibility that the EU may significantly reduce the corresponding maximum residue

levels, even lowering them to the limit of determination, without having any conclusive scientific evidence that substantiates such a decision in line with the WTO SPS Agreement. Against this backdrop, like other Members, Uruguay recalls the importance of taking due account of international standards, guidelines and recommendations and the scientific information produced by international standard-setting bodies recognized at the WTO, such as the Codex Alimentarius.

4.263. 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 authorizations and the grace period have been extended, when compared to the original proposal, in order to accommodate requests.

4.264. Following non-approval and the expiry of all grace periods for stocks of products containing this substance, separate action on Maximum Residue Levels (MRLs) may be taken and a separate notification will then be made in accordance with SPS procedures. The EU would like to inform Members that EFSA has recently started a review of the existing MRLs for dithiocarbamates (group of which mancozeb is part). Interested parties are invited to actively contribute with relevant information to this MRL review through the main authorization holder, as described in document G/SPS/GEN/1494/Rev.1.[52] For advice on alternatives to mancozeb, the EU pesticides database[53] is publicly available and contains information on all active substances, their approval status and their main purpose (e.g. fungicide, insecticide or herbicide). As regards the joint request for the suspension of the processes and entry into force of reduction of Maximum Residue Levels (MRLs) of plant protection products in light of the COVID-19 pandemic in documents G/SPS/GEN/1778 and G/TBT/GEN/296 and subsequent revisions, the EU has informed WTO Members of its position in the last three WTO/SPS Committees (respectively, on 25-26 June 2020 - G/SPS/R/99, 5-6 November 2020 – G/SPS/R/100 and 25-26 March 2021 – G/SPS/R/101). In addition, the EU position is included in document G/SPS/GEN/1814/Rev.1 of 6 November 2020.

4.1.3.23 Kingdom of Saudi Arabia - Technical Regulation for limiting and restricting hazardous materials in electrical and electronic equipment, G/TBT/N/SAU/1166 (ID 666[54])

4.265. The representative of the United States provided the following statement. The United States reiterates its concerns regarding the Kingdom of Saudi Arabia's emergency notification of its "Technical Regulation for the Restrictions of Hazardous Substances (RoHS)," which noted an adoption date of 7 January 2021. We thank Saudi Arabia for sharing its updated draft of the RoHS regulation with the United States on 23 March through the WTO TBT Enquiry Point. We encourage Saudi Arabia to fully take into account comments from interested stakeholders before finalizing the measure. Does Saudi Arabia have an update on when it intends to finalize the regulation? In its notification, Saudi Arabia noted that the measure would enter into force six months from the "date of publication". Does the "date of publication" refer to the 1 December 2020, date of the notification, or a future date on which the finalized measure will be published? We request a reasonable interval for implementation of no less than six months from the date the finalized measure is published to allow time for industry to adapt to these new certification requirements. The Type Approval Conformity Assessment testing and certification regime and factory certifications laid out in the draft regulation raise concerns regarding the feasibility of the procedures and whether the measure has the effect of creating unnecessary obstacles to trade. The United States requests that Saudi Arabia

[52] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-review_en.pdf
[53] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en
[54] For previous statements follow the thread under ID 666.

clarify these requirements and avoid creating any duplicative or unnecessarily trade restrictive conformity assessment requirements.

4.266. According to the draft regulation, producers must send documentation proving compliance, as well as samples of all models of their products, to a SASO-approved conformity assessment body to undergo a conformity assessment procedure as outlined under ISO/IEC 17067. How does SASO envision that conformity assessment bodies will be able to carry out the mandated Type Approval Conformity Assessment on fully assembled electrical and electronic equipment (EEE) given that doing so would require disassembling the product for testing? Further, what EEE parts does SASO consider to be "risky" as mentioned in the regulation? The US stresses that Suppliers Declarations of Conformity as described under ISO 63000 are the usual proof of compliance for RoHS-type regulations due to the need for producers to gather proof of compliance from their numerous parts and materials suppliers. The US requests that Saudi Arabia accept Suppliers Declarations of Conformity as proof of compliance with the RoHS procedures. US industry has also raised concerns that the amount of documentation required in the measure is more extensive than necessary and may require companies to divulge confidential business information without explaining how such information will be protected. Can Saudi Arabia provide specific guidance on what information will be required in product filings and other administrative measures and how confidential business information will be protected?

4.267. The draft regulation requires ISO 9001 or equivalent certification for factories. Can Saudi Arabia clarify which factory in the manufacturing supply chain this certification refers to, as there are numerous parts in electrical and electronic equipment which are assembled by different manufacturers? We understand from SASO that the exemptions have been expanded to include exemptions under EU RoHS Annex III. We ask that the exemptions be further expanded to include exemptions under EU RoHS Annex IV for measuring and controlling instrumentation and equipment. We also ask that Saudi Arabia update the exemptions in the future to adopt additional exemptions that may be added to the EU RoHS, such as uses of the four phthalates added as exemptions to EU RoHS II. Particularly concerning for the toy industry is a deviation from EU RoHS, which changed the conformity assessment requirement from a self-declaration of conformity to having to provide a certificate of conformity to SASO. Can Saudi Arabia clarify which standards the compliance certificates are based on?

4.268. The representative of the European Union provided the following statement. The European Union would like to reiterate its concerns regarding the draft Technical Regulation for Restriction of Hazardous Substances, notified by Saudi Arabia on 1 December 2020 would like to refer to its written comments of 30 March 2021. According to information provided by the Saudi Standards, Metrology and Quality Organisation (SASO), the technical regulation was adopted on 28 January 2021. Could Saudi Arabia confirm the status of the text and share the date of its publication and expected entry into force? Saudi Arabia mentioned in the last Committee that SASO is considering to review some aspects of conformity assessment and the European Union noted the public consultation published on 7 April 2021. Could Saudi Arabia explain the purpose of this public consultation? Is SASO considering further changes to the Technical Regulation for Restriction of Hazardous Substances, including a new notification to the TBT Committee?

4.269. The European Union would like to recall the following concerns. The notified text requires a mandatory third-party conformity certificate, issued by a conformity assessment 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 to businesses. The EU therefore would like to invite 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 know whether conformity assessment bodies not established in Saudi Arabia could be approved by SASO and under which conditions. The EU would also like to invite 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, even if accompanied by the possibility for suppliers to circulate the products that are not fulfilling the requirements of that regulation, for a maximum of one year from the date of publishing of the notified text, would not allow companies sufficient time to prepare for the conformity assessment procedure proposed in the notified text, which differs significantly from European Union practice. In that respect, a transitional period of at least 18 months would be necessary. The notification message for 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 it covers the same products as those covered by 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).

4.270. Whilst we notice the definition of "homogeneous substance" in the notified text, the EU would also like to seek clarification whether the "allowed percentages" of the restricted substances listed in Annex (1.b) of the notified text are to be applied by weight in homogeneous materials as prescribed in Annex II to EU RoHS. More specifically, we would seek clarification whether the "allowed percentages" are to be applied to homogeneous materials/components of electrical and electronic equipment as it is the case in the EU, or to the electrical and electronic device (as defined in the notified text) as a whole. The EU notices that the exemptions in the notified text are not the same as the exemptions included in the Annex III of the EU RoHS. This is significant as the electronics supply chains are global. The EU would also like to seek clarification whether Saudi Arabia plans to align to the future exemptions under the EU RoHS and/or whether Saudi Arabia intends to lay down an exemptions granting mechanism in their legislation. Finally, the EU would like to know what is the relationship between this notified text and the draft Gulf Cooperation Council for the Arab States (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 those in the GCC related text? 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 remains available to discuss this issue with Saudi Arabia bilaterally.

4.271. The representative of Japan provided the following statement. Japan expresses appreciation for the amendment that reflects part of Japan's concerns such as designation of exemptions in the new draft Technical Regulation for Restriction of Hazardous Substances in Electrical and Electronic Equipment (EEE). However, Japan continues to have the following concerns. 1. The Kingdom of Saudi Arabia explained in the last TBT Committee that it chose to apply the international standard ISO/IEC 17067, which is type approval, for granting certificates of conformity. However, Japan understands that it is not feasible for both conformity assessment bodies and manufacturers because thousands, to tens of thousands, of homogeneous materials are contained in one EEE and the test is required to be conducted for each homogeneous material. It would require a tremendous increase in workload and cost to do so. Japan would like to request that the manufacturer's self-declaration of conformity based on the international standard IEC63000 be accepted. Or, Japan would like to request that a more flexible and feasible method be accepted during the reviewing period for conformity assessment that the Kingdom of Saudi Arabia mentioned in the last TBT Committee meeting. 2. Japan would also like to request that the technical regulation exclude EEE and its repair parts and consumables for those EEE already on the Saudi Arabian market before the entry into force of the regulation. It would be impossible for manufacturers to manage products that are already on the market. Also, since batteries have already been regulated by the Technical Regulations on the General Safety of Electrical Batteries which was published on 21 December 2018, Japan would like to request that batteries be excluded from the regulation in order to avoid double regulation. 3. In addition, in order to properly and fully implement the technical regulation, Japan would like to request publication of a detailed guidance and at minimum a one-year of grace period after publication of the guidance.

4.272. The representative of China provided the following statement. In this regulation, suppliers need to obtain a conformity certificate (Type 1a) from an approved certification organization. In order to respond to the testing report requirements described in the notified regulations, a full product testing report is needed, which means that companies need to test every single component, at the homogenous material level, which is extremely time-consuming and resource-consuming. On the contrary, the international standard IEC 63000 allows manufacturers to work with their supply chains to compile technical documentation as evidence of compliance, which is a common procedure or method for restrictions on hazardous substances implemented and accepted by international community. Therefore, it is recommended that the conformity assessment procedures would comply with current global practices, and the preparation of technical documents would comply with IEC 63000. Article 4.4 of the European directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EU-RoHS) provides exemptions for the cables and spare parts for the repair, the reuse, the updating of functionalities or upgrading of

capacity of the equipment which have been placed on the market before the applicable date of the Regulation. The purpose of these exemptions is to extend the lifetime of the equipment and it is therefore beneficial to the environment. It is recommended that Saudi Arabia includes such exemption in the upcoming RoHS regulation.

4.273. The application scope of the draft regulations of this notification is electrical and electronic equipment, but the batteries and accumulators (HS code 8506 and 8507) are included in Appendix 2-b. Based on the differences between batteries and electrical and electronic equipments, and taking reference of the current management and control on batteries and electrical, electronic equipments across the world, it is recommended that batteries and accumulators are excluded from the scope of this regulation. Regarding the allowable percentage of hazardous substances in electrical and electronic equipments or devices specified in Appendix (2), many materials (copper alloys, steel alloys, and high-temperature solders, etc.) are currently unable to meet the limitation requirements in the regulations due to immature technology or no alternative materials. It is recommended to refer to Annex III of the EU Directive 2011/65/EU (RoHS) or the "Exemption List for Application of Restricted Substances in the Compliance Management Catalogue" issued by the Ministry of Industry and Information Technology of China to clarify the corresponding exemptions. It is recommended to clarify the qualification of laboratories, and publish the list of eligible laboratories. In view of the impact of COVID-19, we suggest the transitional period for the implementation of the regulations to be extended from six months to 18 months.

4.274. The representative of the United Kingdom provided the following statement. The United Kingdom would like to thank the Kingdom of Saudi Arabia for their engagement to date on notification G/TBT/N/SAU/1166, which sets out technical requirements for the restriction of hazardous substances in electrical and electronic equipment. The United Kingdom fully supports the Kingdom of Saudi Arabia's endeavours to protect human health. However, we still encourage the use of self-declaration for product conformity, combined with requiring manufacturers to appoint a local "authorised representative" accountable to authorities for product compliance. This would reduce costs and technical and administrative burdens for industry, facilitate trade in support of the Kingdom of Saudi Arabia's Vision 2030 strategy, provide good product compliance governance, and align with international best practice on the proportionate risk management for these products. The United Kingdom remains concerned that the transition time between adoption and entry into force is too short for industry to adjust to the conformity assessment procedures. We understood that the Kingdom of Saudi Arabia was considering an extension to the transition period. We would welcome further information on these deliberations. 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 seeks further information on the health problems detected by the National Surveillance Authorities which justified notification of this measure as urgent, under Article 2.10 of the TBT Agreement. 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.

4.275. 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 remains concerned that these requirements may have a negative impact on trade for a wide range of products. The testing and certification requirements seem to deviate from the internationally accepted RoHS requirements, which are also used in Switzerland and elsewhere in Europe. These widely accepted best practices include supplier's declaration of conformity and technical documentations aligned to the appropriate relevant international standard (ISO 63000). We encourage the Kingdom of Saudi Arabia to consider less trade-restrictive alternatives and take these best practices into account. Finally, we call on the Kingdom of Saudi Arabia to allow for a sufficient implementation period so as to allow the industry to adapt to these new requirements. Switzerland looks forward to further engaging with the Kingdom of Saudi Arabia on this topic.

4.276. The representative of Canada provided the following statement. Canada would like to support the points made by other delegations today and refer to its statement from the February 2021 TBT Committee as noted in paragraphs 2.25 and 2.26 of the minutes of that meeting.

4.277. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia would like to express appreciation for the concerns addressed by the European Union, the United States, Japan, China, the United Kingdom, Switzerland, and Canada and for their valuable comments on this matter. Saudi Arabia aims to protect 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. Consequently, we would like to clarify the following: Saudi Arabia has notified the measure in December 2020 and received comments until May 2021. Currently, in the process of publishing the regulation in the Official Gazette. The transitional period set at 180 days after publishing the regulation in the Official Gazette for Manufacturers to take corrective actions. Saudi Arabia has aligned the last version of the Saudi Technical Regulation with global practices such as EU RoHS Directive. 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. Moreover, the test report is considered valid unless there is any change in the type of materials used during the manufacturing process. In case it is not possible to perform the test on the entire product, the critical components of the device must be tested, which are determined by the manufacturer based on the risk assessment and documents assessing the risk of those components on the final product in accordance with the standard IEC 63000.

4.278. SASO develops conformity assessment activities (certification, audit and inspection, and testing activities) in Saudi Arabia to be one of the tributaries that raise the level of quality in the national industry and the safety of imported goods presented in the Saudi market, by accepting the conformity assessment bodies in the various conformity assessment activities. This process aims to ensure the efficiency of the outputs of the accepted conformity assessment bodies operating in the conformity verification activities within the systems and requirements of the technical regulations approved to provide the necessary activities according to the scopes of acceptance of these bodies. Therefore, SASO chose to engage a notified third-party responsible for granting conformity certificates in accordance with the international standard ISO/IEC 17067 as part of the Kingdom pre-market approach. The technical regulation requirements for Restriction of Hazardous Substances in electrical and electronic equipment are in line with international practices. Therefore, the transitional period set at 180 days after publishing the regulation in the Official Gazette is sufficient to fulfill all requirements.

4.1.3.24 India – Draft Food Safety and Standards (Import) Amendment Regulation, 2020, G/TBT/N/IND/180 (ID 667[55])

4.279. 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 providing Members with the opportunity to comment on this proposed regulation. While we fully support India's objective to ensure the safety of imported food products, we also urge India to observe the principle of transparency in relevant implementing measures of this regulation. Our comments on this proposed regulation were sent to India on 30 December 2020, which sought clarification of a number of points regarding the categories of food to be covered. We look forward to the response from India.

4.280. The representative of the European Union provided the following statement. The European Union would like to highlight its strong concerns with this Indian measure. Many questions for foreign food manufacturers and competent authorities remain unanswered, which would create an unpredictable trading environment. Most importantly, the proposed standards appear much more trade restrictive than necessary to fulfill the intended food safety objectives. We sent you written comments and are still waiting for a written reply. I want to highlight our main elements of concern. The transition period is too short and should be extended to 18 months. India should further clarify the scope of products/food categories. 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. Inspections and audit of foreign food manufacturing facilities as well as registration need to be clarified and simplified.

4.281. The representative of Mexico provided the following statement. Following up on the concern raised about this measure in the TBT Committee in February 2021, the Government of Mexico reiterates the importance of the delegation of India providing more clarity on the products subject

[55] For previous statements follow the thread under ID 667.

to this Regulation and confirming whether alcoholic beverages are part of this list. It will also be important to know the risk-based procedure that will be followed to determine the products covered. 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 product categories or types of products that will be subject to compliance, as well as information on how the on-site inspections or visits will be conducted, and on the entry into force and the current status of this Regulation.

4.282. The representative of the United States provided the following statement. The United States remains concerned with 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. The United States raised this issue at the TBT Committee meeting in February 2021, and India responded that it was reviewing comments received. The United States wishes to reiterate our main concerns, and we ask that India please provide a more detailed response and update on the status of the proposed regulation. 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 lack of detail regarding 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 an updated list of food products included in such "risk" categories? Will stakeholders have an opportunity to submit comments on these categories or appeal risk determinations? Could India please clarify what is meant by "from time to time"? Does India intend to undertake regularly scheduled systematic reviews of food categories? Finally, we ask that India please provide clarity regarding its inspection and audit procedures, including who is financially responsible for a food facility's audit expenses, and a proposed timeline when audits are first required to take place.

4.283. The representative of Japan provided the following statement. Japan shares the concerns on India's proposed draft amendment regulation on food safety and standards. While the regulation would impose additional burdens on business operators who export to India, there are many unclear points yet to be sufficiently explained by India including definitions of "food manufacturing facility", scope of "food" subject to the draft regulation, and registration procedure of the facility inspection and audit. Japan would like India to make TBT and SPS notification and provide WTO Members with the opportunity to make comments on the detailed regulation regarding the scope of food, the registration procedure of facilities and so on. Furthermore, Japan underlines the importance to have sufficient transition period before the implementation of the new rules. Japan consider that 180 days transition period from publication in the Official Gazette is not enough. Japan recommends that this period be extended more than 18 months. Japan would like to urge India to address the concerns and comments from Member countries appropriately so that the proposed new rule would not create unnecessary trade barriers.

4.284. 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 fulfill 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 regulations apply are lacking. Australia is concerned that the proposed measures may not be linked to the risks posed by the imported food. Australia respectfully requests that India recognize the domestic and export regulatory systems of foreign countries, where the system meets equivalent outcomes, in order to reduce duplication in regulatory requirements for producers and ensure government resources are used efficiently to protect consumer health. 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. Australia is grateful for productive discussions held with India earlier this year and recognizes India's commitment to reviewing comments provided in written submissions.

4.285. The representative of Canada provided the following statement. Canada would like to reiterate concerns raised at the February 2021 TBT Committee Meeting regarding India's draft amendment to its Food Safety Standards (Import) Amendment Regulation 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, a number of elements contained in India's proposed order remain ambiguous. Canada would appreciate further details on the target commodities, source-countries, implementation plan, audit rates, compliance actions, and appeals. Specifically, it is unclear what criteria would be used to determine the level of risk for food products imported into India, 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. Further information is also 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. Canada would appreciate if India could confirm its understanding that the measure would apply only to processed products and not to bulk/fresh/caught products such as pulses, horticulture products such as fresh cherries, and fish and seafood products.

4.286. Canada also requests further clarification on whether low-risk foods will be required to meet FSSAI's registration and inspection requirements. In this regard, Canada suggests a risk-based approach which would exempt foods with low food safety risk such as alcoholic beverages. We look forward to receiving responses to our comment letter submitted to India's Enquiry Point on 21 January 2021. 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.

4.287. The representative of Argentina provided the following statement. Argentina wishes to reiterate the concerns raised during the previous meeting of the Committee. As we have already stated, my country has a number of doubts about giving effect to and implementing 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 duly submitted through India's TBT Focal Point and we are yet to receive the corresponding clarifications. We hope to receive them as soon as possible and also hope that this new standard does not become an unjustified restriction, in order to ensure that trade with India, a highly important trading partner for our country's agricultural sector, is not affected.

4.288. In response, the representative of India provided the following statement. We thank the Members for their continued interest in the issue. At this time, the comments received from various stakeholders are being examined.

4.1.3.25 Russian Federation - Draft Technical Regulation on Alcohol Drinks Safety (published on 24 October 2011), G/TBT/N/RUS/2 (ID 332[56])

4.289. The representative of the European Union provided the following statement. In 2012, the Russian Federation notified a draft technical regulation on safety of alcoholic products to be adopted by the Eurasian Economic Union. An updated version was adopted in December 2018 and initially supposed to enter into force on 9 January 2021, however postponed to January 2022. 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 EU took the opportunity of the ongoing revision process of the Eurasian Economic Union Technical Regulation 047/2018 "On the safety of alcoholic products" and submitted on 19 May to the Eurasian Economic Commission a series of drafting proposals. The Russian Ministries of Agriculture, Finance and the Economic Development have also been informed. In light of transparency and considering the trade implications of this regulation, we understand that the revised draft technical regulation will be subject to public consultation and that it will be notified to the WTO under the TBT Agreement.

4.290. We have based our amendments on both the original text of the technical regulation as well as the draft amendment as proposed by the Ministry of Finance of the Russian Federation. We are

[56] For previous statements follow the thread under ID 332.

firmly convinced that the EU proposal, the focus of which is to better align some provisions with international standards and practices for alcoholic products, as well as WTO obligations, would ease the implementation and enforcement of the technical regulation by all operators, facilitate international trade of alcoholic products both ways, and, thus, contribute to the goal pursued by the Eurasian Economic Commission through this text. 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.

4.291. In response, the representative of the Russian Federation provided the following statement. We appreciate the European Union's interest in the Russian Federation and EAEU's regulatory policy. The provisions of the EAEU Technical Regulation on Alcohol Drinks Safety are in full compliance with the Russian and other EAEU members' obligations in the WTO. As stated previously on various occasions, this Technical Regulation does not set any requirements for ensuring protection of intellectual property rights and is not aimed at implementation of the Agreement on TRIPS. In this regard, we do not see any reason to notify this legislation to the Council for TRIPS. As rightly mentioned by the European Union, the EAEU Technical Regulation on Alcohol Drinks Safety was adopted in December 2018 and is supposed to enter into force in January 2022. Despite the fact that the Technical Regulation has not entered into force, draft amendments based on numerous requests from various stakeholders have been prepared by the Russian side and made available on-line for national Regulatory Impact Assessment. After this procedure is finished at the national level, draft amendments will be forwarded to the Eurasian Economic Commission for consideration. Having been preliminary considered at the Eurasian Economic Commission, the draft will be posted for public consultations, notified to the WTO under the Agreement on TBT and will be available for comments of WTO Members.

4.1.3.26 European Union - Draft Implementing Regulations amending Regulation (EC) No. 607/2009 laying down detailed rules for the application of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products, G/TBT/N/EU/44, G/TBT/N/EEC/264, G/TBT/N/EEC/264/Add.1, G/TBT/N/EU/570, G/TBT/N/EU/571 (ID 345[57])

4.292. The representative of the United States provided the following statement. It is very disappointing that the United States must again raise its concerns with the European Union'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 raise this issue here again at the WTO TBT Committee, as well as most recently at the WTO Council for Trade in Goods in March 2021. 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 three years? What does the EU mean when it said "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.

4.293. 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, and February 2021 TBT Committee meetings, please tell us the following: how many applications for traditional terms have been lodged over the last 11 years; how many of those applications have been approved, rejected, or remain pending; what is the average time between application and a final decision; for pending applications, how long have they been waiting; and how many of the applications have come from member States? 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.

4.294. 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

[57] For previous statements follow the thread under ID 345.

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 US/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.

4.295. 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 the October 2020 TBT Committee, and those preceding it. 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.

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

4.297. 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.

4.1.3.27 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/44/Add.10, 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 367[58])

4.298. The representative of the United States provided the following statement. We thank India for taking into account US industry's request that India extend the enforcement period of Phase V of the Compulsory Registration Order (CRO) for electronics and information technology goods by six months to provide industry with the necessary time to adapt products and methods of production to comply with India's CRO requirements. We understand that US industry has expressed concerns that, although India provides six months for industry to comply upon the announcement of each new CRO phase, these announcements do not include the necessary resources and guidance for compliance. Specifically, announcements of each CRO phase thus far have lacked the following necessary resources and guidance, which India has not provided until weeks after the announcement: (i) product series guidelines and FAQs from MeitY; (ii) the new Test Report Format from the Bureau of Indian Standards (BIS); (iii) a BIS portal for submitting applications; and

[58] For previous statements follow the thread under ID 367.

(iv) 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 future Phases, we ask that MeitY provide a transition period of one year, but no less than six months, from the date on which all four of the necessary resources and guidance listed above have been made available.

4.299. The representative of Canada provided the following statement. Canada welcome the delay in the entry into force of the measure, from 1 April to 1 October 2021, as confirmed by India's WTO notification G/TBT/N/IND/44/Add.10 of 22 April 2021. While Canada recognizes the challenges the COVID-19 pandemic poses to India, we note the difficulty firms face in quickly adapting to changes in requirements and seek India's agreement to provide ample time for exporters to modify their procedures. Canada continues to urge India to adopt IEC standards and to recognize test results from internationally accredited labs. As noted in previous meetings, Canada remains concerned by the Compulsory Registration Order, for the following reasons: it requires product testing be done only by Bureau of Indian Standards-accredited labs located within India; it does not allow for the use of international standards; and it does not recognize test results from internationally accredited labs.

4.300. In response, the representative of India provided the following statement. The Ministry of Electronics and Information Technology (MeitY) has notified seven product categories under the phase V Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order (CRO) on 1 October 2020, which is scheduled to be effective from 1 October 2021. The BIS is granting the registrations in consultation with MeitY. Product series guidelines from MeitY are already issued and available on the MeitY website.[59] The test report formats have been issued and are available on the BIS website.[60] Provision for submission of application for Phase – V on BIS portal is already made. The number of laboratories recognized by the BIS for all the products under phase 5 of CRS is as under: Wireless microphone: 28 Labs; Digital Camera: 30 labs; Video Camera: 29 Labs; Webcam (Finished Product): 27 Labs; Smart Speakers (with and without Display): 29 Labs; Dimmers for LED products: 01 Lab; Bluetooth speakers: 26 Labs.

4.301. *Relevant weblinks*: The details are available on the BIS website www.bis.gov.in under the following tab: Laboratory Services << Test Facilities and Testing Charges<< IS- Wise Test Facilities In BIS LAB /Recognised Labs.[61] The test reports formats for phase 5 products have been issued and are available on the BIS website under the following tab: Laboratory Services<<Uniform Test Report Formats to be used by Recognised Laboratories for issuing test reports under Compulsory Registration Scheme.[62]

4.1.3.28 China - Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council), G/TBT/N/CHN/1313 (ID 428[63])

4.302. The representative of the Republic of Korea provided the following statement. Korea welcomes China's recent publication of the Regulations for the Supervision and Administration of Medical Devices, which entered into force on 1 June after a lengthy revision process. With the revised regulation, medical devices in China will be able to go through a more stringent safety management process across the entire product life cycle, from certification and inspection to market distribution and post-market surveillance. We expect this will contribute to maintaining order in the Chinese medical device market and thereby promote market growth. However, there are some parts in the regulation that still require clarification from China. As to our previous enquiry asking about the scope of "qualified testing laboratories", China responded that we should be able to find the answer from the revised regulation. However, it seems that the finalized regulation still does not specify what agencies are to be considered "qualified testing laboratories", which calls for further explanation. Korea also wishes to receive a clear answer on whether the certificates by internationally accredited laboratories can be accepted. Provided they are not, a suggested alternative would be for China to accept the certificates by internationally accredited laboratories or other equivalent foreign laboratories in order to save time and cost in the approval or registration

[59] https://www.meity.gov.in/esdm/standards
[60] https://bis.gov.in/index.php/laboratorys/utrf/
[61] https://bis.gov.in/index.php/laboratorys/testing-facility-and-testing-charges/
[62] https://bis.gov.in/index.php/laboratorys/utrf/
[63] For previous statements follow the thread under ID 428.

process. This will help facilitate trade and appropriately contribute to the growth of China's medical device industry.

4.303. In response, the representative of China provided the following statement. A new revision of the regulation on the supervision and administration of medical devices has been released and will take effect on 1 June 2021. The new regulation reasonably sets clinical evaluation requirements, simplifies the review procedures, and further encourages innovation. Meanwhile, the regulation fully implements the registration system, strengthens the responsibility of enterprises and supervision over the whole process of medical devices. China is working on the following regulations and documents, which will be notified according to the rules. The comments to the regulation will be studied, and the regulation will be released afterward.

4.1.3.29 China - Registration Fees for Drugs and Medical Device Products (ID 466[64])

4.304. The representative of the Republic of Korea provided the following statement. Over the last several years, Korea has repeatedly raised concerns about China's Registration Fees for Drugs and Medical Device Products, and this continues to remain an issue of interest for Korea. Please refer to the record of minutes for Korea's comments made in the previous TBT meetings, and this time, Korea wishes to reiterate our question: when will the notification on the Charging Standards for Drug and Medical Device Registration from 2015 be revised? With the possible revision in mind, we would like to request China to ensure equal treatment between exporters and Chinese domestic manufacturers in imposing registration fees.

4.305. In response, the representative of China provided the following statement. The registration fees for drugs and medical devices are 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.

4.1.3.30 Russian Federation - Rules of cement certification, G/TBT/N/RUS/48, G/TBT/N/RUS/49 (ID 497[65])

4.306. 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. Further to this, the EU regrets that Russia is not willing to provide any information on the state of play of the preparation of the new standard for cement. 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. 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. Given the lack of the notification to this day, the EU would like to ask the Russian Federation to inform about the preparation of this new standard and to share the updated timing for its TBT notification.

4.307. In response, the representative of the Russian Federation provided the following statement. As the issue has been on the agenda of this and other WTO working bodies for a while, we refer to our previous statements made. The amendments to GOST – R "Rules of cement certification" are being discussed internally among relevant Russian authorities. Unfortunately, no precise timeline for the outcome of the discussion can be provided now. Once this work is finalized, we will be glad to inform WTO Members on that.

[64] For previous statements follow the thread under ID 466.
[65] For previous statements follow the thread under ID 497.

4.1.3.31 India - Draft Food Safety and Standards (Alcoholic Beverages Standards) Regulations, 2015, G/TBT/N/IND/51, G/TBT/N/IND/104 (ID 494[66])

4.308. 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 minimize 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.

4.309. 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. In addition to this, alignment of the analysis methods of alcoholic beverages with the OIV is under process. FSSAI via direction dated 22 June 2020 operationalized use of food colours "Tartrazine, Carmoisine, Brilliant Blue, Sunset Yellow and Ponceau 4R" in the food category 14.2.6-Distilled Spirituous Beverages. Further, via direction dated 7 December 2020, revised provisions for using these colours, and one additional colour, Allura Red, was operationalised for use in food category 14.2.6-Distilled Spirituous Beverages. Further, as per appendix A, the colour, namely caramel, beta carotene and grape skin extract, are allowed in aromatised alcoholic beverages.

4.1.3.32 Egypt - Manufacturer Registration System (Decree No. 43/2016 and Decree No. 992/2015), G/TBT/N/EGY/114, G/TBT/N/EGY/115 (ID 505[67])

4.310. The representative of the Russian Federation provided the following statement. The Russian Federation reiterates its statements in respect of Manufacturer Registration System made during the previous meetings of the Committee on Technical Barriers to Trade, Committee on Market Access and Council for Trade in Goods. We urge Egypt to register the Russian steel manufacturer that has been denied market access since 2016 and revise the Registration System to bring it in full compliance with WTO rules. The System untransparent and lacks clear deadlines for the processing of applications which provide opportunities for arbitrary decisions regarding market access for particular companies and for protection of domestic industries from imports.

4.311. 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 implementation of 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. Given the lack of transparency, the EU has some questions to Egypt: Could Egypt clarify the relationship between Decree 43/2016 and Decree 992/2015? This question has been asked before and no clear answer has been provided to the EU. Could Egypt please explain how the Decree 43/2016 is implemented and administered in practice? In particular: Where can companies find the application form and where can this application form and related documents be submitted? What are the related costs associated with the submission of applications? What are the deadlines with regard to the registration from the moment of the application?

[66] For previous statements follow the thread under ID 494.
[67] For previous statements follow the thread under ID 505.

4.312. How can companies follow their application and see if it has been approved or rejected or whether there are documents that need to be corrected or resubmitted because they have expired? In short, how can companies obtain information about their application status at any stage of the process? Could Egypt please explain if Egyptian producers/exporters are subjected to similar requirements and process as EU exporters are under Decree 43/2016? If so, could Egypt specify the legislation subjecting Egyptian producers/exporters to similar requirements? The EU's understanding is that registration, the suspension or cancellation of registration from the General Organization for Export and Import Control's (GOEIC) record is done through a decision of the Minister of Foreign Trade. Can you please point us out to where these decisions are published and provide us with copies of these decisions? According to GOEIC's website, the Minister of Foreign Trade has absolute discretion "and he may exempt from any or all of the registration conditions in the cases he decides". In which instances has the Minister of Foreign Trade exercised this discretion and on the basis of which criteria? The European Union would appreciate a written reply to these questions. 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.

4.313. The representative of Turkey provided the following statement. We join the European Union and Russian Federation to emphasize our ongoing concerns on Egypt's Decree on manufacturer registration system. Despite all the concerns and questions from Members in previous meetings, the structural problems related to this Decree and implementation still continue. In this sense, the system lacks transparency and hence leads to unpredictability, arbitrariness, and additional costs. Turkish exporters continue to report long delays in the registration process and face difficulties in obtaining information about their pending registration requests. In this respect, we would like to reiterate that we still could not get a clear information on the evaluation criteria for the applications to GOEIC, steps to be taken for a smooth registration, and time limitation for the completion of the registration if there is any. 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.

4.314. In response, the representative of Egypt provided the following statement. We would like to refer to your previous statements in the CTG, TBT and Market Access Committee meetings in which a number of the questions raised today have already been addressed including the similar requirements and surveillance mechanisms domestic producers are subject to. We take note of all the questions and concerns that continue to be raised and they will be conveyed to capital and responses delivered in due course. We also conclude by renewing our call to Members whose companies are facing specific difficulties to reach out to us with details of the problems faced so that we can communicate them to the Egyptian concerned authorities and come back with concrete feedback.

4.1.3.33 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 224[68])

4.315. The representative of Japan provided the following statement. Japan would like to thank India for its explanation at the previous meeting. We took note that the purpose of BIS certification is to protect the health of humans, animals and plants, as well as for environmental safety, and all technical regulations issued by the Ministry of Steel are notified to the WTO. At the same time, Japan would like to continue to request that these mandatory standards of steel products in India be implemented in a manner that conforms with the TBT Agreement and that the implementation be no more trade restrictive than necessary to achieve its legitimate objectives. To be more specific, Japan would like to submit the following comments as pointed out at the previous meeting. Even though Japan requested India to accelerate its examination procedure at the last TBT Committee meeting, it is still taking a very long time to get approval of conformity assessment, and it has become usual that no response is given to Japanese steel companies even after a year has passed, especially for new projects. This has not improved since the last Committee meeting.

4.316. Japan understands that India cannot proceed in application and scheduling on-site factory audits by BIS as part of the process of obtaining certification of conformity because of COVID-19 and its prevention measures. Japan requested India to implement any alternative measures at the

[68] For previous statements follow the thread under ID 224.

last TBT Committee meeting, but India has not offered any such measures yet. Therefore, Japan would like to request again that the Ministry of Steel and BIS implement appropriate alternative measures and postpone the enforcement of new mandatory standards. In addition, for some products, India requested Japanese companies to submit future plans for domestic production in India or to switch to local procurement from Indian companies which is not related to the conformity assessment procedures. Japan also did not receive enough explanations on this point from India at the last TBT Committee meeting. Such additional request is not relevant to the conformity assessment procedures, and Japan would therefore like to strongly request again for immediate improvement on this issue.

4.317. 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 Indian Steel and Steel Products Quality Control Order, circulated in G/TBT/N/IND/90 on 25 March 2019. While we fully support India's objective to ensure the safety of imported steel and steel products, we would like to bring to the attention of Indian government the significant difficulties encountered by our companies to obtain the certification required by the Order. There are applications submitted in January 2019 with testing and factory inspection procedures completed in March 2020 and certification is pending without any reasons. We understand the difficulties India faces in administering procedures at its normal pace during the pandemic. However, we still hope that the Bureau of Indian Standards (BIS) implements appropriate alternative measures despite the pandemic to prevent further delays of approval. In addition, considering that the pandemic will continue for some time, we would like to urge India to postpone the implementation of IS standards, in particular IS 17404:2020 on electrogalvanized hot rolled and cold reduced carbon steel sheets and strips, which recently came into force or are about to become effective to allow foreign manufacturers enough time to complete the conformity assessment procedure. We thank India for taking into account our comments.

4.318. In response, the representative of India provided the following statement. *Japan:* Considering the ongoing pandemic and the extent of its impact, the information sought by the said QCO will ensure smooth supply lines of quality grade material at reduced costs and in a time-bound manner. This information is particularly vital, among others, if the importers are importing from the non-BIS licensed manufacturers. As regards the auditing remotely, India is seized of the matter. There is no provision in BIS (Conformity Assessment) Regulations, 2018, to undertake virtual inspection or the use of recognized third-party certification of companies in the country of manufacturing to meet the QCO's in-person audit requirements for foreign manufacturing facilities. However, the Government of India is considering the introduction of relevant enabling provisions to undertake virtual/remote inspection for BIS conformity assessment activities.

4.319. Chinese Taipei: G/TBT/N/IND/90 on 25 March 2019 is related to the Essential Requirement clause included in the QCO regarding "Stampings/laminations/ cores of Transformers (with or without winding)" & "Stainless Steel Pipes and Tubes." In this regard, it may be noted enforcement date for "Stampings/laminations/cores of Transformers (with or without winding)" has been extended till 30 June 2021 and "Stainless Steel Pipes and Tubes" is under enforcement since 16 June 2020. Regarding postponement of the implementation of IS 17404:2020 (Electrogalvanized hot rolled and cold reduced carbon steel sheets and strips), it may be noted that the current date of enforcement is 22 June 2021. The request for the extension of the date of enforcement of the QCO will be examined before the enforcement date. Based on the merits of requests from the stakeholders and licence status from BIS against the standard, an appropriate decision will be taken.

4.1.3.34 China - Cybersecurity Law (ID 526[69])

4.320. 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

[69] For previous statements follow the thread under ID 526.

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.

4.321. Numerous other concerns have been laid out in prior interventions by the United States and other Members at prior Committee meetings. Additionally, the United States reiterates its serious concerns regarding China's Cryptography Law, which went into effect on 1 January 2020. The United States is concerned that this law codifies potentially far-reaching, highly trade-restrictive cryptography-related constraints on foreign ICT products. Because these issues are technically complex and China's approach appears to be both novel and would have a potentially widespread impact in the commercial sector, the United States requests that China undertake in-depth consultations with the US Government, other WTO Members, and global stakeholders. We also 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.

4.322. The representative of the European Union provided the following statement. The EU would like to refer to its statements 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 localization and security assessment requirements, foreign companies operating in China could find themselves in a less competitive situation compared to domestic operators. The EU calls on China to implement the provisions in a non-discriminatory manner, respecting the principles of proportionality, necessity and technology neutrality, and ensuring adequate protection of intellectual property (IP). 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 notify 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.

4.323. 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 February 2021. Japan is concerned with 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.

4.324. 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 May 2021 public consultation process on its revised draft Data Security Law and revised draft Personal Information Protection Law. The Australian Government submitted comments on the first draft of these proposed laws last year. We welcome a number of the revisions to these laws but continue to encourage China to provide as much detail as possible, especially when it comes to issues such as the scope of the laws. Australia reiterates that, consistent with the TBT Agreement, we expect that measures will be implemented in a non-discriminatory manner and in a way that is

no more trade restrictive than necessary. Australia further urges China to consider less trade-restrictive measures that are reasonably available to achieve its objectives.

4.325. 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 government authorities, network providers, users, etc. Since the implementation of the cybersecurity law, it has played an important role in safeguarding the national cyber security. 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.

4.1.3.35 China - Encryption Law of the People's Republic of China by the Office of State Commercial Cryptography Administration (OSCCA) (ID 534[70])

4.326. The representative of the European Union provided the following statement. The EU would like to reiterate its concern relating to 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 the administrative procedures described in the text. These factors will negatively impact business confidence. The EU also notes with concern that the new law does not recognize China's previous commitment made in 2000 that the cryptography-related regulation would only apply to products whose core function is that of providing encryption – the so-called "Year 2000 Clarification" by the 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.

4.327. 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 February 2021. Japan would like to request that China's regulation not hamper foreign companies' activities or market access to China.

4.328. The representative of the United States provided the following statement. The United States supports the statements of the EU and Japan.

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

4.1.3.36 European Union - Regulation (EC) No 1272/2008 (CLP Regulation), G/TBT/N/EU/629 (ID 539[71])

4.330. 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 adopted under the 14th Adaptation to Technical Progress to the CLP Regulation and notified in the document G/TBT/N/EU/629. The EU approved this classification in the absence of comprehensive laboratory 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 in a wide range of products. Additional step in this

[70] For previous statements follow the thread under ID 534.
[71] For previous statements follow the thread under ID 539.

direction is the Chemicals Strategy for Sustainability published by the European Commission in October 2020 that proposes imposition of a ban on the use of most harmful chemicals. 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 initiated scientific study on carcinogenicity of cobalt metal for oral route of exposure. In this regard, we request that the European Union inform if all restrictions and prohibitions of cobalt use introduced following the implementation of the 14th ATP and the Chemicals Strategy for Sustainability will be lifted in case the carcinogenicity of cobalt for oral route of exposure will not be confirmed.

4.331. The representative of Brazil provided the following statement. Brazil supports STC 539 and is concerned with the trade impacts of the reclassification of cobalt as a carcinogenic level 1B. Cobalt is found in trace amounts in the production of nickel, and Brazil is the primary nickel-producing country in South America, exporting around 70 thousand tonnes of nickel, according to 2017 figures. According to industry estimates for the same year, the total value of nickel production reaches USD 12,350 million. Around 56% of the nickel mine production in Brazil is at risk with limitations on the trade of cobalt. We thank the European Union for clarifying some central aspects of the regulation in past meetings of the TBT Committee and we look forward to continuing dialogue on this matter.

4.332. 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. As described in previous statements, 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 European 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.

4.333. 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 a risk assessment. It should be noted that classification under the CLP Regulation is based only on the scientific assessment of the hazards derived from the intrinsic properties of a substance and not on its uses, while potential downstream legal or socio-economic considerations are not part of the principles for hazard classification. Nevertheless, the classification under the CLP Regulation does not in itself restrict the placing on the market of cobalt or cobalt-containing products. When a substance is subject to harmonized classification, only labelling and packaging obligations are triggered for that substance and any mixture containing it, but not for articles (e.g. cutlery or other stainless steel articles). As previously announced, on the use of the bioelution method, the EU has made progress in the development of a harmonized approach at international level. The EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) Scientific Advisory Committee (ESAC) has given a positive opinion on the scientific validity of a bioelution test method. 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 European Commission's proposal and an OECD subgroup has been set up to work on the technical guideline. This expert group met several times and made some good progress, but discussions are still ongoing. The European Commission would welcome any support from third countries to actively participate in the development of the OECD test method on bioelution.

4.334. 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, as previously announced, 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. Two meetings of this sub-group have already taken place, in September 2020 and May 2021, and despite progress made in the last meeting, one additional is foreseen to finalize the discussion. 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. As previously stated, 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.

4.1.3.37 European Union - Organic production and labelling - Maté (erva-mate), G/TBT/N/EU/738 (ID 524[72])

4.335. 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 1 January 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.

4.336. In response, the representative of the European Union provided the following statement. The European Union has replied to Brazil on this issue in previous TBT Committee meetings, as well as bilaterally. 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 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 postponing the entry into application of the organics Regulation by one year (G/TBT/N/EU/738). Regulation (EU) No 2020/1693 of 11 November 2020 amending Regulation (EU) 2018/848 on organic production and labelling of organic products as regards its date of application and certain other dates referred to in that Regulation was published in the Official Journal of the European Union on 13 November 2020.[73] Therefore, 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 its Annex I.

[72] For previous statements follow the thread under ID 524.
[73] OJ L 381, 13.11.2020, p.1.

4.1.3.38 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 567[74])

4.337. 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.

4.338. 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. Moreover, 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. Producers/importers/retail and wholesalers of cheeses and ice cream have currently been indicating similar problems with regard to the date of 1 June 2021, i.e. they are not ready for labelling. Therefore, an extension of transition period is necessary, during which import and/or sale of non-labelled production to Russia would be allowed. This transition period should last at least until the end of 2021 and should cover all products for which labelling started in 2020 and those planned for 2021. Current deadlines seem to be the following: Footwear – started on 1 July 2020; Medicines- started on 1 July 2020; Perfumes and eau de toilette - started on 1 October 2020; Photo cameras – started on 1 October 2020; Tyres - 1 November 2020; Textiles - 1 January 2021; Dairy - 20 January 2021 (voluntary labelling), 1 June (obligatory for ice-cream and cheeses), 1 September 2021 (all products with a shelf-life of more than 40 days), 1 December 2021 (all products with a shelf-life of less than 40 days); Bottled water - pilot project until the end of May, obligatory labelling for mineral water as of 1 December 2021 and all the rest of bottled water as of 1 March 2022; Beer - pilot started as of 1 April and will last until 31 August 2022.

4.339. The scheme will soon have been in operation for a year for certain categories of goods. The EU therefore wishes to enquire whether a regulatory evaluation is planned which weighs costs versus benefits of the implementation of the scheme so far. In accordance with good regulatory practice, such evaluation is unavoidable before consideration of a possible extension of the labelling and tracing requirements to further categories of goods. 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.

4.340. In response, the representative of the Russian Federation provided the following statement. The objective of the Track and Trace System (T&T) is to fight against circulation of illicit products as well as to ensure that taxes due are paid. The system is needed for law enforcement. No law-abiding company can compete with the one that is not paying taxes due. In this sense, the T&T system is levelling the playing field and lawful companies benefit from it. We reiterate our position that T&T System does not meet the requirements for technical regulation set out in Annex 1 of the Agreement on Technical Barriers to Trade. This measure does not set requirements for product characteristics and production methods as well as does not correspond to other elements of the technical regulation

[74] For previous statements follow the thread under ID 567.

definition. In this regard, Russia does not intend to notify the measure to the WTO under the Agreement on TBT. Russia does not consider T&T system disproportionate. The concept of the system in respect of each product category is developed together with the companies involved in manufacturing, imports and distribution of the respective products. 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 as to prepare to them beforehand. As for dairy products mentioned by the EU today, we inform the WTO Members that preparation for implementation of the system with regard to this category of products was initiated two and a half years ago. All the companies involved in manufacturing and distribution of milk products had an opportunity to participate in the pilot project. Most economic operators took part in preparatory work and now face no challenges. We are aware that certain dairy manufacturers are not prepared to comply with the legislation of the Russian Federation from 1 June 2021. To mitigate the situation, Government amended Resolution regulating T&T System in respect of milk products permitting products manufactured before 1 June to be marketed without data matrix codes after 1 June.

4.1.3.39 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 443[75])

4.341. The representative of Colombia provided the following statement. Colombia reiterates its trade concern regarding various elements of Brazil's notification G/TBT/N/BRA/608/Add.1. Colombia's comments were sent through the contact point, and we have also submitted them to the Brazilian authorities in various bilateral meetings. We welcome the willingness to address questions and comments in these discussion spaces. 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 INCI international nomenclature for the declaration of ingredients has not created any health 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. We remain committed to working with the authorities and industry on an equally effective and less burdensome alternative to fulfil the legitimate objective invoked by Brazil.

4.342. The representative of Mexico provided the following statement. This item continues to be of interest to us, and we therefore wish to place on the record our support. Our concern remains, and we therefore ask for our statement from the previous Committee meeting to be reflected in the minutes. 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.

4.343. 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

[75] For previous statements follow the thread under ID 443.

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.

4.1.3.40 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 594[76])

4.344. 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 to May 2021, provided some necessary relief. Likewise, the 11 January 2021 Commission Notice permitting remote audits by Notified Bodies (NBs) was a welcome development. In acknowledging the significant obstacles that travel restrictions and quarantine orders pose to on-site audits during the pandemic, the temporary allowance of remote audits appears to be helping facilitate safe and timely product approval. We support the continued utilization of remote audits, if implemented consistently, to alleviate the assessment backlog and ultimately ensure patients' continued access to much needed medical devices and *in vitro* diagnostic tools. However, several issues remain regarding implementation of both the MDR and IVDR, and US industry remains concerned about its continued access to the EU's USD 125 billion medical device market, USD 20 billion of which is supplied by US products. In particular, we remain concerned about the number of NBs approved to assess conformity to the IVDR, with only four such NBs approved as of April 2021, and the effect this lack of testing capacity may have on continued implementation of the IVDR. Given the large number of products requiring testing under this regulatory framework and the relatively small number of approved NBs, has any serious thought been given to delaying the implementation of the IVDR or to considering other flexibilities such as expanding the grace period to products currently on the market?

4.345. We understand that CEN and CENELEC have accepted the Commission's standards mandate on 12 May just two weeks shy of the MDR being implemented. However, stakeholders remain concerned that the Commission intends to create harmonized European standards to demonstrate compliance with EU legislation rather than use existing international standards. For example, the ISO standard for risk management is a foundational standard that is important to a range of devices. We understand that this international standard has been rejected as a means to demonstrate conformity under the MDR. Manufacturers will need to use EU regional standards that have yet to even be developed. We have heard similar concerns regarding the ISO standard for electrical safety of devices which also applies to a wide range of medical devices – and specifically to life-saving COVID-related devices, such as ventilators. Can the EU explain its rationale for these deviations? 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 - especially given that we are in the midst of fighting a global pandemic.

4.346. 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). GMDN was developed with the support of ISO and the then Global Harmonization Task Force (now the International Medical Device Regulators Forum) and is widely adopted by the medical device industry and used by over

[76] For previous statements follow the thread under ID 594.

70 national medical device regulators to support their activity. We are concerned that the Commission'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 addressed interoperability concerns, and has not made any progress on mapping CND to GMDN so as to harmonize the UDI systems and reduce duplication for industry. 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. The EU has repeatedly stated in bilateral discussions and in published documents that it intends to map its nomenclature system to GMDN, but we have yet to see any action by EU that demonstrates any attempt to map to GMDN. In fact, the EU recently published its European Medical Device Nomenclature for public consultation but does not propose any steps toward mapping to GMDN. Could the EU explain what actions it is taking to map to GMDN?

4.347. The representative of Japan provided the following statement. We appreciate the March update of the MDCG guidance development and publication plan. We request that MDCG guidance be published in accordance with this plan and transition period be established to comply with the guidance. We also would like to request EU to develop and make public the mapping of EMDN (European Medical Device Nomenclature) and GMDN (Global Medical Device Nomenclature). We have received many reports from the companies undergoing technical document review that there has been no progress for a long period of time since the start of the review and the completion of the review and issuance of the Certificate by the MDR DOA are not foreseeable. In several cases, more than one year has passed since the start of the technical document review. We would like to request the regulatory authorities to investigate the causes of the prolonged technical document review by NBs and to explain how to take measures to improve the situation. The MDR requires strict clinical evaluation of Class I, IIa, and IIb medical devices, and we request that the regulatory authorities consider simplifying the clinical evaluation requirements for Class IIa, and IIb medical devices, similar to regulations in other countries such as 510(k) in the US and third-party certification in Japan, so that the MDR does not become more trade restrictive than necessary. The workload of NBs is still being 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 are also requesting the prompt issuance of guidance documents for the IVDR and a timeline for their issuance as early as possible.

4.348. The representative of China provided the following statement. China thanks the EU for the reply, but still remain concerned about the IVDR. We are looking forward to the consideration of and reply to our following concerns. Postpone the transition deadline of IVDD and IVDR for two years. According to estimates, about 85% of the *in vitro* diagnostic medical devices entering the EU must obtain a CE certificate after a technical documents review by a Notified Body, rather than adopting the form of "self-declaration". The proportion is only 15% in the case of IVDD. For a large number of *in vitro* diagnostic devices that have obtained valid IVDD certificates, they still need to be re-certified according to the requirements as new products. Manufacturers are facing 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 or updated the list of EU harmonized standards nor the more detailed certification guidelines, and no laboratory has been authorized by the EU as 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 conduct tests in authorized laboratories and obtain certificates issued by the notified body in a timely manner. Manufacturers are unable to complete 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 the 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.

4.349. The representative of the Republic of Korea provided the following statement. In line with the comments from other Members, Korea reiterates its concerns on the Medical Device Regulation, which will likely have a significant impact on medical device exporters. Although the MDR entered into force as of 26 May, the concerns expressed by the Members in the last TBT meeting have not yet been fully addressed. In particular, the number of designated Notified Bodies, which is 20 under

MDR and 4 under IVDR, does not seem to be sufficient to review all the applications and accommodate the needs of medical device manufacturers that are waiting or expected to be authorized. In addition, even though the regulation has already been implemented, the MDCG guidance is missing certain information such as post-market surveillance requirements, which could cause a great deal of inconvenience and confusion to manufacturers. For the above-mentioned reasons, Korea requests the EU to increase the number of designated NBs, extend the validity period of previously issued MDD certificates for a seamless transition towards MDR, and provide sufficient information and necessary guidelines to help manufacturers adapt to the new regulation.

4.350. 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 with the number of notified bodies and the rate of new approvals. There still appears to be insufficient capacity to carry out the certification and approval activities provided for in the regulations. We are also concerned 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 another nomenclature system is being introduced. We are concerned the lack of harmonization and alignment could undermine the interoperability. Will this be reconsidered or will there be an exercise of mapping the new European codes to the current GMDN codes?

4.351. The representative of Singapore provided the following statement. Singapore supports the concerns raised by the other Members on this specific trade concern. We wish to reiterate the concerns raised in our previous statement at the February 2021 TBT Committee meeting regarding the bottlenecks in the certification of medical devices, and the substantial challenges that these bottlenecks pose towards continued access to the EU's medical device market. We look forward to further engaging the EU to find a mutually satisfactory solution on this matter.

4.352. In response, the representative of the European Union provided the following statement. The Medical Device Regulation officially entered into application on 26 May 2021. This new Regulation significantly improves and upgrades the regulatory system for medical devices, replacing the former two Directives. This change is not a cliff-hanger for CE compliant medical devices, as the grace mechanism, a similar but more stringent approach than grandfathering, foresees that valid Directive certificates can remain on the market until May 2025. The IVDR's corresponding date of application remains the same (26 May 2022). It has become evident that there are some delays in the preparation from parts of industry in view of the new requirements. The Commission continues to monitor the impact of these problems in order to avoid any shortages of devices and is working closely with competent authorities, Notified Bodies and industry associations to continuously assess the situation and, if needed, identify solutions. Currently, we have 20 MDR designated Notified Bodies and 5 Notified Bodies under the IVDR, with more following in the pipeline. In addition, and pursuant to a January 2021 Commission notice on audits and surveillance assessments under the MDR and IVDR, 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, has been provided. Interesting to international partners is that 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 organizations cover some of the EU's trade partners such Australia, Brazil, Canada, Japan and the US.

4.353. 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 24 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. As regards implementation work, the Commission and member States are continuing work on implementing acts and guidelines. To date, there have been above 70 published guidance documents, including several key guidance on clinical requirements. On standardization, we are happy to report that progress on this topic has been made and that preparatory work for the first publication of a set of harmonized standards under the new Regulations is currently underway. Furthermore, the expert panels, who have a role in the conformity assessment procedures of certain high-risk products, are

officially running and processing applications. In addition, the registration module of the EUDAMED database was made available on December 2020 and the Unique Device Identification (UDI) registration module is foreseen to go live in September 2021. As reported in previous meetings, the other parts of the EUDAMED database will be made available in a gradual manner.

4.354. As regards the UDI, allow us to underline the fundamental difference between Unique Device Identification and the Nomenclature, which are two topics which seem to be confused in high-level discussions. While the UDI system employed in the EU is based on internationally agreed upon principles, the Nomenclature, also known as the language of use, will be different. This was a decision which was taken after careful assessment and consideration. The EU would like to stress, once again, that the EU's choice for creating the European Medical Device Nomenclature was founded on the need for a sensibly structured nomenclature which is transparent, open, completely publicly accessible and downloadable for free. There are currently no other nomenclature systems offering those characteristics. It is important to clarify that the choice of this nomenclature does not constitute a barrier and to avoid misinformation and confusion in this respect. 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.

4.1.3.41 Republic of Korea - Ballast Water Management Act (ID 606[77])

4.355. The representative of the European Union provided the following statement. The EU would like to recall its concerns raised at previous Committee meetings 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. EU industry has been in contact with the Korea Institute of Ocean Science and Technology (KIOST) in order to finalize the requirements. However, the issuance of the Type Approval Certificate (TAC) has continued to remain elusive. It is our understanding that there are three open issues, which seem to be largely related to interpretation or clarification of results of already performed tests. Firstly, testing required by KIOST has already been approved by a globally-recognized classification society DNV GL, which, in its assessment, has applied the requirements as stated in the BWMS Code MEPC.300(72). The issue at hand lies in KIOST's interpretation of these requirements, which introduces an element of uncertainty in the certification procedure. Furthermore, testing required by KIOST has been conducted in 2019, which should satisfy concerns raised regarding limitation levels. EU industry will send another report, issued by independent DNV GL, in order to close this matter. Secondly, as regards the validity verification of the shipboard testing, new reports have been submitted to KIOST. We hope these will be sufficient to satisfy KIOST's demands.

4.356. Thirdly, KIOST is requesting additional data to show that the preparation for the MPN analysis method was performed on-board despite the fact that this has already been confirmed in a previously submitted report from the independent lab that performed the necessary on-board testing. EU industry will send the newly requested information. Overall, it appears that the issuance of the certificate is being delayed by a non-willingness to accept interpretations of the BWMS Code made by other administrations and independent classification societies, and requiring more details that, in some cases, have already been provided. To underline, this ongoing certification procedure has taken more than two years in the Republic of Korea. By contrast, the same certification is automatic in one EU member State, when the testing is carried out by an approved Recognised Organisation (RO) such as DNV GL, or can require between three weeks and three months in other member States; even in other Asian countries, the procedure has only taken up to eight months. Therefore, the EU would like to emphasize the importance of a prompt issuance of the certificate and thanks the Republic of Korea for facilitating an earlier reduction in the fee request.

4.357. In response, the representative of the Republic of Korea provided the following statement. Korea appreciates the interest of EU in Korea's Ballast Water Management Act. Korea would like to deliver the official response from the regulatory authority. As explained at various meetings such as the WTO and FTA meetings, Korea 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, Korea 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

[77] For previous statements follow the thread under ID 606.

deliberation process (first round) was completed on 4 January 2021, and the Ministry of Oceans and Fisheries notified the company of the deliberation results. The company can obtain a type approval certificate by passing only a few tests with relaxed requirements. However, it has not yet completed such tests, having instead submitted related foreign government type approval data and technical materials on 3 March 2021. So, Korea carried out deliberation (second round) on the submitted data and materials and notified the company on 8 April 2021, that it is required to conduct only two seawater tests for the land-based test and validity verification for the shipboard test. However, the company submitted additional materials, which are currently under review, on 25 May 2021. Korea would like to inform the EU 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. Regarding the data submitted by the European company, we will complete the deliberation process as soon as possible and notify the company of the results. 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.

4.1.3.42 Qatar - Ministry of Public Health Circular regarding shelf life for cheese (ID 602[78])

4.358. 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 import requirements for UHT milk and white cheese that entered into force the following day, on 1 June 2019. The EU regrets that Qatar did not notify these requirements to the WTO under neither the TBT nor the SPS Agreements. The implementation of these rules continues to cause serious disruptions to EU exporters as compliance with these requirements is not feasible for certain cheeses and milk products, that as consequence cannot be exported to Qatar anymore. The EU is particularly concerned about the stringent restrictions on the shelf-life that disadvantage imported products in comparison to local products, but also about certain product characteristics for UHT milk and white cheeses, in particular obligatory addition of vitamins to milk and low-fat-only requirement for certain white cheeses. These requirements are not in line with CODEX Alimentarius relevant international standards, are not science-based and do not guarantee the safety of imported products. The measures therefore appear to be more restrictive than necessary to fulfill 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. This measure has been in place for two years without any clarity provided by Qatar on when this measure will be lifted. 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, 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.

4.359. The representative of Canada provided the following statement. Canada joins 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. While Qatar has provided assurances that the relevant measures apply equally to domestic and imported products, some exporting countries, such as Canada, are faced with logistical limitations that make it impossible to comply with Qatar's new 45-day shelf-life requirements given the 50-55 days of ocean transit from Canada to Qatar. As such, Canadian exporters of paneer cheese are unable comply with this new requirement. Canada remains concerned that Qatar's measure will effectively favour domestic or close proximity sourcing of these products and limit imports of these products. Canada appreciates the responses Qatar provided on this issue in the context of its Trade Policy Review which took place in March 2021. However, details on how Qatar's new shelf-life requirements were established, including the scientific basis to support its approach, are lacking or remain unclear. Canada would encourage Qatar to share additional information in this regard. In closing and as stated in previous TBT Committee meetings, in light of Qatar's stated objective of ensuring the safety and quality of products sold in its market, Canada 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.

4.360. The representative of the United States provided the following statement. We regret we must once again raise concerns 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

[78] For previous statements follow the thread under ID 602.

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. We have urged Qatar to suspend implementation of this measure until Qatar fulfills its WTO TBT transparency obligations for nearly two years with no response. If a determination is made to no longer raise this issue at future TBT Committee meetings, we emphasize this is not an indication we are no longer concerned, or that Qatar has mitigated the measure's impact on trade.

4.361. In response, the representative of Qatar provided the following statement. Qatar has taken note of the continued concern of the European Union, Canada, and the US 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 fulfillment 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.

4.1.3.43 India - Air Conditioner and its related Parts (Quality Control) Order, 2019, G/TBT/N/IND/110, G/TBT/N/IND/74 (ID 598[79])

4.362. The representative of China provided the following statement. At present, there are only six months before the implementation of Air conditioner QCO order on 1 January 2022. Under the current severe situation of the global epidemic, it is difficult for BIS to appoint staff to conduct on-site inspection to factories, which seriously affects enterprises' application for BIS certification. In this respect, China suggests that: Suspending the implementation of Air conditioner QCO order until the risk of certification activities is decreased. Using information and communication technology (ICT) to conduct remote video inspection to maintain compliance certification activities.

4.363. In response, the representative of India provided the following statement. Foreign inspection visits are on hold due to the prevalent restrictions on international travel imposed by the Government of India, but in some instances by the Government of other respective countries because of the ongoing COVID-19 pandemic. As soon as the situation of COVID-19 improves and the restriction lifted, India will plan the inspections (factory visit). There is no provision in BIS (Conformity Assessment) Regulations, 2018, for remote assessment or any other means for inspection.

4.1.3.44 Kingdom of Saudi Arabia - Saber Conformity Assessment Online Platform / Saleem Product Safety Program (ID 615[80])

4.364. The representative of the United States provided the following statement. The United States continues to reiterate 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. 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. US industry reports that the HS codes on the Saber system, including those listed on Saber's website, often do not match international HS codes. Can the Saudi Arabia Standards, Metrology, and Quality

[79] For previous statements follow the thread under ID 598.
[80] For previous statements follow the thread under ID 615.

Organization (SASO) provide the list of products, using complete HS Codes having 10 digits, for which SASO will require third-party certification and new certificates of conformity instead of self-declarations? US companies have indicated that their manufacturers and importers have been required to provide accreditation to ISO 17025, a standard for testing labs, as part of the certificate of conformity process. Requiring manufacturers and importers that do not test at their facilities to provide accreditation to ISO 17025 for their facilities is overly burdensome. Would SASO remove this requirement for such manufacturers and importers, and also consider exempting such companies from this requirement if the third-party testing lab used is accredited by ILAC signatories for testing?

4.365. Industry stakeholders have requested that more detailed guidance be provided to Notified Bodies on how to implement the Saber platform for toys in order to increase efficiency of the system and to reduce compliance costs while ensuring consistency among Notified Bodies. Can SASO please update the guidance document for toys to allow for the following? Allow one GCTS QR code and one registration number for a group of similar toys; limit the number of documents and samples Notified Bodies need to review for GCTS "groups"; and define groupings broadly by type of toy, e.g. dolls, actions figures and their accessories, rather than by ten-digit HTS code; under or over three years of age; and whether or not the toy contains a battery, with no limit on the number of Stock Keeping Units (SKUs) in a group. US exporters report that the process for conformity assessment differs among Notified Bodies in terms of the required tests and number of required samples. How is SASO working to ensure that all Notified Bodies implement the conformity assessment procedures in the same manner?

4.366. 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. While the European Union would like to thank the Kingdom of 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 is 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. 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.

4.367. The European Union would like to raise the following five points: With regard to request of test reports from the GCC Conformity Tracking Symbol (GCTS), we understand that Notified Bodies are requesting test reports in cases where test reports are not necessary. (Specifically for EN71-9, which is not a harmonized standard providing presumption of conformity with the EU Toy Safety Directive, and for phthalates, which is in many cases irrelevant). It would be useful to clarify with the Notified Bodies what are the legal requirements. On the selection of representative item, we welcome the "grouping approach". However, we understand that there are still issues when adding items to an existing group as Notified Bodies request samples of all products and also charge companies to select the representative items. We believe this is unnecessary and could be done based on pictures/documentation. On Saber, we would like to highlight a problem that the industry encountered for specific products. In the situation where a product is a toy according to the customs codes, but it is not a toy according to the GSO technical regulation (for example because it is a product for older children/people), it seems impossible to proceed as there will be no GCTS awarded and this is a requirement in Saber. We believe it is mainly a technical/IT issue but still it has an important negative impact as these products cannot be imported. We would like to highlight also an issue related to products imported without GCTS (GCC Conformity Tracking Symbol). We understand that a European company saw many of their products on the market in Saudi Arabia without the GCTS. It seems the retailers have no link to them and in certain cases the manufacturer has not even obtained the GCTS for these products and is not able to import/sell these toys. It appears these products are imported without respecting the rules, which means there is no level-playing field and it can also reflect badly on the company. We would be interested in understanding how such a situation is possible and if you have any information in this regard. Finally, we would like to have further information on SASO RoHS. We understand that electronic toys are in scope and the requirements for the conformity assessment procedure could be specifically problematic. It seems

that additional documentation or tests could be required for toys that already go through the GCTS and are also fully compliant with the EU Toy Safety Directive and EU RoHS. In this regards, we recall the importance and need to keep the conformity assessment requirements simple and without additional technical documentation. In conclusion, the European Union would like to 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.

4.368. The representative of Switzerland provided the following statement. Switzerland reiterates 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. 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 and registration is required for the same 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.

4.369. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia would like to express appreciation for the concerns addressed by the United States, the European Union and Switzerland regarding Saber Conformity Assessment Online Platform/Saleem Product Safety Program. SALEEM programme works by developing integrated systems of regulations and standards that conform to internationally recognized professional practices by creating 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. Specifically, essential requirements for human and animal health, environment protection, and to ensure the effectiveness of the services provided by legislative and regulatory bodies to achieve safety by the 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 1-7 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 a UX design project to improve the importer's experience in registering their product and applying for their required certifications. 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.[81]

4.370. The validity of the certificate is one year for the certification of conformity and three years for the Saudi quality mark and the G-Mark. However, the test report can be valid for three to five years if no change occurs in the production line or the product's composite. In Saber platform, clients can search by six digits and select from the results for the nearest description of their product. In terms of GSO toy regulation, GCTS tracking symbol must be issued through the GSO platform. Once the GCTS is obtained, the shipment certificates can be easily issued through the 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 the consumer from high/medium risk products based on international best practices. The technical regulations can be found on the official website of SASO via below link.[82] Please note that Saudi Customs is the

[81] https://saber.sa/home/hscodes
[82] http://www.saso.gov.sa/en/laws-and-regulations/technical_regulations/pages/default.aspx

entity responsible for the HS code, and we recommend visiting their website to find the right HS code that matches the product description.

4.371. SASO is committed to reviewing some details of these conformity assessment procedures 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 laboratory) must be certified by SASO to be able to issue test reports for energy efficiency products. The conformity assessment procedures done by a manufacturer 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 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. Finally, SASO audits the conformity assessment procedures and requirement to ensure fair trade.

4.1.3.45 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 (ID 608[83])

4.372. The representative of Costa Rica provided the following statement. Costa Rica maintains its trade concern 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 for Mexico to indicate the scientific basis or international reference standard used to define the key parameters of the standard in question, including providing relevant justification for the use of the front-of-pack warning sign as supplementary nutritional information, and 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.

4.373. Turning to the consumption by children of products containing added caffeine or sugar substitutes, Costa Rica requests the delegation of Mexico to refer to either the international reference standard used or the risk analysis establishing the risk posed to children by the consumption of products containing these ingredients. Costa Rica believes that the measure adopted by Mexico could generate inconsistencies with TBT Agreement obligations, in particular those established in Articles 2.2 and 2.4. 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 provide information about the status of this draft Amendment.

4.374. The representative of Paraguay provided the following statement. Paraguay reiterates its support for this item and its concern regarding this regulation, refers to its previous statements and asks for them to be included in the minutes of the 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

[83] For previous statements follow the thread under ID 608.

nutritional labelling's lack of harmonization with international guidelines could impede trade between countries.

4.375. The representative of Guatemala provided the following statement. We recognize Mexico's right to protect people's health and to provide consumers with information on the food they buy. We thank Mexico for the response it provided during the previous meeting, which was endorsed in the report of the meeting, in particular its indication that there is no expiry date as a permanent mechanism in the use of a supplementary label. Guatemala would like to ask whether the Government of Mexico will issue a Technical Regulation explicitly stating this, as the Agreement published on 1 October 2020 still has transitional provisions at the end of the publication. The first one clearly states that it will enter into force on 1 April 2021 and expressly excludes the use of supplementary labels on front-of-pack labelling. We recall that 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.

4.376. In response, the representative of Mexico provided the following statement. The delegation of Mexico is participating actively in the front-of-pack labelling standard-setting work through the Codex Alimentarius. However, the lack of an international standard on the subject at this time does not prevent a Member from issuing Technical Regulations on front-of-pack labelling on pre-packed foods and non-alcoholic beverages in order to protect its legitimate public interest objectives. We would also clarify that the technical and scientific evidence supporting the amendment to Mexican Official Standard NOM-051-SCFI/SSA1-2010 is available in the bibliography chapter for consultation by any interested party. Regarding the questions on this measure, 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, G/TBT/M/82 and G/TBT/M/83. In addition, it would be particularly relevant to recall that the Government of Mexico granted a period from 1 April to 31 May 2021 for the marketing of products without penalty if they only complied with the new front-of-pack labelling system on their labels, and not with other commercial and health information that came into force on 1 April 2021. This was so as to recognize the need for stock turnover of products that were already at the final point of sale to the consumer before 1 April 2021. The delegation of Mexico reiterates its willingness to clarify any doubts that the Members of this Committee may have on the implementation of this Technical Regulation. Such concerns may be sent in writing via the WTO contact point.

4.1.3.46 India – Toys (Quality Control) Order, 2020 (IND/131); Amendment in Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017- Schedule-I (Import Policy) (IND/143), G/TBT/N/IND/131, G/TBT/N/IND/143 (ID 632[84])

4.377. The representative of the European Union provided the following statement. The European Union is concerned about India's Toys Quality Control Order 2020 (QCO), and the Amendment in Policy Condition No. 2(ii) 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. The EU would like to reiterate its strong concern in relation to the Quality Control Order and in particular to the certification requirements 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 a 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, and 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.

4.378. 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

[84] For previous statements follow the thread under ID 632.

fulfilling the requirements laid out by the Quality Control Order there is no way for European companies to comply, as exports to India require in-person audits by BIS, which are not yet possible in the current context. It is difficult to envisage BIS auditors travelling to foreign plants in these conditions. As previously suggested, the EU would therefore request India to allow third-party audits or virtual audits of third country factories (such flexibility is allowed for domestic manufacturers). We understand that the Indian Government is considering virtual audits and we would appreciate further details in this regard. In the meanwhile, it could be helpful to allow imports of toys, under the continued enforcement of the DGFT system 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, European 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 raised by the EU.

4.379. The representative of China provided the following statement. It is suggested that India fully consider the requirements which will cause repeated testing and charges in the toy import policy and simplify Customs clearance procedures. India's current toy import policy requires each consignment of toys to be sampled for testing and charged, and the certification rules in the QCO also require each series of toys to be tested and charged. According to the test price stipulated by the BIS, sample testing (per sample) is charged about $150, which means that the testing cost of a toy exported to India by a foreign toy manufacturer is about $300. China believes that the current Toy Import Policy and the certification rules in the 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 Article 5.1.2 of TBT Agreement, China kindly requests India to fully consider the concern that repeated testing and charging in the QCO and DGFT Notification No. 33/2015-20 which lead to a significant increase in costs of toy enterprises exporting to India, to simplify Customs clearance procedures and shorten Customs clearance time. Due to the huge dual demand for toy certification testing and import testing in short term, it is suggested to exempt imported toys from testing, enlarge the lists of third-party labs and accept 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, less than 10 labs can meet IS 9873 and IS 15644 standards at the same time and operate normally, therefore it is difficult to meet the huge dual needs of certification testing and import testing, affecting the testing efficiency. According to Article 5.2.1 of TBT Agreement, it is suggested that India exempt the import toys with the Standard Mark from testing in a certain period of time for the purpose of saving testing resources and speed-up of certification, and enlarge the lists of third-party labs in Schedule-II of Indian Bureau of Standards (Conformity Assessment) Regulations 2018 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.

4.380. It is recommended that India cancel the factory testing facilities requirements for all items such as electrical toys testing. In October 2020, BIS published the procedure of "10 steps to BIS Licence for Toys" on its official website as the implementation rules of the Toys (Quality Control) Order, 2020. Step 4 in the new procedure stipulates that factories producing electronic toys need to be equipped with the testing facilities and instruments for the requirements of clause 8,9,10 in IS 15644:2006. However, these testing facilities are relatively expensive and highly technically demanding, making it difficult for small and medium-sized enterprises. And these tests usually need to be completed by third-party labs outside. Requiring the factory of toys to set up these testing facilities is unnecessary and unreasonable. According to Article 5.1.2 of the TBT Agreement, it is recommended that the India cancel the factory testing facilities requirements on all items such as electrical toys. It is recommended that India adopt the currently-used international remote video censorship or other ways to solve the certification as soon as possible. Under the context of the COVID-19 pandemic, BIS auditors are unable to carry out the on-site inspection on foreign toy manufacturers, which make foreign toy manufacturers unable to export toys to India without the certification. It is suggested that India adopt the currently-used international remote video censorship or other ways to solve the certification problem as soon as possible.

4.381. The representative of Canada provided the following statement. While Canada appreciates the importance of toy safety, Canada continues to be concerned by the increasingly restrictive toy measures India is putting in place which, in Canada's view, are not improving the safety of the Canadian toys exported to India. We continue to seek responses to the written questions that Canada sent to India in April 2020, and which raised the following concerns: the need for in-country product

testing; the failure to use international standards; requirements to nominate and retain an in-country Indian representative; the need to provide a performance bank guarantee; and the value of providing an indemnity bond. Moreover, Canada continues to seek the cessation of the Quality Control Order that requires Indian officials to conduct inspections of toy factories in exporting countries, at the exporters expense. Owing to COVID-related travel restrictions, these inspections cannot be undertaken and, consequently, Indian imports have stopped. We recognize the constraints that the COVID-19 pandemic is currently placing on India, but, at a minimum, Canada is urging India to consider conducting virtual inspections of foreign toy manufacturing plants to attest their safety.

4.382. The representative of Hong Kong, China provided the following statement. Hong Kong, China would like to thank the European Union and China for raising this specific trade concern, to which we would like to add our support. Hong Kong, China is concerned about the entry into force of India's measure, namely the Toys (Quality Control) Order, 2020 (the Order), and the Amendment in Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017-Schedule-I (Import Policy), with effect from 1 January 2021. On the bilateral and capital level, Hong Kong, China already outlined to India on 19 March 2021 the concerns raised by our toy manufacturers and exporters. So far, we have not yet received any feedback from India. To recap, the toy manufacturers and exporters in Hong Kong, China are concerned about the new requirement for physical inspections of overseas factories by officials from the Bureau of Indian Standards (BIS) and the requirement for factory audits by designated Indian firms. Under the travel restrictions arising from the COVID-19 pandemic, it is uncertain whether the required physical inspection by BIS officials can be performed in a timely manner. The toy manufacturers and exporters in Hong Kong, China also note that only a few of the accredited laboratories responsible for the testing of toys are operating normally in India during the pandemic. In addition, there are costs associated with obtaining the licences and the Standard Mark, including visiting charges, testing charges, other administrative costs for processing of application by the BIS, the need to print the Standard Mark on the primary packaging, etc.; such costs will create financial burden and undue obstacles to non-Indian toy manufacturers and exporters. We understand that the export of toys to India by toy manufacturers and exporters in Hong Kong, China have come to a standstill due to the new requirements under the Order. Hong Kong, China is committed to resolving this issue with India amicably. While we recognize the importance of upholding the safety standard of toy products, we respectfully request India to critically reassess the new measures imposed under the Order and consider alternative solutions, so as to provide a level playing field for foreign manufacturers and exporters. Hong Kong, China looks forward to receiving India's early response to the concerns raised by our toy manufacturers and exporters.

4.383. In response, the representative of India provided the following statement. Foreign inspection visits are on hold due to the prevalent restrictions on international travel imposed by the Government of India, but in some instances by the Government of other respective countries because of the ongoing COVID-19 pandemic. As soon as the situation of COVID-19 improves and the restriction lifted, India will plan the inspections (factory visit). BIS has recognized a number of laboratories for carrying out toys 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 below link.[85] Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry has issued the Toys (Quality Control) Order, 2020 under the provisions of BIS Act, 2016 and Rules and Regulations framed thereunder, which envisages conformity assessment scheme-I of BIS (Conformity Assessment) regulations, 2018. As per Scheme I of Schedule II of BIS (Conformity Assessment) Regulations, 2018, the applicant must submit a complete test report of the product issued from a third-party laboratory and the application. The testing of sample drawn during the factory inspection is also carried out in a third-party laboratory. Under Scheme-I, a third-party laboratory is defined as "a laboratory established, maintained or recognized by the Bureau or Government laboratories empanelled by the Bureau or any other laboratory decided by the Bureau's Executive Committee".

4.384. As regard marking and labelling requirement, it may be mentioned that under the Scheme-I, BIS licence will be granted to a manufacturer of toys as per the Indian Standard and all varieties (maybe called items/families /models/SKU etc.) of toys covered in the standard will get covered under the same licence. No separate application and standard mark are required to cover families of similar toys. Further, to cover all the varieties in a standard under the licence, BIS will be issuing

[85] http://164.100.105.198:8096/bis_access/iswise_v2.html

grouping guidelines intending to specify a minimum number of varieties of toys to be tested to consider covering a larger number of varieties in the scope of the licence. This will be with the aim of optimum testing to ensure the safety of all toys for children. The marking of standard mark concerning standard and licence number is a requirement as per the provision of BIS (Conformity Assessment) Regulations and applies to all manufacturers in India as well. The standard mark is essential for the common consumer to understand and identify that product is certified and safe to use. This is already in practice for more than 200 products under mandatory certification and being implemented by more than 1,000 manufacturers of various countries under the FMCS scheme of BIS. As per the Toys (Quality Control) Order, 2020, every toy shall conform to corresponding Indian Standards specified therein and shall bear the standard mark under the licence from BIS as per Scheme-I of BIS (Conformity Assessment) Regulations, 2018. Under the provisions of Scheme-I, BIS grants a licence to use or apply Standard Mark (ISI mark) on goods and articles as per Indian Standard and not as per International Standards. IS 9873 (Part 1,2,3,4 & 7), specified in the QCO, are identical with International Standard ISO 8124 (Part 1,2,3,4 & 7). Part (9) of IS 9873 is an indigenous standard published to restrict certain phthalates esters in toys and children products. However, the test method used is identical to ISO Standard. Further, IS 15644 is also identical with International Standard IEC 62115.

4.1.3.47 Australia - Maturation requirements for imported alcohol (ID 636[86])

4.385. The representative of Brazil provided the following statement. Brazil continues to follow closely Australia's proposal to amend current regulations dealing with alcoholic beverages. In past Committee meetings, we have shared our concerns with Australian technical requirements applicable to cachaça, the Australian Customs Notice Nº 2007/19, which 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. 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.

4.386. Brazil acknowledges progress in the course of action proposed in the last public consultation. 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". We kindly urge Australia to answer the following questions, which have not been addressed in its previous statements. 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?

4.387. 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 provide the following update to the matter raised by Brazil. 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 unmatured alcohol products under section 105A of the Customs Act. The review process is considering potential options for treating unmatured

[86] For previous statements follow the thread under ID 636.

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 provided 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.[87] The Government is considering 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 Australian Border Force (ABF). The ABF is taking the issues raised by Brazil into consideration as part of the ongoing reform process.

4.1.3.48 India – FSSAI's Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and the new implementing veterinary certificate for dairy products (ID 633[88])

4.388. 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.

4.389. In response, the representative of India provided the following statement. The provision for non-animal rennet in the manufacture of cheeses is not newly introduced in our regulations. 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. The requirement of a veterinary certificate has been recently aligned with our FSSR regarding the prohibition on the use of animal rennet. 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. Hence, FSSAI has not introduced any new requirement.

4.1.3.49 India - Order related to requirement of Non-GM cum GM free certificate accompanied with imported food consignment, G/TBT/N/IND/168 (ID 651[89])

4.390. 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 shares India's food safety concerns. However, we would like to highlight the following concerns. The criteria for the selection of the 24 food crops listed in Annexure 1 is not clear. The EU invites India to explain the rationale behind such selection. Non-GM origin cum GM-free certification per consignment should not be required, at least for the listed crops for which no GMOs are authorized

[87] www.homeaffairs.gov.au/reports-and-publications/submissions-and-discussion-papers
[88] For previous statements follow the thread under ID 633.
[89] For previous statements follow the thread under ID 651.

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 an official statement to India on the non-GM nature of the crops concerned, which would replace individual certificates for each consignment. For listed crops for which GM varieties are authorized in the exporting country (for the EU, this applies to maize, soybean, cotton, Argentina 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.

4.391. 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 GMs. 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 GMs, there are very strict traceability and labelling requirements applicable to food that contains GMOs. This allows a strict and effective separation between non-GM and GM products, with the exception of those containing GM ingredients in a proportion of less than 0.9%, provided the presence is adventitious or technically unavoidable. This means that the EU's tolerance limit is even stricter than that indicated by FSSAI in its clarification dated 8 February 2021, i.e. 1%. All authorized GMOs in the EU are registered in the publicly available EU GM register, which is managed and regularly updated by the EU Commission. 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 existing EU regulatory provisions already offer satisfactory assurance that EU produce exported to India is in compliance with Indian's requirements. The Indian requirement, imposing non-GM origin cum GM free certification for all consignments of the listed crops, goes beyond what is necessary to achieve the stated objective and puts an additional burden, and therefore costs, on EU exporters (and the related operators along the supply chain). Therefore, the EU considers that the Order is disproportionate and creates unjustified barriers to trade. The EU would be grateful if the above-mentioned comments could be taken into account and replied to.

4.392. The representative of the United States provided the following statement. The United States again reiterates serious concerns with India's measure mandating "non-GM (genetically modified) origin and GM free certificates" for certain agricultural imports into India, notified on 2 September 2020, as G/TBT/N/IND/168, and a later notified entry-into-force date of 1 March 2021. The United States would like to remind India of our previous statements delivered at the October 2020 and March 2021 TBT Committee meetings, which detailed our continued concerns regarding India's implementation of this measure. The United States urges India to withdraw this requirement, for which India has not provided science-based justification despite multiple US requests. India should explain the scientific rationale for the measure and provide any relevant international standards on which this measure is based. If India is unable to withdraw this requirement, we request that India consider alternative approaches that are implemented in a non-discriminatory manner, and in a way that is no more trade-restrictive than necessary. In January 2021, the US proposed technical cooperation with India to develop alternatives to the non-GM origin and GM-free certificate. We look forward to the Food Safety and Standards Authority of India's (FSSAI) response to this proposed technical cooperation opportunity.

4.393. The representative of Brazil provided the following statement. Since India has not yet provided any explanation on the points raised by Members regarding STC 651 in the past Committee meetings, Brazil would like to reiterate its concerns. 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 5.1.2 of the TBT Agreement. Said regulation might be already impacting Brazilian exporters.

4.394. The Indian regulation is 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 fulfill any legitimate objective under the scope of the TBT Agreement. We kindly ask India to reassess this draft measure. Moreover, could India please indicate the studies and the relevant international studies it relied upon in order to draft this regulation?

4.395. The representative of Colombia provided the following statement. Colombia supports this trade concern regarding the Order adopted on 12 October 2020 by the Food Safety and Standards Authority of India (FSSAI), 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 (GMOs). The certificate must be issued by the relevant national authority of the exporting country. At this time 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". We request India to provide information on the entry into force of this regulation, on which matter we reiterate that a reasonable interval should be allowed between the publication of technical regulations and their entry into force, in order to allow time for exporters, and particularly in developing countries, to adapt their products or production methods to the requirements of the importing Member. We request India to revise this regulation, consider alternative ways to avoid the creation of unnecessary obstacles to international trade and to re-submit the notification of the regulation in order to have access to the relevant information.

4.396. The representative of Japan provided the following statement. Japan shares the concerns on India's 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 Member countries. Despite our request to consider the comments and concerns from Member countries to India, it is very regrettable that the order has come to effect this March. Japan controls the import, distribution, and cultivation of GM food through the safety assessment conducted under the Japanese domestic regulation The non-approved GM variety cannot be imported to Japan or distributed domestically. India's requirement to attach the "non-GM origin and GM free certificates" to the specific food items which are already appropriately controlled in the exporting countries is unnecessary and excessive measure. Thus, Japan would like India to waive the requirement to attach the certificate for such controlled food items from Member countries.

4.397. The representative of Australia provided the following statement. Australia thanks India for their ongoing engagement and cooperation regarding the use of non-GM with GM-free certificates - in particular India's response to queries on this item raised during both the WTO SPS and TBT Committee meetings earlier this year. 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 emphasise 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.

4.398. The representative of Paraguay provided the following statement. Paraguay reiterates its position and refers to its statement made at the previous meeting[90], in which it stated the technical reasons for which it considers that the regulation contained in notification G/TBT/N/IND/168 could be more trade-restrictive than necessary to fulfill any legitimate objective under the TBT Agreement. We hope that India revises this measure to address our concerns and those of many other Members, as expressed to this Committee.

4.399. The representative of Canada provided the following statement. Canada would like to reiterate concerns raised at the October 2020 and February 2021 TBT Committee Meetings regarding the implementation of India's August 2020 Order, notified to the TBT Committee under G/TBT/N/IND/168, which mandates that a non-genetically modified or GM-free certificate accompany imported consignments of 24 imported food products listed in the Order's Annex I. While we understand India's commitment to ensure the health and safety of its population, it is unclear how India's non-GM certification requirement will fulfill 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 India's Order disproportionately impacts the ability of GM-producing countries to export to India and unnecessarily restricts international trade. We strongly encourage India to consider the scientific and technical information in support of a less burdensome approach to meeting the Order's stated food safety goals. Therefore, Canada requests once again that India suspend the implementation of this measure and allow trade to continue without a certificate requirement. This would provide an opportunity for India to further engage with Members to discuss and consider an alternate, less trade-restrictive approach that would meet India's objectives and minimize disruptions to trade. Canadian officials would be pleased to contribute to these discussions and share its extensive experience in this area. In addition, considering that the Order's stated objective is "to ensure the safety and wholesomeness of articles of food imported into India", we are of the view that it should be notified to the WTO Sanitary and Phytosanitary (SPS) Committee. Lastly, Canada looks forward to receiving detailed responses to its comments submitted through India's TBT Enquiry point in October 2020.

4.400. The representative of Uruguay provided the following statement. Uruguay recognizes India's right to take measures to guarantee the safety of food and the health of its population. However, Uruguay wishes to recall that 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. Therefore, in Uruguay's view, there would not appear to be any 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. Bearing in mind the above-mentioned objective, we would like to ask the delegation of India why it has not yet notified this measure to this Organization's Committee on Sanitary and Phytosanitary Measures. Uruguay wishes to stress the importance of Members establishing measures based on scientific principles and particularly of applying such measures with the objective of minimizing the negative trade effects, in line with the provisions of the TBT and SPS Agreements. We await any comments that the delegation of India may make in response to Members' concerns expressed in both Geneva and New Delhi, including in a joint note submitted by a number of countries – one of which being Uruguay – in January this year, to which a reply has not yet been received.

4.401. 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. New Zealand remains concerned that India's requirements regarding non-GM certification for specific foods is imposing further restrictions and costs on existing trade in goods covered by the measure. New Zealand encourages India to accept a country-wide assurance as an alternative consignment-based non-GM certification. We would appreciate clarification on 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

[90] G/TBT/M/83, paras. 2.384-2.386.

notes the measure is implemented under food safety legislation. If the protection of human health is the objective, in whole or in part, can India advise whether it intends to also notify the measures to the SPS Committee, given its relevance to provisions within the SPS Agreement, particularly Codex Alimentarius? We refer to New Zealand's more detailed written submission of 2 September 2020 on India's notification G/TBT/N/IND/168 which outlines its concerns that remain relevant today. We refer India to the comments New Zealand made on this measure at the most recent meeting of the SPS Committee. New Zealand strongly requests India adopt the least trade-restrictive alternative/s for those countries that have not approved the release of any genetically modified crops into the environment.

4.402. The representative of Argentina provided the following statement. Argentina would like to once again express its concern regarding the new Order issued by the Food Safety and Standards Authority of India (FSSAI), notified in document G/TBT/N/IND/168, which requires imports of food products to have a certificate of Non-GM product origin. We stress the importance of basing any measure of this type on scientific principles so that it does not become an unnecessary barrier to international trade. Scientific evidence shows that duly authorized GM products are as safe as their conventional equivalents and there is no justification for discriminating between one or the other. We hope that India will amend the notified Order soon. We recall that we have already submitted more detailed comments and specific questions through the 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.

4.403. In response, the representative of India provided the following statement. It may be noted that Genetic Engineering Approval Committee (GEAC) is empowered under the Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989 of the Environment Protection Act (EPA) 1986 for approval of proposals relating to 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 import of processed food via letter dated 12 October 2020.

4.1.3.50 Russian Federation - Federal Law n° 468 on wine making and wine growing in the Russian Federation (ID 650[91])

4.404. The representative of the United States provided the following statement. The United States continues to request that Russia notify implementing measures to the WTO TBT Committee, provide at least 60 days for interested stakeholders to comment on the measure, and take submitted comments into account before finalizing these measures. The United States also continues to seek a response to our comments on Federal Law n° 468 submitted to Russia's WTO TBT Enquiry Point in August 2020. Does Russia intend to respond to comments received from WTO Members? Of particular concern to the United States is Article 24 of the Law, which outlines prohibited technological methods for the production of wine. More specifically, sub-article 11 refers to the use of imported wines in the production of wine in Russia. Can Russia please confirm if foreign wines imported in bulk for bottling in Russia are permitted and, further, if these products can be labelled as wine produced in the foreign country and bottled in Russia? Lastly, we understand that Russia is in the process of aligning Federal Law n° 468 with EAEU Technical Regulation 047/2018 on the safety of alcohol products. We also understand that the Eurasian Economic Commission requested that the Russian Federation draft and submit amendments to the Technical Regulation by 30 April 2021. Can Russia provide an update on the status of that process?

4.405. The representative of the European Union provided the following statement. Russia has adopted a measure "Federal Law Nº 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 and discrepancies between the Law and

[91] For previous statements follow the thread under ID 650.

OIV provisions. 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 authorized (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.

4.406. The EU has been informed that Russia has sent letters to some EU member States requesting consultations and detailed information exceeding the normally exchanged information and mutual assistance between competent authorities in relation to the wine sector. The Commission has sent the reply on behalf of the member States and is ready to provide any relevant information in this respect. A process of alignment of EAEU TR47 is currently on-going. The EU sent proposals of amendments aiming at improving the alignment to international standards. The EU hopes these will be considered and retained in order to facilitate international trade both ways. 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.

4.407. The representative of Australia provided the following statement. Australia thanks the Russian government and industry for its recent engagements on this issue. Australia understands Russia has adopted "Federal Law Nº 468 of 27 December 2019 on wine making and wine growing in the Russian Federation", which entered into force on 26 June 2020. Australia notes the value of Australian wine exports to the Russian Federation has slightly increased since the implementation of the law. However, Australia still maintains concerns regarding several import barriers posed by the Federal law. As noted at previous TBT Committees, these include: The mandatory declaration of vintage and variety required under the new law 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.

4.408. 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. 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. 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". Australia understands that the implementation of the technical regulation has been postponed to allow harmonization work with the Russian Law. Australia encourages Russia to take into account concerns raised by Members during the harmonization phase, including ensuring the technical regulation aligns with international production standards. We look forward to Russia notifying the WTO of these measures accordingly.

4.409. The representative of Argentina provided the following statement. Argentina would like to once again highlight its concern regarding the implementation of the Law on wine making and wine growing in the Russian Federation (Federal Law No. 468 – FZ). We are particularly concerned about the unilateral alterations of the product name, which could result in misinformation regarding the product and consumer confusion. Under the new Law, "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 process or oenological procedure and is not blended with other beverages or substances. Our country trusts that through constructive dialogue with stakeholders, appropriate amendments can be made to the standard in order to avoid unnecessary obstacles to trade.

4.410. 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, Australia and Argentina. Statements will be sent to relevant Russian authorities for consideration. We refer to our previous statements on this subject in the WTO working bodies. Today, in response we would like to highlight the following. The Federal Law on winemaking and winegrowing entered into force on the 26 June 2020. The Law is aimed to develop and improve Russian internal wine 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. Despite raised concerns about the Federal Law, statistics show that imports of wine to the territory of the Russian Federation did not substantially decline. As for the TRIPS Agreement, we stress that this Law does not cover intellectual property rights 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.

4.1.3.51 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 662[92])

4.411. The representative of the United States provided the following statement. The United States recalls its February 2021 intervention and thanks Panama for recent bilateral discussions. Unfortunately, no progress has been made toward addressing our concerns. We continue to receive reports of rejected or detained US onion shipments, and we are concerned about the impact on US potato exports when the potato regulation enters into force on 2 June 2021. Given the negative impact on US onions, the potential impact on US potatoes, and Panama's lack of transparency, we again urge Panama to suspend implementation of both regulations indefinitely in order to address WTO Members' concerns. Panama has yet to explain its rationale or technical justification for these measures. As we have explained, Panama's harvest date requirement presents an unnecessary trade barrier, and we have not heard of any other country in the world imposing such a requirement. Onions and potatoes can be marketed for many months after harvest due to quality of the seed, variety selection, good supply chain practices, cold storage, and other technologies. We reiterate, again, that the relevant international standard in Codex specifically excludes vegetables from "use-by date" or "best-before date" labelling requirements and clarifies that providing a "date of manufacture" or "date of packaging" is optional. Panama's zero sprouting requirement does not appear necessary or practical. The market differentiates between different quality grades of onions and potatoes. Entire shipments should not be rejected because a few sprouted onions were found.

4.412. The representative of Canada provided the following statement. Canada would like to join the United States to signal its concerns with Panama's new quality requirements for fresh potatoes established by the Ministry of Industry and Commerce on 20 February 2020. Canada is Panama's second largest supplier of fresh potatoes. It has recently come to our attention that the implementation of Panama's new quality requirements could have a direct impact on Canadian exports to Panama. We therefore share some of the concerns raised by the United States in their intervention. Canada understands that Panama has twice delayed the implementation of these measures. However, in light of the potential trade implications these new requirements could have on Canadian exports, Canada respectfully supports the request of the United States that Panama delay its entry into force. This would provide sufficient time to engage bilaterally on this issue to discuss elements of concern and explore potential options to find a viable solution. Canada looks forward to further discussions with Panama on these new requirements.

4.413. The representative of the European Union provided the following statement. The EU joins the trade concern voiced by the US and Canada. Our exporters are also facing similar difficulties in agro-food trade with Panama. The European Union would like to express the importance of speedy, consistent and transparent SPS procedures carried out by independent authorities and the need to avoid unnecessary TBT barriers. The European Union is prepared to work bilaterally with Panama to find a satisfactory solution.

4.414. In response, the representative of Panama provided the following statement. The delegation of Panama takes note of the comments from the United States, Canada and the European Union, which I will forward to my Ministry. The delegation of Panama has continued to hold bilateral capital-to-capital meetings aimed at resolving this issue, and we will continue our efforts to find a mutually

[92] For previous statements follow the thread under ID 662.

satisfactory solution. We will share with the Committee any information that we receive as a result of these conversations.

4.1.3.52 European Union - Wine labelling requirements – listing of importers for multiple destinations (ID 659[93])

4.415. The representative of Australia provided the following statement. Australia thanks the EU for clarifying their labelling requirements at the previous TBT Committee meeting. Given that wine is regularly exported to the EU through the UK, and that Brexit has heavily impacted this arrangement, we reiterate our concerns raised at previous meetings. We look forward to working closely with the EU on this issue to ensure a mutually satisfactory outcome that is no more trade restrictive than necessary.

4.416. In response, the representative of the European Union provided the following statement. As explained in previous TBT Committees, the indication of the "importer" is a compulsory indication for wine imported into the EU and the importer is understood as 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 provided it 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).

4.1.3.53 European Union - Waste Framework Directive, G/TBT/N/EU/778 (ID 658[94])

4.417. The representative of India provided the following statement. The Republic of India has been raising this STC in the last two TBT meetings. The EU has given a response in the last TBT meeting held in February 2021. We thank the EU for the detailed reply; however, the concerns raised by India are still not addressed. Hence, we reiterate the statement made in the February 2021 TBT meeting and request the EU to respond to the issues of concern not addressed so far and which are listed here. The Non-EU companies have no provision of an Only Representative (for its compliance), thus they have to share the product details with the buyers; there is an issue of sharing intellectual property/Know-how sharing, which will act as a barrier to trade implicitly. The non-EU companies are treated unfairly. They have to depend on the EU buyers as they will have no choice to do the activities by themselves. EU buyers may require unnecessary testing and declarations in situations where it may clearly be a non-SVHC product/article. EU-buyers may insist on certain specific testing facilities to be used and would have undue cost implications on the non-EU suppliers. Since major industries are impacted because of the COVID-19 pandemic, the deadline must be extended for the industry to comply with these new requirements/special provisions for compliance

4.418. The representative of China provided the following statement. We suggest that the EU provide a sufficient comment time and transition period in accordance with WTO/TBT Agreement. In view of the information security issues that concern all parties, it is suggested that the EU provide relevant documents and hold seminars to explain how data security is protected in this field.

4.419. In response, the representative of the European Union provided the following statement. The European Union (EU) would like to thank India and China 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 recall that extensive information was provided to Members in the past two Committees and would like to reply to the specific further questions by India. First, the European Union would like to reiterate that only legal entities established in the EU can make SCIP notifications. The Waste Framework Directive contains no provisions for an "only representative" for non-EU companies, as it happens under REACH for the purpose of registration. However, in order to support non-EU companies to fulfill their obligations, European Chemicals Agency (ECHA) has developed a "foreign user" functionality in its submission tool. An EU importer may set up contractual agreements with their non-EU suppliers of articles to act on their behalf (as a "foreign user"), regarding the submission of data to the SCIP database. However, the responsibility of the SCIP notification and its content still lies with the EU importer of articles originating from third countries. Under the Waste Framework Directive, similarly as under

[93] For previous statements follow the thread under ID 659.
[94] For previous statements follow the thread under ID 658.

REACH, the EU can only hold accountable those legal entities that operate in its territory. For further information see Q&A no 1665 published on the website of the ECHA.

4.420. Second, as regards confidential business information, only the data that is strictly necessary to ensure safe use of articles by consumers and waste operators is requested and will be made publicly available. Guidance is available on the ECHA website explaining what information is needed and how to prepare SCIP notifications. It should therefore be possible to prepare a SCIP notification without revealing confidential business information or the know-how of the product. Third, neither Article 9 of the Waste Framework Directive, which defines notification obligations to ECHA, nor Article 33 of REACH, specify the need for testing or specific requirements such as the use of specific test facilities. It is up to importers of articles into the EU to obtain the necessary information from non-EU suppliers, including justification regarding the absence of SVHCs in the product/article. Finally, both the obligation to notify and its date of application have been laid down by the co-legislators in the revised Waste Framework Directive, and the Commission is not empowered to modify them. Furthermore, the deadline has already past, the obligation applies from 5 January 2021 and ECHA had, by end of April, received over 12 million submissions to the database. The European Union expects that, to a certain extent, suppliers can build on arrangements put in place to comply with the existing obligation under Article 33 of the REACH Regulation to provide information on the presence of substances of very high concern in articles. The European Union would like to refer to the statement from the past TBT Committees for more information and remains available to provide replies with regard to the SCIP database to interested Members.

4.1.3.54 France - New legislative requirements about index of repairability 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 657[95])

4.421. The representative of China provided the following statement. China appreciates France's efforts to fight against waste and boost the circular economy and fulfill the transparency obligation under WTO, and give replies to our comments. But from the perspective of no creating unnecessary trade barriers, in accordance with the requirements specified in Article 2.12 of the TBT Agreement, we raise following comments once more. It is suggested to delay the implementation of penalty clauses related to violation of the repairability index information in Environmental Law L.541-9-4. At present, in addition to washing machines, smart phones, laptops, televisions, and electric lawn mowers (batteries, cables, and robots), France has not yet released the specific evaluation requirements for the repairability index of other electronic and electrical products, and has not published any related implementation plans. Even if France immediately releases the requirements for the repairability index except the above products, excluding the time for all other parties to review, the transition period for each manufacturer is only half a year, which would make troubles to enterprises that have been devoted to compliance of their productions and sales. Therefore, it is obviously not reasonable to impose penalties since 1 January 2022 for violations of the obligation of information reporting. We propose to delay the entry into force of Environmental Law L.541-9-4. It is suggested to amend Article L541-9-2 of the Environmental Law. The new decree would apply to products placed on the market after the decree coming into force, rather than products on sale. The reasons are as follows.

4.422. If a large number of products that have been placed on the market are to be rectified for compliance, it will take a lot of time and cost; some products may be delisted, so it is not reasonable and does not conform with the concept of green environmental protection. In addition, Article L411-1 of the French "Consumer Code" states that "From the first time they are placed on the market, products and services must meet the requirements in force relating to the safety and health of persons, the fairness of commercial transactions and consumer protection. The person responsible for placing a product or service on the market for the first time verifies that it complies with the regulations in force." "Placed on the market" is used as a control switch. Therefore, it is recommended that Article L541-9-2 of the Environmental Law could not apply to the products that are already sold on the market.

4.423. It is suggested to clarify the relevant law enforcement entities and law enforcement responsibilities, as well as the customs clearance and market supervision of products in France before the penalty clause enters into force on 1 January 2022. The reasons are as follows. At present,

[95] For previous statements follow the thread under ID 657.

the regulations related to the repairability index have taken into effect, and the related penalties will be implemented in the future. However, the law enforcement body is not clear, during the period from 2021 to 2022, the following issues will cause difficulties for economic operators (including manufactures). Will the French customs inspect and prohibit then on-compliant products? Will relevant agencies in the French market put forward compliance requirements for related products according to law? Therefore, it is recommended to clarify the relevant law enforcement entities and law enforcement responsibilities, and explain the above issues. It is suggested that France releases the applicable product catalogue scope in Article L541-9-2 of the Environmental Law, provide the specific applicable time schedule of the product laws and regulations, and specify an example template for each type of applicable product for repairability index assessment, so as to facilitate compliance rectification for the enterprise.

4.424. In response, the representative of the European Union provided the following statement. For the time being, even though the general regulation (Décret no 2020-1757 du 29 décembre 2020) includes all electric and electronic products in its scope, the requirements only concern the product categories for which a technical regulation ("arrêté") has been adopted: front-loading washing machines, smartphones, laptops, TV monitors, and electric lawn mowers (three types: with electric cable, with battery, robot). The requirements apply only to products put on the market from the date of entry into force of the regulation, i.e. 1 January 2021. The official regulatory texts (décret and arrêtés) can be found below.[96] The market surveillance authorities will carry out random controls as of 1 January 2022. The controls will focus on the effective presence of the repairability index on the products and on the veracity of the information provided as part of the repairability index. There are currently no requirements for other product categories. A reflection is ongoing about an extension of the requirements to other product categories. However, no decision has been taken yet. In any case, if such an extension takes place, France will notify the new implementation measures to the WTO, and there will be a transition period to allow economic actors to get ready for the implementation. Several technical documents (instructions manual, calculation grid, graphic charter) are available in French and English in order to help manufacturers and retailers to comply with the regulation. They can be found below.[97]

4.1.3.55 Chile - Technical specifications for the design of energy efficiency labels for washing machines, G/TBT/N/CHL/297, G/TBT/N/CHL/325 (ID 654[98])

4.425. 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. Korea wants to express our gratitude to Chile for responding to Korea at the February 2021 TBT Committee Meeting. Chile said that it was currently reviewing a new regulation regarding the energy efficiency label for washing machines and would try to reflect stakeholders' opinions, including those of Korea. Korea would like to be informed of the revision's current status and whether or not Korea's opinions have been reflected in the revised standards. In addition, Korea requests that Chile notify the WTO before the implementation date and provide sufficient time for Korean companies to prepare for the new regulation.

4.426. In response, the representative of Chile provided the following statement. As Chile has previously reported, the recent focus has been on implementing Law No. 21.305 on energy efficiency, which was published in February and should result in a number of sectoral regulations entering into force by next February. The Chilean Ministry of Energy has prioritized its work on the above-mentioned regulations, and would like to inform the Korean delegation that it has not yet been possible to begin amending the energy efficiency protocol for washing machines. When it does become possible to make these amendments, a transparent national and international public consultation process shall be conducted and will be reported to this Committee.

4.1.3.56 Republic of Korea - Revision of Safety Conformation Criteria for Textile Products for Infants, G/TBT/N/KOR/678 (ID 652[99])

4.427. The representative of the European Union provided the following statement. The EU would again like to raise its concerns with regard to the Republic of Korea's requirements for conformity

[96] https://www.ecologie.gouv.fr/indice-reparabilite
[97] https://www.ecologie.gouv.fr/indice-reparabilite
[98] For previous statements follow the thread under ID 654.
[99] For previous statements follow the thread under ID 652.

testing of textile products for infants. The EU pays the utmost attention to and underlines the importance of product safety in its market, including that of product safety for infant clothing. Any item of baby wear for sale in the EU must comply with the EU's General Product Safety Directive (2001/95/EC). Additionally, there are several European standards that apply specifically to children's clothing. In particular, the harmonized standard 14682 contains requirements to ensure that cords and drawstrings are placed safely on apparel for babies and children up to 14 years. This is to avoid strangulation and choking hazards. Furthermore, any item of baby wear on the EU market must comply with the REACH Regulation (registration, evaluation, authorization and restriction of chemicals). Several chemicals commonly used in apparel production are restricted under REACH. The EU believes that the extra testing required by Korea is more trade-restrictive than necessary to fulfill a legitimate objective. 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.

4.428. Due to this measure, a huge amount of clothing samples have to be sent to Korea for testing, resulting in a substantial increase of testing and certification costs for European producers. As an example, the total testing costs for infant clothing of an EU producer increased by 30% in 2018 compared to 2017 and by 1154% in 2019 compared to 2017. The corresponding sales figures were a decrease of 13% and 19%, respectively. Hence, these costs are independent of sales and not one-off in nature. In an effort to facilitate the customs procedures, EU companies applied to the Korea Customs Service (KCS) to be recognized as a "best practice company" last year. However, according to the reply from KCS, this application requires Korean Agency for Technology and Standards (KATS) to provide KCS with information about the post management plans for the companies and this information was not completed by the deadline hence the consultation between KATS and KCS was not concluded, and ultimately, KCS could not approve the companies as best practice companies. Could Korea please provide some assistance as regards the procedures between KCS and KATS in applications for "best practice company" status? The EU kindly requests that the Korean authorities take the necessary steps to remove this trade barrier. In order to alleviate the issue, the EU requests that Korea allow the required conformity testing to be performed outside of the country by an internationally accredited laboratory according to the Korean product standard.

4.429. In response, the representative of the Republic of Korea provided the following statement. Korea appreciates the interest of EU in Korea's regulation for Textile Products for infants. Korea and EU have been having several meetings to resolve these concerns since early last year, including the meeting last April right before this TBT Committee meeting. 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. Regarding the EU's concerns about a substantial increase in testing and certification costs for European manufacturers 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. As for the relationship between the increase of testing and certification costs and the decrease of sales figures, we have not found any basis for this claim nor any direct connection between them during the relevant period. Regarding customs procedure, the role of the Korea Customs Service is prescribed by the Customs Act. Regarding the topics which are not included in our response, Korea thinks those topics are related to a few specific stakeholders so they could be more effectively handled outside of the WTO TBT meeting. Korea sincerely hopes to resolve the EU's concerns in a mutually beneficial manner in the near future.

4.1.3.57 India - Testing and Certification of telegraph (The Indian telegraph (Amendment) Rules, 2017) and 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/159, G/TBT/N/IND/160, G/TBT/N/IND/158 (ID 646[100])

4.430. The representative of China provided the following statement. We suggest that India provide a sufficient comment period and transition period in accordance with WTO/TBT Agreement and accept test results from laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories, and speed up product application approval.

4.431. The representative of the United States provided the following statement. The United States remains concerned that India is no longer accepting test results from foreign laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories as proof of conformity to India's Mandatory Testing and Certification of Telecom Equipment (MTCTE) procedures. We would be interested in India's views on why it does not recognize such test results, particularly since India is an ILAC member. Considering the scope of the test requirements under the MTCTE, the technical complexity involved, as well as disruptions to product testing and certification caused by the COVID-19 pandemic, the United States reiterates its request that India recognize all relevant test results, including electromagnetic interference and electromagnetic compatibility (EMI/EMC) results, from ILAC-accredited laboratories, for at least one year from the date of publication of any future MTCTE phases. 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 non-certified products, including new models. We understand that Phase III of the MTCTE could be implemented by the end of 2021. Can India provide any information on Phase III, including potential timelines for implementation?

4.432. The representative of Canada provided the following statement. As Canada noted in previous meetings of the Committee, we appreciate the extension, to 30 June 2021, of the 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). Canada hopes that this extension will be prolonged beyond 30 June and, recognizing the challenge posed by the COVID pandemic, that firms will be notified as early as possible. Can India provide us with information on this possibility? We continue to 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. We also wish to reiterate our concern 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.

4.433. In response, the representative of India provided the following statement. 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 now 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 the 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. 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 to provide firms with at least one year to comply with any future phases of the MTCTE shall be considered at

[100] For previous statements follow the thread under ID 646.

the time of launch of future phases of MTCTE. Phase-III of MTCTE is under consideration, and timelines for implementation will be intimated when the proposal is finalized.

4.1.3.58 European Union - Testing methods for prohibited chemicals of regulation on cosmetic products, G/TBT/N/EU/752 (ID 680[101])

4.434. The representative of China provided the following statement. We suggest that the EU clarifies the testing methods for volatile nitrosamines contained in nail polish products.

4.435. 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, which was elaborated in our statement for the TBT Committee in February 2021. The EU would like to refer China to this previous statement as well as to the written reply of 4 February 2021.

4.1.3.59 Nigeria - Onerous testing and conformity requirements by societe generale de surveillance, (SGS) for machinery and their parts (ID 679[102])

4.436. The representative of India provided the following statement. The delegation of India raised this concern in the February 2021 TBT meeting. The Republic of India is deeply concerned about Nigeria's onerous certification and conformity requirements, which adversely affect the Indian exports to Nigeria. Under the current system, all Nigerian importers must obtain a Product Certificate and a SONCAP Certificate (SONCAP is a pre-shipment verification of conformity to Nigerian standards) for each consignment. The process of obtaining a Product Certificate and meeting the conformity assessment requirement is onerous, intensive, and expensive. It involves an elaborate two-step process, briefly explained below. First step: Obtaining Product Certificate: to place an order for importing to Nigeria, the importer needs a Bank in Nigeria to issue Form M. This Form M can only be issued based on product certificate. The product certificate is given 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 product certificate is a circulatory and highly trade-restrictive process. Secondly, the validity of a product certificate issued by Nigerian authorities is only six months, which is a very short time. This adds an extra burden on the exporter in terms of the cost and time required to obtain another product certificate.

4.437. Second step: Obtaining SONCAP Certificate: Once the order for a product is placed and the product certificate requirement is met (as mentioned in the first step), but before the product is exported to Nigeria, a SONCAP Certificate for each consignment is required. This requirement of obtaining a SONCAP certificate is in addition to the product certificate requirement. This process of conformity assessment for each shipment is cost-intensive and involves onerous procedures. Countries establish such onerous conformity assessment requirements for products that have implications for human health, plant/animal health or environment, or products of prohibited category or originating from restricted countries. In other words, the degree of risk associated with importation is determined for placing such stringent conformity assessment requirements. However, in Nigeria's case, except for few products, each consignment is required to carry a SONCAP certificate. The requirement of a SONCAP certificate for each consignment appears to be violative of Article 5.2 of the TBT Agreement, 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. Also, it must not be more trade restrictive than necessary to fulfill a legitimate objective. We consider these measures to be highly trade restrictive and create unnecessary obstacles to trade. Hence, Nigeria is requested to consider simplifying the procedure for obtaining the product certificate. Nigeria is also requested to share the risk assessment study done to arrive at the following decision: a) requirement of a product certificate for all products; b) six months validity of product certificate; 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.

[101] For previous statements follow the thread under ID 680.
[102] For previous statements follow the thread under ID 679.

4.438. In response, the representative of Nigeria provided the following statement. Nigeria wishes to thank India for its interest in this issue. Nigeria notes that some of the issues raised by India are inaccurate and wishes to state that the measures and its applications are in accordance with the provisions of the WTO Agreement and International Best Practices. Regarding the issue of Product Certificate, these certificates are issued on behalf of Nigeria by mandated International Accredited Firms pursuant to the provisions of the Agreement on Pre-shipment Inspection. These firms are also guided by the PSI Code of Practice of the Testing, Inspection and Certification Council (TIC Council). On India concern regarding Nigeria requirement of a product certificate for all products, it is pertinent to note that the certificate is an attestation that Pre-Shipment verification has been undertaken based on: (i) the WTO Agreement on Pre-shipment Inspection and subsequent recommendations thereof and (ii) the WTO Agreement on Customs Valuation. Being a certificate, it is necessary for each and every consignment to meet this requirement. However, contrary to India's claims that Products Certificates are required for all products, Nigeria wishes to state that Food and Medicines are exempted from this requirement. Also, chemicals used as raw material by bonafide manufacturers and industrial machineries are exempted. Other products exempted include military wares and equipment and used automobiles of models over ten years.

4.439. On the issue of validity of Product Certificate, India's contention regarding six-months validity of Product Certificate is inaccurate. Under the existing guidelines, there exist three routes for Product Certification depending on the product type, risk and effects on health, environment, national security, and consumer trust. Route A – Product Certificates are for unregistered category. These are for products purchased one-off or off the shelf. These products are of high risk thus the need for inspection, product sampling and testing. The Product Certificate which is for single use is valid for six months. Regarding Routes B and C – Importers under these routes are covered by Products Certificate with one-year validity and multiple use. The difference between B and C is that C is open to manufacturers for brand protection. These routes also factor in various risks associated with products. Regarding India's concern on the requirement of obtaining a SONCAP certificate for each consignment, Nigeria wishes to state that prior to the adoption of the Pre-Verification of Conformity (PVoC) to Standards, named "Standards organization of Nigeria Conformity Assessment Programme (SONCAP)", notification containing detailed procedure for the programme was duly issued to WTO and thereafter circulated amongst Members including India for review and comments. The comments by Members which centred around the need for the provisions of paragraph 4 of Article III of GATT 1994 and Paragraph 5.1.1 of Article 5 of the TBT Agreement to be respected was taken into account by Nigeria. This birthed the Mandatory Conformity Assessment Programme (MANCAP) scheme for locally manufactured goods. The SONCAP certificate as an end process document meant to attest that all other requirements of inspection and testing as provided by the relevant standards for the products have been carried out. Being a certificate, it is necessary for each and every consignment to meet the requirement. However, contrary to India's claims that SONCAP Certificates are required for all products, Nigeria wishes to state that some products exempted from Product Certificate requirement which are mentioned earlier, are also exempted from SONCAP Certificate requirements.

4.440. Regarding India question on the less trade-restrictive measures that were considered before finalizing the present mechanism, Nigeria wishes to state that the requirements for Product and SONCAP certification are least trade restrictive. The requirement for Product Certificate is to enable Nigeria to achieve the legitimate objectives set out in the 3rd sentence of Article 2.2. This is because the need to take measures to curb the high prevalence of counterfeit and sub-standard imported products in Nigeria market cannot be overemphasized. These imported counterfeit and sub-standard products have negative effects on health, environment, national security, consumer trust as well as the performance of genuine products in the markets. Also, Nigeria requirement for SONCAP is consistent with its obligation under paragraph 5.1 and 5.2 of the TBT Agreement. Non-fulfillment of the objectives of the Product and SONCAP certification requirements, poses serious hazard to the lives and livelihood of Nigerians. The requirements for Product and SONCAP certification are not onerous, intensive, expensive, or trade restrictive. Rather, these requirements are Trade Facilitating and less trade restrictive. The alternative measures that were considered prior to the adoption of this measures include: (i) Destination Inspection. This scheme is more trade restrictive and likely to pose numerous difficulties including massive port congestion, unnecessary increase in time and cost of business; (ii) Flat single use product certificate with six months validity for all imported consignments regardless of the risk given the high prevalence of counterfeit and sub-standard imported products in Nigeria market; and (iii) the possibility of SON undertaking Pre-Shipment verification on behalf of Nigeria. This would have posed difficulties given Nigeria's small technical staff with high attrition rate. In conclusion, India may wish to note that the preamble of the TBT

Agreement clearly states that a Member shall not be prevented from pursuing a legitimate objective at the level it considers appropriate. Furthermore, Nigeria as a developing country is also a beneficiary of the flexibilities of Article 12.4 of the TBT Agreement.

4.1.3.60 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 670[103])

4.441. The representative of China provided the following statement. We suggest that: (i) At present, upon application, the United States grants exemption for sink-type dishwashers, but the exemption period has not been specified, which will inevitably bring unnecessary obstacles to trade. We recommend that the US clarifies the exemption period for sink-type dishwashers. (ii) Given that most types of dishwashers currently include a quick wash function of less than one hour, we recommend that the US clarifies the differences between dishwasher products with a washing process of less than one hour and those currently with quick cleaning function of less than one hour, and classification basis for the two dishwashers.

4.442. 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 dishwashes.

4.1.3.61 United States - Appliance Efficiency for Sprinkler Bodies, G/TBT/N/USA/1489 (ID 653[104])

4.443. The representative of China provided the following statement. We appreciate the efforts from the US to improve the performance of sprinkler bodies, and we suggest that (i) the US clarifies the application scope of sprinkler products. (ii) as the accuracy requirements of the pressure level test points in 1(c), 3(b) and 3(f) of Appendix B of WaterSense (r) Specification for Spray Sprinkler Bodies are inconsistent with the accuracy requirements of the international standard ISO15886-3:2012 5.1. It is suggested that the US could provide the basis for the accuracy requirements. (iii) Please clarify the distance between the needle valve and the outlet pressure sensor in Appendix B, 3(c) which is not clear.

4.444. In response, the representative of the United States provided the following statement. China did not submit comment to the United States through the USA WTO TBT Enquiry Point nor did it provide us any points in advance of this meeting. We have sought information from California, but it is taking some time. We will take the concerns back with us and engage the State of California, accordingly. Any information received will be communicated bilaterally with China.

[103] For previous statements follow the thread under ID 670.
[104] For previous statements follow the thread under ID 653.

4.1.3.62 India - Toys (Quality Control) Order, 2019, G/TBT/N/IND/131 (ID 587[105])

4.445. 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. As we noted at the last meeting, 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 continued inability of the Bureau of Indian Standards (BIS) to conduct in-person audits of foreign manufacturing facilities during the COVID-19 pandemic. US industry continues to report that, although BIS authorities are currently auditing domestic manufacturing facilities, they have yet to start audits of overseas manufacturing plants, despite firms having submitted applications soon after the August 2020 BIS release of the QCO Product Manual. To date, companies with manufacturing facilities outside of India report that India has not provided any information about scheduling audits by BIS inspectors and are unclear when BIS inspectors will resume traveling for such audits. 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, due to auditing delays, foreign manufacturers are unlikely to bring new toys to the Indian market in 2021. We support the Indian government's objective to ensure the quality of toys on the market, and US industry has sought to provide alternative solutions to help India achieve those objectives while still facilitating trade in toys. Such alternative solutions include virtual audits or the use of recognized third-party certification of companies in the country of manufacturing to meet the QCO's in-person audit requirements for foreign manufacturing facilities. Will India consider these alternative solutions in lieu of in-person audits by BIS inspectors?

4.446. In response, the representative of India provided the following statement. Foreign inspection visits are on hold due to the prevalent restrictions on international travel imposed by the Government of India, but in some instances by the government of other respective countries as well in view of the ongoing COVID-19 Pandemic. As soon as the situation of COVID-19 improves and the restriction lifted, India will plan the inspections (factory visit). The average time taken to grant a licence is generally four to six months after scheduled factory audits. This may vary for reasons like delay in response to queries raised, if any; organizing inspection(s); deposition of samples with lab and remittance of dues, etc. This does not account for delays related to COVID-19. As per Toys (Quality Control) Order, 2020 issued by the Department of Promotion for Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, every toy specified therein shall bear the standard mark under a licence from BIS as per Scheme-I of BIS (Conformity Assessment) Regulations, 2018. There is no provision in BIS (Conformity Assessment) Regulations, 2018, to undertake virtual inspection or the use of recognized third-party certification of companies in the country of manufacturing to meet the QCO's in-person audit requirements for foreign manufacturing facilities. However, the Government of India is considering the introduction of relevant enabling provisions to undertake virtual/remote inspection for BIS conformity assessment activities.

4.1.3.63 United Kingdom - Wine labelling and documentation requirements at the end of the Brexit transition period (ID 663[106])

4.447. The representative of Australia provided the following statement. Australia thanks the UK for the response they provided in the previous TBT Committee and for the arrangement to allow 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. We reiterate the concerns we have raised in previous meetings, noting that the United Kingdom continues to work with industry to develop streamlined labelling and documentation requirements. Australia seeks the United Kingdom's assurance that these requirements will not be unnecessarily trade restrictive. Australia appreciates the bilateral engagement to date on this issue and looks forward to working closely with the UK on this issue to ensure a mutually satisfactory outcome.

4.448. The representative of Uruguay provided the following statement. We wish to refer to our previous statements on this matter and once again express our interest in remaining informed of the regulatory requirements and conditions that will apply to the importation of wine into the United

[105] For previous statements follow the thread under ID 587.
[106] For previous statements follow the thread under ID 663.

Kingdom market from 1 October 2022, in particular with respect to documentation and labelling, and in such requirements being the least trade-restrictive possible.

4.449. In response, the representative of the United Kingdom provided the following statement. The United Kingdom would like to thank Australia for its interest in our wine labelling and documentation requirements following the end of the United Kingdom-European Union transition period.[107] We would also like to thank Australia for the constructive engagement we have had on this topic bilaterally. Referring to our previous statements for greater detail, our regulations[108] allow for either a European Union or a United Kingdom importer's details 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 can be marketed in Great Britain. Additional details may be included on the label if they do not appear in combination with the words "imported by" or "importer", and do not confuse consumers as to the identity of the importer. The United Kingdom will continue to accept wine import certificates (VI-1[109]) issued by the European Union for wine entering the United Kingdom from non-European Union countries.[110] Further details of the labelling and certification measures that apply are available on the UK Government website.[111] We appreciate Australia's recognition of our collaboration with industry to develop a streamlined and user-friendly system for labelling and documentation requirements. We welcome further bilateral engagement with Australia on this matter.

4.1.3.64 Kingdom of Saudi Arabia - Concerns on conformity assessment practices of Saudi Arabia against Turkish products (ID 683[112])

4.450. The representative of Turkey provided the following statement. Turkey would like to reiterate its serious concerns raised in the previous meeting as regards the discriminatory and unnecessarily burdensome product safety inspections conducted against Turkish products at Saudi customs. We witness that unjustifiably discriminatory treatment of Saudi Arabia against Turkish products with regard to conformity assessment procedures has been continuing in an ever-increasing manner leading to serious delays, high costs and bottlenecks for Turkish exporters. To put it more concretely, border compliance for Turkish-origin goods at Saudi Customs is completed in five months on average. In fact, we have been witnessing some cases where this period reached 300 days. In one specific case, we were informed that the customs clearance of the products of a Turkish white goods manufacturer took almost six months. It was reported that 42 containers covered in 20 bills of lading had been held at customs ranging between 137 to 186 days. In fact, these goods were held at the customs for 109 to 160 days even after the approval they received from the relevant Saudi agencies that the products met all the requirements mentioned in the relevant technical regulation and successfully passed the conformity assessment carried out at customs. This stands in direct contradiction with the principle justification given by Saudi Arabian authorities for such long delays, that is, the testing and inspections conducted to check out the compliance of the products with the relevant technical regulation, and the customs tariff classification declared.

4.451. Turkey cannot make sense of such long delays which contradict with the existing customs practices of Saudi Arabia explained in 2020 Doing Business Report. This report states that "time to import: border compliance" in Saudi Arabia takes 72 hours, which is equal to three days. Moreover, the Secretariat Report of the Saudi Arabian Trade Policy Review states that a risk-based conformity assessment scheme is carried out for product safety inspections, and a simplified procedure is

[107] 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), 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.

[108] See the Common Organisation of the Markets in Agricultural Products (Miscellaneous Amendments) (EU Exit) (No. 2) Regulations, SI 2020/1453. For further guidance, see https://www.gov.uk/guidance/importing-and-exporting-wine

[109] VI-1 arrangements are contained in the retained Regulation 2018/273 as amended by the Agricultural Products, Food and Drink (Amendment etc.) (EU Exit) Regulations 2020, SI 2020/163.

[110] See The Common Organisation of the Markets in Agricultural Products and Common Agricultural Policy (Miscellaneous Amendments) (EU Exit) Regulations 2019 (2019 No. 828).

[111] https://www.gov.uk/guidance/importing-and-exporting-wine

[112] For previous statements follow the thread under ID 683.

conducted to facilitate product transits in case of a necessity for inspection. Turkey's experience stands in direct contrast with this information. There are also cases where Turkish products are inspected in accordance with the conformity assessment procedures applied for a different product or rejected at customs due to problems related to labelling, despite bearing the exact same labelling as before. Given ongoing restrictive practices of Saudi Arabia against Turkish products, including burdensome product safety inspections, Turkish exports to Saudi Arabia fell by 98% in the first quarter of 2021 compared to the same period of the previous year.

4.452. Evidently, Turkey is seriously concerned about these trade restrictive practices of Saudi Arabia against Turkish goods. We believe the regular treatment of Turkish products at Saudi customs are in clear violation of, *inter alia*, the Articles 5.1.1 and 5.1.2 of TBT Agreement on non-discrimination, and avoidance of unnecessary barriers to trade. As is well known, the TBT Agreement is intended to achieve a balance between upholding legitimate regulatory policy objectives and avoiding the creation of unnecessary obstacles to trade. TBT Agreement also aims to prevent the Members from creating arbitrary or unjustifiable discrimination between countries in international trade. In this respect, we would like to remind Saudi Arabia once again that regulations and conformity assessment procedures should not be more strict, or be applied more strictly than necessary and access for suppliers of like products originating in the territories of the Members should not be less favourable than those accorded to suppliers of like products of national origin or originating in any other Member country. Therefore, 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 products.

4.453. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. We take note of the concern raised by Turkey and want to assure that the Kingdom of Saudi Arabia always affirms its commitments to all trade rules stipulated in the WTO agreements. In response to the concern, as we did on several occasions both bilaterally and here in this house at the multilateral level, there are no restrictions or discrimination imposed on Turkish imports to Saudi Arabia. We would like to emphasize once again that our borders and markets are open to all goods and products, including those coming from Turkey. In addition, we would like to reiterate that Saudi authorities do not interfere in consumers' preferences nor encourage buyers to trade with products based on its country of origin.

4.1.3.65 India - Plain Copier Paper (Quality Order) 2020, G/TBT/N/IND/140 (ID 681[113])

4.454. The representative of Indonesia provided the following statement. Indonesia appreciates India for the discussion in the virtual bilateral meeting on February. However, Indonesia regrets that India is yet to provide substantive response to Indonesia's concern. Indonesia remains concerned about the provisions stated in Plain Copier Paper (Quality Control), Order 2020. The certification shall be carried out only by Bureau of Indian Standards (BIS) based on the Conformity Assessment Regulation 2018 through the Scheme 1 of Schedule-II which shall require factory visit, sampling and testing of the product as well as licensing procedures. Indonesia regrets that India has ignored the current pandemic situation that made factory visit an impossible task to do due to travel ban and social distancing policy. Therefore, Indonesia urges India to consider the use of remote assessment in conducting factory visit or any relaxation policy as a means to facilitate trade and minimize technical barrier to trade, particularly in this difficult time. Indonesia would like to reiterate its previous statement where Indonesia is of the view that the concerned regulation has impacted and become a trade barrier for the exporters as there is no clarity regarding the mechanism of the regulation. Therefore, Indonesia requests India to postpone or provide sufficient transition time to allow industries to comply with the regulation. Indonesia urges India to adopt available International Standard as a basis for testing method. Indonesia is also aware 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, Indonesia kindly reminds India to notify this technical regulation to WTO TBT, as the addenda of the previous notification.

4.455. In response, the representative of India provided the following statement. We thank Indonesia for its interest and the statement. At the moment we are engaged with the concerned ministry and will revert with a reply soon.

[113] For previous statements follow the thread under ID 681.

4.1.3.66 India - Pneumatic tyres and tubes for automotive vehicles, G/TBT/N/IND/20, G/TBT/N/IND/20/Add.1, G/TBT/N/IND/40, G/TBT/N/IND/40/Rev.1 (ID 133[114])

4.456. The representative of Indonesia provided the following statement. Indonesia thanks India for having a bilateral meeting with Indonesia at the side-line of the TBT Committee meeting on 26 February 2021. However, until this time Indonesia regrets that India fails to provide response to our concern. As Indonesia is aware, based on our knowledge, India has imposed loyalty or marking fees for tyre products with IS marking. Indonesia remains concerned that the imposition of marking fees is burdensome and has become unnecessary obstacle to trade. The imposition of marking fees is also having no legitimate justification with no strong relation to protection of human health, safety or prevention from deceptive practice. At the same time, Indonesia is also aware that India has imposed import restriction for certain types of tyre. This import restriction provisions were issued shortly after India banned the importation of tyre products to India for a period of six months as in notification no. 12/2015-2020 dated 12 June 2020 regarding Amendment in Import Policy of Tyres. These policies have impacted Indonesia's export and disrupted the flow of goods to India. Indonesia is of the view that this policy is not in line with non-discriminatory principle as set out in Article 2.1 of the TBT Agreement. Indonesia therefore urges India to comply with the TBT Agreement, particularly with non-discrimination principles as stated in Article 2.1 of TBT Agreement. Indonesia is looking forward to India's response on this issue and requests India to review the policy to ensure compliance with non-discriminatory principle.

4.457. In response, the representative of India provided the following statement. India has noted the concern raised. At the moment, we are engaged with the concerned ministry and will revert with a reply soon.

4.1.3.67 Viet Nam - Cybersecurity Measures (ID 544[115])

4.458. 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 Members have raised in order to ensure the Cybersecurity Law is implemented in the least trade-restrictive manner possible. Does Viet Nam have any updates to share with us on the status of the draft decree.

4.459. The representative of Canada provided the following statement. Canada would like to support the points raised by other delegations related to Viet Nam's cybersecurity measures.

4.460. The representative of Australia provided the following statement. Australia would like to register its ongoing interest in this matter and also refer to our previous statements.

4.461. The representative of the European Union provided the following statement. The European Union shares the Member's concerns on the Vietnamese Cyber Security 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 updated information on the adoption of 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 Cyber Security 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 and that it gives sufficient time for comments. The European Union encourages Viet Nam to develop and implement Cyber Security measures in full respect of WTO principles, such as non-discrimination and proportionality and to take into consideration available international standards and practices.

4.462. In response, the representative of Viet Nam provided the following statement. We would like to reiterate that the 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. Our process has been transparent with an open mind. All stakeholders' comments have been fully taken into consideration. The draft Decree for implementing

[114] For previous statements follow the thread under ID 133.
[115] For previous statements follow the thread under ID 544.

certain articles of this Cybersecurity Law has been submitted to the Prime Minister and will be issued soon.

4.1.4 Brief report from Secretariat on beta version of the TCD

4.463. The Secretariat updated the Committee on the beta version of the Trade Concerns Database (hereafter "TCD" beta version), developed in 2021 jointly with the SPS Team and IT Division. It was recalled that the TBT Committee has maintained an information management system (the TBT IMS) since 2009 and, as technology had developed, the platform needed to be replaced. The Secretariat was currently working on replacing the TBT IMS in a staged process. The TCD was the first part of that process. It would replace the TBT IMS search function for STCs. It had several advantages compared to the old system. First it integrated TBT and SPS information in one place (previously this was contained in separate IMS databases). Second, it enabled Members to easily access and consult the integrated history of a trade concern, including all statements and related notifications (all in one place). Third, it improved upon the search functions previously available. It would also allow for more precise searches, including by Member, by meeting, keywords, products (and this across both TBT and SPS STCs). The Secretariat stressed that the database improved on access already available to Members and the public on STCs through the TBT and SPS IMS and the minutes of meetings. Since the last meeting of the Committee, the Trade Concerns database included all historical data on TBT STCs in all three official WTO languages. The Secretariat welcomed any feedback.

4.464. The representative of the European Union asked if her delegation's statements were in the public domain.

4.465. The Secretariat clarified that what was available on the TCD was not the statements that had been uploaded to eAgenda, but the records of the STC discussions that were in the minutes. So, while indeed, the information and access to the TCD was publicly available, the platform enabled a *better* access to the information contained in the minutes when made public (derestricted) according to currently existing procedures.

4.466. The representative of the United States noted that the TCD provided easier access to the public for statements made. It appeared that, with eAgenda, the minutes were more fulsome that they had been in the past. This could perhaps be a topic discussed in a "Friends of eTools" group with interested Members. She proposed that such a meeting would have three different purposes: (i) informational – so that Members and users of the platforms would be better informed; (ii) for interested delegations, the Friends of eTools group could be used to collaborate and exchange experiences; and (iii) it would provide a vehicle for feedback to the Secretariat. Discussions in the Group could include several topics, such as specific concerns database, ePing and eAgenda.

4.467. The representative of Mexico raised similar points to those of the US and the EU. Matters were still being discussed internally and Mexico expressed a wish to participate in the Friends of eTools group.

4.468. The Chair welcomed Members' interest in a Friends of eTools Group. He invited any Member that would like to be part of such a group to flag this interest to the Secretariat (una.flanagan@wto.org).

4.2 Exchange of Experiences

4.2.1 Transparency

4.469. The Chair recalled that the Committee's Annual Review (G/TBT/45), contains details on Members' statements of implementation under Article 15.2.

4.470. The Secretariat noted that ePing continued to be of interest for a variety of stakeholders and had around 14,000 subscribed users, around half from the public sector, 40% from the private sector and the remainder from NGOs and academia. Enquiry Points and other officials tasked with managing notifications could request enhanced access to the system, allowing them to use ePing to reach out to domestic subscribers, as well as other Enquiry Points. In addition, they could post, on a voluntary basis, comments and replies on notifications via ePing's international forum, in line with the TBT

Committee's 8th Triennial Review recommendation in this regard. The Secretariat continued to receive a high number of requests for training on transparency generally and on ePing specifically. Since the beginning of the year, the Secretariat had conducted a series of virtual training workshops for public and private stakeholders in seven countries, often in collaboration with their Enquiry Points. These included ePing workshops for the private sector in the Bahamas and St. Lucia as well as a training programme on transparency and ePing for South African trade officials and regulators, which would be complemented by an additional module for the private sector. In addition, the Secretariat had collaborated with ePing partner UN Department for Economic and Social Affairs (UNDESA) to deliver ePing training for stakeholders in Bangladesh, Bhutan and Vanuatu, in the context of a programme for LDCs in the process of graduation. Furthermore, the Secretariat had delivered a series of training sessions in the context of an overarching ITC project for Viet Nam, which saw the launch of ePing in Vietnamese. This was an innovative project which brought together government officials, SPS/TBT Enquiry Points, the trade promotion agency and the Foreign Trade University, with the aim of assisting MSMEs in accessing export markets.

4.471. The Secretariat had conducted a survey earlier in the year to receive user feedback on ePing. A document summarizing the results and highlighting key takeaways would be issued once the analysis of the more than 1400 replies was finalized.[116] Preliminary findings suggested that ePing was highly appreciated by users. At the same time, useful suggestions had been made for possible enhancements, including an ePing App. Finally, the Secretariat had started work on a revamped and more integrated online platform, which would bring under one roof the various online tools, including the TBT IMS, the TBT NSS, ePing and the new Trade Concerns database. The Secretariat was planning to invite interested Members to provide inputs and suggestions during the development of this integrated platform. Considering interest expressed in the Committee for a "Friends of eTools" group, the Secretariat would aim to schedule a first meeting in July.

4.472. The representative of Viet Nam provided information on the launch of the Vietnamese version of ePing. She explained that as ePing was recognized as a useful tool for Vietnamese enterprises, particularly SMEs, the system was being disseminated to them as well as to ministerial and local TBT Points since 2017. While Vietnamese enterprises had expressed interest in the system, language issues had made it difficult for them to assess the content of notified measures. In the context of an ITC project with *Vietrade*, Viet Nam had indicated its interest in addressing this language barrier. In response, ITC and WTO had facilitated the completion a Vietnamese version of ePing, which had been officially launched on 29 April with the participation of Vietnamese Government agencies, associations, SMEs, universities and related organizations as well as the ITC and WTO. The Foreign Trade University students were also contributing to the project by translating TBT and SPS notifications into Vietnamese, which were then circulated to SMEs via ePing. The representative indicated that the number of registered ePing users in Viet Nam had risen considerably in 2021. However, the number was still small compared to the large number of SMEs in Viet Nam and it was hoped that more would be subscribing following this initiative. She also expressed Viet Nam's gratitude towards the ITC and the WTO for their support with the project.

4.473. The Secretariat updated the Committee on COVID-related notifications. To date (June 2021), 153 COVID-related TBT notifications had been submitted since the pandemic started in early 2020. This represented about 40% of the total number of COVID-related notifications to the WTO. As many as 31% of the TBT notifications had been submitted by Brazil. A wide range of products were covered in the TBT notifications, including PPEs, medical equipment/supplies, foods, live animals. Most of the notifications were on conformity assessment procedures and about trade-facilitating measures (providing more flexibility) e.g., using remote assessments technologies, electronic certification, mutual or unilateral recognition. Many notifications were temporary (generally for six months or one year) – they were mainly about streamlining certification procedures, ensuring the safety of medical goods, and making food available by relaxing technical regulations. The Secretariat would continue to monitor COVID-19-related measures by maintaining its dedicated webpage.

4.2.2 Conformity assessment procedures

4.474. The Chair recalled that since the last meeting of the Committee, new submissions had been received from Colombia and South Africa; these were contained in documents JOB/TBT/406 and JOB/TBT/407, respectively. There was now a total of eight submissions (also from the European Union in JOB/TBT/322, the United States in JOB/TBT/326, Australia in JOB/TBT/347, Japan in

[116] G/SPS/GEN/1933-G/TBT/GEN/317.

JOB/TBT/349, Canada in JOB/TBT/358, and China in JOB/TBT/391). He noted that the most recent discussions on the development of guidelines had been summarized in the Aide Memoire, JOB/TBT/273/Rev.8 circulated on 26 May.

4.475. The representatives of Colombia and South Africa introduced their submission (for the details, see JOB/TBT/406 and JOB/TBT/407, respectively). Colombia asked the Chair about next steps.

4.476. The Chair said, regarding further progress, that further submissions from Members were welcome. He noted that there were currently eight submissions on the table from a range of Members in the Committee, and one approach, depending upon Members' views, would be to ask the Secretariat to compile a basic outline, an "elements" document for comments from the Membership. This could be due mid-October and discussed at the November meeting.

4.477. The representative of the European Union recalled the importance of the development of non-prescriptive practical Guidelines on Conformity Assessment. They would help regulators identify elements for conformity assessment they could be used in designing appropriate and proportionate procedures. The European Union had presented a submission where it provided several ideas and proposals for consideration as a basis for the future Guidelines. She reiterated that this work should not be prescriptive and should take into account different approaches to conformity assessment across the Membership. The European Union appreciated that also Colombia and South Africa had recently presented submissions.

4.478. The representative of the United States joined the EU in thanking Colombia and South Africa for the proposals today. In terms of a way forward she was of the view that more clarity was needed in terms of the timing. The Committee was currently holding a very long meeting; there was also the Triennial Review to consider in November. She stressed the limitations to the virtual format.

4.479. The representative of Colombia shared the comments made by the United States on the potential difficulties faced by delegations when tackling both the conformity assessment guidelines as well as the Ninth Triennial Review in 2021; this could lead to a burdensome agenda, also considering that the next regular meetings would fall just weeks before the Ministerial Conference (MC12).

4.480. The representative of South Africa said that her delegation, too, would need more time to work on the Guidelines, and to keep up with work on the Triennial Review.

4.481. The representative of the United States noted, in addition, that there were ongoing bilateral meetings that were also being done virtually – and this entailed more effort than holding them in-person in Geneva.

4.482. The Chair understood the concerns with respect to workload. He suggested that the Committee revert to conformity assessment *after* the Triennial Review, perhaps at an informal meeting in February 2022. He noted that it was, nevertheless, possible to work in parallel on both topics (Triennial Review and conformity assessment guidelines) as had been demonstrated by Members' various inputs to date. He sought again Members' guidance on the notion of an elements paper: this could, perhaps, be something that the Committee could look at in February 2022? If so, the Committee could request the Secretariat to start work on the elements given that there were currently eight submissions from a range of Members.

4.483. The representative of the European Union noted that delegations might have to show more discipline in the discussions on STCs as that, too, took up a lot of time – and took away resources from a discussion of more substantive issues. The EU was supportive of a discussion in February and an elements paper form the Secretariat as soon as possible to give time for internal discussions.

4.484. The representative of Canada said that the Chair's proposal made sense. There was need for time to consider both the contents of the elements paper as well as to have a dedicated discussion of it. He agreed with previous speakers about the uncertainty of scheduling on the margins of existing meetings given the length that it was taking the Committee to get through the STC part of the agenda. Canada's view was that the Chair's proposal was pragmatic: to schedule the discussion for next year was probably the best way of approaching it.

4.485. The representative of the United States supported the comments made by Canada and while she appreciated what the EU was saying, it was difficult to control the time of the STC discussion. It was preferable for the US to focus on the conclusion of the Ninth Triennial Review.

4.486. The Chair proposed that the Committee hold a dedicated informal meeting next year (2022) to discuss its work on conformity assessment, and that this meeting be informed by an elements paper prepared by the Secretariat to be provided at the end of the current year (2021). This would enable Members to focus on the Triennial Review during the rest of the year, and preparations for MC12. The Secretariat would follow up in due course with a date for the dedicated informal. The Chair stressed that this approach needed to be seen as just another step in a road in the Committee's work on the guidelines; it would certainly not lead to the adoption of the Guidelines in February 2022 – it was simply an opportunity to discuss where the Committee was at, and, hopefully, to welcome further proposals from Members as well as comments on the elements paper. He asked if the Committee could accept the proposal. It was so agreed.

5 TECHNICAL COOPERATION ACTIVITIES

5.1. The Secretariat updated the Committee on its technical assistance activities. It was noted that on 27 May, the Secretariat had organized a Virtual Technical Assistance regional activity for English-speaking African countries. This had been a roundtable with 70 participants from 19 countries in the region with participation from WHO (on Covid-19 and TBT), ARSO (the African Organization from Standardization). A similar formula for virtual roundtables would follow in other regions. It was also noted that ITTC had submitted to beneficiary Members a questionnaire on their technical assistance priorities for the next two years (2022-2023). As in previous years, TBT featured among the top priorities for Members for the next two years.

6 OBSERVERS

6.1 Updates

6.1. The representative of the BIPM provided an update. The full content of this update is contained here.

6.2 Pending Requests

6.2. Regarding pending requestions for observer status, the Chair recalled that documents G/TBT/GEN/2/Rev.16 and RD/TBT/1/Rev.8 provided updated information on observers in the TBT Committee, including pending requests. He noted that two new requests had been received in (2021); one from the Arab Industrial Development, Standardization and Mining Organization (AIDSMO) and the other from the United Nations Institute for Training and Research (UNITAR). He said that, regarding previous requests for observer status in the Committee – and SMIIC in particular – further to a request from Turkey, he had reached out to some Members to try to find a solution to the current situation. However, he was not aware of any further information or developments on this matter and he had no information that would lead him to believe that the situation had changed from where the Committee stood at the last meeting.

6.3. The representative of Turkey thanked the Chair for his efforts. She welcomed the opportunity to correct some misunderstandings about the SMIIC so that Members could make a well-informed decision on the SMIIC's request to have an observer status at the TBT Committee. Turkey understood from the latest intervention by the US (at the last TBT Committee meeting), that the US considered the SMIIC a regional metrology organization and had expressed objections on the basis that two globally recognized metrology organizations (the BIPM and the OIML) already had been granted observer status. However, the SMIIC submission and mandate were not limited to metrology. Being an affiliated institution of the Organization of Islamic Cooperation (OIC), the SMIIC aimed at developing infrastructures by establishing uniformity in standardization, conformity assessment, accreditation and metrology activities, and thus eliminating technical barriers to trade among its members. The SMIIC also had important activities in the field of halal which Turkey thought deserved more attention as this issue was becoming a frequent item on the agenda of the TBT Committee. The SMIIC worked on the adoption of a single-halal standard and the establishment of a trust-worthy certification system among the OIC countries to avoid unnecessary technical barriers to trade. The SMIIC had already issued halal standards and provided guidelines for halal certification accreditation.

In this respect, the SMIIC's work and expertise held great potential to provide significant support for halal trade facilitation. Turkey stated once again that the SMIIC stood ready to answer all queries from Members regarding its request for observer status at the Committee.

7 DATE OF NEXT MEETING

7.1. The Chair recalled three further points[117]:

a. Any comments on the update of advance draft Chair's report on our Ninth Triennial Review Informal meetings, emailed to the delegates' contacts list last Friday, were due by Friday 11 June in mark-up please.

b. Further to earlier discussions, the Secretariat would provide a communication by the end of the week with a date for the informal discussion on conformity assessment procedures for February 2022. Also, as part of this, communication, we will include the details for an informal meeting for the "Friends of eTools" for TBT.

c. In relation to the Ninth Triennial Review, any Member that wished to provide further information to elaborate or revise their proposal already on the table were asked to submit this information by 15 June 2021.

7.2. The Chair recalled that the next regular meeting of the Committee was scheduled for 10-12 November 2021. This regular meeting would be preceded by an informal meeting on the Ninth Triennial Review on 8-9 November 2021. The full schedule of meetings for 2021 was contained in JOB/TBT/364/Rev.2 and the preliminary meeting dates for 2022 were contained in JOB/TBT/408.

[117] Subsequent to the meeting the Chair issued ICN/TBT/4.