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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 9-11 MARCH 2022

CHAIRPERSON: MRS ELISA MARIA OLMEDA DE ALEJANDRO

Note by the Secretariat¹

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1 ADOPTION OF THE AGENDA

1.1. The <u>Committee</u> adopted the agenda contained in <u>WTO/AIR/TBT/22</u>.

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.

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2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Specific Trade Concerns

2.1.1 Added and withdrawn concerns

2.1. The representative of Costa Rica added STC ID 608² and STC ID 609.³

2.2. The representative of <u>Australia</u> explained that it withdrew STC number 45 in the Annotated draft Agenda (Annex 2 of JOB/TBT/441)⁴ because Australia chose not to engage with Russia at this time. Australia condemned Russia's unprovoked and unjustified attack on Ukraine. Australia said that Russia's actions breach international law, the UN Charter and the sovereignty and territorial integrity of a neighbouring state. Australia supports Ukraine in opposing Russia's hostilities. Australia called on Russia to withdraw its forces from Ukrainian territory and seek a diplomatic solution. Australia also supported collective action by the international community to impose costs and increase leverage on Russia and those in Russia who bear responsibility. Australia also supported imposing significant economic sanctions on Russia and Belarus and will continue to support international measures to sanction Russia's behaviour.

2.3. The representative of <u>China</u> reported a good bilateral exchange with the United States, and therefore withdrew STC number 2 in the Annotated draft Agenda.⁵

2.4. The representative of the <u>European Union</u> expressed the EU and its member States' full solidarity with Ukraine and the Ukrainian people. The EU condemned in the strongest possible terms Russia's unprovoked and unjustified military aggression against Ukraine which grossly violates international law and the UN Charter and undermines international security and stability.

2.5. The representative of the <u>Russian Federation</u> raised a point of order that the EU was intervening outside of the scope of the TBT Committee.

2.6. The <u>Chairperson</u> asked the EU to finish their statement, after which the Russian delegation would take the floor.

2.7. The representative of the <u>European Union</u> regretted the interruption. The EU demanded that Russia immediately cease its military action, withdraw all its troops from the entire territory of Ukraine and fully respect Ukraine's territorial integrity, sovereignty, and independence within its internationally recognised borders. The EU resolutely supported Ukraine in their own fight of self-defence and the Ukrainian armed force in defending Ukraine's territorial integrity and population in accordance with Article 51 of the UN Charter. At all times, the EU said Russia must respect its responsibilities under international humanitarian law. Russia also must stop its misinformation campaign and cyberattacks. In addition to the statement made, the EU withdrew all STCs against Russia.⁶

2.8. The representative of the <u>Russian Federation</u> called on Members to refrain from interventions on issues and events which are outside the scope of the TBT Committee and the WTO itself and within the focus of other international organizations and diplomatic agencies.

³ Colombia - Food Prioritized for its Sodium Content, Certification Requirements (ID 609).

² 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 (ID 608)

⁴ Russian Federation - Federal Law n° 468 on wine making and wine growing in the Russian Federation (ID 650).

⁵ United States - Trade regulation rule on care labelling of textile wearing apparel and certain piece goods.

⁶ Russian Federation - Federal Law n° 468 on wine making and wine growing in the Russian Federation (ID 650), Russian Federation - Draft Technical Regulation on Alcohol Drinks Safety (published on 24 October 2011) (ID 332), Russian Federation - Rules of cement certification (ID 497), and 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).

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2.9. The representative of the <u>United Kingdom</u> said Russia's assault on Ukraine was an unprovoked premeditated attack against a sovereign democratic state and a fellow Member of this organization. The United Kingdom and its international partners stand united in condemning the Russian Government's reprehensible actions which are an egregious violation of international law and the UN Charter. The United Kingdom said that as permanent member of the UN Security Council, Russia has a particular responsibility to uphold international peace and security. Instead, Russia was violating the borders of another country and its actions are causing widespread suffering. The Russian government has shown that it was never serious about engaging in diplomacy, and it deliberately worked to mislead the world in order to mask its carefully planned aggression. The United Kingdom said that Russia must urgently de-escalate and withdraw its troops. Russia must be held accountable and stop undermining democracy, global stability and international law.

2.10. The representative of the United States reiterated its strong support for Ukraine during this unimaginably difficult time. The United States paid tribute to the heroism of the Ukrainian people, their armed forces and their leaders. The United States also expressed its appreciation to the many Members around the globe which are taking action in cooperation and coordination with the United States. Our important work together will continue. United States condemned Russia's pre-meditated and unprovoked attack on Ukraine and the United States equally condemned Belarus' regime for aiding Russia's war of aggression. President Putin's premeditated war has brought catastrophic loss of life and human suffering. Russia was solely responsible for the death and destruction and the world must hold Russia accountable. Russia's actions constituted a clear violation of Article 2.4 of the United Nations Charter which states that all member states shall refrain in international relations from the threat or use of force against the territorial integrity or political independence of any state. The United States called upon Russia to immediately cease its use of force against Ukraine and refrain from any further unlawful threat or use of force against any UN member state. The United States was united with its allies and partners in our commitment to ensure the Russian Government pay the severe economic and diplomatic price for its further invasion of Ukraine. Our work at the WTO focuses on trade but the Organization cannot be neutral to the struggle at hand. The WTO was predicated on certain values, among these that a fair and just international order is one built on rules not power, on reciprocity not predation and on transparency not perfidy. The United States said the actions of Russia are incompatible with the rules-based system we have built and worked to improve. The United States added that it had intended to support STC number 45 in the Annotated draft Agenda⁷, but was withdrawing all STCs against Russia.

2.11. The representative of <u>Canada</u> strongly condemned Russia's unjustifiable and unprovoked invasion of Ukraine. Canada said the attacks are causing widespread humanitarian consequences and resulting in the senseless death of innocent people. The international community must be seized of this issue. This was not just an attack on Ukraine. This was an attack on international law, including the UN Charter as well as democracy, freedom and human rights. Canada withdrew support for STC number 47 in the Annotated draft Agenda⁸ and instead supported STC number 53 in the Annotated draft Agenda⁹.

2.12. The representative of <u>Japan</u> echoed the previous statements regarding the situation in Ukraine. Japan believed this was very much relevant to this Committee and to the WTO in terms of consistency with international law. Japan was seriously concerned about the situation in Ukraine and said that it constitutes the infringement of a WTO Member's sovereign rights and territorial integrity, and is a violation of international law. It is totally unacceptable, and Japan strongly condemned it. Japan joined the international community to deal with the situation by standing alongside with Ukraine and its people.

2.13. The representative of <u>Ukraine</u> noted the concern and reaction of one Member. Russia stated that because WTO is a trade-related organization, Ukraine and other WTO Members should refrain from politization of this institution and instead engage constructively in substantive dialogue. We believe that by undue politization Russia meant avoiding reference in this forum to the military invasion and aggressive full-scale war launched against Ukraine 14 days ago. The attacks which jeopardized the very ability of Ukraine to participate in substantive dialogue referred to by Russia,

 $^{^7}$ Russian Federation - Federal Law n° 468 on wine making and wine growing in the Russian Federation (ID 650).

⁸ Indonesia - Government Regulation 28 of 2021 – Implementing Regulation (for the

Manufacturing/Industry Sector) to Law No. 11 of 2020 the "Job Creation Act" (ID 724).

⁹ Indonesia - Halal Product Assurance Law No. 33 of 2014 and its implementing regulations (ID 502).

as our infrastructure suffers constant attacks, and as our experts are either hiding in bomb shelters or are forced to flee their homes along with 2 million of Ukrainians and other foreign citizens present on the territory of Ukraine.

2.14. Ukraine thanked those Members who spoke today and during other committee meetings. Ukraine was very grateful to all Members who have stood with Ukraine in these terrifying times and have adopted or are in the process of adopting strong economic sanctions against the Russian Federation. Ukraine also thanked the Developed Countries Coordinating Group which recently excluded the Russian Federation from its deliberations. Ukraine called on other WTO Members not to remain indifferent in the face of this unprecedented and illegal aggression of the Russian Federation. Given that the Russian Federation has clearly violated the basic principles and values that the GATT and the WTO have promoted for almost 80 years since the end of World War II, Ukraine urged Members to consider whether the Russian Federation's continued participation in this organization, including this and other WTO meetings, would be consistent with the objective and purpose of the WTO. Ukraine did not see how Members can conduct economic relations with the Russian Federation within the WTO on a business-as-usual basis in the presence of these awful circumstances.

2.15. The representative of <u>Switzerland</u> echoed the statements made by previous speakers on the situation in Ukraine. Switzerland condemned the Russian military attack on Ukraine in the strongest possible terms. This attack constituted a violation of the territorial integrity and sovereignty of Ukraine as well as a violation of international law, in particular of the UN Charter. Switzerland called on Russia to respect its international obligations and to reverse its actions as well as to withdraw its troops and contribute to de-escalation. Switzerland called on all actors to respect international law including international humanitarian law.

2.16. The representative of <u>New Zealand</u> joined other Members who have made statements on Ukraine and Russia. New Zealand extended its full support to our colleague present from Ukraine. We must recognize that international trade has been greatly impacted by the conflict, and it was not irrelevant. New Zealand strongly condemned Russia's unjustifiable and unprovoked invasion of Ukraine. Russia's action breached international law and the sovereignty and territorial integrity of a neighbouring state. New Zealand strongly supported Ukraine in opposing the Russian assault. The attacks were causing widespread humanitarian consequences and resulting in the senseless deaths of innocent people. New Zealand supported collective action by the international community to impose costs on Russia and those in Russia who bear responsibility.

2.17. The representative of the <u>Republic of Korea</u> backed the previous speakers on the situation in Ukraine. The Korean Government strongly condemned Russia's armed invasion against Ukraine as a violation of principles of the UN Charter. The use of force that caused innocent casualties cannot be justified under any circumstances. Ukraine's sovereignty and territorial integrity and political independence must be respected. In connection with this, Korea withdrew STC numbers 10¹⁰ and 33 in the Annotated draft Agenda¹¹ against Russia.

2.18. The representative of the <u>Russian Federation</u> said discussion of events in Ukraine in the TBT Committee was senseless and counterproductive from its point of view. Given this, Russia refrained from comments on the issue. Russia said its stance was set forth in public statements of the Russian government and the Minister of Foreign Affairs as well as in Russia's statements during the meetings of UN Security Council, UN General Assembly, High Commission of Human Rights as well as other relevant international fora. Russia said that in numerous international platforms, WTO Members repeatedly expressed their commitments to strengthen multilateralism and support rules-based non-discriminatory and transparent multilateral trading system with the WTO at its core. Russia regretted that the efforts of certain Members was contributing to fragmentation of the multilateral trading system, instead of engaging constructively in a substantive dialogue on the key issues of the global trade agenda. On the contrary, all Members needed to combine their efforts to improve the WTO's function and demonstrate its continued relevance for international trade.

2.19. The representative of <u>Turkey</u> considered the ongoing aggression against Ukraine unacceptable. Turkey called for immediate cessation of military operations and withdrawal of all

¹⁰ Russian Federation - Procedure for the Import of Products Subject to Mandatory Conformity

Assessment into the Customs Territory of the EAEU (Decision No. 130, 2021)

¹¹ Russian Federation - On Safety of Wheeled Vehicles (TR CU 018/2011) (ID 687).

forces from Ukraine. The humanitarian crisis should be stopped immediately. Turkey reiterated its call for an urgent humanitarian response, dialogue, and diplomacy. Turkey said its firm support for the unity, sovereignty and territorial integrity of Ukraine will continue.

2.1.2 New Specific Trade Concerns

2.1.2.1 Malaysia - Guideline for Approval of Electrical Equipment (Electricity Regulation 1994) Information Booklet 2018 Edition (GP/ST/N0.14/2017), <u>G/TBT/N/MYS/90</u> (ID 729¹²)

2.20. The representative of the <u>Republic of Korea</u> provided the following statement. The Republic of Korea appreciates this opportunity to provide our comments regarding Malaysia's "Guideline for Approval of Electrical Equipment (Electricity Regulation 1994) Information Booklet 2018 Edition", notified to the WTO Members on 11 June 2019 as <u>G/TBT/N/MYS/90</u>, and in force since 1 February 2021. Korea fully respects and supports Malaysia's efforts to introduce energy efficiency regulation for the safety of its people and the protection of the environment. And we sincerely appreciate your official reply on 29 October 2021 to our enquiry regarding the said regulation. The reply from the Malaysian Energy Commission (EC) stated that there is no need to renew the QR code on the energy efficiency label every year under the current regulations, but the local situation is understood to be different. Therefore, we request Malaysia to confirm the alignment between the relevant regulation and their actual application. The regulation requires "importers/manufacturers to include a QR code in the energy efficiency label (the star rating sticker) so that, by scanning the QR code, consumers can check the product certification information, including the expiry date of Certificate of Approval (COA), from the Malaysian Energy Commission website". As a COA is valid for a year, certification must be renewed annually, and the QR code from the renewed COA must be attached to the product.

2.21. In this regard, the QR code also gets changed at the certification renewal, which causes a problem of having to replace the label every year. This adds to the manufacturer's burden in cost and time for discarding the old labels, and printing and reattaching the new ones. In addition, scanning an old QR code that has not been renewed will show an expired certificate for the product, which may cause confusion to consumers. To resolve these difficulties, Korea submitted an enquiry on 10 May last year, requesting Malaysia to improve the regulation, and we received a reply from Malaysia clarifying that "importers or manufacturers are not required to change the QR code in the energy efficiency label for every COA renewal of household electrical appliances". However, we have later found that (i) a new QR code different from the previous one was issued and (ii) scanning the previous QR code on the existing label directs the user to the EC website that only shows the old and expired COA information, as a result of certification renewal by a local company in Malaysia in early January this year. Therefore, Korea once again requests that Malaysia re-confirm the relevant regulation and the actual COA renewal process. Many countries such as the European Union, China, and the United Arab Emirates, do not require changing QR codes in energy efficiency labels every time the certification is renewed. In line with this international practice, Korea reiterates its request that Malaysia revises its regulation to require updating only the information on the website accessible via the QR code, instead of changing the QR code, at the renewal of COA.

2.22. In response, the representative of <u>Malaysia</u> provided the following statement. We would also like to thank the Republic of Korea for submitting enquiries pertaining to the said regulation through our WTO TBT Enquiry Point in May and October last year, in which Malaysia has responded. Malaysia takes note of the Republic of Korea's concern regarding the implementation of the QR code as stipulated under the guideline. In this regard, Malaysia would like to reaffirm that provisions of the guideline are in place. We are currently in close consultations with the Energy Commission of Malaysia to study the issues raised by the Republic of Korea. Meanwhile, Malaysia would like to seek the Republic of Korea's understanding in this matter, and we look forward to further engaging with Republic of Korea bilaterally to address their concerns.

2.1.2.2 Mongolia - Draft Law on controlling the circulation of alcohol beverages, and fight against alcoholism, <u>G/TBT/N/MNG/14</u> (ID 730¹³)

2.23. The representative of <u>Mexico</u> provided the following statement. The delegation of Mexico refers to the Draft Law on controlling the circulation of alcohol beverages, and fight against

 $^{^{\}rm 12}$ For previous statements follow the thread under $\underline{\rm ID~729}.$

¹³ For previous statements follow the thread under <u>ID 730</u>.

alcoholism, notified to the Members of this Committee by the Government of Mongolia on 12 August 2021 in document <u>G/TBT/N/MNG/14</u>. The notified measure contains provisions of concern to Mexican exporters in the alcoholic beverage industry as it bans sales of such products through electronic channels. While Mexico respects Mongolia's aim, we believe that this ban, far from contributing to reducing the harmful use of alcohol, limits the ability to control and trace lawful sales of alcoholic drinks, thereby promoting illegal distribution channels or suspect products. In addition, it is important to emphasize that this ban takes place in a context where, owing to the health emergency caused by COVID-19, online sales provide an alternative means of buying and selling products, suited to isolation and social distancing. Another of the Draft Law's provisions of concern is its ban on alcoholic drinks with an alcohol content greater than 35% alcohol/volume, which will have a direct impact on Mexican exports of drinks such as mezcal and tequila, both of which exceed that percentage. It should be noted that, if the aim is to reduce the harmful use of alcohol, the ban on alcoholic drinks with an alcohol/volume percentage above 35% will not contribute to achieving this goal, as the excessive consumption of drinks with a low alcohol content also represents a threat to consumer health.

2.24. On the other hand, branding-related restrictions are also of concern to Mexican exporters, as branding is an international practice intended to inform the consumer of the quality of the products they are purchasing, their reputation and the potential consequences of their misuse. In light of this, the Mexican delegation requests that the delegation of Mongolia, in view of the commitments in Articles 2.2 and 2.4 of the TBT Agreement, share information on the alternatives studied prior to the determination of the requirements in the Law and on how these requirements constitute less restrictive alternatives in view of the legitimate objective that Mongolia seeks to achieve. We would also like information on the international standards used as a basis for developing this measure. In addition, we request that the delegation of Mongolia share information about the following steps and confirm the date of the measure's entry into force. If this measure entered into force on 1 January 2022, as established in the notification circulated to WTO Members, Mongolia would be in breach of the commitment to grant a reasonable interval of not less than six months, as established in paragraph 5.2 of the Ministerial Decision on Implementation-related Issues and Concerns, adopted by WTO Members on 20 November 2001. The delegation of Mexico thanks the delegation of Mongolia for giving its consideration to this statement and reiterates its availability to attend bilateral meetings that will allow our concerns on this issue to be addressed.

2.25. In response, the representative of <u>Mongolia</u> provided the following statement. Mongolia thanks Mexico for bilateral trade interest with Mongolia. We take note of the questions raised by the delegation of Mexico. We have forwarded them to the capital and will be replying through bilateral meetings as well as TBT eAgenda.

2.1.2.3 United States - Energy conservation program: test procedure for circulator pumps, <u>G/TBT/N/USA/1815</u> (ID 731¹⁴)

2.26. The representative of <u>China</u> provided the following statement. Firstly, the US did not reply to China's question "Do small vertical pipeline pumps include end suction close coupled (ESCC) pumps that can be used vertically". An end suction close coupled pump also meets the definition of a small vertical in-line pump by the Circulator Pump Working Group (CPWG) when it is vertically use. Unclear definitions of small vertical in-line pumps may create unnecessary trade barriers. It is recommended that the US clarifies "whether the small vertical in-line pumps include end suction close coupled pumps (ESCC) or not". Secondly, China suggests that US adds schematic diagrams to help understand the definitions of "mechanically-coupled pumps" and "close-pumps", so as to avoid misunderstandings. Thirdly, for pressure control type circulator pumps, the US has given an equation for PERCIRC but has not yet provided scientific evidence for the PERCIRC weighting assignments, which may create unnecessary trade barriers. China suggests that the US provide scientific evidence for PERCIRC weighting assignments to pressure control type circulator pumps. Fourthly, an "integrated design pump" means a pump with associated piping and accessories from which the individual pumps cannot be easily separated. China suggests that the US clarifies the efficiency testing method for this type of pump.

2.27. In response, the representative of the <u>United States</u> provided the following statement. I just would like to note that we have not received any comments to the US Enquiry Point on <u>G/TBT/N/USA/1815</u> from China, and the first time we are hearing about these concerns are on the

 $^{^{\}rm 14}$ For previous statements follow the thread under $\underline{\rm ID~731}.$

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floor of the TBT Committee. We really do encourage China to submit comments through the US Enquiry Point in advance by the deadline that is provided in the notification so that we can answer the technical concerns that you have. If you bring them here without any advance warning we really are not able to answer the technical questions or respond in any way that is substantive. So I will note here that the Department of Energy draft regulation to the TBT Committee was notified in <u>G/TBT/N/USA/1815</u>, and the comment period closed on 18 February 2022. We did not receive any comment from China or any of its stakeholders. The United States will take into consideration all comments received during the open comment period and respond to each substantive comment in the next published rulemaking document on Test Procedures for Circulator Pumps.

2.1.2.4 Kingdom of Saudi Arabia - Corporate average fuel economy standard (SAUDI CAFE) for all light duty vehicles, <u>G/TBT/N/SAU/1226</u> (ID 732¹⁵)

2.28. The representative of <u>China</u> provided the following statement. 1. It is recommended to add the conversion method of WLTC. 2. For new energy vehicles as PHEV and BEV, it is recommended to introduce NEDC and WLTC, and add testing methods according to relative UN regulations, and put forward targeted energy consumption requirements. 3. For derogation of companies with annual global sales of no more than 10,000 vehicles, it is recommended to change the sales requirements to "companies whose annual sales volume in Saudi Arabia does not exceed 10,000 (or a smaller number). 4. To fully realize the CAFE target, it is suggested to accelerate the construction of new energy infrastructure, develop subsidy policies for new energy vehicles, encourage and support a rapid development of new energy vehicle industry, and gradually implement the 3rd phase fuel consumption policy according to the development of new energy infrastructure.

2.29. In response, the representative of the <u>Kingdom of Saudi Arabia</u> provided the following statement. We take note of the concerns raised and we will convey them to the capital and reply in due course. A technical statement was circulated following the meeting.¹⁶

2.1.2.5 South Africa - Regulations relating to the composition, production and labelling of wine and spirits intended for sale in the Republic of South Africa, <u>G/TBT/N/ZAF/48/Rev.2/Add.1</u> (ID 733¹⁷)

2.30. The representative of Mexico provided the following statement. The delegation of Mexico refers to the Regulations relating to the composition, production and labelling of wine and spirits intended for sale in the Republic of South Africa, notified to the Members of this Committee on 20 December 2021 in document G/TBT/N/ZAF/48/Rev.2/Add.1. First of all, we would like to thank the Government of South Africa for the opportunity to provide comments during the public consultation that concluded on 12 February 2022. Both the industry and the Government of Mexico participated in this process to share concerns about what we believe could have an impact on Mexican exporters of tequila and mezcal, as well as on potential exporters of raicilla and bacanora. Although South Africa has already responded to the comments submitted by Mexican industry, there has not yet been a response to the comments submitted by the Government of Mexico. Could the delegation of South Africa let us know when this response is likely to be issued? In addition, and with the aim of following up on our concerns in a timely manner, we would be grateful if the delegation of South Africa would provide us with a contact point through which we could request a bilateral meeting, if necessary. The delegation of Mexico thanks the delegation of South Africa for giving its consideration to this statement and reiterates its thanks for the transparency in the amendment of these Regulations.

2.31. The representative of the <u>European Union</u> provided the following statement. The EU thanks South Africa for notifying their proposed revisions to their alcohol beverage composition, production, and labelling regulations on 12 December 2021. The EU sent written comments on 16 February. Our key concerns relate to the following categories: spirit aperitif, gin, description of pot still brandy and vintage brandy. In addition, we suggested the creation of a new category called "spirit drink" for products that do not fall under other categories due to their alcohol content. We look forward to receiving written replies from South Africa to our detailed written comments.

 $^{^{15}}$ For previous statements follow the thread under $\underline{ID 732}.$

¹⁶ <u>G/TBT/W/771</u>.

 $^{^{17}}$ For previous statements follow the thread under $\underline{ID 733}$.

2.32. The representative of the <u>United States</u> provided the following statement. The United States thanks South Africa for notifying their proposed revisions to their alcohol beverage composition, production, and labelling regulations on 12 December 2021. The US appreciates South Africa's prompt response to our comments submitted on 11 February 2022. The United States encourages South Africa to address our concerns with regard to how flavoured spirit products will be classified if they have an alcohol content of over 30% but less than the alcohol content required to be classified under the specific spirit category, for example, 43% alcohol by volume (abv) for whiskey. The United States is concerned that this measure would unnecessarily restrict imports of certain US flavoured spirits that contain between 30% and 43% alcohol by volume. We look forward to continued engagement with South Africa to address these concerns and ensure trade of US flavoured spirits is not unnecessarily disrupted.

2.33. In response, the representative of South Africa provided the following statement. South Africa thanks Mexico for the interest shown and questions/concerns shared with us regarding the notification to the WTO of the proposed amendment to the Draft Regulations Governing the Composition, Production and Labelling of Wine and Spirits Intended for Sale in the Republic of South Africa. We also thank the EU and the US for their question and comments in that regard. The document number for the notification is G/TBT/N/ZAF/48/Rev.2/Add.1 circulated on 17 December 2021. According to our records, South Africa received only one set of comments from Mexico through our National TBT Enquiry Point - the SABS - regarding the possible effects that the draft regulation could have on the marketing of Tequila, Mezcal, Bacanora and Raicilla, 100% agave beverages. These comments related to Technical Barriers to Trade (TBT) as well as Intellectual Property (IP) elements within the draft regulation. South Africa responded to all the concerns raised by Mexico through a formal letter dated 15 February 2022. We also have now taken note of the statement by the EU and the US in support of the STC raised by Mexico. South Africa remains available to engage with Members to provide further clarifications and address any questions and concerns. We believe the issues raised could indeed be resolved through a bilateral engagement. Should Members concerned wish to request a bilateral meeting, our South African Permanent Mission in Geneva can be contacted to facilitate such engagements.

2.1.2.6 European Union - Specific test procedures and technical requirements for the type-approval of motor vehicles with regard to their event data recorder and for the type-approval of those systems as separate technical units, <u>G/TBT/N/EU/838</u>, <u>G/TBT/N/EU/871</u> (ID 734¹⁸)

2.34. The representative of <u>China</u> provided the following statement. 1. Article 2 and Article 3 stipulate that vehicle type approval shall comply with "UN Regulation No 155 Uniform provisions concerning the approval of vehicles with regards to cyber security and cyber security management system", but this article does not indicate how to prove the compliance. Therefore, China suggests that this part should be revised to "The crash-related data that the EDR records and stores shall be protected against manipulation, which shall be justified by complying UN R155", which means if the motor vehicle has obtained type approval according to UN R 155, it shall be deemed as complying with the requirements of Article 3. 2. For the transitional period, Article 2 adopts technical requirements from UN R 160 Chapter 5. According to the provisions of 11.3 in UN R 160, the transitional period for type approval is before 1 July 2026, whereas the EU will enforce UN R 160 on 6 July 2022. We recommend that the regulation be consistent with the implementation transitional period specified in article 11.3 of UN R160. (Article 11.3 of UN R160: Until 1 July 2026, Contracting parties applying this Regulation shall accept type approvals to the original version of this Regulation, first issued before 1 July 2024.)

2.35. In response, the representative of the <u>European Union</u> provided the following statement. The EU would like to note that that the notified draft was notified under reference number <u>G/TBT/N/EU/838</u> in accordance with the TBT Agreement on 27 September 2021 with a 60-day commenting period. China submitted comments on 26 November 2021. The EU has prepared the following reply to those comments. With regard to Article 2 of the notified draft, the Chinese authorities recommended that information documents and approval marks, including for Separate Technical Units, should be added to the notified draft or added to Regulation (EU) 2020/683. The EU would like to clarify that the process of revising Regulation (EU) 2020/683 is ongoing and those amendments will be adopted before the date on which the requirements of notified draft will become applicable (6 July 2022). The TBT consultation of this revision was launched on 8 February 2022

 $^{^{\}rm 18}$ For previous statements follow the thread under $\underline{\rm ID~734}.$

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under reference number <u>G/TBT/N/EU/871</u> and the commenting period will expire on 9 April 2022. With regard to Article 3, China recommended specific wording. China explains that they understand the intention of this provision as to provide that the motor vehicle shall be deemed to comply with the requirements of Article 3 if it has been type-approved according to UN Regulation No. 155. However, the EU considers that such purpose is best achieved by the present text. In this regard, Article 3 establishes a presumption that material compliance with UN Regulation No. 155 would result in compliance with the obligation to protect the data against manipulation.

2.36. Finally, regarding China's observations on the 01 Series of Amendments to UN Regulation No 160, the EU would like to clarify that only the 01 Series of Amendments meet the requirements laid down in Regulation (EU) 2019/2144 of the European Parliament and of the Council (General Safety Regulation or GSR), which is the basic act for the notified draft on Event Data Recorders. The GSR requires the detailed technical requirements and test procedures for EDR to become applicable on 6 July 2022. The notified draft must comply with the GSR, as this is the basis on which it is being adopted. Therefore, it must provide for the application of the 01 Series of Amendments as from the aforementioned date. The revised draft takes into account the obligations of the EU and of the EU member States under the 1958 Agreement, providing that approvals in accordance with UN Regulation 160 granted outside the EU shall be accepted as an alternative to an approval in accordance with 01 Series of Amendments to UN Regulation No 160, for the purposes of granting an EU approval, as well as registration, sale and entry into service until, respectively, 1 July 2024 and 1 July 2026.

2.1.2.7 Canada - Pest control products regulations (ultraviolet radiation-emitting devices and ozone-generating devices), <u>G/TBT/N/CAN/656</u> (ID 735¹⁹)

2.37. The representative of <u>China</u> provided the following statement. China suggests that Canada adds "for such products, the certification of the exporting country meeting relevant standards can be accepted and recognized" in its amendment, which not only ensures the safety and reliability of products but also makes benefits for enterprises, avoiding technical barriers to trade.

2.38. In response, the representative of Canada provided the following statement. UV radiationemitting and ozone-generating devices that make claims to control or kill bacteria and viruses on surfaces, objects, in water, and in the air are more widely and increasingly available for sale in Canada since the pandemic. Health Canada has not yet received sufficient evidence to demonstrate that all UV and ozone-generating devices can be used safely or work as claimed. On 7 June 2021, Canada's Minister of Health enacted an Interim Order under the Pest Control Products Act to address significant risks to human health and safety posed by these devices. As the Interim Order expires 7 June 2022, Canada is proposing amendments to the Pest Control Products Regulations to continue the health and safety protections established under the Interim Order, with some changes. The proposed amendments subject certain UV radiation-emitting and ozone-generating devices to the Pest Control Products Act and its Regulations. These devices require registration under the Act through Canada's existing submission review process unless they meet specified conditions. If they meet those conditions, the device is authorized to be imported, manufactured, sold and used in Canada. The conditions for authorization in question are intended to protect human health and safety. Electrical safety certification, by a body accredited by the Standards Council of Canada, is one of these conditions, and ensures that there are no hazards, such as fire and electrical shock, posed by the devices in question. These provisions reflect similar existing Canadian federal and provincial laws on device safety.

2.39. Canada is committed to its obligations under the WTO Agreement on Technical Barriers to Trade, including the non-discrimination obligation. The proposed regulatory amendments accord the same treatment to both domestic suppliers in Canada and suppliers from other WTO Members. Any organization from a WTO Member dedicated to electrical safety certification can apply to be accredited by the Standards Council of Canada. The requirements for accreditation and the standards that accredited organizations certify are the same regardless of country of origin. Accredited organizations, including international organizations, can complete the certification work in the countries exporting their devices to Canada. It is our understanding that one North American organization accredited in Canada has an affiliate in China and may comply with the certification

 $^{^{19}}$ For previous statements follow the thread under $\underline{ID 735}$.

requirement proposed in the regulatory amendments. Canada would be pleased to share the name of this organization separately with the Chinese delegation.

2.1.2.8 European Union - Proposal for a regulation of the European Parliament and the Council laying down harmonised rules on artificial intelligence (Artificial intelligence act) and amending certain union legislative acts (ID 736²⁰)

2.40. The representative of <u>China</u> provided the following statement. We support EU to regulate artificial intelligence, however, in order not to create unnecessary trade barriers, China would like to raise concerns as follows. 1. It is suggested to narrow the definition of "artificial intelligence system" by eliminating Annex I (b) and (c) or further specifying the technologies mentioned in Annex I (b) and (c). Firstly, the scope of definition as to "artificial intelligence system" in article 3 (1) and Annex I of the act is too broad. The wording of the definition indicates a large number of software applications, it is unreasonable to classify all of which as artificial intelligence. Secondly, the expansion of the scope of definition as to AI would also expand the scope of high-risk AI enterprises, which would result in that the enterprises covered in this regulation would be much more than the 10% expected by the European Commission, greatly increasing the burden of enterprises and regulator, which is inconsistent with the legislative purpose of the EU.

2.41. 2. It is suggested to lay down relevant classification guidance of prohibited artificial intelligence referred to in article 5 (1). The wording "prohibited artificial intelligence practices" uses vague and subjective phrases such as "subliminal techniques", "beyond a person's consciousness", "materially distorting a person's behaviour", etc. For providers, to judge which applications or technologies constitute "unacceptable risks" by those phrases would bring significant compliance risks. It is suggested to provide a more precise definition or a limited negative list. 3. It is suggested to eliminate the requirement of "Free of errors and complete" in article 10 (3). If not, please further clarify the definition. The new data would be generated in AI training and testing, and the datasets would be enriched after placing on the market. Few datasets could comply with the "free of errors and complete", which is inconsistent with the current state and development of the AI industry. The act regulates AI systems from the angle of traditional products without considering the dynamic characteristics of the life cycle of machine learning systems development. Therefore, it is suggested to eliminate this requirement. If not, please further clarify the definition.

2.42. 4. It is suggested to eliminate the requirement to provide source code in article 64(2) and point 4.5 in Annex VII. "The market surveillance authorities shall be granted access to the source code of the AI system" in article 64 is not directly and necessarily related to assessing the requirements set out in Chapter 2, Title III. Firstly, the explainable AI is still at the forefront of research, even AI system developers cannot "fully understand" AI systems, that is, providing the source code cannot necessarily meet the needs that market supervision departments assess whether AI systems conform to requirements. Secondly, providing source code could not prevent AI system errors. The source code assessment could not replace the systematic verification and actual testing; the latter is more direct and effective in identifying or correcting harmful results and verifying whether the AI system is in line with its design. Finally, the obligatory provision of source code also deviates from the common international practices of protecting source code as a commercial secret. 5. It is suggested that, to protect all data information from providers, confidentiality obligation for the Commission, the member States and their market surveillance authority, notified bodies and other participating bodies should be emphasized and specified in article 70. In this act, AI providers are required to provide a large number of data-sets and technical documents. Therefore, the EU shall strengthen the controls on data information security in some respects.

2.43. 6. It is suggested to keep Penalties in article 71 consistent with the NLF. Penalties under the NLF are usually regulated by member States, such as RED, LVD and EMC, as "The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation". If in this act the penalties are not regulated by member States as the above, it is suggested to revise the calculation measures of the penalties in article 71, and reassess the fines, to make sure the penalties are proportionate to the performance. For example, it is necessary to consider modifying the fines of "total worldwide annual turnover" to the fines of "turnover in the EU market". In addition, this article is too strict to the non-compliance (under Chapter 2, Tittle III) which may result in fines of 4% of worldwide turnover. It is suggested to classify fines between essential requirements and other administrative requirements with reference to NLF. 7. It is suggested to add applicable

 $^{^{20}}$ For previous statements follow the thread under <u>ID 736</u>.

transition period for 48 months in Chapter 2. The presumption of conformity shall be carried out by the provider after the publication of the harmonized standards. It usually takes more than 36 months for standards bodies to lay down new standards, and another 12 months is needed to adjust products and systems, conduct conformity assessments and prepare all required documentation.

2.44. In response, the representative of the <u>European Union</u> provided the following statement. We are currently preparing written replies to your written comments. Let me react to some key issues raised by you today. As regards the definition of artificial intelligence (AI), we aimed to adopt a definition as technology neutral as possible so it can be applied over time to innovation and market developments. The proposal builds on the internationally recognised definition of OECD, with only minor adjustments, such as the inclusion of "content" (generative AI systems) and the addition of an annex with the list of techniques and approaches. The annex aims to provide legal certainty to operators and supports the dynamic character of the overall definition, insofar as the European Commission can update the list and clarify its scope when required due to technological and market developments. It is important to note that, in order for a certain system to be classified as AI for the purpose of the AI Act, it is not enough that any of the techniques in Annex I is used, but the system must also fulfil the "functional" definition in Article 3(1). While the prohibitions in Article 5 use abstract formulations to cover a variety of use cases of harmful practices, these concepts are not new to Union law and they have already been used in court case law and other Union legal acts. As appropriate, the European Commission may issue guidelines on these concepts, including illustrative examples of practices that could be covered.

2.45. In relation to "free of error and complete datasets", Article 8 specifies that all requirements should be implemented in light of the intended purpose of the system and the risk management, which takes into account the acceptable risks and is limited to what is feasible according to the state of the art (Articles 9(3) and 9(4)). To avoid any doubts, further clarification in this sense may also be made in Article 10 (a point already considered by the Council of the European Union). The proposal clearly protects the source code as intellectual property (see Article 70(1)a.). On that basis, Article 64(2) makes the access to source code dependent on two strict cumulative conditions: 1) there must be a reasoned request on the side of the market surveillance authority, and 2) access must be necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 of the AI Regulation. This strikes a balance between intellectual property rights protection and safety protection to safeguard important public interests, in line with our international agreements and commitments. Article 70 also requires national competent authorities and notified bodies involved in the application of the AI Regulation to respect the confidentiality of information and data obtained in carrying out their tasks and activities. This is also extended to other national public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights who may gain access to the technical documentation (Article 64(6)). The penalty system in the proposed AI Regulation builds on the EU's new legislative framework system but also on other existing legislation, such as General Data Protection Regulation. This implies that EU member States remain responsible for laying down the rules on penalties, including administrative fines, applicable to infringements of the AI Regulation. However, some harmonization elements are provided, e.g. on the capping and types of infringements associated. Finally, the rationale for the shorter transitional period is to empower EU member States to lay down and adopt the relevant rules on penalties ahead of the general application date of the AI Regulation.

2.1.2.9 United States - Secure equipment act of 2021 (ID 737²¹)

2.46. The representative of <u>China</u> provided the following statement. The Secure Devices Act of 2021, requires the Federal Communications Commission (FCC) to revise the device authorization rules and to refuse to authorize information and communication devices that "pose a threat to US national security", including mobile phones, tablets, base stations, wireless routers, surveillance cameras and so on. Therefore a number of Chinese information and communication equipment enterprises, are involved. FCC authorization is a mandatory equipment access requirement for information and communication products to enter the US market. Once the authorization is stopped, it causes great trade barriers. China hopes the US to stop implementing the act, treat information and communication equipment of all Members equally, and follow the principle of national treatment and MFN and grant fair market access opportunities.

²¹ For previous statements follow the thread under <u>ID 737</u>.

2.47. In response, the representative of the <u>United States</u> provided the following statement. The Federal Communications Commission is charged with issuing implementing regulations, and those proposed regulations are scheduled to be developed and published by 22 November 2022 and will be notified to the WTO TBT Committee accordingly so we will let China know when that has been notified and would encourage you to provide comments.

2.1.2.10 European Union - Regulations affecting spices (Regulation number EU 2021/2246, dated 15 December 2021) (ID 738²²)

2.48. The representative of <u>India</u> provided the following statement. The Republic of India is deeply concerned with the abrupt changes in the EU regulations and bringing them into effect without giving time to exporters to implement changes. This has impacted the Indian spice exporters adversely. The said Regulation is a concern under both TBT and SPS Agreements; hence it is being raised in both the Committees. As per the Regulation (Regulation no. EU 2021/2246 dated 15 December 2021), consignments of spices from India should be accompanied by an Official Certificate (Health Certificate), stating compliance with maximum residue levels of ETO (Ethylene oxide expressed as the sum of ethylene oxide and 2-chloro-ethanol). The Regulation applies to all products which fall under the CN Codes from 0904 to 0910 and 2103, thereby covering all spices and most of the spice products. Regulation 2021/2246, which was adopted by EU on 15 December 2021 with the date of taking effect as 6 January 2022, was notified on the WTO SPS website only on 14 January 2022, as a regular notification, after eight days from the date of taking effect. The standard 60 days for consultation with the membership was not provided. Further, it had no provision for the comments.

2.49. The result of these abrupt changes in the regulations stranded many Indian spice consignments at several EU ports since December 2021 as the Port Health authorities are demanding 100% testing of ETO (in the case of consignments shipped before 6 January 2022) and an official certificate issued by India (in the case of consignments shipped on or after 6 January 2022). Cultivating and harvesting spice crops take up to six months. The cumin seed, for example, is sown at the end of October/November 2021 and harvested in February/March 2022, i.e., 90 days crop. Hence the EU's MRL notification of 15 December will not be compliant with the current harvest cycle. The regulations and special conditions prescribed by the EU are trade-restrictive and render high costs and difficulties to the exporters, thereby posing a trade barrier to export spices from India. The trade barriers imposed by the EU pose the risk of disruption of India's export of spices and other food products to the European Union. India, therefore, requests the EU to provide sufficient transition time and the implementation of the said Regulation may be put on hold and consider implementing Regulation no. EU 2021/2246 to India spices from the next harvest cycle onwards.

2.50. In response, the representative of the European Union provided the following statement. During 2021, several incidents of foodstuffs contaminated with ethylene oxide led to measures taken by the competent authorities of member States of the European Union, in order to ensure that only safe products remain in the market. Ethylene oxide (EtO) is classified in the EU as carcinogen and mutagen and reprotoxic disinfectant, and thus it is not allowed for food and feed in the Union. In accordance with legal provisions for the products contaminated with ethylene oxide, no safe level of exposure for consumers can be defined and hence any level consumers may be exposed to, presents a potential risk to their health. The EU is aware that ethylene oxide is largely used in third countries to treat certain foodstuffs before export, as indicated in the high number of Rapid Alert System for Food and Feed (RASFF) notifications. Indeed more than 50 notifications have been submitted in 2021 through the RASFF, which showed contamination with ethylene oxide of a broad range of commodities like several spices, guar gum, locust beans (including mucilages and thickeners derived from locust beans), calcium carbonate and food supplements containing botanicals originating in India. The Indian authorities were asked to take follow-up actions; nevertheless, non-compliant consignments of a wide range of commodities continued to arrive to the Union. As a consequence, the European Union has decided to take measures in order to mitigate the possible risk for the health of European consumers, since the problem appeared to go beyond findings relating to the responsibility of individual stakeholders for the compliance of their exports with EU rules.

2.51. Commission Implementing Regulation (EU) 2019/1793²³ lays down the list of food and feed of non-animal origin and compound food subject to special conditions governing their entry into the

²³ Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain

²² For previous statements follow the thread under <u>ID 738</u>.

Union, as well as to a temporary increase of official controls in its Annex II. Several commodities from certain third countries, including India, were added to Annex II to that Regulation, amended by Regulation (EU) 2021/2246²⁴, in order to strengthen the protection of public health in the EU, with respect to serious and high risk of contamination by ethylene oxide of many commodities exported to the EU. Thus, each consignment of those commodities listed in Annex II shall be accompanied by an official certificate stating that the products have been sampled and analysed for ethylene oxide and by the results of sampling and analyses showing compliance with Regulation (EC) No 396/2005²⁵ on maximum residue levels of ethylene oxide. In addition, the consignments are subject to a harmonized level of official controls upon their arrival to the EU border. In addition to spices, other products originating in India were listed in Annex II to Regulation (EU) 2019/1793 and are therefore subject to official controls and emergency measures governing their entry into the Union. Those products are sesamum seeds, due to the risk of contamination by ethylene oxide (and salmonella) and locust beans, locust beans seeds, mucilages and thickeners, whether or not modified, derived from locust beans or locust bean seeds, guar gum, sauces and preparations thereof, mixed condiments and mixed seasonings, mustard flour and meal and prepared mustard, calcium carbonate and food supplements containing botanicals, due to the risk of contamination by ethylene oxide.

2.52. The Indian authorities were informed about the latest changes and amendments to Regulation (EU) 2019/1793 in December 2021. The Indian authorities are aware of the certification requirements for the products concerned. The EU would like to clarify that the measures under discussion are not TBT measures, but SPS measures and that they were notified under the SPS Agreement (G/SPS/N/EU/538). Therefore, any further discussion on these measures, if considered necessary, should take place at the SPS Committee. In response to several requests for a smooth transition and, in order to allow for the continuation of safe trade for the commodities concerned in view of the serious risk of contamination by ethylene oxide, a consensus on transitional arrangements was found with member States. In this context, member States agreed to allow the entry into the Union, until 17 February 2022, of consignments of the commodities added to Annex II to Regulation (EU) 2019/1793 due to the risk of contamination by ethylene oxide which were not accompanied by a health certificate, provided that such consignments were shipped to the Union before 6 January 2022 and are subject to 100% of official controls, including sampling and laboratory analysis at border control posts. The European Union would like to stress that measures were taken since findings suggested that importers had not met their primary responsibility to ensure that products exported to the European Union complied with EU requirements for the safety of products.

2.1.2.11 European Union - Implementation of access regulation regarding collagen for human consumption (ID 739²⁶)

2.53. The representative of <u>China</u> provided the following statement. According to Commission Implementing Regulation (EU) 2021/405, China is included in the list of third countries authorized for the entry of collagen into EU in ANNEX IX, ANNEX XII and ANNEX XIII. EU should implement the above regulation and remove the warning on the registration page: "Collagen is not listed in the Annex to Commission Decision 2002/994/EC. According to Article 2 of the same Decision, collagen originating from China is not authorized to be imported into EU", otherwise, it will cause great trade barriers for China's products.

2.54. In response, the representative of the <u>European Union</u> provided the following statement. Commission Decision $2002/994/EC^{27}$ as last amended by Commission Implementing Decision (EU)

third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660. (OJ L 277, 29.10. 2019, p. 89).

²⁴ Commission Implementing Regulation (EU) 2021/2246 of 15 December 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council. (OJ L 453, 17.12.2021, p. 5).

²⁵ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

 $^{^{26}}$ For previous statements follow the thread under <u>ID 739</u>.

²⁷ Commission Decision 2002/994/EC of 20 December 2002 concerning certain protective measures with regard to the products of animal origin imported from China (OJ L 348, 21.12.2002, p. 154).

2015/1068²⁸, applies to all products of animal origin imported from China and intended for human consumption or animal feed use. The Decision lists food and feed products authorized to be imported from China into the EU. Article 1 of this Decision applies to all products of animal origin imported from China and intended for human consumption or animal feed use. Articles 2 and 3 of this Decision indicate possible derogations to the provisions in Article 1, which are included in parts I and II of the Annex to this Decision. Since collagen is not included amongst the possible exceptions (parts I and II of the Annex), it is actually not authorized to import collagen from China into the EU.

2.1.2.12 United Kingdom - EC marking certificate for export of home textile items (ID 740²⁹)

2.55. The representative of India provided the following statement. The Republic of India is concerned about the Non-Tariff Barrier of CE Marking for Personal Protective Equipment imposed by the United Kingdom, specifically, about the markings affixed on two textile items i.e. Oven Gloves and Pot Holders. Post-Brexit, the United Kingdom has adopted EC Regulation (EC) No. 765/2008 and Decision No.768/2008/EC for the CE Marking. The CE Marking indicates the conformity of the product with the Union Legislation applying to the product. The scope of the current certification requirement includes specific information like size, colour, filling, fabric material etc. Some of the challenges faced by the Indian manufacturers and exporters are: a. The fabric design and colour between the importers vary, but the EC certificate remains valid for a particular design alone, forcing manufacturers and exporters to seek a new certification for every design and colour. b. Obtaining an EC certificate is time-consuming. It takes between 12 to 16 weeks to complete the entire certification process. c. The certification costs are very high, ranging between INR 150,000 and 200,000. d. The impact of high CE certification cost is adverse on smaller consignments. e. Different buyers in the United Kingdom place orders with different designs and colours. These designs vary within a season and between the seasons. But each of these orders needs a separate certificate. f. Besides, MSMEs primarily employ women to produce these products. The barriers imposed by these regulations negatively affect MSMEs, gender, and e-commerce. In a nutshell, instead of facilitating trade, this regulation is erecting artificial barriers. Hence, to remove this technical barrier and align with Article 2.2 of the TBT Agreement, the United Kingdom is requested to authorize certification bodies to issue generalised certificates and or allow a change in the shell fabric design, colour length and width of the product. This, besides trade facilitation, will be beneficial to the exporters, MSMEs, e-commerce and the customers alike.

2.56. In response, the representative of the <u>United Kingdom</u> provided the following statement. As we have not received any information from you on this issue in advance, we are sorry that we cannot comment on the specifics of your statement, but we will refer your concerns to capital and respond in due course via your Enquiry Point.

2.1.2.13 European Union - Commission implementing decision (EU) 2017/1357 on a restriction of Standard EN 60335-2-9-2003+A 13-2010 (ID 741³⁰)

2.57. The representative of <u>China</u> provided the following statement. China would like to suggest the following. 1. Standard EN 60335-2-9-2003+A13-2010 is applicable to the safety of domestic portable electric appliances with cooking functions such as baking, roasting and grilling with a rated voltage not exceeding 250 V. The air fryer is a class of portable electric household appliance that uses convection of hot air and requires internal and external circulation to heat food, the principle of which is fundamentally different from that of a conventional oven. If the EU fully adopts the standard EN 60335-2-9-2003+A13-2010 for testing the safety requirements of air fryers, this would lead to a mismatch between the testing provisions and the product, which would create unnecessary international trade barriers. EU should reconsider the classification of products based on the principles of operation of air fryers and set out the safety requirements and performance test methods that are compatible with the products. 2. The European Commission has restricted the "temperature rises are not measured on surfaces within 25 mm from the ventilation openings" in its Implementing Decision (EU) 2017/1357. As the air fryer is a product with internal and external circulation of hot air, the temperature rises on the surfaces within 25 mm of the ventilation openings

²⁸ Commission Implementing Decision (EU) 2015/1068 of 1 July 2015 amending Decision 2002/994/EC concerning certain protective measures with regard to the products of animal origin imported from China (OJ L 174, 3.7.2015, p. 30).

 $^{^{29}}$ For previous statements follow the thread under $\underline{ID\ 740}.$

 $^{^{30}}$ For previous statements follow the thread under <u>ID 741</u>.

are high. The implementation of the temperature rise requirements specified in Table Z101 of EN 60335-2-9:2003+A13:2010 would result in the inconformity of air fryers with the EU market access requirements. It is recommended that the EU reassess the scientific basis of this restriction and exempt air fryers from the temperature rise measurement.

2.58. In response, the representative of the <u>European Union</u> provided the following statement. The Commission Implementing Decision follows a formal objection by Germany and Norway respectively in June 2014 and July 2014. The formal objections of Germany and Norway stated that Section 11 "Heating" of the standard includes insufficient provisions regarding temperature limits of accessible non-functional surfaces. In particular, the standard allows several exclusions to the temperature limits, authorizing the manufacturer to double or not to apply the temperature limit values depending on the size, design or the surface part of the appliance, and requiring at most a warning notice or label. In this respect, Section 7.1 of the standard only requires a warning to be put on the surface with the highest temperature within the parts exceeding the limit values. The colours of the warning label may differ from international warning colours which may confuse the users. Additionally, as a result of the ambiguity of the requirements under the standard, the standard can be interpreted as making it possible to omit the measurement of the temperature rises in certain parts of a given product, which may lead to the disregard of or doubling of the temperature limit values applicable under the standard with regard to the entire product.

2.59. As a result, the risk of burning for persons and domestic animals is still present and the standard as such should not give the presumption of conformity with Directive 2014/35/EU. Having examined standard EN 60335-2-9:2003, as last amended by A13:2010, in the Low Voltage Directive Working Party, which is a group of sectoral experts, together with EU member States and stakeholders, the European Commission together with the majority of experts from member States agreed with the arguments presented by Germany and Norway. Consequently, it was concluded that the standard fails to meet the safety objectives laid down in point 1(c) of Annex I to Directive 2014/35/EU, in conjunction with point 2(b) of that Annex. Taking into consideration the safety aspects to be improved and pending a suitable revision of the standard, the Commission Implementing Decision provides for the relevant restriction in its Annex 1, namely that the concerned restricted parts do not confer a presumption of conformity. Since the raise of the formal objection and the publication with restriction of the standard EN 60335-2-9, the Commission continuously puts effort, together with stakeholders and European Standardisation Organisation, to reach a new version of the standard, which would fulfill the objectives of the Low Voltage Directive 2014/35/EU. The EU would like to emphasize that the concerned standard fulfils the definition of a standard as contained in Annex 1 point 2 of the TBT Agreement, namely that it is a "Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory."

2.1.2.14 India - Approved models and manufacturers of solar photovoltaic modules order, 2019 (ID 742³¹)

2.60. The representative of <u>China</u> provided the following statement. 1. The Indian F.NO.283/54/2018-GRID SOLAR "Approved Models and Manufacturers of Solar Photovoltaic Modules Order, 2019" distinguishes between imported and domestic products manufacturers, and imported products and manufactures are treated unfavourably. In terms of review and feedback time, overseas enterprises are discriminated. The overseas enterprises are in less favourable competition condition, while Indian domestic manufacturers have advantages and are protected. It is not consistent with National Treatment of GATT and Articles 2.1, 5.1 and 5.2 of TBT. China suggests that the Ministry of New and Renewable Energy (MNRE) of India and the National Institute of Solar Energy (NISE) to adjust the measures, treat domestic and foreign companies equally, besides, audit process and time schedule should be publicized, so as to improve the certification efficiency. 2. In NISE's Documentation and On-Site verification process, the certification standards and process rules are not clear, lack of guidance for the manufacturers, no effective feedback and communication in ALMM audit application process. It is against transparency principle in GATT and TBT Articles 5.1, 5.2 and 5.6. A clear certification standards and auditing process should be publicized.

2.61. 3. After charging Chinese companies for high ALMM application and testing fees, on-site inspection and audit have been delayed due to the COVID-19 epidemic. Considering the persistence of the global epidemic and foreseeable travel restriction policies, it is obviously not possible for on-

 $^{^{31}}$ For previous statements follow the thread under <u>ID 742</u>.

site inspection of overseas manufacturers. Alternative solutions should be considered, such as entrusting a Chinese certification body to conduct on-site inspection to support the necessary remote video inspection. Besides, we request the Indian side to postpone the implementation of the ALMM Act until eight months after the completion of the on-site inspection. 4. The fees charged for ALMM certification were unreasonable. Currently, this certification fee is evaluated and charged according to the total production capacity of the manufacturer, which is much higher than the actual production capacity quota allocated for export to India market. Therefore, this measure is against the obligation to control the fee in Article 8.1(a) of GATT, not to create unnecessary obstacles to trade in TBT Agreement. It is recommended that the Indian side follow the Agreement and set a reasonable price standard. 5. From the perspective of the necessity for the formulation of the Decree (The Approved Models and Manufacturers of Solar Photovoltaic Modules Order, 2019 (ALMM) (Compulsory Registration Requirements), the requirements of BIS certification can indeed fully fulfil the purpose of ensuring the quality of photovoltaic modules, and the additional ALMM certification list is unnecessary, burdensome and can become an obstacle to trade. 2019 ALMM Decree restricts trade while no further contribution in achieving legitimate objectives, it is against Article 2.2 of TBT Agreement. China suggests that Indian withdraws the ALMM decree.

2.62. In response, the representative of <u>India</u> provided the following statement. India has not received any information on this issue in advance; we cannot comment on any statement uploaded today or tomorrow. We will, however, refer such a statement to the capital for a response later.

2.1.2.15 European Union - Regulation (EU) 2022/30 on network protection, safeguards for the protection of personal data and privacy and protection from fraud, G/TBT/N/EU/823 (ID 743³²)

2.63. The representative of <u>China</u> provided the following statement. 1. EU clarifies the regulatory timeline for the new regulation, and whether it is valid for newly launched products or all products on sale; 2. EU publishes relevant test standards and conformity assessment guiding documents as soon as possible, allowing manufacturers to conduct product regulatory compliance analysis in advance and to modify product design in time to meet regulatory requirements; 3. EU takes reference on the current status of the related enterprises' readiness during the development of this standard. It is to ensure that before the implementation of the regulation, there are enough test laboratories and certification bodies which have the test environment and test resources needed, and can accurately assess the product compliance. All these can ensure the effective implementation of the regulation.

2.64. In response, the representative of the European Union provided the following statement. Commission Delegated Regulation 2022/30 was notified on 23 July 2021 with a 60-day commenting period under reference number G/TBT/N/EU/823. China submitted comments on 18 September 2021 to which the EU replied on 4 November 2021. In its comments, China raised several issues, one of which was the recommendation to extend the transition period of 30 months. In this regard, the EU provided in its reply that the proposed transition period reflects the balance between the various interests and concerns at stake. On the one hand, the public interest requires to swiftly reinforce the level of protection offered by certain radio equipment placed on the EU market. On the other hand, stakeholders need time to adjust. China also recommended that the EU consider the feasibility of classifying the products of different risks, to which the EU provided that the measure renders applicable some of the essential requirements established in Article 3(3) of Directive 2014/53/EU to certain categories or classes of radio equipment. The choice of the specific categories or classes of radio equipment to be covered has been guided by the existence of particular risks associated with these types of radio equipment. A risk analysis would also have to be performed by the European Standardisation Organisations in the process of elaborating the relevant standards. The Commission Delegated Regulation 2022/30 was adopted on 29 October 2021.

2.1.2.16 Republic of Korea - Regulation for supporting low carbon solar module product (ID 744³³)

2.65. The representative of <u>China</u> provided the following statement. 1. The life cycle assessment (LCA) report submitted by Chinese Company in accordance with ISO14040 has not been recognized by the ROK, while the report based on the same calculation method has been recognized by EU

 $^{^{32}}$ For previous statements follow the thread under $\underline{\text{ID 743}}$.

³³ For previous statements follow the thread under <u>ID 744</u>.

member States. China hopes that Korea side could clearly explain its implementation criteria for the review of the LCA report. Before formulating/issuing the implementation criteria for LCA report review, the submitted reports should be reviewed in accordance with ISO and other international standards, and the report review process and requirements should be made public. 2. The Korea side should publish the list of qualified third-party certification institutions for companies' choices. 3. The reviewing time of the report should consider other Members' practices, that is, approval shall be completed within 30 days after acceptance, so as to improve the efficiency. 4. As too much trade secret data and industry sensitive information are submitted which is unnecessary and unreasonable, the Korean side should reasonably set the scope of data submission in accordance with international practice.

2.66. In response, the representative of the <u>Republic of Korea</u> provided the following statement. We have not received any information regarding your Specific Concerns prior to your comments. So we are not prepared with replies specifically today. Nevertheless, we will convey your comments faithfully to our competent regulatory authority for internal discussion and provision of an appropriate response. And in this regard, if China submit us your comments in writing, the responsible authority could reply in writing also.

2.1.2.17 European Union - Regulation (EU) 2019/320 on caller location in emergency communications from mobile devices, <u>G/TBT/N/EU/589</u> (ID 745³⁴)

2.67. The representative of <u>China</u> provided the following statement. 1. China recommends that the EU fully considers whether the industry has prepared or not when formulating regulations and conformity assessment procedures in the future and before the regulations are implemented, to conduct research on the readiness of test environment and testing resources meeting the requirements of the regulations in the industry, and the products can be fully evaluated to ensure that the regulations can be implemented more effectively; 2. China recommends that the EU should consider the enforceability of the regulation and postpone the mandatory implementation date by more than six months (i.e. after 17 September 2022); or introduce a relevant exemption clause, that manufacturers are allowed to prove their product meeting the requirements by self-declaration before 17 September 2022.

2.68. In response, the representative of the <u>European Union</u> provided the following statement. Commission Delegated Regulation 2019/320 was notified on 24 July 2018 with a 60-day commenting period under reference number <u>G/TBT/N/EU/589</u>. No comments were received during the commenting period. The Delegated Regulation aims to ensure that hand-held mobile telephones with advanced computing capabilities (commonly known as "smartphones") ensure access to emergency services. This will be done by requiring mobile device producers to support technical solutions for the reception and processing of location data derived from Wi-Fi signals, and data from Global Navigation Satellite Systems (GNSS) compatible and interoperable with at least the Galileo system (Galileo is the European global navigation satellite system established under Regulation (EU) No 1285/2013) for the purpose of making emergency communications more effective. In the description of the objective, the EU has previously provided that the impact on mobile device manufacturers were expected to be minimal as they are targeted towards those mobile phones that are already GNSS-enabled. Nearly all new smartphones currently on the market have GNSS capability. The Delegated Regulation would simply reinforce current market trends by adding legal certainty. The Commission Delegated Regulation 2019/320 was adopted on 12 December 2018.

2.1.2.18 Indonesia - Remote factory audit for air conditioners (ID 746³⁵)

2.69. The representative of <u>Thailand</u> provided the following statement. Thailand appreciates Indonesia's clarifications on factory audits for issuing or renewing SNI certificate for air conditioners through our TBT enquiry points and bilateral meeting in November 2021. However, we still have concerns regarding the onsite factory audits. Due to COVID-19 international travel restrictions, companies have difficulties to obtain or renew SNI certification since Indonesia does not allow remote factory audits. Therefore, Thailand encourages Indonesia to consider allowing remote factory audits for air conditioners to facilitate trade and minimize technical barrier to trade in the future. As Thailand and Indonesia are members of the Association of Southeast Asian Nations (ASEAN), we would like Indonesia to consider the possibilities of utilizing ASEAN Harmonised Regulatory Regime

 $^{^{34}}$ For previous statements follow the thread under <u>ID 745</u>.

 $^{^{35}}$ For previous statements follow the thread under <u>ID 746</u>.

for Electrical and Electronic Equipment (AHEEER) to improve the trade flows between Thailand and Indonesia. Thailand would appreciate Indonesia's consideration of our concerns and look forward to the successful collaboration with Indonesia.

2.70. In response, the representative of Indonesia provided the following statement. Indonesia would like to reiterate its response through the enquiry point that based on the Circular Letter of the Head of BPPI No 202/BPPI/IND/VIII/2020 dated 10 August 2020, certification process for mandatory SNI in the industrial sector is carried out in accordance with the provisions stated on the Minister Regulation. It includes requirement for on-site factory visit both for domestic and foreign manufactures. As such, all domestic and foreign manufacturers are also required to undergo onsite factory visits/ inspection as part of the conformity assessment procedures. Conformity assessment procedure is conducted based on conformity assessment scheme stated in the related regulation. For foreign manufactures, onsite inspection and/or factory visits can still be conducted as long as the destination countries open their border for representative from Indonesia conformity assessment body to perform the onsite inspection. Ministry of Industry has no authority to prevent conformity assessment body to perform onsite inspection to a particular country due to COVID-19 circumstances. Indonesia would also like to inform Thailand that according to the report of SNI Certification, several products in Thailand have been successfully inspected on-site by Indonesian certification body. Related to the acceptance of conformity assessment through AHEEERR mechanisms, will be discussed in ASEAN fora.

2.1.2.19 Japan - Inspection system for sports goods and toys and non-acceptance of test reports from Indian test houses (ID 747³⁶)

2.71. The representative of India provided the following statement. The Republic of India is concerned about the trade barriers faced by the Indian sports goods and toys exporters to Japan. There are two issues: the lab testing and certification of toys exported from India to Japan and the 100% inspection of consignments that arrive in Japan instead of a test check of samples. Under Japan Food Sanitation Law (JFSL) (Act Number 233, 1947), Lab-verified compliance with Sections IV and V of the JFSL is mandatory for applicable children's products before they can enter the Japanese market. Further, ST Standards and ST Mark programmes are established by the JTA (Japan Toy Association) to cover the legal aspect of the JFSL. To distribute and sell toys in Japan, manufacturers must demonstrate that they are compliant with the Japan Food Sanitation Act (JFSL) and/or with the Japan Toy Safety Standard (ST Standard). In addition, all toys compliant with the ST standard must display the Safety Toy Mark (ST Mark). Japan Toys Association, a government recognized organisation, has nominated agencies to test and certify toys meant for the Japanese market. Unfortunately, no agencies/ labs in India are assigned or accredited to carry out such tests. In previous interactions between the agencies of both countries, Japan has promised to share a list of such agencies outside Japan, including those labs in India, that are nominated by JTA to carry out tests and certify the toys. But so far, this information is not available.

2.72. Further, despite India's testing labs being ILAC accredited, their certificates are not accepted by the Japanese authorities. Presently the toys manufacturers are sending samples to Japan for certification. These barriers imposed compel Indian manufacturers to send the products to testing labs in Japan, resulting in avoidable high costs. However, we understand that Japan accepts the certification provided by several other countries but not India. Finally, no sample inspections of consignments are done for the consignments that arrive in Japan. Instead, the entire consignment of sports goods and toys is inspected, which causes delays and additional costs to exporters. The insistence of certificates from Japanese labs and the insistence of 100% inspection of sports goods and toys imports from India are inconsistent with Article 5.1.2 of the TBT Agreement. Hence India requests Japan to: a. Share the list of labs outside Japan accredited by ILAC to test and certify sports goods and toys. b. Expand the coverage of accredited labs in India. c. Accept the certificates issued by the Indian Test houses accredited by ILAC and expand the coverage of labs in India for accreditation. d. India also requests Japan to stop 100% testing of sporting goods and toys imported into Japan form India.

2.73. In response, the representative of <u>Japan</u> provided the following statement. I would like to express my appreciation for India's continuous bilateral trade interest with Japan. However, it is regretful that India had no communication with us as we have contacted with your side through Enquiry Point and Permanent Mission in Geneva last month in order to understand India's concern.

 $^{^{36}}$ For previous statements follow the thread under <u>ID 747</u>.

In fact, Japan even requested information on this matter in June of last year but India had no response and withdrew the issue at that time of the TBT meeting. However just today India provided relevant information in the form of the STC statement here that Japanese government will of course consider and get back to you accordingly.

2.1.2.20 India - Import Policy of Air Conditioners with Refrigerants (ID 748³⁷)

2.74. The representative of Thailand provided the following statement. Thailand would like to thank India for providing an opportunity to Thailand to express our concerns on the import policy of air conditioners with refrigerants through a bilateral meeting in November 2021. However, Thai companies still meet difficulties in exporting air conditioners with refrigerants to India and we would like to raise our concerns as follows: Thailand notes that the Notification No. 41/2015 dated 15 October 2020 issued by the Ministry of Commerce and Industry of India, prohibiting the import of air conditioners with refrigerants to India has not been notified to WTO. This measure lacks scientific evidence to identify whether there is any advantage, disadvantage, or difference in importing air conditioners with refrigerants or without refrigerants. Thailand would like to point out that, compared to domestic companies, Thai companies have to undergo more processes which affect opportunities for placing air conditioners in the markets. Thus, this measure does not provide the same treatment for domestic and imported air conditioners but creates unnecessary obstacles to international trade. Moreover, filling in refrigerants after importing could affect the quality of the products. Thailand would like to reiterate that this measure is against non-discriminatory principles in the TBT Agreement. According to Article 2.1 of the Agreement, "products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country". Hence, Thailand strongly requests India to review this measure by taking into account the non-discriminatory principles, and consider allowing the import of air conditioners with refrigerants in order to avoid creating unnecessary obstacles to international trade.

2.75. In response, the representative of <u>India</u> provided the following statement. India would like to thank Thailand for their statement and interest in the issue and for the bilateral engagement earlier on. The measure in question was necessary to apply standards in reducing risks to human, animal and plant life and health. Besides, it is consistent with India's commitment to the Montreal Protocol. Further, as per the Ozone-Depleting Substances (Regulation and Control) Amendment Rules 2014, the import of air conditioners containing Group VI substances (HCFCs) has been prohibited since 1 July 2015.

2.1.3 Previously raised concerns

2.1.3.1 China - Requirements for information security products, including, inter alia, the Office of State Commercial Cryptography Administration (OSCCA) 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS) (ID 294³⁸)

2.76. The representative of the <u>European Union</u> provided the following statement. Regarding the Multi-Level Protection Scheme (MLPS), 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 are prescribed by the "Guidelines for grading of classified cybersecurity protection", (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.

2.77. The representative of <u>Japan</u> provided the following statement. Japan continues to have concerns regarding China's "Regulation on the Administration of Commercial Cipher Codes" and "Cyber Security Multi-Level Protection Scheme." Japan would like to refer to the previous statement we made at the last TBT Committee in November 2021. Japan requests that China provide relevant information regarding the current revision process for the "Regulation on the Administration of Commercial Cipher Codes" for which the public consultation was scheduled to be finished by 19 September 2020, and for the current drafting process of Cyber Security Multi-Level Protection

 $^{^{\}rm 37}$ For previous statements follow the thread under $\underline{\rm ID~748}.$

 $^{^{38}}$ For previous statements follow the thread under <u>ID 294</u>.

Scheme that China explained at the last TBT Committee, and that those regulations be implemented in a transparent manner.

2.78. 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 and companies equally. China implements mandatory testing and certification on commercial encryption products that involve national security, national economy, people's livelihood, and public interest, and implements voluntary testing and certification on other commercial encryption products. Regarding the MLPS concerned by the two Members, with technology development, in response to more complicated cyber security circumstances, the information security multi-level protection scheme needs to be improved. Based on experience in past years and responding to new development, Cyber-security Law stipulates that China will carry out the cyber-security MLPS, which is based on information security MLPS. To fulfill the requirements in Cyber-security Law, regulation on cyber-security MLPS is under drafting, which was published for comments and will replace the former administrative measures on information security MLPS.

2.1.3.2 China - Cyberspace Administration of China – Draft implementing measures for the Cybersecurity Review of Network Products and Services (ID 533³⁹)

2.79. The representative of the <u>European Union</u> 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 and were subsequently amended in January 2022, and entered into force on 15 February 2022. 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 Amended Measures contain few explanations of the issues we raised before and new issues have arisen since. The EU regrets that the Measures were adopted without a longer grace period, of at least 12-months, so that companies would have sufficient time to prepare for compliance with the Amended Measures. The Amended Measures have significantly increased the scope of application and many processors need time to understand and cope with their compliance obligations and the related business impact.

2.80. The Measures expand the scope of the application from Critical Information Infrastructure Operator's (CIIO) purchase of network products and services, to all data processors carrying out data processing activities. The expanded scope is very broad. For all the other data processors, which are not Critical Information Infrastructure Operators nor IPO need, it has left huge uncertainty as to whether or not the review is required and whether or not the data processors shall submit a review to the regulator. It is unclear who would be a "data processor" or when they would be engaged in "data processing activities". Understanding the scope of a data processor engaged in such activities would be necessary to the extent that it determines if and when an application would have to be filed. The EU urges China to clarify if "a data processor carrying out data processing activities" applies only to a data process data outside of China.

2.81. The EU seeks clarification on the following points. 1. The continued use of "listing in a foreign country". Does this indicate the regulatory intention to exclude operators listed in Hong Kong from the obligation of applying for a mandatory Cybersecurity review? 2. Based on the previous draft, entities subject to Cybersecurity reviews have changed from "data processors" to "online platform operators". The final Measures do not define "online platform operators", but the Draft Regulations define it as "data processors who provide Internet platform services such as information publishing, social networking, transaction, payment or audio-visual services". The EU urges China to clarify if the scope of "online platform operators" is narrower than "data processors", which was used previously and excludes self-operated e-commerce services of fast-moving consumer goods companies that do not provide online platform services. The vagueness of "online platform operators" leaves room for interpretation by regulators. 3. Neither "core data" nor "important data" are clearly defined. The Measures include important telecommunication products as one kind of

 $^{^{39}}$ For previous statements follow the thread under $\underline{\text{ID 533}}$.

"network products and services". However, the Measures still do not provide a specific scope of "network products and services". This leads to the definition of "important communication product" to be even more unclear. Therefore the EU urges China to clarify these terms as soon as possible. The EU urges China to ensure clarity, transparency and objectiveness in the security review so that the Measure does not become a market access barrier.

2.82. The representative of Japan provided the following statement. Japan has its interest in and concerns with regard to the Cyber Security Review and would like to refer to the previous statement we made at the last TBT Committee in November 2021. The amendment of Cybersecurity Review Measures entered into force in China in February 2022. It is unclear whether the definition and scope of "Critical Information Infrastructure Operator" refers to the definition of "Critical Information Infrastructure" provided under the "Regulations on the Security Protection of Critical Information Infrastructure", and there is no definition for "Network Platform Operator". Therefore, it is uncertain what kind of businesses could be subject to the cybersecurity review under the Measures. Predictability is important for conducting sound business and Japan requests that China operate the regulations in a transparent manner to ensure appropriate predictability so that the regulation does not become an impediment to business.

2.83. In response, the representative of <u>China</u> provided the following statement. In recent years, with the development of network information technology and further opening-up of cyberspace in China, more and more network products and services have entered into the key information infrastructure sectors. While taking advantage of the convenient conditions for providing products and services, some network products and services providers illegally access users' important data, control and interfere with critical information infrastructure operation, stop the supplies of its technologies, products, and services for non-technical or commercial reasons, which poses serious risks and challenges to the national cyber security of China, especially the supply chain security of critical information infrastructure. Drawing on common international practices, China formulated the Draft implementing measures for Cybersecurity Review of Network Products and Services in 2017. In June 2020, the Measures for Cybersecurity Review came into effect, while the Draft implementing measures for Cybersecurity Review of Network Products and Services (Trial) was abolished at the same time. From 15 February 2022, the revised Cyber Security Review Measures came into force.

2.84. The establishment of a cyber security review system aims to detect and avoid risks and hazards brought to critical information infrastructure by purchasing products and services as early as possible, ensuring the supply chain security of critical information infrastructure, and safeguarding national security through cyber security review. In accordance with laws and regulations, the Chinese authority administers the Internet and strengthens cybersecurity and data security management. This is not only necessary to safeguard personal information security and national security, but also the common practices of other Members. The security review does not discriminate against foreign technologies and products or restrict the entry of foreign products into the Chinese market. China will, as always, welcome foreign products and services to enter the Chinese market as long as they comply with the laws and regulations.

2.1.3.3 India - Quality Control Orders for Chemical and Petrochemical Substances,						
<u>G/TBT/N/IND/116</u> ,	<u>G/TBT/N/IND/121</u> ,	<u>G/TBT/N/IND/122</u> ,	<u>G/TBT/N/IND/123</u> ,			
<u>G/TBT/N/IND/124</u> ,	<u>G/TBT/N/IND/125</u> ,	<u>G/TBT/N/IND/126</u> ,	<u>G/TBT/N/IND/127</u> ,			
<u>G/TBT/N/IND/128</u> ,	<u>G/TBT/N/IND/129</u> ,	<u>G/TBT/N/IND/130</u> ,	<u>G/TBT/N/IND/132</u> ,			
<u>G/TBT/N/IND/133</u> ,	<u>G/TBT/N/IND/134</u> ,	<u>G/TBT/N/IND/135</u> ,	<u>G/TBT/N/IND/136</u> ,			
<u>G/TBT/N/IND/137</u> ,	<u>G/TBT/N/IND/138</u> ,	<u>G/TBT/N/IND/139</u> ,	<u>G/TBT/N/IND/140</u> ,			
<u>G/TBT/N/IND/141</u> ,	<u>G/TBT/N/IND/142,</u>	<u>G/TBT/N/IND/144,</u>	<u>G/TBT/N/IND/150</u> ,			
<u>G/TBT/N/IND/151</u> ,	<u>G/TBT/N/IND/152,</u>	<u>G/TBT/N/IND/153</u> ,	<u>G/TBT/N/IND/154,</u>			
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,			
G/TBT/N/IND/201,	G/TBT/N/IND/202,	G/TBT/N/IND/203,	G/TBT/N/IND/204,			
<u>G/TBT/N/IND/205</u> , <u>G/TBT/N/IND/206</u> , <u>G/TBT/N/IND/208</u> (ID 630 ⁴⁰)						

2.85. The representative of <u>Thailand</u> provided the following statement. Thailand once again would like to thank India for the opportunity to discuss the impacts of the Quality Control Orders for Chemical and Petrochemical Substances to Thai exporters in the bilateral meeting in November last year, where India has clarified the licensing process for imported products, which usually takes 3-5

 $^{^{\}rm 40}$ For previous statements follow the thread under $\underline{\rm ID~630}.$

months with onsite factory audits. However, in the light of the COVID-19 pandemic and international travel restrictions, India suspends onsite factory audits and provides no alternatives for the factory audits to facilitate the licensing application. This situation delays the granting of the licence and directly affects foreign manufacturers who cannot export their products to India. To reduce the impacts of the measures while the pandemic is still ongoing, Thailand would like to reiterate our request for India to consider implementing alternative measures. Thailand understands the difficulty in conducting regular onsite factory audits during the pandemic, therefore, Thailand suggests that India implement remote factory audits. In the case that remote factory audits cannot be conducted, Thailand requests India to extend the enforcement date of the measures for 360 days.

2.86. 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 chemicals and petrochemicals products under the HS chapters 28 and 29. The EU took note of all Indian TBT notifications pertaining to Quality Control Orders (QCOs) for chemical and petrochemical substances over the past two years. The EU would like to recall that some QCO notifications do not have a determined date of entry into force. In fact, the entry into force is dependent on the adoption date, which is not indicated in the notification. Could India provide structured information regarding the planned time for the adoption of these measures? Furthermore, the EU noticed that there is an increasing number of TBT-notified Indian QCOs on chemicals and petrochemicals that are not implemented. The European Union wishes to seek reasons for repeated postponement of implementation of notified measures in this sector. Given the confusion this situation creates, the EU would like to call, once more, on India to provide an updated list of chemicals and petrochemicals, which have already been implemented and of those that are yet to be implemented, together with copies of relevant Quality Control Orders.

2.87. The European Union would like to recall its request for clarifications explaining the reasons for establishing India-specific Quality Control Orders when these chemical and petrochemical products already comply with internationally recognized 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 barriers to international trade. The EU would also like to encourage India to align the BIS standards with well-established and recognized international approaches.

2.88. The representative of the United States provided the following statement. As of March 2022, India's Ministry of Chemicals and Fertilizers (MoCF) notified 44 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 continue to highlight US industry's concerns regarding the Polyethylene Material for Moulding and Extrusion (Ouality Control) Order, 2020 (Polyethylene QCO), notified as G/TBT/N/IND/191, which mandates the marking of the smallest unit-level package of polyethylene product delivered to the customer with "designation codes" identifying an array of technical information (e.g., a product's melting point, density, processing method, and application.) It would be helpful if India could explain the intended objective of the labelling and who the labelling is intended to inform. We reiterate US industry's comments that such requirements have not been applied to polyethylene products in other markets and there has been no perceived need for such information given the technical knowledge of the customers involved in the commercial transaction. We remain interested in hearing how India has taken stakeholder input into account as to how industry can best comply with the new designation code measures.

2.89. We have reported US industry's concern that, as proposed, requiring the labelling and affixation of information in print, with alphanumerical code unique to India, on either the polyethylene product's bag or its smallest unit-level packaging delivered to the customer will impose administrative burdens leading to inefficiencies, delays, and additional costs for exporters. We are concerned about possible confusion on the part of the Indian customer in deciphering the code as the product moves through the chain of custody, as well as confusion on the part of any third country customer to whom such labelled products might be exported to from India. Given Indian dependence on imports, particularly with regard to specialty grade resins, such labelling may disrupt Indian

imports of, and access to, essential materials used by Indian health care, pharmaceutical, and other high value Indian export-critical sectors. We recommend that India provide the website links to and/or complete copies of the BIS proposed standards as well as any referenced standards in the notified QCOs and any future QCO notifications. With respect to the previously notified QCOs, we recommend that such website links and/or copies be notified as addenda. Without access to the BIS standards, Members and industry may be unable to understand the QCOs or provide meaningful comments.

2.90. The representative of <u>The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu</u> provided the following statement. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu would like to reiterate its concerns about the Order issued by India's Ministry of Chemicals and Fertilizers on phthalic anhydride and n-butyl acrylate, and terephthalic acid, which were notified by <u>G/TBT/N/IND/116</u>, <u>G/TBT/N/IND/123</u> and <u>G/TBT/N/IND/124</u>. Firstly, we would like to thank India for postponing the enforcement date on the products concerned until 22 June 2022. Secondly, given that the pandemic will not likely end in the short term and it is still difficult to conduct on-site inspections under the current situation, we would like to urge India to postpone the implementation of the above mentioned products once again. In addition, we still suggest that India implement alternative measures during the pandemic regarding all products concerned, such as allowing testing laboratories and inspection bodies from other WTO Members to participate in the conformity assessment procedures and accepting their reports or remote factory inspection, to address the difficulties of physical inspection resulted from international travel restrictions.

2.91. The representative of Singapore provided the following statement. Singapore echoes the concerns raised by other Members, and we would like to reiterate our concerns expressed at the previous meetings of this Committee. We remain concerned about the operational challenges that we had outlined previously vis-à-vis the labelling requirements for polyethylene materials used for moulding and extrusion. We respectfully request for India to positively consider alternatives that have been proposed by the industry to meet the information requirements of the Quality Control Orders on polyethylene products, to ensure that the mandatory labelling requirements are not too onerous and challenging for the industry to comply with. We also understand that India is looking to allow virtual inspections as part of the certification process. We remain interested in, and look forward to working with India to initiate these inspections, whether virtual or in-person, as soon as possible, to facilitate progress in the certification process for the industry. For any new additional Quality Control Orders, Singapore would like to reiterate our 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, to enable interested parties to acquaint themselves with the new requirements, and provide meaningful comments to India. Finally, we respectfully urge India, as per its obligations under the TBT Agreement, to align the standards within the Quality Control Orders with international standards which already exist, to reduce industry's compliance costs, and to ensure that measures imposed are not more trade-restrictive than necessary.

2.92. In response, the representative of <u>India</u> provided the following statement. As per the provisions of the QCO, the products specified therein shall bear a Standard Mark under a valid licence from BIS as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. Under this Scheme, factory inspection is a mandatory requirement for the grant of licence. Licence to use the Standard Mark on a product is granted after assessing the manufacturing and testing capabilities through factory inspection of the manufacturing premises. During this visit, conformity of the product to the requirements of the relevant Indian Standard is also established through in-house factory testing or testing at a third-party testing laboratory or a combination of both. At present, there is no provision in BIS (Conformity Assessment) Regulations, 2018, to undertake virtual inspection for conformity assessment activities as an alternative. Factory inspections were on hold due to the restrictions on international travel because of the COVID-19 pandemic. However, the nomination of BIS officers is being considered for carrying out the factory inspection for applications received from foreign manufacturers. Mainly, where the country to be visited facilitates the visit of fully vaccinated BIS officers who carry negative RT-PCR test reports, without any restrictions like quarantine and RT-PCR test upon arrival.

2.93. In accordance with the Code of Good Practice of WTO-TBT Agreement and as a policy, BIS tries to align Indian Standards with International Standards of ISO and IEC, where available and to the extent possible, considering the specific climatic/environmental conditions and technological development in the country. Around 80% of Indian Standards, for which corresponding ISO & IEC standards are available, are harmonized with their ISO/IEC counterparts. In response to the

statement of the US and Singapore, the details of QCOs and the relevant standards are available on the BIS website.⁴¹ As regards the point made by the EU about standards being voluntary, whereas mandatory standards being technical regulations. India requests the EU to refer to India's reply in its previous statements of TBT meetings.

2.1.3.4 Bangladesh - Hazardous Waste (E-waste) Management Rules, 2019, <u>G/TBT/N/BGD/3</u>, <u>G/TBT/N/BGD/3/Add.1</u> (ID 620⁴²)

2.94. The representative of the <u>United States</u> provided the following statement. On 10 June 2021, Bangladesh published an updated draft of its Hazardous Waste (E-Waste) Management Regulation, 2021 (E-waste Rules). US industry shared its comments and concerns with the draft regulation with the Ministry of Environment, Forest and Climate Change in September 2021, and reiterated its remaining concerns in January 2022. Based on an unofficial translation of the regulation and industry reports , we understand that the updated draft E-waste Rules removed threshold limits for a number of substances, a request that both US industry and the US Government had made in response to the original notification, <u>G/TBT/N/BGD/3</u>. While we appreciate these changes, the June 2021 draft of the E-waste Rules lacks certain exemptions commonly granted by regulators in other countries with respect to the remaining substances. For instance, although lead is commonly categorized as hazardous, exemptions are usually provided for certain uses of lead, e.g., use in the solder of certain electronics exposed to high and low temperatures, use in shielding of X-ray and MRI machines. The absence of such exemptions can potentially disrupt the supply of important electrical and electronic goods in Bangladesh. Thus, we encourage Bangladesh to grant exemptions commonly granted by regulators in other markets, as highlighted in stakeholder comments.

2.95. Furthermore, we continue to lack clarity regarding how Bangladesh plans to implement the E-waste Rules. Specifically, the E-waste Rules appear to lack information on implementation timelines, product reporting (particularly if products fall under more than one category), registration deadlines, information that would inform the design of an effective e-waste management system, and points of contact within the Bangladeshi government to whom industry can direct clarifying questions. We urge Bangladesh to make this information available to the public, so that industry can engage regulators and comply with the E-waste Rules. The United States also asks that Bangladesh confirm whether it will release a more detailed explanatory guide to the E-waste Rules for industry. Given the broad scope of the E-waste rules, we encourage Bangladesh to provide a reasonable transition period, of at least one year, for industry to adapt its products or methods of production to the new requirements. Further, has Bangladesh considered how long it would take for the development, establishment, and certification of e-waste management systems, including benchmarks used by certified operators? Finally, we ask that Bangladesh notify the latest revised E-waste Rules to the WTO TBT Committee, provide a public comment period of at least 60 days, and take comments received into account before finalizing the regulation.

2.96. In response, the representative of <u>Bangladesh</u> provided the following statement. Bangladesh thanks the US for their continued interest and concern about the Bangladesh E-waste Management Rule, 2021 (initially it was 2019, it is revamped). In this regard Bangladesh likes to refer to its statement made in the last TBT Committee meeting and also the submission in <u>G/TBT/W/759</u> dated 22 June 2021. Bangladesh would also like to discuss bilaterally with the US regarding the concerns, and our submission and reply.

2.1.3.5 India - Indian standards and import restrictions in the automotive sector (Quality Control Orders): wheel rims, safety glass, helmets, <u>G/TBT/N/IND/118</u>, <u>G/TBT/N/IND/147</u>, <u>G/TBT/N/IND/167</u> (ID 649⁴³)

2.97. The representative of the <u>European Union</u> provided the following statement. India has defined and introduced specific standards and certification requirements for a number of products across sectors that require on-site, in person audits - the so-called Quality Control Orders (QCOs) which require physical audit at manufacturers premises by an auditor of the Bureau of Indian Standards (BIS) in order for products manufactured in third countries to receive the approval for exports to India. However, for almost two years Indian auditors are not in a position to conduct international

⁴¹ <u>https://standardsbis.bsbedge.com/</u> and <u>https://www.bis.gov.in/index.php/product-</u> certification/products-under-compulsory-certification/scheme-i-mark-scheme/.

⁴² For previous statements follow the thread under <u>ID 620</u>.

 $^{^{\}rm 43}$ For previous statements follow the thread under <u>ID 649</u>.

audits due to the COVID-19 pandemic. Unfortunately, India has refused to consider meaningful alternative options, such as virtual audits or audits conducted by internationally recognised third agencies/entities. Consequently, European Union companies, despite doing all that is necessary to meet the Indian requirements, are not able to obtain the required Indian certification or marking. Thus, while EU and other foreign companies are not able to access the Indian market due to the lack of alternatives to physical audits on India's side, Indian auditors are conducting domestic audits that allow domestic companies to receive certification/marking and place their products on the market.

2.98. This is a clear case of discrimination against EU and other foreign manufacturers. In this context, the EU welcomes the steps taken by the BIS to allow its auditors to audit foreign manufacturing plants. However, according to EU industry such audits have not yet been possible, despite the confirmation by a number of EU embassies that fully vaccinated BIS officials do not have to be quarantined at EU entry. In fact, some of the foreign manufacturers had even deposited licence fees. This delay of physical audits perpetuates the current difficult situation of EU importers, prolonging the discrimination between local and foreign companies. The EU would welcome any update by India on when foreign audits would resume. The EU would like to recall that the QCOs in question have a protectionist orientation and the ever-increasing number of QCOs is 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 for products already certified under established international standards. In this context, the QCOs would add little value for Indian consumers, making the reason of their introduction not evident.

2.99. Furthermore, the implementation of the QCOs for foreign companies with production facilities outside India is likely to continue to prove difficult due to the existing restrictions on international travel in view of the ongoing COVID-19 pandemic. In addition, when international travel recommences, the BIS will be faced with a large backlog of applications that the EU hopes would be cleared in a transparent and non-discriminatory manner. Furthermore, we would like to receive some clarity from India on the validity of these physical audits. We understand that they have limited validity of two years only, after which the procedure for renewal of authorization is not clear. The current procedure is already unduly cumbersome and costly requiring a renewal every two years will add the difficulty of doing business and ensure that the supply chain continues to operate in uncertainty. At a time when businesses across the world have been heavily impacted by the COVID-19 pandemic, it would be important to facilitate trade. That is why the EU would like to voice once again its concerns regarding the QCOs on automotive safety glass and wheel rims.

2.100. The EU appreciates further postponement of the QCO on safety glass until 1 April 2023. The planned entry into force of the QCO on wheel rims, set for 21 September 2022, is of concern, given that continued COVID-19 pandemic and restrictions on international travel may not allow for its actual implementation. It is worth noting that the supply chain cycle from physical audit to import of wheel rims in India is between four to six months long, taking into account the production, and travel time. An implementation date of 21 September 2022 implies that audits have to be conducted immediately, without any further delay, otherwise, the risk is that on 21 September 2022, when the QCO for wheel rims is due to enter into force, production lines may come to a standstill due to the lack of supply of BIS-compliant wheel rims. Such a situation would negatively affect carmanufacturing operations of EU companies in India, which would undoubtedly have a negative impact on the Indian economy and Indian consumers. Therefore, the EU would like to suggest that India considers further postponement, of at least six months, of the entry into force of the QCO for wheel rims, with a view to ensuring the continuity of imports of this product into India.

2.101. The EU would also like to urge India to consider virtual audits or audits performed by BIS recognized third-party certification experts in the location of the manufacturing plants. Without such flexible options, and taking into account the persisting COVID-19 restrictions, India should consider longer lead-times for the implementation of BIS requirements (e.g. 12 months). The EU would also like to reiterate that safety glass and wheel rims manufactured in the EU are subject to a rigorous certification process, in line with established international standards, which are not much different from the Indian ones, introduced by the QCOs in question. The EU would therefore like to repeat its suggestion to keep the BIS marking as optional for components, which are already in compliance with the UN marking requirements. The EU would like to ask India if it would be ready to accept provisionally UN certificates and markings. The EU, therefore, requests India to reconsider the introduction of the QCOs on automotive safety glass and wheel rims. 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.

2.102. In response, the representative of India provided the following statement. As acknowledged by the EU, India has already postponed entry into force of subjected QCOs. The products under mandatory certification are notified by the concerned Line Ministries (Regulator) of the Government of India through the issuance of Quality Control Orders (QCOs). As per the provisions of the QCO, the products specified therein shall bear a Standard Mark under a valid licence from BIS as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. Under this Scheme, factory inspection is a mandatory requirement for the grant of licence. Licence to use the Standard Mark on a product is granted after assessing the manufacturing and testing capabilities through factory inspection of the manufacturing premises. During this visit, conformity of the product to the requirements of the relevant Indian Standard is also established through in-house factory testing or testing at a third-party testing laboratory or a combination of both. At present, there is no provision in BIS (Conformity Assessment) Regulations, 2018, to undertake virtual audits for conformity assessment activities as an alternative. Factory inspections were on hold due to the restrictions on international travel because of the COVID-19 pandemic, this is no discrimination against the EU or any other country. However, the nomination of BIS officers is being considered for carrying out the factory inspection for applications received from foreign manufacturers. Mainly, where the country to be visited facilitates the visit of fully vaccinated BIS officers who carry negative RT-PCR test reports, without any restrictions like quarantine and RT-PCR test upon arrival.

2.1.3.6 China - Commercial Cryptography Administrative Regulations (ID 644⁴⁴)

2.103. The representative of the <u>European Union</u> provided the following statement. The EU is concerned about this implementation measure of the Cryptography Law, and sent comments to the State Cryptography Administration of the People's Republic of China (SCA) in September 2020. 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 and 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.

2.104. In response, the representative of <u>China</u> provided the following statement. The Revised Regulations on the Administration of Commercial Cryptography are listed in Legislation Plan. The revision of the Regulations will follow the law-based, democratic, and scientific principles. And it will be open, transparent, and on a scientific basis.

2.1.3.7 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, <u>G/TBT/N/MEX/465</u>, <u>G/TBT/N/MEX/465/Rev.1</u> (ID 678⁴⁵)

2.105. The representative of the <u>United States</u> provided the following statement. The United States would like to refer back to its statement from the November 2021 TBT Committee on this STC. Could Mexico please provide an update on the status of this measure now that it has notified a revision to the TBT Committee? How will Mexico harmonize the 2019 update to the NOM-223 cheese standard, with the NOM-223 cheese CAP versions developed through 2020–2021, and an expected 2022 update to the NOM-223 cheese standard? Once finalized, will implementation of the cheese CAP measure move forward based on Mexico's Quality Infrastructure Law or the law it replaced, the Federal Law on Metrology and Standardization? The United States urges Mexico to halt the

⁴⁴ For previous statements follow the thread under <u>ID 644</u>.

⁴⁵ For previous statements follow the thread under <u>ID 678</u>.

finalization of the measure and consider less trade-restrictive alternatives as previously proposed by the US Government, other WTO Members, and industry stakeholders.

2.106. The representative of <u>Australia</u> provided the following statement. Australia would like to reiterate its concerns that Mexico's measure notified as <u>G/TBT/N/MEX/465</u> appears discriminatory and more trade restrictive than necessary. Australia recognizes the original objectives of the proposed measures and welcomes the review of the procedure in light of Mexico's international commitments. We look forward to receiving Mexico's reply to our comments on its notification. We kindly request an update for the release date of the new version of the procedure for public consultation.

2.107. The representative of the <u>European Union</u> provided the following statement. The European Union would like to join this trade concern and to Mexico for the revised text notified on 8 February, which is currently under analysis. According to information from EU industry, some aspects of the conformity assessment procedure (CAP) for the Mexican Official Standard NOM-223-SCFI/SAGARPA-2018 on cheese would cause difficulties for EU exporters. The EU would like to ask about the state of play of the ongoing revision of the measure.

2.108. In response, the representative of <u>Mexico</u> provided the following statement. On 8 February, Mexico notified a new version of the Conformity Assessment Procedure in document <u>G/TBT/N/MEX/465/Rev.1</u>, with a deadline for submitting comments of 9 April. We therefore invite Members to participate in this new public consultation process.

2.1.3.8 European Union - Draft EU Batteries Regulation (implementation of the European Green Deal), <u>G/TBT/N/EU/775</u> (ID 685⁴⁶)

2.109. The representative of China provided the following statement. 1. Regarding Article 7 and Annex 2, the EU should regulate the carbon footprint after the battery product carbon footprint calculation method is unified and should set a scientific and reasonable carbon footprint threshold according to the carbon peak and carbon neutral targets of different Members. It is suggested that the EU could make public the progress of carbon footprint calculation methodology so that other Members could join in the discussion on carbon footprint. Given that China has comprehensive data and supply chain on battery sector, China is willing to participate in the development of carbon footprint methodology. 2. Regarding Article 8, it is suggested to cancel the "Minimum share of recycled content" in the current stage and give it consideration after setting up the methodology of the calculation and verification for the amount of recycled content. 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. China considers that it is unreasonable to require the minimum share of recycled materials before clarifying the scientific methodology. In addition, the industry also considers that the recycled proportion of cobalt is relatively high. It is suggested to delete the requirement for "each batch per manufacturing plant" and modify the requirement to "each battery model", so as to simplify the process. 3. EU should reassess the performance indicators of batteries in terms of electro-chemical performance and durability, minimum average duration, health status and life expectancy, and set scientifically reasonable performance indicator requirements according to different service conditions of the products.

2.110. 4. It is suggested that the EU could cancel the disclosure of the technical documents containing commercial secrets of enterprises on the premise of meeting the regulatory purpose. Some items in article 7, article 8, and appendix 2 are required to provide the technical information, but the technical information about the battery content, the material and processing involve some core secrets, such as the content of cobalt, nickel, lithium contained in batteries, and data about carbon emissions of materials like electrolyte, and isolation membrane in the process of production, which increases the risk of leakage of business secrets of the enterprise. 5. Regarding Article 13 and Annex, it is suggested to clarify the format and position of labels and QR codes. The position of labels and QR codes referred in the regulation is not clear as affixing labels and QR codes to cells, modules or battery packs. It is suggested to use e-labelling (QR code) to cover all of the labelling in Article 13, instead of requiring physical labelling and QR code at the same time. E-labelling has become mainstream in the world, such as the United States, Canada, China, Singapore and many

⁴⁶ For previous statements follow the thread under <u>ID 685</u>.

other members, they all allow the use of E-labelling. It is suggested to delete the requirement in Part A of Annex VI that the label should reflect the information of "date of placing on the market". In fact, when the battery is manufactured, the manufacturers generally don't know the exact date for the batteries to be placed on the market. It is very difficult for manufacturers to provide this information.

2.111. 6. Regarding Article 39, it is suggested to extend the transitional period from 12 months to 24 months. The content of regulation is comprehensive, and the management system would take quite a long time, so due diligence needs a long transitional period. 7. The regulation stipulates the due diligence scheme of the supply chain in section 72 of Chapter 10. This investigation can be officially authorized by EU to conduct supply chain due diligence in other markets, it is recommended that EU should consult with relevant market regulatory authorities of other parties before authorizing the supply chain due diligence investigation, and the investigation can only be carried out if both parties agreed. 8. The proposed regulation requires all product batteries can be disassembled and replaced by end-users or independent operators, which may greatly influence the design of portable electronic products (such as mobile phones, tablets, etc.), and bring new risks to battery installation. Based on the current market situation, EU should add the following contents into the regulatory compliance: if portable electronic products batteries are designed to be disassembled and replaced by a manufacturer-trained or authorized professional service provider, it shall be deemed to meet regulatory requirements. 9. Provided that the formal date of entry into force is uncertain and it also needs a long time to complete the general legislative process in the EU. In view of the labelling requirements specified in the regulations involve changes in hardware equipment, and the related technical documentation also needs time to be prepared, which imposes a great burden on manufacturers, it is recommended that the EU provides at least 12 months for the transition period to the manufacturers.

2.112. The representative of the <u>Russian Federation</u> provided the following statement. The Russian Federation reiterates its statements made during the previous meetings of the Committee on TBT with regard to the proposed measure. We appreciate efforts of the EU in the fields of fighting climate change and protection of environment. However, we are still concerned with the lack of scientific data and international standards as a basis for proposed conditions for access to the EU market as well as material recovery targets for waste batteries. We urge the EU to conduct its trade-related climate policy in compliance with the WTO rules and relevant climate agreements without creating obstacles to trade and preserving sufficient level of competition between imports and domestic manufacturing.

2.113. In response, the representative of the European Union provided the following statement. The EU would like to recall that the Batteries Regulation proposal was presented on 10 December 2020 and notified to the WTO on 26 January 2021 with a commenting period of 90 days. During the commenting period, the EU received written comments from China, Japan and Canada to which the EU replied on 18 October 2021. Regarding some of the general issues raised by the Delegation of China, the EU would like to remind that 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. The introduction of minimum levels of recycled content of cobalt, lead, lithium and nickel in batteries is part of the EU's effort to foster the circular economy and have markets for secondary raw materials work efficiently. The EU has estimated the availability of such materials recovered from waste by 2030 and 2035 on the basis of the best available evidence and information. The EU has included the possibility to adjust the targets in 2027 should trends in availability differ significantly from those estimates. The EU has taken good note of the point raised by China concerning the disclosure of the technical documents with commercially sensitive information and will assess this case by case for the different provisions of the proposed Regulation. Moreover, the EU would like to reassure that there will be sufficient time to consider the feedback received on the notified draft prior to adoption. Implementing and delegated acts that will be developed under the notified draft will involve consultation of stakeholders, though the exact way in which this will be done is to be determined in each case. Drafts of those implementing measures and delegated acts will be notified to the WTO in accordance with the TBT Agreement.

2.114. The application dates for some of the provisions in the notified draft are indeed 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 the notified draft. In fact, it is clear that at least some of the application dates need to be reassessed, because the regulatory process is still ongoing. The European Parliament will vote this week (week 10), and the Council is expected to conclude their position next week (week 11). The two will then come together to decide on the final Regulation. This process is likely to conclude in the second half of this year. In conclusion, the EU stresses that the notified draft seeks to fulfil multiple, interlinked objectives including the protection of the environment and human health and safety, all of which are legitimate policy objectives under Article 2.2 of the TBT Agreement. For the reasons specified above, the EU considers that the notified draft is not more trade restrictive than necessary to fulfil these legitimate policy objectives, taking into account the risks that non-fulfilment would create. Regarding Article 2.1 of TBT Agreement, the EU does not consider that the notified measure gives rise to a risk of discrimination within the meaning of that provision. The notified draft therefore fully complies with the provisions of the TBT Agreement.

2.1.3.9 European Union - Withdrawal of the approval of the active substance alphacypermethrin, <u>G/TBT/N/EU/770</u> (ID 694⁴⁷)

2.115. The representative of Brazil provided the following statement. Brazil would like to express its concerns related to European notification 770 regarding the Commission Implementing Regulation proposal to withdraw the approval of the active substance alpha-cypermethrin. Alphacypermethrin is registered in Brazil as an insecticide used against harmful pests that damage a variety of crops, including soy, cotton, corn, citrus, watermelon, peanut, coffee, among other products exported to the European Union. 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. 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, Brazil would like to kindly encourage the EU to adopt MRLs for imported products in accordance with the limits set under the Codex Alimentarius.

2.116. The representative of <u>Paraguay</u> expressed support for and solidarity with the people of Ukraine, especially colleagues and friends from the country's representation to the WTO and their families, as they go through this difficult time. The WTO was an organization founded on respect for international law and, as such, could not fail to defend the strict observance thereof. The multilateral trading system was, and must continue to be, a tool that contributes to peace and stability. In this regard, the representative reiterated that the Republic of Paraguay condemned the attacks on the Ukrainian people, which were in violation of the principles of sovereignty and international law, and reiterated the need to find a mutually acceptable and long-lasting peaceful solution.

2.117. Paraguay provided the following statement. We thank Brazil for raising its concern in relation to the withdrawal of the approval of the active substance alpha-cypermethin by the European Union prior to the potential reduction of its MRLs. Paraguay wishes to reiterate the importance of this substance in controlling pests that attack crops of great economic importance to the country, such as maize, soybean, sunflower and cotton. In this regard, Paraguay once again requests that, during the review of the MRLs on this substance, the European Union take into consideration information on pesticides provided by the specialized agencies recognized by the WTO, such as the Codex Alimentarius, and reconsider its approach and base its decisions on conclusive scientific evidence and real risk weightings, in accordance with international standards and principles.

2.118. In response, the representative of the <u>European Union</u> provided the following statement. As explained in the TBT Committee last November, 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

⁴⁷ For previous statements follow the thread under <u>ID 694</u>.

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 fulfil his regulatory obligations, the approval for Alpha-cypermethrin had to be withdrawn according to Article 21(3) of Regulation (EC) No 1107/2009. As regards Maximum Residue Levels (MRLs), a review of the whole group of cypermethrins is currently ongoing by the European Food Safety Authority (EFSA). Existing Codex maximum residue limits and import tolerances will be considered in this review. EFSA intends to finalise the review in the second half of 2022. After that, the EU will consider the outcome and follow up on it, if appropriate. If there was a need for a specific measure on MRLs, such a measure would be notified to the WTO/SPS Committee. If Brazil and other Members consider it necessary to ensure that MRLs for Alpha-cypermethrin on relevant crops that were based on previous and now obsolete EU uses 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. 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.

2.1.3.10 European Union - Chemical strategy for sustainability (implementation of the European Green Deal) (ID 690⁴⁸)

2.119. The representative of the <u>Russian Federation</u> provided the following statement. The Russian Federation is still concerned with the strategy developed by the EU, which implies potential restriction and even prohibition of materials that classified as hazardous ones regardless of whether the scientific basis for that has been provided or not. We note that the core legal act for classification of chemicals and substances of the EU is the CLP Regulation. Currently, this regulation allows to make strict classification decisions without sufficient scientific data in accordance with the precautionary principle. One recent example of this practice is cobalt classification under the 14th ATP to the EU CLP Regulation. Such an approach can lead to unjustifiable prohibition of materials. We urge the EU to implement the strategy in full compliance with the WTO rules and principles.

2.1.3.11 India - Chemical Fibers and Yarns: PSY, IDY, FDY, POY, PSF, and SMF for use in Cement-Based Matrix (Quality Control) Orders, 2020, <u>G/TBT/N/IND/188</u>, <u>G/TBT/N/IND/188</u>, <u>G/TBT/N/IND/190</u>, <u>G/TBT/N/IND/190</u>, <u>G/TBT/N/IND/192</u>, <u>G/TBT/N/IND/194</u> (ID 717⁴⁹)

2.120. The representative of the <u>Republic of Korea</u> provided the following statement. Regarding India's six Quality Control Orders (QCOs) for Chemical Fibers and Yarns (PSY, IDY, FDY, POY, PSF, and SMF⁵⁰) notified to the WTO on February 2021 as <u>G/TBT/N/IND/185</u>, <u>G/TBT/N/IND/188</u>, <u>G/TBT/N/IND/189</u>, <u>G/TBT/N/IND/190</u>, <u>G/TBT/N/IND/192</u> and <u>G/TBT/N/IND/194</u>, Korea submitted comments twice concerning the enforcement dates and improvement of the regulations in August 2021 and November 2021. Korea appreciates India for granting an additional grace period until April 2022 in response to our comments so that some of the difficulties of Korean companies were resolved. Korea would like to reiterate several concerns that remain unresolved for Korean companies in relation to India's six QCOs.

2.121. Firstly, despite the one-time suspension of enforcement by the Indian government, there are still some difficulties in appointing a local Indian agent and conducting on-site inspections due to the COVID-19 pandemic. Therefore, we request that India provide an additional grace period of six months at least. Secondly, there is currently no published information on detailed test procedures and where to affix the ISI mark, making compliance with the regulations difficult. Therefore, we request that India provide detailed information needed in implementing the regulations. Thirdly, the notified BIS regulations deviate from international practices. Countries such as the United States and Germany, operate a unified certification system of which a local laboratory issues the certificates after conducting testing. On the other hand, India's regulations require products to be tested twice, once in an on-site inspection and once at a designated testing laboratory, increasing the burden of

⁴⁸ For previous statements follow the thread under <u>ID 690</u>.

 $^{^{49}}$ For previous statements follow the thread under <u>ID 717</u>.

⁵⁰ PSY: 100 Percent Polyester Spun Grey and White Yarn; IDY: Polyester Industrial Yarn; FDY: Polyester Continuous Filament Fully Drawn Yarn; POY: Polyester Partially Oriented Yarn; PSF: Polyester Staple Fibres; SMF: Synthetic Micro-Fibres for use in Cement Based Matrix.

certification on the industry. Accordingly, we request that India integrate the product testing procedures to tests conducted by laboratories recognized by the BIS and exempt testing during the on-site inspection.

2.122. Fourthly, among the regulated items, PF POY, FDY and IDY share the same properties and raw material composition, only their respective manufacturing process are different. Nevertheless, they are classified as separately regulated items, increasing the burden of certification. We request that India reclassify these three types of items so they can be regulated as one polyester filament item. Lastly, after BIS certification, redundant administrative procedures are performed in the process of affixing the ISI mark, resulting in excessive certification costs⁵¹ for BIS certification compared to other certifications in general. Therefore, after issuing the BIS certificate, we request that India mitigate the relevant certification procedures, by such as recognizing the BIS certification number declared in shipping documents in substitute for ISI mark attachment.⁵² Your reply on this matter would be deeply appreciated.

2.123. The representative of the <u>European Union</u> provided the following statement. The European Union (EU) would like to express its support to this trade concern raised by the Republic of Korea. The proposed measures require products to be tested twice, including local audits and designated laboratory tests. This represents additional burden to the EU industry related to registration, bank-guarantee and certification. The control by the Bureau of Indian Standards (BIS) is seen as disproportionate as the products do not present risk to health and safety, as they are subject to a detailed testing for safety and quality control in the EU before being exported. Furthermore, the notified measures deviate from international standards. There is also a concern expressed by EU industry related to the requirement to submit confidential information such as machinery make and ID number, names of raw material suppliers, etc. It would be highly appreciated if the scope of the Quality Control Orders is restricted to information related to standards.

2.124. In response, the representative of <u>India</u> provided the following statement. As acknowledged in Korea's statement, the issue has mainly been addressed. As this issue is raised again, it has been relayed to the capital. Korea will be communicated on receipt of a response from the capital.

2.1.3.12 United States - Protecting Against National Security Threats to the Communications Supply Chain through the Equipment Authorization Program and the Competitive Bidding Program, <u>G/TBT/N/USA/1771</u> (ID 714⁵³)

2.125. The representative of <u>China</u> provided the following statement. China had to raise this concern again. The draft only targets five Chinese enterprises and identifies Chinese products as security threats without the basis of technical standards and measurement, which violates the WTO principles of non-discrimination and transparency. China would like to suggest that the United States could make public the progress of making these rules as soon as possible. In this regard, we raise our concerns as follows. 1. China suggests revoking the new provision 47 CFR 2.903. It prohibits the authorization of certain telecommunications equipment and services under provision 47 CFR 1.50002, but 47 CFR 1.50002 lists only five companies of China, which violates non-discriminatory principles in TBT Agreement. 2. For Section III. A of the draft regulations, it is recommended to provide technical standards which could judge the national security threats, and that the FCC shall authorize the products that comply with the safety technical standards. The draft regulations prohibit the authorization of certain telecommunications equipment and services under provision 47 CFR 1.50002, on account of national security threats. As the technical standard and measurement index are not publicized, it is not consistent with WTO/TBT transparency principles. It is recommended to set up technical standards and measurement index, notify WTO and provide at least 60 days for Members' comments. 3. For section III.A.3 of the draft regulations, it seeks comments on whether to revoke any of the authorizations that have been previously granted for "covered" equipment on the Covered List(47 CFR 1.50002). It is proposed not to revoke the authorizations. Currently, the equipment authorizations that have been previously granted are obtained strictly following the then-

⁵¹ Certification cost per item (USD 24,000) + Annual renewal cost (USD 1,540+marking cost) required, Total certification cost of at least 30 million KRW per item.

⁵² Currently, Oeko-Tex, REACH, etc. include copies of their certificate in shipping documents or send the copies to customers separately.

⁵³ For previous statements follow the thread under <u>ID 714</u>.

effective regulations, TCB-certified by the FCC, or SDOC process prescribed by the FCC. There is no violation of the situations mentioned in provision 2.939 of section III.A.3.

2.126. In response, the representative of the United States provided the following statement. The United States notified the proposed rules, "Protecting Against National Security Threats to the Communications Supply Chain Through the Equipment Authorization Program and the Competitive Bidding Program," to the WTO on 3 September 2021. This action is a Notice of Proposed Rulemaking (NPRM) (ET Docket No. 21-232) by the United States Federal Communications Commission (FCC), adopted on 17 June 2021, in which the FCC proposes to revise rules related to its equipment authorization processes to prohibit authorization of any "covered" equipment on the recently established Covered List, included in PUBLIC LAW 116-124 Secure and Trusted Communications Networks Act of 2019, enacted by U.S. Congress 12 March 2020. The FCC accepted formal comments on the Equipment Authorization Notice of Proposed Rulemaking until 18 October 2021, and China's comments were submitted on 18 September 2021. In total, the FCC has received nearly 250 comments, including from China. All of the comments are available to the public and can be found on the FCC's website. United States appreciates China for its comments. The final rule will include information on all substantive comments received, and how the comments were taken into account. Information on any rule changes will be notified to the WTO as an addendum to the original notification.

2.1.3.13 China - National Standard of the P.R.C., Lithium Ion Cells and Batteries Used in Portable Electronic Equipments - Safety Technical Specification, <u>G/TBT/N/CHN/1576</u> (ID 706⁵⁴)

2.127. The representative of the <u>Republic of Korea</u> provided the following statement. The Republic of Korea would like to express its sincere gratitude for China's kind reply to the STC statement raised by Korea at the last WTO TBT Committee meeting in November 2021 with regard to China's draft amendment of "National Standard of the P.R.C., Lithium Ion Cells and Batteries Used in Portable Electronic Equipment – Safety Technical Specification" (GB 31241-20XX). Korea fully understands China's position that the deletion of the exceptions clause, which waives cell body marking requirements when agreed between manufacturers, was a necessary revision to guarantee the traceability, identification and safety of products, because cells without proper identification markings have caused confusion to market regulation in China in recent years. However, if the draft amendment is implemented as it is, it would have a severe negative impact on Korea's electrical and electronic products industry, so we would like to reiterate our comments once again.

2.128. Cells are only parts, and their export destinations are determined only when the cells are finally assembled into battery packs or end-products, and most countries, such as the European Union, the United States and Japan, set cell body marking exceptions provisions in accordance with the international standard, IEC 61960-3. Therefore, it is difficult to provide a separate cell body marking procedure solely for products to be exported to China. In order to comply with China's cell body marking requirements, replacement of production facilities and rework of existing products must be made, which will be quite costly and time-consuming, laying an excessive burden on relevant manufacturers. Korea requests that China maintains the exceptions regarding cell body marking requirements in consideration of these difficulties in the industry. If the amendment must inevitably be implemented without modification, we request that a sufficient grace period of more than one year be given in consideration of the time required for the industry to adapt to the new regulation.

2.129. In response, the representative of <u>China</u> provided the following statement. The identification is very important for the safe use of cells and batteries. As an important component of a battery, cells cannot be traced or identified effectively without necessary identification information. Cells without identification have caused much confusion in market regulation in recent years. Therefore, through investigation and extensive consultation during the formulation, GB 31241-20xx proposed relevant requirements for cell body identification. China will not consider deleting exceptions.

 $^{^{54}}$ For previous statements follow the thread under <u>ID 706</u>.

2.1.3.14 European Union - Regulation (EC) No 1272/2008 (CLP Regulation), <u>G/TBT/N/EU/629</u>, <u>G/TBT/N/EU/826</u> (ID 539⁵⁵)

2.130. The representative of <u>Brazil</u> provided the following statement. In August, the European Union notified a draft regulation proposing changes to Part 3 of Annex VI of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures (CLP), which introduce a stricter classification of reproductive toxicity to 2-ethylhexanoic acid (2-EHA) from Repr. 2 to Repr. 1B. The revaluation process was initiated in 2014, when ECHA requested new studies to be carried out, specifically an Extended One-Generation Reproductive Toxicity Study (EOGRTS). A Substance evaluation (SeV) process was then carried on by Spain, which recommended maintaining the previous classification of reproductive toxicity (Repr.2, H361d). At the time, the only modification suggested was the introduction of an explanatory note, which clarified the fundamentals of the classification in question. The competent authorities then opened a public consultation for the submission of comments on the dossier resulting from the SeV and additional information by authorities of other member States and members of the private sector. During this period, Germany and France submitted a reclassification proposal to Repr. 1B, based on analysis of analogy (also called "read-across") with the substance valproic acid.

2.131. The use of read-across relies on the assumption that, due to the presence of similar chemical aspects, the substances in question will have similar effects when exposed to the same tests, and thus, will reveal the same toxicity. According to our private sector, this does not seem to be the case. The reproductive toxicity studies specific to 2-EHA, which contradict the applicability of readacross with valproic acid, make up the best technical information to support the classification of reproductive toxicity, as they are a direct analysis of the substance, without relying on assumptions of similarity. Studies specific to 2-EHA conclude that the most appropriate classification would be the Repr. 2. The EU has claimed that its analysis has considered studies specific to 2-EHA and not only read-across ones. Brazil is still concerned, though, that the more restrictive classification adopted by the EU is not justified. Brazil would also like to note that, according to the EU, the reclassification of the product as 1B would not entail higher costs associated with the registration process of chemicals. Nevertheless, the reclassification will still have a negative impact on the preferences of importers of the substance, who will have the wrong indication of its actual level of risk. We believe, therefore, that these regulatory changes would be more trade-restrictive than necessary to fulfill the EU legitimate objectives of health protection. Brazil thanks the EU for its statement in our last meeting, clarifying procedural aspects of its legislation. We also appreciate the written reply to the comments from our private sector in the public consultation. In this sense, we would like to ask if the EU could provide an update on the status of the proposal, regarding the current and next steps of the process towards adoption and entry into force.

2.132. The representative of the <u>Russian Federation</u> did not make a statement during the meeting. A technical statement was circulated following the meeting.⁵⁶

2.133. In response, the representative of the <u>European Union</u> provided the following statement. The European Union would like to thank Brazil for raising this issue and for the written comments concerning the classification of the 2-ethilhexanoic acid (2-EHA) in the 18th adaption to technical and scientific progress (ATP) of the Classification Labelling and Packaging (CLP) Regulation.⁵⁷ The EU notes that the written reply to the comments of Brazil was sent shortly after the last TBT Committee, on 25 November 2022. Therefore, the EU would like to reiterate the main points and refer to the written reply for details. The EU would like to note that the draft 18th adaption to technical and scientific progress (ATP) of the Classification Labelling and Packaging (CLP) Regulation was presented for a final consultation at the meeting of Competent Authorities on REACH and CLP (CARACAL) on 19 October 2021. Based on that consultation, as well as on all previously received comments, including comments from WTO Members, the EU concluded that the proposed classification of the substance 2- ethylhexanoic acid (2-EHA) is appropriate and the 18th ATP was adopted by the Commission on 16 February. The two months objection period for the European

⁵⁵ For previous statements follow the thread under <u>ID 539</u>.

⁵⁶ <u>G/TBT/W/769</u>.

⁵⁷ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353 31.12.2008, p. 1), consolidated version available at: <u>https://eur-lex.europa.eu/legal-</u> <u>content/EN/TXT/?uri=CELEX%3A02008R1272-20211001</u>.

Parliament and the Council is ongoing and if there are no objections, the measure should be published in the EU Official Journal in the second half of April.

2.134. The proposed classification of 2-EHA is based on the scientific opinion of the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA), which assesses all reliable and adequate scientific evidence that is available. In June 2020, the RAC concluded that 2-EHA should be classified as toxic to reproduction, Category 1B for development. RAC reaches its conclusions by applying the classification criteria in Annex I of the CLP Regulation, which are fully aligned with the corresponding classification criteria for reproductive toxicity under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). These criteria also stipulate that an evaluation of substances chemically related to the material under study may also be included. The relevant section of the RAC opinion describes the available evidence from studies carried out with the substance 2-EHA itself and complements it with information on valproic acid. RAC considered valproic acid a substance related to 2-EHA not only based on structural similarity, but also on a similar developmental toxicity profile in animal studies. The EU can therefore not agree with the argument in the comments submitted by Brazil that RAC based its conclusion solely on a read-across from valproic acid instead of considering information on 2-EHA itself, and considers that the assessment carried out by RAC and the conclusions that were drawn were fully compliant with the classification criteria of the CLP Regulation and GHS. The EU hopes that these responses sufficiently clarify the points raised.

2.1.3.15 European Union - Transitional periods for MRLs and international consultations (ID 580⁵⁸)

2.135. The representative of <u>Colombia</u> provided the following statement. Colombia reiterates its grave concern regarding the international consultation procedures adopted by the European Union (EU) and the transition periods granted prior to the entry into force of provisions under which the EU does not approve the marketing of certain plant protection substances and amends maximum residue levels (MRLs). These concerns are being reiterated because the EU has so far not responded to any of the requests concerning the granting of longer transition periods and has not taken into consideration the comments made during international consultation periods. We reiterate that there are no alternatives that would help to resolve the problems and uncertainty that short transition periods cause for fruit- and vegetable-producing countries. These measures create additional burdens for agricultural producers, who need to make decisions on the use of crop protection products a year or more before the final product arrives on the European market. This is particularly complex for products with long production and harvest cycles, as well as for processed and frozen foods.

2.136. Furthermore, Colombia maintains that notification to the WTO of non-renewal, the MRLs to be applied and transition periods should not be made by the EU as a simple formality within the regulatory process. We recall that the notification must be submitted within a time frame that allows the Members concerned to submit substantive observations and comments for genuine consideration by whoever is developing the technical regulation. 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 is known, countries should be able to "make the relevant adjustments", given that the WTO must first be notified of this information and the public consultation period must be held. On this occasion, we would like to ask the EU some specific questions. How are the comments submitted by countries taken into account? What is the procedure for analysing the technical and scientific information submitted during the public consultation period? In what cases have changes or modifications been made to 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.

2.137. The representative of the <u>United States</u> provided the following statement. We continue to raise our concern about the European Union's (EU) transitional measures for pesticide maximum residue levels (MRLs). We repeat our request that the EU extend transition periods to allow adequate time for US and third country producers to move lawfully produced food products through the channels of trade, including shelf stable products that have long shelf lives. We recall longstanding concerns that trading partners do not know with certainty what the impact of the EU's active

 $^{^{\}rm 58}$ For previous statements follow the thread under <u>ID 580</u>.

substance nonrenewal decisions will be on future MRLs. We seek confirmation that the EU will allow for longer, more reasonable transition times for MRLs where the EU has not identified risk to consumers based on dietary exposure. We would have some serious trade concerns if MRLs and import tolerances are lowered or withdrawn, subsequent to an active substance non-approval or restricted approval decision, in a manner that is disproportionate to the level of risk to human health, and which appears more trade restrictive than necessary.

2.138. In addition, we reiterate our concern about the EU's consideration of import tolerance applications. Our past experience indicates that the review of additional data is often only considered after the EU notifies its intent to issue a nonrenewal notice. Once again, the United States reiterates its request that the EU retain existing MRL levels while import tolerances are under consideration, and that the EU fully completes science-based risk assessments prior to setting new MRLs. The EU's policy of enforcing MRLs at the time of importation for imported goods instead of at the time of production as applies for domestic goods, is an inconsistency that causes disruptions in trade for products destined for the EU market. Trading partners have found themselves racing to move shipments through customs to prevent rejections or turning back orders because a product that complies with an existing EU MRL standard at the time of production could face rejection at EU borders. EU growers do not face the same timelines under the current regulatory provisions. We therefore again request that imported products' MRLs be considered on the EU market at the time of production, the same as for European products.

2.139. The representative of <u>Uruguay</u> 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. In our view, any changes should be gradual, and a reasonable period of time, of at least two years or two harvests, should be granted to raise awareness in the production sector and among technical advisers, and to ensure that effective substitutes for the active ingredients for whose MRLs a reduction is sought are available on the market. It is inappropriate to change the rules drastically in the middle of a harvest season, given the impact this may have on international and domestic marketing. My delegation reiterates its call on Members to adopt regulatory decisions based on internationally accepted standards or to provide conclusive scientific evidence when it is strictly necessary to depart from these standards in order to meet their legitimate objectives, as provided for in the relevant WTO Agreements. Even in cases where the European Union decides, based on a full risk assessment, that it is necessary to reduce the MRLs for active substances used in the agricultural production of other Members, we encourage it to take into consideration the need to grant transitional periods that are adequately and sufficiently long to make the relevant adjustments.

2.140. The representative of <u>Brazil</u> provided the following statement. Brazil supports the concerns raised under STC 580 and would like to refer to our previous statements on this agenda item. We respectfully bring to the attention of the EU its obligations under Article 2.12 of the TBT Agreement, which relate to the establishment of a reasonable interval between the publication of technical regulations and their entry into force, except in cases of urgent problems of safety, health, environmental protection or national security. It is of utmost importance that the EU provides adequate transitional periods, especially for those cases in which the scientific opinions of the EFSA on the toxicity of substances are "inconclusive" or only indicate a "suspected risk". Transitional periods should also be compatible with the production processes, so as to allow producers – and especially small farmers – to adapt to the new regulations.

2.141. The representative of <u>Canada</u> 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 rapid deletion of MRLs and import tolerances for substances no longer approved in the EU seems disproportionate to the level of risk to human health and is more trade-restrictive than necessary. Canada reminds the EU of the reality of agricultural supply chains, including multi-year inventory and the extensive shelf lives of products. The current transition periods make it very difficult for exporters to adapt to the new requirements given the distance travelled from the source. Transition periods of one year, particularly where there are no dietary risks of concern, allow trade to continue uninterrupted, while providing sufficient time for producers and exporters to adapt to new EU requirements. The EU has found a way to accommodate the need of its domestic

stakeholders to ensure food security and minimal food waste through the use of emergency authorizations. Noting the important role of trade in achieving these goals, Canada urges the EU to extend the transition periods for MRLs on imported goods to allow agricultural supply chains the time to adapt to new requirements.

2.142. The representative of <u>Costa Rica</u> provided the following statement. We reiterate our support for the concern, as in previous meetings, as well for the request to extend the period of compliance with the new tolerances that are being established for various substances, in view of the serious impact they have on agricultural production in our countries. It is impossible for agricultural production in Costa Rica to adjust to new requirements or tolerances within the period established, when the registration of new molecules alone entails a complex assessment process lasting over six months. 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 owing to the COVID-19 crisis, the implementation of more restrictive measures or additional burdens on international trade in agricultural products constitutes a challenge that is hampering worldwide economic recovery efforts, especially in developing countries. In this regard, we would like to remind the EU of the request made in documents <u>G/SPS/GEN/1778</u> and <u>G/TBT/GEN/296</u> - Request for the Suspension of the Processes and Entry into Force of Reductions of Maximum Residue Levels (MRLs) for Plant Protection Products in light of the COVID-19 Pandemic.

2.143. The representative of <u>Paraguay</u> provided the following statement. As with other similar concerns, we are concerned that the European Union's approach to limiting the use of substances is more trade-restrictive than it needs to be for it to achieve its legitimate objectives under the TBT Agreement. Similarly, the reduction of MRLs, on the basis of the argument that it is impossible to determine whether the use of many substances is safe and the lack of conclusive scientific evidence, even in cases where the Codex Alimentarius has identified certain substances as being safe, is not in line with Members' obligations under the SPS Agreement. The pursuance of such policies will cause significant trade damage to the economies of developing countries and jeopardize their ability to achieve sustainable development goals, including those related to food security. We urge the EU to: reassess its approach; base its decisions on conclusive scientific evidence and real risk weightings, in accordance with the relevant international principles and standards; ensure import tolerances; and, where necessary, provide adequate transitional periods that take into account the realities of the production processes and geographical locations, including distances, of its trading partners, as the six-month period is insufficient for adapting productive systems.

2.144. The representative of <u>Ecuador</u> provided the following statement. Ecuador is extremely concerned about the "transition periods" granted by the European Union (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 in all countries, and particularly in developing countries, 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. Ecuador is aware that the EU allows its farmers to request emergency authorizations so that, in certain particular situations, they can use active substances that have already been banned in the European market. For Ecuador, it is important to know whether, 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.

2.145. The representative of <u>Guatemala</u> provided the following statement. The importance of establishing transitional periods that closely follow the stages of crop production was reiterated following the lowering of maximum residue levels (MRLs) notified by the European Union. In particular, more time is required for the adaptation of crops grown in tropical countries, and to find alternative substances, which in some cases means having to wait for suitable production cycles to commence application and testing. As a result, the six-month period that the European Union considers to be the time required to make technical changes to agriculture is not feasible. We reiterate our concern that our ideas for focused discussions on finding solutions have not been heard and accepted. We support the questions raised by Colombia and look forward to the European Union's replies.

2.146. The representative of <u>Chile</u> provided the following statement. The delegation of Chile is pleased to comment on the STC recently raised in relation to the tolerances being set by the EU for different plant protection substances, which affect Chile's foreign trade in agricultural products.

2.147. The representative of <u>Panama</u> provided the following statement. Like the delegations that took the floor before us, we express our deep concern over the transitional periods for MRLs. We urge the EU to provide a reasonable transitional period to allow industry to adapt to these changes.

2.148. In response, the representative of the European Union provided the following statement. The EU has provided detailed information on transitional periods for Maximum Residue Levels (MRLs) at previous TBT Committees, in particular, at the TBT Committee meeting in May 2020. 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 be 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.

2.149. 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. The EU therefore kindly invites Members not to raise issues concerning transitional periods for MRLs at the TBT 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 <u>G/SPS/GEN/1778</u> and <u>G/TBT/GEN/296</u> and subsequent revisions, the EU position is included in the document of 28 May 2021 with double reference <u>G/SPS/GEN/1814/Rev.2</u> and <u>G/TBT/GEN/315</u> circulated in both Committees.

2.1.3.16 China - Draft Administrative Measures for Registration of Overseas Producers of Imported Foods, <u>G/TBT/N/CHN/1522</u> (ID 611⁵⁹)

2.150. The representative of Canada provided the following statement. Canada remains concerned that China's recently implemented administrative measures for the registration of overseas manufacturers of imported food negatively impacts trade. Over the years, Canada and China have implemented many bilateral arrangements that have successfully maintained the safe trade in food between our respective nations. However, Canada continues to be concerned that the administrative measures being implemented by China are overly burdensome and unjustified. These measures are broad and overarching in scope and will have a significant impact on Canadian exports to China. Canada remains disappointed that Decree 248 was adopted and published by the General Administration of Customs of the People's Republic of China (Customs China) immediately following the comment deadline without sufficiently taking into account comments and concerns from WTO Members. Moreover, Canada is disappointed that China went ahead with implementation of Decree 248 on 1 January 2022, and did not heed the requests of many WTO Members to delay implementation for 18 months to allow additional time for competent authorities and industry to understand and comply with these new requirements. With the recent implementation of Decree 248 and the launch of the online China Import Food Enterprise Registration (CIFER) system, Canada is deeply troubled by the serious barriers to trade these measures are creating, including significant financial and resource impacts on both industry and foreign competent authorities.

2.151. Canada would like to emphasize that the implementation of the CIFER system was unexpected by trading partners, and this system was not included in the proposed measure notified by China in $\underline{G/TBT/N/CHN/1522}$. Canada is therefore disappointed that China did not inform or

 $^{^{\}rm 59}$ For previous statements follow the thread under $\underline{\rm ID~611}.$

engage with trading partners prior to the implementation of CIFER, nor did China provide a reasonable transition period for competent authorities and industry stakeholders to adapt to this new system. Prior engagement would have limited disruptions to trade and addressed the concerns currently being raised by competent authorities and industry stakeholders. Despite repeated requests from trading partners, there remains limited engagement, information, and guidance from Customs China regarding the implementation of the CIFER system, which is resulting in continued uncertainty and increasing concerns. As well, industry has faced delayed clearance of shipments due to this new system. For example, Canada notes that there is insufficient information and guidance from China to undertake and complete the process to register medium risk establishments that inadvertently missed the October 2021 deadline. The registration process is overly detailed and confusing, lacking the step-by-step process and defined timelines for both competent authorities and industry. This is creating unnecessary barriers to trade and adding pressures to exports on commodities that were previously eligible to export from accessing the Chinese market.

2.152. As a result, Canada immediately requests that China provide, without undue delay, a grace period of 18 months for medium risk commodities during which the establishment information in CIFER will not be used by Chinese border officials to determine export eligibility. This grace period would extend until 1 July 2023, and apply to: (i) all the companies that were eligible to export to China as of 31 December 2021, and (ii) the companies currently registered in CIFER. Canada stresses that this grace period is needed to afford companies sufficient time to register and/or amend their registrations. Additionally, Canada notes that we continue to expect China to add to the CIFER system, without undue delay, all approved Canadian establishments that were approved by China, but had not yet been included in the list of approved Canadian products and facilities eligible to export to China. As many questions remain regarding the registration process from both industry stakeholders and foreign competent authorities, Canada urges China to create a contact point for all queries from both industry and competent authorities. If this is not possible, then Canada calls on China to work directly with companies for the completion of their registrations. Canada underscores that trade disruptions will continue if detailed guidance is not adequately provided and all associated timelines are not clearly explained and defined. Canada strongly urges China to outline all timelines in a transparent manner and develop clear guidance documents to address the questions and concerns from both industry and competent authorities. In conclusion, Canada remains deeply concerned about the impact these measures have on trade. These measures have resulted in resource pressure and confusion for competent authorities and industry due to the lack of details and transparency from China regarding the implementation of these new requirements.

2.153. The representative of Indonesia provided the following statement. Indonesia thanks China for its prompt responses as well as the mechanism carried out in the progress of registering Indonesia to enable business actors continue distributing their products in China. Indonesia fully respects the rights of China's authority to protect the health and safety of its people by ensuring the safety aspects of food products consumed in China's market. Indonesia plays a significant role in contributing China's food supply, including the provision of food raw materials needed by the Chinese market, and committed to continue doing that. For this reason, Indonesia hopes that this policy will not disturb Indonesia's export process to China. Indonesia recognizes that a registration process is necessary to ensure effective supervision of products circulating in China and compliance to occupational safety, health & environmental protection. However, the implementation of this policy has inevitably created obstacles for our industry. Thus, we require further clarification on the following matters to rationalise the food product registration process. Indonesia requests explanations and guidelines regarding the compatibility of the Harmonized System (HS) Code with the CIQ Code considering that the CIQ Code is specific only to China, while HS code is already available as the common system for international trade. Indonesia requests China to provide complete guidelines for using the website <u>https://cifer.singlewindow.cn/</u>. In addition, we expect China authorities to make improvements to the website to clarify the difficulties experienced by business actors regarding: The registration submission page on the web always displays each field with a blank condition, particularly on the homepage of the basic information menu, productionrelated information, checklist and statement, and for attachment information cannot be accessed for data input and document upload. This happens either on self-registration or by a competent authority. The addition of menus /features on the GACC website is done without notice and cannot be used according to its initial purpose.

2.154. Indonesia requests China to clarify the time/timeline of the registration process. Indonesia request China to provide a contact point/contact person who can provide quick response in handling the registration process. Indonesia hopes China would consider a relaxation in the implementation

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of registration to prevent major losses for business actors exporting to China, as is currently being experienced by several Indonesian business actors who have been affected by the demurrage. China has been a valued and strategic trading partner for Indonesia for a broad range of products, including food and beverages. Indonesia wishes to continue becoming a strategic trading partner to China and fervently hopes that China reconsiders the timing for the implementation of this measure. Indonesia awaits China's response and looks forward to bilateral discussion on this prominent matter.

2.155. The representative of The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu provided the following statement. Given the wide range of our food industries that have been or may have been affected by this measure, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu has been closely following the implementation of the measure. Many concerns over the measure remain even after it took effect on 1 January 2022. First, the lack of sufficient information about registration requirements and operational guidelines on how to follow the requirements is one of the biggest difficulties we face. This issue is even more critical for those facilities that need to file the application by themselves. Without sufficient guidance, the facilities are unable to complete registration, and trade may be disrupted as a consequence. To avoid trade disruption, we urge China to designate an enquiry point that can provide effective and timely assistance for facilities to contact directly with concerns about the online registration system. Also, we urge China to hold an information session in the WTO for trade partners to learn more about the General Administration of Customs of China (GACC)'s implementation of the measure. Second, there are also concerns over the measure's review and approval procedure. Standard or anticipated processing periods are unknown. So is the stage of the application. In addition, some of our facilities were rejected by the GACC without further explanation, while others cannot correct their application in the registration system.

2.156. Under Article 5.2.2 of the TBT Agreement, Members shall ensure that the standard processing period of each conformity assessment procedure is published to the applicant and, upon request, the applicant is informed of the stage of the procedure. We request that the GACC comply with the requirements set out under the TBT Agreement, including the transparency requirement and informing the applicant in a precise and complete manner of all deficiencies and allowing corrective actions. Third, other difficulties we face include the ambiguity of HS code categorization and the scope of the products subject to this measure. Some of our facilities reported that their products have faced customs clearance suspension for no reason. Ever since China made notification to the WTO in 2020, we have expressed our concerns and sought clarification from China several times through both bilateral channels and this forum; however, we have yet to receive a sufficient and detailed response from China. We therefore once again urge China to offer sufficient and detailed guidelines and designate an enquiry point. Also, as any measure of this magnitude requires far more time for industries to implement, we urge China to offer a longer grace period for implementation so as to avoid serious trade disruption. We also suggest that China temporarily allow entry of all products from registered facilities. This additional time will allow facilities to accurately enter or update the product information in their online registration.

2.157. The representative of Australia provided the following statement. Australia respects the right of WTO Members to address the safety and quality of imported food products in accordance with the TBT Agreement and without unnecessarily restricting trade. Australia acknowledges China's recent implementation of measures under its Regulation on Registration and Administration of Overseas Manufacturers of Imported Food (Decree 248). While some implementation issues are to be expected, Australia remains concerned about a number of issues and delays surrounding the registration of food producers within China's registration systems. In particular, Australia has in good faith provided information for registration of establishments that has not been accurately reflected in China's registration system. This is causing significant industry concern and, for some commodities, is trade restrictive. Similarly, the difficulty Australian businesses and competent authority are experiencing in effecting changes to the Australian facility registration on the CIFER system (E-Government Platform for the Origin of China's Imports) are causing delays in the clearance of product at point of entry. In light of the above, Australia respectfully requests that China adapt a flexible approach to implementation until 1 July 2023, during which they would allow entry of products in line with historical trade, in addition to entry under China's new system of registration, pending completion of outstanding applications, corrections or updates to online registrations.

2.158. Australia notes that China is still managing the transition to the new measures and updates to China's registration systems are occurring sporadically. Australia would like to request that China

meets its obligations to provide Members with transparent timeframes for updates and appropriate guidance to minimise disruptions to trade and confusion at the border. Australia suggests that it would be valuable for China to provide information to trading partners, for example through an information session, and directly to registered facilities through assigned GACC (General Administration of China Customs) contact points to assist with resolving issues. Australia reminds China that its regulations must not be used to discriminate against imported goods, and that delays in processing registration renewals and new applications from overseas food producers may lead to imported foods being treated less favourably than China's domestic product. Australia would appreciate China's transparency on timeframes for processing these applications, in line with its obligations. Australia urges China to address these issues promptly and remains willing to work with China to minimise trade disruptions.

2.159. The representative of <u>Brazil</u> provided the following statement. Brazil would like to once again raise STC 611 regarding new requirements for the registration of overseas producers of imported foods. So far, both bilaterally and at the TBT Committee, the Chinese government has not been able to clarify the risk analysis that grounded such disproportionate requirements for a wide range of food products. We understand that these requirements constitute unnecessary obstacles not only to our private sector, but also to our regulators, which must operate as the Competent National Authority for a much wider range of products. In April 2021, the General Administration of Customs of China (GACC) published Decrees n. 248 and 249, which deal, respectively, with administration of registration of foreign establishments and management of the safety of imported and exported food. Article 7 of Decree n. 248 defines the products for which registration will require the recommendation of the Competent National Authorities. Could the Chinese side specify the Harmonized System (HS) codes for the foods covered in this article?

2.160. Article 5 of Decree n. 248 requires that the food safety management system of the country where the producer is located has passed GACC's equivalence assessment or review. Could China explain how and when it intends to carry out these assessments? Could China indicate the criteria and procedures used to establish such equivalence, especially for regulators of processed foods and "health foods"? The Brazilian private sector also expressed concern with the packaging requirements contained in Article 15 of Decree n. 248. Could China provide a longer adaptation period for labelling requirements? If there are delays in the issuance of the registration number by the GACC, will the Chinese government allow for the importation of products without marking the registration number? Considering the need for label design and printing, will the Chinese Government publish in advance additional labelling requirements such as font size and colour, format, visibility, placement and use of stickers? Finally, as Decrees 248 and 249 came into force in the beginning of this year, we would like to highlight that our national health authority has been experiencing difficulties in using the system to make its recommendations as a competent national authority. Would it be possible to grant a longer period of adaptation?

2.161. The representative of the <u>European Union</u> provided the following statement. The EU would like to express its concerns regarding the implementation of Decree 248 of the Chinese Customs Administration, which entered into force on 1 January 2022. The EU does not question the right of China to ensure that imported food products come from legitimate sources; we share and support this objective. However, problems persist with the registration of exporting businesses. The EU urges China to: allow registered facilities to export any related product for a period of 18 months, regardless if it is registered for that particular HS code; maintain an open dialogue to solve implementation issues in a pragmatic way; facilitate new registrations by providing supporting material and guidance documents in English; and facilitate amendments/corrections to existing registrations. The EU would like to thank China for its constructive dialogues on Decree 248 but underlines the importance of solving the implementation issues in order to reduce disruptions to trade.

2.162. The representative of the <u>United States</u> provided the following statement. The United States notes that China implemented this measure, published as Decree 248, on 1 January 2022. We remain concerned with such a trade-impacting regulation, and question the food safety and public health benefits, and whether such benefits are based on science or risk. In particular, we are very concerned that this measure now requires our competent authorities to take on administrative functions to assist certain US facilities to register via China's online single window portal, and manage their access to this portal. Such administrative actions are fundamentally the responsibility of China's domestic food safety regulators. To be specific, it is not the responsibility of US competent authorities to administer China's new online registration system. Thus, we request that Chinese competent

authorities either communicate directly with exporting facilities or allow these facilities to self-register via China's online single window portal, as many other types of facilities are permitted to do.

2.163. In addition, we note that there are a number of unanswered questions and points of clarification regarding Decree 248. China has only provided some limited guidance, and much more is needed. China's insufficient guidance and haphazard implementation of Decree 248 is causing trade disruptions and considerable confusion for US manufacturers and competent authorities. For example, our industry has reported shipments being held up at ports in China due to erroneous or missing information in China's online system that cannot be readily added or revised. Specifically, concerns include missing or erroneous harmonized tariff (HS) codes in the system, duplicate facility registrations, as well as many other concerns. None of these administrative problems can be remedied by US Government authorities and must be resolved by the relevant Chinese authorities. Meanwhile, US companies accumulate demurrage and other port fees while they await action by Chinese authorities to release the shipments. As we have noted before, any measure of this magnitude requires significant implementation time for producers, exporters, and competent authorities. Therefore, we ask that China allow trade to continue to be unaffected by this measure for a period of 18 months to allow for sufficient quidance from the Chinese authorities, including addressing the concerns and questions by exporting countries. We also ask that China administer its new registration system without requiring foreign competent authorities to act as intermediaries between China and exporters; and we request time for companies to properly register with China's single window and make any necessary corrections to their information in the system.

2.164. The representative of Japan provided the following statement. Japan shares the concerns with other Members on China's regulation on the Decree 248. Japan understands China's efforts to enforce the Decree 248 as announced. However, the lead time for the enforcement seemed to be too short and the scope and procedure of the registration have been frequently changed, which caused confusion and lack of transparency for manufacturers that exported their commodities to China. In concrete terms, firstly, it is unclear what kind of information is required for the registration. For example, though Article 10 lists the information required for the registration, GACC's CIFER system requires the HS code and CIQ code for the registration, which are not listed in Article 10. Secondly, the scope of Decree 248 is unclear. GACC frequently changes the list of commodities that require the registration of the facility to be produced. This means that the border of the scope between the registration under Article 7, registration by the Government, and the registration under Article 9, the registration by private entities, is frequently changing. Moreover, related to the first problem, the HS code and CIQ code are sometimes deleted in CIFER system without notice when the application under Article 7 is transcribed to the application under Article 9 or vice versa. These problems also create unnecessary obstacles to trade. We hear that when each commodity is exported to China, Customs Office checks not only whether the commodity comes from registered facility but also whether the commodity matches with Chinese HS code and CIQ code that were input at the time of registration.

2.165. The problem is that the current CIFER system does not accept the application to add or modify the HS code and CIQ code to the already registered facility. So when a commodity comes to fall within the scope of Decree 248 due to the change of the scope after the registration of the facility, the exporter has no means to export the commodity in accordance with the Decree 248 due to the lack of renewal process of the original registration. Another case that shows lack of transparency is that though Article 2 of Decree 248 stipulates that the scope of the Decree is the registration of the facilities that manufacture, process or store food, GACC recently required an exporter to register the fishing vessel that has no processing nor storage equipment. Lack of transparency creates unforeseeability of the trade with China. We suggest that China take account of the comments and concerns from the WTO Members. Japan also requests China to allow imports from registered facilities regardless of registered commodities till 1 July 2023, as a grace period for CIFER system to work smoothly enough for manufacturers to complete registration without stress or confusion. Japan suggests China to set contact points for exporters to communicate with GACC directly and correct their already registered information by themselves.

2.166. The representative of <u>Turkey</u> provided the following statement. Turkey reiterates its support to Members that have raised this issue to the agenda. Although the requirements requested from our competent authorities regarding the fulfilment of the Draft Administrative Measures for Registration of Overseas Producers of Imported Foods of China have been completed so far, this regulation imposes a great burden on both the exporters and the competent authorities of the

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exporting countries especially considering the complexity of the new system of registration process. We consider that Decree 248 covers a wide range of food items, and the implementation of the Decree need further clarifications. We think that this practice, which does not classify products based on a risk assessment, in fact does not fully meet the human health concerns targeted by this legislation. Turkey believes that this aforementioned regulation restricts trade more than necessary. Therefore, Turkey would like to ask China to review this legislation from a risk-based perspective and narrow its scope of products, in addition to extend the adoption period for this regulation.

2.167. The representative of the <u>Republic of Korea</u> provided the following statement. As in the previous TBT Committee meetings, the Republic of Korea continues to share the concern raised by the delegations of the United States of America, Chinese Taipei, the European Union, Brazil, Australia, Indonesia, and Canada, regarding China's Administrative Measures for Registration of Overseas Products of Imported Foods. Korea respects China's right to ensure food safety and recognizes its efforts to accommodate concerns that were raised by Member states before the Administrative Measure entered into force this year. However, Korea remains concerned as our requests has not been duly addressed by China and therefore repeat our request. First, we request China to provide rationale on the Administrative Measure, in particular, Article 7 of Decree 248 which expands its coverage to low-risk products. Moreover, Korea would like to ask China to share the scientific data or risk analysis used to select the 14 categories that requires confirmation of conformity from competent authorities. Korea believes food safety is a legitimate objective under the TBT Agreement but its implementing measures shall not be more trade-restrictive than necessary.

2.168. Second, competent authorities are already experiencing heavy administrative burden, having to review registration applications of overseas producers, and to confirm they are in continuous compliance with China's regulations and standards after registration. Furthermore, China's new online registration system was not fully operated, which led to several confusions such as incorrect information, mismatched products, etc. We therefore recommend China to work directly with overseas facilities for the application process, rather than involving competent authorities. We also request China to designate a contact point for effective communication and to correct information in the registration applications. Korea believes this will save time and money for not only China but also overseas facilities and authorities. With respect to this, Korea would like to ask China to provide a time frame of the whole registration and compliance process to increase certainty and predictability. As China is a very important trade partner to Korea, being the 2nd largest market for Korean food products, changes in China's regulations significantly impact bilateral trade. Therefore, Korea requests China to address our concerns and will wait for China's response.

2.169. The representative of <u>Mexico</u> provided the following statement. The delegation of Mexico refers to Decree 248, notified to the Members of this Committee on 16 November 2020 in document G/TBT/N/CHN/1522 and which entered into force on 1 January 2022. While the Government of Mexico has established coordinated mechanisms to ensure that the registration of Mexican companies exporting to China can be carried out in a satisfactory manner to avoid delays to export processes, we consider it of great importance that the relevant authorities in China commit to ensuring that this new scheme does not lead to delays for products that fully comply with the requirements established for importation to that country. The delegation of Mexico thanks the delegation of China for giving its consideration to this statement and reiterates the importance of ensuring that the measures adopted by Members of this Committee are aligned with international commitments and do not have the effect of creating unnecessary technical barriers to trade.

2.170. The representative of <u>Switzerland</u> provided the following statement. Switzerland shares – and supports - the concerns expressed by other Members regarding the two decrees 248 and 249 published by the General Administration of Customs of the People's Republic of China (GACC). Switzerland understands and supports China's objective to ensure that only safe food is imported. We regret that the measures still include all food categories irrespective of their risk-profile and seem to be more trade restrictive than necessary to ensure the safety of imported food products. We therefore reiterate our concerns expressed in previous meetings. Switzerland encourages China to brief all interested WTO Members on the implementing rules at the earliest possible date. It is important that we all have access to the same information, which can be shared with competent authorities and the industry. Switzerland also encourages China to provide a contact point at GACC for facilities in order to allow them to contact GACC directly in case of concerns about the online registration system. Furthermore, Switzerland invites China to allow entry of all products from

registered facilities until 1 July 2023. This additional time would enable facilities to accurately enter or update product information in their online registration.

2.171. The representative of <u>India</u> supported concerns raised on this STC.

2.172. The representative of <u>Chile</u> provided the following statement. The delegation of Chile thanks the Chair for the opportunity to support the trade concern raised by the United States, Canada, Australia, the European Union, Brazil, Japan, Indonesia and Chinese Taipei, and supported in the room by the delegations have already taken the floor. The measure notified by China, on which Chile has made timely comments, has entered into force and has created complications for both Chilean food-exporting companies and the competent authorities. The delegation of Chile recognizes food safety as a legitimate policy objective to be pursued, but this should not be done by using measures that restrict international trade more than necessary. My delegation is concerned by the implementation of the notified regulations, as there are deficiencies in the registration system that make it difficult or, in some cases, impossible to register production establishments that export to China on a regular basis. In some cases, this has led to unnecessary delays in the shipment of products that meet the sanitary requirements for entry to China. Regarding this measure, the delegation of Chile requests that the requirement for mandatory registration be postponed in order to avoid interrupting the current flow of trade. A number of Chile's registration application processes are currently suspended owing to malfunctions in the GACC-administered IT system; there is no definite timeframe for the resolution of these issues, which creates uncertainty and delays to shipments that have already been promised.

2.173. In response, the representative of <u>China</u> provided the following statement. 1. The revision of the Draft administrative measure for registration of overseas producers of imported foods follows the principles of open, transparent, and complies with international rules and common practices. In order to effectively implement the Food Safety Law and its implementation regulations, the GACC has revised the above-mentioned administrative measure for registration, which was publicized on 12 April 2021, and came into force on 1 January 2022. We have notified the measure to the WTO, and adopted reasonable comments. Besides, the transitional period is in line with the requirements in the TBT/SPS Agreement. 2. While strengthening food safety supervision, trade facilitation is fully considered in this measure. All categories of food specified in the Food Safety Law are included, among which, "official recommendation registration" is adopted for the overseas production enterprises of 18 categories of food, while "self-application by enterprises" with relatively simplified procedures is adopted for the overseas production enterprises of food other than 18 categories.

2.174. 3. Preparation works carried out before the implementation of the regulation. To ensure smooth implementation, GACC has issued the interpretation of the rules, the guide for registration applications, supporting documents and forms for registration applications, and the operation manual for the registration information system. In September 2021, GACC contacted Members who exported food to China, informed the relevant requirements and procedures for the registration of overseas enterprises, and made reasonable arrangements to speed up the auditing process. By the end of 2021, the GACC has held video conferences with 114 Members, conducted training for more than 2,000 overseas enterprises, and answered various questions raised by Members. 4. Since the implementation of the regulations, as of 25 February 2022, more than 100 Members have provided the list of enterprises recommended for registration, a total of 64,036 overseas manufacturers engaged in 31 food categories are registered. So far, implementation of this measure goes well.

2.1.3.17 Peru - Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA (ID 618⁶⁰)

2.175. The representative of <u>Colombia</u> provided the following statement. Colombia thanks Peru for its consideration of the concern regarding the use of adhesive advertising warning labels under paragraph 8.3 of section 8 of the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA. However, we are raising this STC once again given that DS 018-2021-SA simply extends the deadline for the use of adhesive labels to 31 March 2022; this will very soon expire and has created significant uncertainty for business owners and trade operators. Colombia considers that the option to use adhesive labels should be permitted on a definitive basis and that the deadline should no longer be allowed to be extended for further periods of time. Furthermore, Colombia reiterates that the policy under which this standard is adopted, while,

⁶⁰ For previous statements follow the thread under <u>ID 618</u>.

understandably, seeking to promote and protect public health, should be implemented in a manner that is no more restrictive than necessary and that does not subsequently create an unnecessary obstacle to trade. Colombia also considers that allowing the use of adhesive labels does not distort the purpose of the Peruvian standard, since the warnings, whether included on adhesive labels or printed directly on the packaging of products, will continue to be clear, legible, prominent and comprehensible, as required by the regulations.

2.176. This technical measure on labelling that is so specific to a particular country, which must be implemented in the product's country of origin and does not allow the use of adhesive labels with the required information, is a technical barrier to trade; it constitutes a major access barrier, particularly for small and medium-sized enterprises. Moreover, as far as Colombia is aware, there is no knowledge of there having been, during the period of application of the standard permitting the use of adhesive labels, any situations that led to non-compliance with consumer information standards. We welcome the bilateral talks that have taken place at different levels, and the progress reported. We ask Peru to take these considerations into account and, in its regulatory review, allow the use of adhesive labels on a permanent basis.

2.177. 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 018-2021-SA, the entry into force of the prohibition on stickers was delayed until 31 March 2022. 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. If a permanent solution is not feasible before the end of the month, Brazil would like to request to Peru, at least, another postponement of the entry into force of the measure.

2.178. The representative of the <u>European Union</u> provided the following statement. The European Union (EU) appreciates that Peru further extended the possibility for imported products to use stickers for compliance with labelling requirements for processed foods, until 31 March 2022. However, the EU would like to repeat once again the urgent invitation to Peru to provide for a permanent possibility for imported products to use stickers. As the deadline of 31 March approaches, trade is already being severely disrupted because retailers in the Peruvian market have stopped buying products with stickers. Such disruption is akin to what happened in the months leading to the last year's deadline of 30 June and it represents significant losses for importers and producers, as well as disruption of trade flows and unavailability of the affected products in the Peruvian market. The EU recognizes that reliable information to the Peruvian consumer and protection of public health are legitimate objectives. Nevertheless, the obligation to print information on the product package is unnecessarily 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. We invite once again Peru to bilaterally work with the EU on this issue.

2.179. The representative of <u>Costa Rica</u> provided the following statement. Costa Rica wishes to reiterate its trade concern 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 of Peru. The Permanent Mission of Peru in Geneva informed our delegation in a timely manner that the entry into force of this standard was being postponed until 31 March this year. Although this postponement has offered 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 of the negative repercussions on trade that a potential discontinuation of the use of adhesive labels would have. It should be noted that the use of adhesive labels is widely recognized internationally, as such labels achieve the same public health protection and consumer information purposes achieved by permanent labels. At the CODEX level, for example, Articles 8.1.1 and 8.2.1 of CODEX-STAN 1-1985, General Standard for the Labelling of Prepackaged Foods, permit the use of supplementary and 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.

2.180. 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 fulfilment of the proposed legitimate objectives. The fact that Peruvian legislation, in other instruments, permits the use of an adhesive or additional label no doubt shows that there are less trade-restrictive measures through which it is possible to fulfil the proposed legitimate objectives, in accordance with the obligations regarding technical barriers to trade established in the relevant World Trade Organization Agreement and in the existing Agreement between our countries. Costa Rica would like to emphasize once again, as it has already done before this Committee, that in light of the current global situation and the post-COVID-19 economic recovery, 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 reiterate Costa Rica's wish that the Peruvian authorities to remove the proposal to prohibit the use of stickers and maintain the possibility of permitting their permanent use.

2.181. The representative of <u>Chile</u> provided the following statement. The delegation of Chile would like to note that the regulations established in Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Peru, has caused concern among companies and guilds exporting foods to that country, as the acceptance of sticker-based labelling is temporary. Chile would be grateful if Peru would reconsider the established timeframe, which expires at the end of this month.

2.182. The representative of <u>Guatemala</u> provided the following statement. We reiterate the recognition of Peru's right to protect people's health and to provide consumer information on foods. However, we are concerned that the extension of the use of adhesive labels expires on 31 March 2022, which leaves importers without any legal certainty. As stated in previous meetings, relevant international standards, where they exist, shall be used to avoid unnecessary obstacles to international trade. The CODEX CXS 1-1985 General Standard for the Labelling of Prepackaged Foods states that a supplementary label may be used on imported products that do not comply with Peruvian regulations, which should accurately reflect the information on the original label. We once again call on Peru to reconsider regarding the permanent use of supplementary adhesive labels, as a number of trading partners have already done and as has been previously discussed in this Committee. The use of this adhesive label is widely recognized internationally, as it achieves the same public health protection and consumer information purposes that Peru is seeking to achieve.

2.183. In response, the representative of <u>Peru</u> provided the following statement. Peru reiterates 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 area. In this connection, Peru is seeking to ensure that the information contained in the Manual of Advertising Warnings (MAP) reaches consumers clearly and effectively to enable them to make informed choices. In response to the concerns expressed by some Members, Peru, by means of Supreme Decree No. 018-2021-SA, extended again, until 31 March 2022, the period during which the use of adhesive warning labels is allowed, as 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. In that regard, significant time has been granted for adaptation to the requirements established by the Peruvian regulations since their issuance. Lastly, we reiterate that Peru wishes to honour its WTO commitments and therefore reaffirms its commitment to not preparing, adopting or applying technical regulations that may create unnecessary barriers to trade, as established in the Agreement on Technical Barriers to Trade.

2.1.3.18 European Union - Non-renewal of the approval of the active substance mancozeb, <u>G/TBT/N/EU/712</u> (ID 627⁶¹)

2.184. The representative of <u>Colombia</u> provided the following statement. Colombia reiterates its concern regarding the measure notified by the European Union (EU) in document <u>G/TBT/N/EU/712</u> of April 2020 relating to non-renewal of the approval of the active substance mancozeb. As we have already explained, the EU has adopted measures resulting in the non-approval of the use of plant protection products, which is affecting exports from Colombia. Measures on the suspension or non-approval of the marketing of numerous active substances and the subsequent reduction of their MRLs to the minimum detection level are being taken without any sound scientific evidence and without proof that such measures are the least trade-restrictive means of achieving an appropriate level of protection. On this occasion, we would like to ask the EU once again about the relationship between the notification in document <u>G/TBT/N/EU/712</u> on mancozeb and the notification in document <u>G/TBT/N/EU/712</u> on mancozeb and the notification in document <u>G/TBT/N/EU/712</u> on mancozeb and the notification in document <u>G/TBT/N/EU/712</u> on the recall that, even though in this and various other cases we have requested that the EU provide information on the time frames for the adoption of the standard and on the implementation of maximum residue levels, the EU has failed to respond to these requests. We ask it to please respond to these concerns.

2.185. 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. In line with the above, 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. Lastly, we once again invite the EU to follow the recommendations for good regulatory practices, under which standards must be based on clear and objective information, and which promote open dialogue with stakeholders, transparency and the minimizing of market distortions.

2.186. The representative of Paraguay provided the following statement. This concern and the non-renewal of the approval of the remaining substances were already discussed extensively both in this Committee and in the SPS Committee because of the subsequent reduction in the MRLs. Paraguay therefore refers to its previous statements and reiterates its cross-cutting concern with regard to the EU's decision not to renew the approval of these substances without a proper risk analysis and without complying with scientific principles. Paraguay shares the objectives that the EU seeks to address with these policies, but does not share its adopted method for attaining them because it is not based on conclusive scientific evidence and does not consider less trade-restrictive options or valid alternatives for hazard control that, based on the requirements for emergency authorizations and the number of such authorizations approved for mancozeb, we can assume the EU agrees do not exist in this case, including in relation to the EU's climate conditions. This is exacerbated in countries like Paraguay that have climatic conditions and pest-pressure levels that are very different from those in the European Union and that can be safely and effectively controlled by substances such as mancozeb. We echo Colombia's questions on how the Members concerned by the process can participate in the analysis that the European Food Safety Authority (EFSA) is conducting on the MRLs for mancozeb and on how comments submitted by Members will be taken into account.

2.187. The representative of <u>Australia</u> provided the following statement. Australia recognizes the European Union'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

⁶¹ For previous statements follow the thread under <u>ID 627</u>.

(MRLs) and effects this may have on trade, including wine exports to the EU. Australia seeks clarification on whether stocks which are in-market prior to the required period from entry into force of this regulation will continue to be eligible for sale in the EU. This was raised in the previous Committee meeting but Australia is not aware of the EU's position. Australia also notes that the EU has recently made several plant protection product non-renewal decisions and subsequent changes to relevant MRLs which are impacting Australia's trade with Europe. Australia seeks further clarification on how this decision will impact future decisions around MRLs. Australia also notes that our competent domestic authority and Codex have determined MRLs for dithiocarbamates that ensure the continued protection of human, animal and environmental health while allowing trade to continue.

2.188. The representative of Brazil provided the following statement. Brazil would like to convey once again its concerns regarding the non-renewal of the approval of the active substance mancozeb, according to European TBT notification G/TBT/N/EU/712. 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 substance for the management of fungicide resistance to control soybean rust. 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. In light of the insufficient transitional period granted by the EU, such crops cannot have their treatments changed in time for exportation to the EU market before the entry into force of the regulation. Brazil would like to urge European authorities to consider establishing transition periods that are adequate to the production cycle of the affected crops. Brazil also respectfully asks the EU to align MRLs with limits established under the framework of Codex Alimentarius and to consider less trade-restrictive alternatives that would also safequard its legitimate policy objective and to grant treatment to Brazilian farmers no less favourable than that granted to European farmers.

2.189. The representative of <u>Costa Rica</u> 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. We support the statements of the delegations that have already taken the floor. Costa Rica recognizes that Members have the right to determine the appropriate level of sanitary or phytosanitary protection needed to protect human, animal or plant life or health, and to establish measures to that end. In turn, may we remind Members that these measures must be science-based and should not create unnecessary barriers to trade, especially at a time when the pandemic continues to affect the economic recovery of international markets. To assess just how crucial the substance mancozeb is to agricultural production in Costa Rica, it is sufficient to note that it is currently used for more than 20 crops that are grown for export and domestic consumption, and is therefore vital to ensuring the supply of food. Mancozeb is also used to combat pests of economic importance, particularly in banana production.

2.190. 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 subsequent economic recovery, and find an alternative substance so that Costa Rican farmers can continue to grow bananas and export the volumes required to meet the EU market demand.

2.191. The representative of <u>Chile</u> provided the following statement. The delegation of Chile welcomes the earlier statements concerning the EU's non-renewal of the approval of the active

substance mancozeb and echoes the trade concern raised at this meeting and previous meetings of the Committee.

2.192. The representative of Guatemala provided the following statement. Guatemala maintains its position regarding this concern on measures to suspend or not to market active substances and to reduce MRLs as part of the process, in relation to which 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. Mancozeb is key for the production of a number of strategic agricultural crops that are exported to the European Union, such as fruit and vegetables, which would also affect tropical countries. In terms of other types of agrochemicals, there are very few alternatives with multi-site properties available on the market for the control of fungi. This means that 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 providing the same effectiveness. Black Sigatoka is caused by the fungus Mycosphaerella fijiensis, which invades and necrotizes the leaf tissue, causing leaf death in perennial banana and plantain crops. Black Sigatoka is the disease that has the greatest economic impact on banana and plantain crops worldwide and is only successfully controlled with mancozeb. The ban on the use of mancozeb will have a negative social and economic impact on the country, given that a number of crops are a significant source of employment and foreign exchange generation, and of food for the families that depend on such crops.

2.193. The representative of Ecuador provided the following statement. Ecuador reiterates its concern regarding the non-renewal of the substance mancozeb. Mancozeb is a fungicide used throughout the world for a wide range of strategic crops, a number of which are produced in Ecuador. Examples include bananas, cocoa, broccoli, pineapples, pitahayas, mangoes and cape gooseberries. This compound is important for pest management in countries with tropical climates - like Ecuador - in which pest behaviour follows patterns that are very different from those prevailing in countries with four seasons, meaning that chemical pesticides for agricultural use with the active ingredient mancozeb are vital for agricultural production. Prohibiting the use of mancozeb - without effective alternatives - could have a very significant economic impact on small-, medium-, and large-scale producers in Ecuador, as well as on consumers in the European Union (EU), because the supply of our products would be affected. I must point out that the way in which this substance is applied in banana production means that 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%. It is concerning that there are currently no approved and properly registered alternatives to this substance that are as effective as mancozeb.

2.194. 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 information relating to this substance. We wish to recall 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. 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.

2.195. The representative of <u>Uruguay</u> provided the following statement. Mancozeb is an active substance that is authorized and widely used in a safe manner in many countries, including 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, as a result of the ongoing review process, the European Union may significantly reduce the corresponding MRLs, 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.

2.196. The representative of <u>Panama</u> provided the following statement. The delegation of Panama reiterates its concern regarding the non-renewal of the active substance mancozeb. Mancozeb is vitally important for the country's main crops, especially bananas. At present, there is no other active ingredient that can replace mancozeb, leaving the industry without any phytosanitary tools and consequently 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 and plant life or health, but such measures must be science-based and should not create unnecessary barriers to trade. In view of the above, Panama reiterates its request to the EU to follow the recommendations of good practice and we join other Members' enquiry as to how the European Union will take account of the comments submitted by Members.

2.197. In response, the representative of the European Union provided the following statement. We have provided detailed explanations on this issue in previous TBT Committees. 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 this substance was not renewed. EU member States had to 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). Possible grace periods granted by EU member States, in line with Article 46 of Regulation 1107/2009, expired, at the latest on 4 January 2022 after 12 months from its entry into force. The EU would like to inform Members that EFSA has started a review of the existing Maximum Residue Levels (MRLs) for dithiocarbamates (group of which Mancozeb is part). We informed Members at the last TBT Committee meeting that interested parties had been 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.1.62 The EFSA scientific opinion on dithiocarbamates is expected to be published in the first half of 2022. For advice on alternatives to Mancozeb, the EU pesticides database⁶³ 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 position is included in the document of 28 May 2021 with double reference G/SPS/GEN/1814/Rev.2 and G/TBT/GEN/315 circulated in both Committees.

2.1.3.19 India – Draft Food Safety and Standards (Import) Amendment Regulation, 2020, <u>G/TBT/N/IND/180</u> (ID 667⁶⁴)

2.198. The representative of <u>Mexico</u> provided the following statement. The delegation of Mexico refers to the Draft Food Safety and Standards (Import) Amendment Regulation, notified to the Members of this Committee by the Government of India on 25 November 2020 in document <u>G/TBT/N/IND/180</u>. Considering that this issue was repeatedly raised in this Committee in its three meetings in 2021, we appeal to the good offices of the delegation of India to respond to this enquiry as soon as possible. In response to the statement we made in this Committee in November 2021, the delegation of India explained that the comments received from interested third parties continued to be analysed. We would therefore be grateful for them to share with us any updated information in that regard. As we have mentioned, this measure is of great importance to Mexico's industry and Government and we are therefore very interested in being able to follow it up in a timely manner. The delegation of Mexico thanks the delegation of India for giving its consideration to this statement.

⁶² https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-review_en.pdf.

⁶³ https://ec.europa.EU/food/plant/pesticides/eu-pesticides-db_en.

⁶⁴ For previous statements follow the thread under <u>ID 667</u>.

2.199. The representative of the European Union provided the following statement. The European Union would like to refer to its previous statements on this matter. At the outset, the European Union recalls that it sent written comments and is still waiting for a written reply. We again ask that India please provide a written reply. We understand that on 10 November 2021 FSSAI has adopted and published a revised and final version of the measure, which will become applicable as of June 2022. However, many questions put forward by foreign food (and drink) manufacturers and competent authorities remain unanswered, and this tends to create an unpredictable trading environment. The measure appears much more trade restrictive than necessary to fulfil the intended food safety objectives. The European Union would like reiterate already raised concerns. The scope of the application of the measure remains unclear: the revised and now final and adopted measure provides for a registration obligation. Even though it is provided that this obligation shall apply to food (and drink) products presenting a specific risk, no list of such products exists in the rules themselves. With less than six months left before the entry into application, it is now urgent that India clarifies the intended scope of these new rules. The inclusion on the list of low-risk products, in particular wines and spirits since they have inherently stable nature, would be disproportionate. Therefore, the European Union would appreciate if India could clarify whether products which are inherently stable and do not present sanitary risks such as spirits or wine, will be excluded from the scope of these new obligations. The measure provides for registration and inspection of foreign food (and drink) manufacturing facilities. However, further clarity is needed with regard to the definition of "facilities" and the modalities related to inspections (and audits) of these facilities. Last but not least, the transition period initially foreseen is not sufficient and should be extended to 24 months.

2.200. The representative of the <u>United States</u> provided the following statement. The United States remains concerned with India's draft measure, notified to the WTO TBT Committee as <u>G/TBT/N/IND/180</u>. This draft regulation leaves many unanswered questions for foreign food manufacturing facilities, competent authorities, and other stakeholders. The United States has raised this issue at previous TBT Committee meetings, 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 and the scientific and technical information India will use to determine the specific "risk" for food product categories. We again ask that India please provide further information on this measure and its plan for implementation.

2.201. The representative of <u>Japan</u> provided the following statement. Japan shares the concerns with other Members on India's proposed draft amendment regulation on food safety and standards. The regulation would impose additional burdens on business operators who plan to export to India. However, there are many unclear points yet to be explained by India including definitions of "food manufacturing facility", scope of "food" subject to the regulation, and the registration procedure for facilities inspection and audit. Japan requests India to submit TBT and SPS notifications and provide WTO Members with the opportunity to comment on the regulation in details such as scope of food and facilities registration procedure. Moreover, Japan emphasizes the importance to provide a sufficient transition period before the implementation of the new rules. Japan considers the transition period of 180 days from publication in the Official Gazette is still not sufficient. Japan suggests that the transition period be extended to more than 18 months. Japan requests India to sincerely address Members' concerns and comments and to ensure the proposed new rule does not create unnecessary trade barriers.

2.202. The representative of <u>Australia</u> provided the following statement. Australia recognizes the right of the Indian Government to take measures necessary to protect public health. Australia thanks India for their engagement on this issue during a technical discussion between the Food Safety and Standards Authority of India (FSSAI) and the Department of Agriculture, Water and Environment in late 2021. FSSAI advised at that time that the proposed regulations will not apply to all food establishments. Australia would welcome written confirmation of this advice from FSSAI. Australia also recommends that the regulation should be amended to clarify the categories of food included. The proposed measures should be linked to the risks posed by the imported food. Australia is happy to work with India to support a more risk-based approach to food safety.

2.203. The representative of <u>Canada</u> provided the following statement. Canada would like to reiterate concerns raised at the TBT Committee meetings in February, June and November 2021

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 amendments remain ambiguous. As previously stated, 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. In addition, Canada remains concerned with the measure's on target commodities, source-countries, implementation plan, audit rates, compliance actions and appeals. We are of the view that India's approach in these areas could create unnecessary obstacles to trade. Canada notes that India has yet to respond to comments submitted to India's enquiry point on 21 January 2021. We would appreciate if India could inform when it expects to provide the requested details. In closing, Canada recalls its request to India to notify these amendments to the SPS Committee given that India's proposed regulation covers food safety measures aimed at protecting human health and safety.

2.204. In response, the representative of <u>India</u> provided the following statement. The FSS (Imports) First Amendment Regulations, 2021, provides the legal framework for the registration and inspection of Foreign Food manufacturing facilities intended for export to India. As prescribed, the registration and inspection of such facilities may be based on the risk associated with the food category as specified by the Food Authority from time to time. The detailed guidelines in this regard may be separately published, including SOP, procedural information, and guidance for the foreign food manufacturers to comply with the said regulations. It may be noted sufficient time for implementation shall be provided for compliance.

2.1.3.20 Egypt – Halal Certification Measure, based on Egyptian Standard ES 4249/2014 General Requirements for Halal Food According to Islamic Sharia, <u>G/TBT/N/EGY/313</u>, <u>G/TBT/N/EGY/313/Add.1</u> (ID 718⁶⁵)

2.205. The representative of <u>Canada</u> provided the following statement. Canada joins the United States, the European Union and other intervening Members to raise its continued concerns with Egypt's new halal certification requirements for all imported food and beverage products which came into effect as of 1 October 2021. While Canada understands Egypt's objective to ensure that Egyptian consumers are confident that they are buying and consuming Halal-certified products in agreement with Islamic Sharia, we also believe that such measures should not create unnecessary barriers to international trade or be more trade-restrictive than necessary to fulfil that objective. While Canada appreciates Egypt notifying this measure to the WTO TBT Committee in December 2021, it failed to do so prior to the implementation date of 1 October 2021. As set out in Article 2.9 of the TBT Agreement, Members have an obligation 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. A reasonable amount of time, understood as a period of not less than six (6) months, should be provided between the publication of a regulation and its entry into force to allow time for industry and Members to review and implement the new requirements. This was obviously not the case with this measure.

2.206. Canada is also concerned with the lack of details, documentation and specificity on how these requirements will be implemented and how specific products will be impacted. For example, the proposed new regime only specifies one Egyptian certification body that will have the authority to certify halal products for the Egyptian market, and to our understanding, this has already significantly raised the halal certification fee which will have to be borne by exporters of halal product to Egypt. The new measure could result in a certification process that is overly burdensome, costly and more trade restrictive than necessary to achieve Egypt's stated objective. Canada strongly encourages Egypt to have open and transparent discussions with trading partners to share information, further clarify the requirements under this new measure and consider the impact it may have on trade. Until then, we respectfully request that Egypt suspend the implementation of the measure.

2.207. The representative of the <u>European Union</u> provided the following statement. The European Union would like to express its concerns with regard to the requirements on halal certification as of 1 October 2021 based on the Egyptian Halal standard 4249/2014. The EU industry is worried about

 $^{^{\}rm 65}$ For previous statements follow the thread under $\underline{\rm ID~718}.$

the negative impact this measure would have on food and beverages imports to Egypt. The EU regrets that Egypt notified to the TBT Committee the requirements for the importation of meat, poultry and their products, milk and dairy products only on 1 December 2021, after their entry into force in October, and that the notification did not include the text of the measure. The EU recalls that, according to Article 2.9.4 of the WTO TBT Agreement, Members shall allow a reasonable time (at least 60 days) for other Members for written comments on their draft measures, so that comments can be taken into account. In any case, the EU submitted written comments on 26 January 2022 and would welcome a reply by the Egyptian authorities.

2.208. The EU would like to thank Egypt for useful bilateral contacts. We welcome some of the steps envisaged to mitigate the negative impact of the measures, such as the grace period until 15 December 2021 during which, certification by "IS EG Halal" was voluntary and for free. We also appreciate the acceptance of imports of milk and dairy products without a Halal certificate until 28 February 2022 and the exclusion of crude milk from a Halal certificate, both notified in Addendum 1 of 7 January 2022. Nevertheless, some of those facilitations were only temporary and the companies will not have sufficient time to adapt to the new certification and labelling requirements. This is why the EU would urge Egypt to postpone the implementation of this measure and to provide for a reasonable adaptation period of at least one year, in accordance with Article 2.12 of the TBT Agreement. The EU would like to invite Egypt to reconsider the decision to grant the right to certify the compliance with halal requirements to a single company, IS EG Halal, and to provide for a Halal certification system that would allow multiple, well-established certification entities, in accordance with the international best practices. Re-certification by IS EG Halal of products from establishments already certified by other companies would lead to longer time to market and higher costs for consumers, while Egypt is suffering food security problems, aggravated by the coronavirus pandemic. The EU would welcome clarification on whether multiple Halal certification entities, including from third countries, would continue to be allowed for imports, as it is understood from point 6 of the TBT notification form. The EU would like to ask Egypt to consider keeping the Halal certification and labelling voluntary, in order to pursue the legitimate objective of ensuring reliable information without unduly hindering trade flows. Consumers should be able to decide whether to buy halal-certified food or not, based on clear labelling.

2.209. The EU would appreciate if Egypt would consider further trade facilitating measures, such as requiring halal certification for the product and not per container, as well as proportional costs of halal certification that take into account the international practice and correspond to the service rendered. The EU understands that the new requirements on halal certification will certify the compliance with Egyptian standard ES 4249/2014 on General requirements for "halal" food products in accordance with the provisions of Islamic Sharia. According to the available information in the TBT notification form G/TBT/N/EGY/313, this standard is under revision and will be notified to the WTO TBT Committee. The EU would like to ask about the status of the revision and the timeline of the TBT notification. Finally, the EU would like to ask Egypt about the concrete steps envisaged to provide comprehensive information about the new measures and clear written and publicly available guidance to stakeholders, including detailed description of the certification procedure, its duration, costs, and required documents, as well as process for registration of suppliers, and the product coverage (with HS codes). The EU would also like to know whether Halal certificates will be required for products that are not 100% milk, but which contain milk or milk ingredients amongst others. The EU is ready to work with Egypt on solutions that would prevent the negative impact this measure would have on food and beverages imports to Egypt.

2.210. The representative of the <u>United States</u> provided the following statement. The United States continues to recognize Egypt's right to provide its consumers assurance with regard to the halal status of certain products. We appreciate Egypt's notification of <u>G/TBT/N/EGY/313</u> to the WTO TBT Committee on 1 December 2021, and an Addendum on 7 January 2022. The United States submitted comments to Egypt's TBT Enquiry Point on 28 January 2022 and 24 February 2022. We look forward to receiving a response. Our goal is to ensure that US exporters can comply with all Egyptian import regulations. In order for our exporters to effectively comply, it is paramount that Egypt is transparent about its requirements. This is particularly important given the current need for predictive trade flows in a challenging pandemic-caused environment. We understand that Egypt is revising the requirements contained in <u>G/TBT/N/EGY/313</u> for mandatory halal certification, including changing the scope of products that would be covered under the future measure. Could Egypt please clarify whether our understanding is correct and please provide a timeframe as to when we can expect notification to the TBT Committee? Will Egypt provide a comprehensive list of HS lines covered by the future measure? The United States has concerns about the lack of transparency regarding

Egypt's implementation of current halal certification requirements. The United States invites Egypt to provide information on fee schedules, audit procedures, labelling requirements, export registration requirements, etc.

2.211. In G/TBT/N/EGY/313, Egypt noted that it would need to approve certification bodies. However, it is unclear how Egypt currently approves certifiers and whether that process is changing. For many years, certification bodies around the world have successfully certified halal product for export to Egypt. It has been nearly three years since Egypt delisted a number of US halal certification bodies that had previously been approved to certify meat and poultry exports to Egypt. Could Egypt please state the reasons for delisting these certifiers and explain how these certifiers can be relisted? The United States invites Egypt to publish and notify to the WTO information about the process and standards used to approve or delist certification bodies, as well as any proposed changes. The United States notes that having a diversity of certification bodies available to conduct halal certification is important to ensure that halal services remain open and competitive. When Egypt limited halal certifiers for US beef and poultry products to a single certifier in 2019, certification fees increased by 1,000%, resulting in higher prices to Egyptian consumers. The United States requests Egypt to share information about how it is ensuring that certification fees are commensurate with the services provided. The United States thanks Egypt for sharing a document entitled Annex I: Global Documents needed for Halal Certification of the Establishments. However, the document does not indicate whether it is a mandatory official Egyptian regulation or a voluntary guideline. We are concerned that this document conflates food safety and halal (e.g., "safety data sheet," "analysis for heavy metals and pesticide residue," etc.).

2.212. We request that Egypt identify the source of Annex I and notify it to the WTO TBT Committee. We ask that Egypt please separate these food safety requirements from its halal-related requirements. The United States strongly urges Egypt to immediately delay and suspend implementation of any new halal certification requirements until all concerns have been addressed, including those relating to changes regarding halal certification bodies. We also request an implementation period of at least six months before enforcement to give exporters and halal certifiers a reasonable time to modify operations to meet any new halal certification requirements. In closing, the United States recognizes Egypt's right to require appropriate halal certification, but we expect Egypt to fully meet its WTO obligations when implementing new requirements that have the potential to disrupt trade.

2.213. The representative of Australia provided the following statement. Australia thanks Egypt for ongoing bilateral communication and engagement on the implementation of new Halal certification requirements for IS EG Halal. We welcome Egypt's notification of details around these new requirements to the TBT Committee on 1 December 2021, via G/TBT/N/EGY/313. Australia appreciates advice that imports of meat, poultry, milk and dairy products must be accompanied by a Halal certificate issued by an exporting country certification body as determined by Egypt's General Organisation for Veterinary Services. We also appreciate provision of the revised draft standard, ES 4249/2014 - General requirements for Halal food products in accordance with the provision of Islamic Sharia - particularly the additional annex - Global documents needed for Halal certification of the Establishment - which is being considered for inclusion. We further welcome the advice received bilaterally that Egypt intends to notify further changes to product scope for IS EG Halal certification requirements, and that implementation will only occur after Members have been provided an opportunity to comment and for those comments to be considered. In addition to this, Australia requests that a further notification clarifying the determination of Halal certification bodies by Egypt's General Organisation for Veterinary Services and rationale behind requested documents under the proposed additional annex to ES 4249/2014 be provided. Australia is also grateful for Egypt's notification of any proposed changes to any intended changes to those standards complementary to ES 4249/2014. Australia welcomes ongoing discussion on the implementation of Egypt's new Halal certification measures to ensure they meet Egypt's policy goals while also ensuring measures are not more trade restrictive than necessary.

2.214. The representative of <u>New Zealand</u> provided the following statement. New Zealand welcomes the opportunity to speak in support of the concerns raised by the European Union, Canada, and the United States. We thank Egypt for its bilateral engagement to date on this matter. As outlined at the last TBT Committee, New Zealand understands that Egypt is implementing changes under Prime Ministerial Decree (No. 35/2020) to require that certification of relevant halal standard(s) shall only be undertaken by IS EG Halal. Certification from other Halal assurance bodies will not be accepted for goods imported into Egypt. New Zealand also understands that the measures may apply to a

broad category of food and drink products imported into Egypt, irrespective of whether Halal labelling is applied to those goods, and irrespective of whether these goods have previously been treated as Halal. For example, fresh fruit, vegetables, milk and other dairy products that do not include any other ingredients or additives. New Zealand still has serious concerns with these measures. New Zealand would like to draw Egypt's attention to its WTO obligations, including its obligations under the TBT Agreement concerning the use of conformity assessments, including under Articles 5 and 6, and the requirement that measures not be more trade restrictive than necessary. New Zealand would like to better understand what consideration Egypt has accorded to less trade-restrictive alternatives.

2.215. We are also interested in what factors led Egypt to introduce a measure that only allows conformity with the relevant Halal standard(s) to be determined by a single commercial body, and requires Halal certification of products, which have commonly been treated as Halal. We also share concerns as mentioned by the US, that if SPS measures are being imposed on manufacturers with additional sanitary information being required for registration with IS EG Halal, these should remain out of scope for Halal certification and be addressed by sanitary certification and management by the relevant Competent Authorities for SPS matters. New Zealand would like to thank Egypt for the WTO notification <u>G/TBT/N/EGY/313</u> dated 1 December 2021, though we would like to note that a final updated Egypt Halal Standard 4929-2014 is yet to be provided and notified to the TBT Committee in accordance with Article 5.6.2 of the TBT Agreement. New Zealand would also like to thank Egypt for the extension for dairy certification requirements until 28 February 2022. We request that the new measures be suspended until all WTO obligations, including dairy Halal certification, including those requiring consultation with other WTO Members, have been met.

2.216. The representative of <u>Paraguay</u> provided the following statement. Paraguay shares Egypt's concern that consumers be provided with certainty regarding the purchase and consumption of Halal certified products; however, as a food exporter to Egypt, we continue to follow closely the implementation of this measure and the information that Egypt can give us about it. In particular, we still do not have specific information about the products that would be covered by this measure, certification procedures, costs or labelling requirements, as well as other information needed to assess the adaptation of operators. With respect to the certification and labelling obligation, even for those products that do not claim to be Halal, we request that Egypt confirm this requirement and consider keeping certification on a voluntary basis in order to meet the legitimate requirement to provide accurate information to consumers without it becoming a trade restriction. Paraguay requests that Egypt delay the implementation of the new Halal certification requirements until Members have all of the information requested and trade operators have had enough time to adapt in order to ensure their compliance.

2.217. The representative of <u>Switzerland</u> provided the following statement. Switzerland is following this matter with interest and supports the concerns expressed by other Members with regard to the requirements on halal certification based on the Egyptian Halal standard 4249/2014. We are concerned over the potential negative impact of these measures on bilateral trade. While Switzerland recognizes Egypt's legitimate objective of providing consumers with reliable information on the halal integrity of certain products, we expect Egypt to fully comply with its WTO obligations. The measures appear to be more trade restrictive than is necessary to ensure legitimate objectives are met. In this respect, we call on Egypt to provide flexibility for the continued recognition of foreign Halal certification bodies and the acceptance of foreign Halal certificates. Furthermore, we are concerned that extending halal certificates to products other than livestock and poultry products could create additional costs for businesses and increase prices for consumers, which would have a negative impact on bilateral trade. Switzerland invites Egypt to comply with the notification obligations under the TBT Agreement and provide detailed information about the new measure, including detailed description of the certification procedure, its duration and cost, as well as the product coverage.

2.218. The representative of <u>Argentina</u> expressed its concern and deep regret with regard to the current situation in Ukraine. As Foreign Minister Cafiero said in his statement in the High-level Segment of the Human Rights Council, Argentina reiterated the request to the Russian Federation to cease immediately the use of force, and it condemned the invasion of Ukraine and the military operations on its territory.

2.219. Argentina provided the following statement. Argentina reiterates its concern about this measure along the lines expressed at the previous meeting of this Committee. Argentina thanks Egypt for the notification submitted on the amendment to the new Halal regulations. In relation to

this notification, Argentina would like to: emphasize that doubts remain about the scope of the regulation, the products included and the implementation mechanisms, taking into account that the documentation submitted is not completely clear or precise in its definitions; ask Egypt to formally submit complete documentation specifying the details included in the proposed regulation; underline that we agree with other countries on the need for detailed information on timeframes, procedures and labelling, and call on Egypt to consider delaying the entry into force of this regulation until there is sufficient clarity. Lastly, we wish to state that Argentina sent comments through the WTO Focal Point, when the notification was submitted by Egypt on Halal last January, and hope that Egypt will take these into account in the corresponding legislation.

2.220. The representative of <u>Chile</u> provided the following statement. Chile supports the STC recently mentioned by Canada, the United States and the European Union. Chile is concerned by the lack of alternatives for certifying products, such as agreements between ISEG Halal and certification entities in third countries, given that Chile is home to internationally recognized certification centres that could be recognized by Egypt, thereby avoiding the creation of unnecessary barriers to trade.

2.221. The representative of <u>Ukraine</u> thanked Members for continuing to express their support to Ukraine in the course of this meeting.

2.222. Ukraine provided the following statement. We would like to thank Egypt for their submission of notification and information that has been provided to our Enquiry Point so far. For the reasons outlined yesterday, I do not have any further specific details to provide today but would like to indicate our continued interest in this issue at hand.

2.223. In response, the representative of <u>Eqypt</u> provided the following statement. Egypt thanks Canada, the European Union, the United States, Australia, New Zealand, Paraguay, Switzerland, Argentina, Chile and Ukraine for raising this issue and their continued engagement on this matter recognizing Egypt's right to determine appropriate halal certification requirements. Egypt notes the issues that have been raised in today's meeting and former meetings concerning Egypt's Halal certification requirements with respect to meat, poultry and their products and milk and dairy products (except for crude milk). Since the last TBT Committee meeting in November 2021, Egypt has made two notifications to the TBT Committee, <u>G/TBT/N/EGY/313</u> and <u>G/TBT/N/EGY/313</u> /Add.1, in which the product coverage and timelines for entry into force have been clarified. Any change in product coverage shall be duly notified. Furthermore, Egypt through its TBT Enquiry Point has replied to the questions received from our trading partners concerning the measure at hand, and is currently in the process of replying to the questions that have been recently received and the follow-up questions received on 31 January 2022.

2.224. Taking into account the issues and concerns raised by Member countries, Egypt has taken a number of facilitating measures including allowing imports of milk and dairy products that are not accompanied by a Halal certificate to enter into Egypt until 28 February 2022. It is important to note that since the adoption of the measure no imports of milk and dairy products have been denied entry into Egypt. Hence, it is believed that businesses have been provided an appropriate period of time to adapt to the set requirements. Furthermore, Egypt is currently considering further facilitating measures based on the comments received from WTO Members and shall be duly notified once adopted. As for meat, poultry and their products, Halal certification requirements have been in place since many years ago, and they are not a newly introduced measure. Halal certificates issued by the certification bodies in the exporting country are accepted provided that the relevant Egyptian regulatory authority (the General organization for veterinary services (GOVS) in this case) approves and recognizes this body.

2.225. The relevant authority has recognized IS EG Halal companies in the different countries as the certification bodies to issue this certificate. Noting that those certification bodies are established and operating according to the relevant laws of the country in which they are established including in the United States of America, Uruguay, India, New Zealand, Germany. It is worth mentioning that previous companies issuing the Halal certificates have not abided by the requirements set by the relevant Egyptian Authorities. The certification process starts with registration at the recognized certification body, whereby: (i) The supplier registers on the ISEG HALAL website, then fills out the application form and completes the required documents. A date is then set for an audit visit (whether physically or virtually) of the facility or factory to verify the application of halal requirements; (ii) Once the facility is approved, IS EG will provide a supervisor to continue overseeing the facility. This supervisor will provide ease of mind that all produce is Halal; (iii) When products are approved by

an IS EG supervisor, the produce will be certified as Halal and the certificates will be issued; (iv) The supplier then obtains an account registered in the electronic system of ISEG HALAL, and after checking and shipping the shipments, the supplier uploads the shipment documents to his electronic account. Worth mentioning, is that there are no authentication costs associated with the Halal certificate; (v) There are no charges relating to approving the facility. However, the cost of issuing the certificates per container is dependent on the type of the product and the quantity; and (vi) The process takes an average time of seven working days. Finally, I would like to express Egypt's readiness to continue its bilateral exchanges on the subject matter with all interested trading partners.

2.1.3.21 China - Cosmetics Supervision and Administration Regulation and Regulation for Notification of Non-special Cosmetics, <u>G/TBT/N/CHN/1310</u>, <u>G/TBT/N/CHN/1311</u>, <u>G/TBT/N/CHN/1331</u>, <u>G/TBT/N/CHN/1453</u>, <u>G/TBT/N/CHN/1454</u>, <u>G/TBT/N/CHN/1459</u>, <u>G/TBT/N/CHN/1460</u>, <u>G/TBT/N/CHN/1515</u>, <u>G/TBT/N/CHN/1524</u>, <u>G/TBT/N/CHN/1525</u>, <u>G/TBT/N/CHN/1526</u>, <u>G/TBT/N/CHN/1527</u>, <u>G/TBT/N/CHN/1539</u>, <u>G/TBT/N/CHN/1615</u>, <u>G/TBT/N/CHN/1626</u> (ID 576⁶⁶)

2.226. The representative of the Republic of Korea provided the following statement. The Republic of Korea appreciates China for its close cooperation through bilateral channels, and for providing a response to Korea's comments concerning the specifications and regulations under this STC. However, Korea continues to be concerned as China's response did not provide an answer to Korea's enquiry but only gave a general explanation on the implementation of measures, and did not duly address Korea's concerns in the finalized specifications and regulations. First, exporters to China are required to specify the sources and quality data of all ingredients in their applications, which is demanding more information than that of other countries. Korea would like to request China to provide an evidence-based explanation for its measures as such information may contain trade secrets that are critical to businesses, and China's requirements are more rigorous than necessary to fulfill the objectives of ensuring product safety and compliance with China's domestic market norms. Furthermore, according to Appendix 12-14, businesses are required to disclose information on ingredient safety, which is concerning since businesses' intellectual property and commercially sensitive information may be unprotected. At the TBT Committee meeting in June 2021, China replied such information are not publicly available and legal provisions that protect confidential information will be added in cosmetic-related specifications and regulations. In relation to this, Korea would like to request China to provide explanation of the provisions in detail.

2.227. Second, China's regulations stipulate that test reports required for cosmetic product registration must be issued by testing laboratories that have obtained the China Metrology Accreditation (CMA). During the last meeting, China replied a number of foreign laboratories within the country has obtained CMA. However, Korea requests China to offer flexibility by recognizing test reports from foreign laboratories located overseas or internationally recognized laboratories that comply with international standards such as Good Clinical Practice or Good Laboratory Practice. Third, as per Article 13 of the New Cosmetic Ingredients Authorization and Registration Regulation, exporters are required to provide evidence that proves their test results of alternative test methods are equivalent to the results of in vivo toxicity testing method, or animal testing. Korea would like to request China to recognize alternative test methods approved by the OECD or other international organizations without requiring the submission of equivalence evidence. Fourth, regarding the "Administrative Measures on Cosmetic Labelling," Korea requests China to ensure that labelling requirements comply with internationally recognized practices. In particular, Korea requests China to maintain its current regulation on the requirement of ingredient declaration in cosmetic labelling. In most countries, cosmetic ingredients are subject to declaration when the substances are at a 1% or higher concentration. However, China's proposed regulation requires substances that are at a 0.1% or higher concentration to be declared, and substances at a concentration lower than 0.1% to be declared as "other ingredients in small amounts." With regard to this, Korea requests China to harmonize its regulations with international practices so as not to raise unnecessary barriers to trade. Fifth, under the Specifications for Cosmetic Efficacy Claim Evaluation, China requires summarized scientific evidence that supports cosmetic efficacy claims to be disclosed on NMPAdesignated websites. Korea, however, requests China to pare down the information it requires, as the information may contain trade secrets or undisclosed information that are critical to businesses. In the last meeting, China responded trade secrets protection laws will be strictly complied with

⁶⁶ For previous statements follow the thread under <u>ID 576</u>.

when managing the registration and filing of cosmetic products. Regarding this, Korea would like to request China to provide concrete explanation on the measures taken for compliance.

2.228. The representative of <u>Australia</u> provided the following statement. Australia respects the right of Members to implement technical measures for legitimate policy purposes and in accordance with obligations under the TBT Agreement. Australia remains concerned that measures under China's Cosmetics Supervision and Administration Regulation (CSAR) and its various implementing regulations, which entered into force on 1 May 2021, are more stringent than necessary to ensure the safety and quality of imported cosmetics. We thank China for its response to our comments in January this year on notification <u>G/TBT/N/CHN/1626</u> on Good Manufacturing Practice (GMP). Australia however remains concerned that the implementation date for this regulation was given by China as effective from 1 January 2022. Australia notes that this draft regulation was only notified to the WTO in September 2021, with comments due on the notification by 19 November 2021. Australia requests that China provide a transition period until at least January 2023 for cosmetics manufacturers to consider the regulation's requirements and make adjustments to their processes.

2.229. Australia also thanks China for its response to notification <u>G/TBT/N/CHN/1615</u> on the Provisions for the Supervision and Administration of Children Cosmetics. Australia remains concerned that China has maintained its requirement for mandatory animal testing of cosmetics products to be used on children, regardless of the level of risk presented by individual products. Australia is a reliable supplier of high quality and safe cosmetics products domestically, and to international markets. As we have said before, the Australian Government stands ready to work with China and discuss the CSAR, including subordinate regulations such as those for children's cosmetics. Australia would like to work with China to achieve clarity and certainty for businesses and to ensure trade in cosmetics can occur under transparent, science-based and non-discriminatory conditions. Australia welcomes the opportunity to exchange information and promote a better understanding of our respective regulatory systems for cosmetics.

2.230. The representative of the <u>United States</u> provided the following statement. It is unfortunate that the significant trade concerns that the United States raised with respect to the Cosmetics Supervision and Administration Regulation (CSAR) implementing measures remain. As published, these measures will pose significant risks to companies' intellectual property and are not proportionate to cosmetics' low risk compared to medical products; and we have serious concerns whether it accords unequal treatment to imports. First, we have significant concerns that the only means China provides importers to establish conformity with good manufacturing practices requires animal testing if their respective governments do not issue good manufacturing practice or manufacturing export certificates. We question China's rebuttal to the comments of several WTO Members that its requirements for imports and domestic products are equivalent. The United States reiterates its request that China consider the several less trade-disruptive means previously suggested for importers to demonstrate conformity to China's requirements. For instance, providing a means to establish conformity with ISO 22716, the ISO standard for cosmetics good manufacturing practice, would be a far more effective means of establishing companies' compliance with the elements of good manufacturing practice than animal testing. Second, we understand that the Good Manufacturing Practices for Cosmetics (GMP), a draft of which was notified as G/TBT/N/CHN/1626, was recently published as final in China. We ask China to confirm that for the purposes of overseas inspections, foreign manufacturers will be considered in conformity with Chinese GMP if their GMP practices are in conformity with international GMP standards.

2.231. Third, the United States remains concerned that CSAR and its implementing measures require overly extensive information to assess product and ingredient conformity to China's regulatory requirements. We are disappointed that China has not pared back these highly burdensome requirements. Fourth, we consider that China has failed to address concerns of the United States and cosmetics intellectual property rights holders, including the request that NMPA provide a legally enforceable mechanism to monitor and protect trade secrets and confidential business information (CBI) in cosmetics filings, as identified by companies, within China. Fifth, we are disappointed that China continues to frequently require duplicative in-country testing to assess product claims without considering internationally validated methods or data and testing from international labs accredited to Good Laboratory Practices or Good Clinical Practices. Allowing foreign laboratories with facilities in China to conduct this testing does not address this burdensome practice. Sixth, the United States remains concerned with the new cosmetics labelling requirements and requests additional clarification. While we appreciated China's clarification that only the contents of foreign product safety and efficacy claims must correspond with the Chinese label, we would greatly

appreciate if China would confirm that it will not require foreign labelling to exactly match the Chinese label. Our industry would also appreciate a means whereby US importers could engage with NMPA on questions arising from CSAR implementation, including regarding the new requirements and use of NMPA's new online platforms for product and ingredient filings. We request that China continue to consider how these trade concerns expressed by the United States and many other WTO members may be resolved in the implementation of CSAR, so as to support its successful implementation.

2.232. 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 10 September 2019, stipulates that microbiological, physical, chemical, toxicological, and human safety and efficacy evaluation tests relevant to cosmetics registration and filing must be conducted by the testing laboratories in China that obtained CMA (China Inspection Body and Laboratory Mandatory Approval). Japan understands foreign capital testing laboratories in China can obtain CMA. However, testing laboratories in foreign countries are not within the scope of CMA. Japan would like to request a more flexible framework in which test results obtained by foreign laboratories with the equivalent qualifications and abilities as those of Chinese testing laboratories are accepted. In addition, regarding test methods, the implementing regulations of the "Cosmetics Supervision and Administration Regulation" 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 understands the same restrictions and conditions are imposed regarding imported and domestic products. However, Japan would like to request that China accept internationally accepted methods such as alternative test methods established by the OECD, or the ISO so as not to be more restrictive than necessary in proving safety and efficacy.

2.233. 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 "Administrative Measures on Cosmetic Labelling", which was promulgated on 3 June 2021, Japan would like to express its following three concerns. 3. Article 5 stipulates that the content of the added Chinese labels, such as information regarding product safety and efficacy, must be consistent with the original labels. We are concerned that the fact that Chinese characters are also used in Japanese may cause problems. For example, under Japanese regulations, it is obligatory to attach a label to indicate that an ingredient has some effect but does not belong to the medicine category, but the Chinese character for "medicine" is used on the label. However, some things that do not belong to medicine contain a character which means medicine in the Chinese language, so it will be possibly regarded as "pharmaceutical products" and not compliant with Chinese regulations. Under old regulations, it was permitted to explain, in the Chinese label, that the Chinese character "guasidrug" in the original Japanese label does not mean it is a pharmaceutical product. Japan would like to ask for clarification that the same correspondence will be acceptable from now on. Due to the above, Japan would like to request that China assure that the labelling stipulated by the regulations of the country of origin does not have to match the content on the Chinese label, including the content related to product safety and efficacy.

2.234. 4. Regarding Article 6, Japan has concerns that multiple company names and addresses on the label may cause misunderstandings on the part of consumers 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 should indicate only 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. 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 all ingredients of 0.1% or less must be labelled separately under the title "other trace ingredients" and can be described in no particular order. Many cosmetic ingredients can perform their desired function even at 0.1% or less. 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. Moreover, the "Provisions for Cosmetics Registration" stipulate that overseas inspections are to be conducted in accordance with relevant regulations of overseas inspections.

2.235. Regarding "Interim Measures on the Administration of Overseas Inspections of Cosmetics", Japan would like to continue to express concerns on the following three points. 6. 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. 7. 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 of 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.

2.236. 8. 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 regulations being implemented. 9. 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 Filing 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 be formulated in a way that reflects international trends and comments from all stakeholders. 10. 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.

2.237. 11. 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 (freckleremoving/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. 12. 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. 13. Article 32 of "Standards of Information Filing for Toothpaste Notification (Draft for Comments)" stipulates that the abstract of an efficacy evaluation report must 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. 14. Article 36 of "Specifications for Cosmetics Registration and Filing" newly requires that registrants or filers retain samples of each batch of cosmetics produced for future inspection. It also stipulates that the number of retained samples must be able to meet the requirements for conducting registration and filing tests. In addition, article 31 of "Provisions for the Supervision and Administration of Cosmetics Production and Distribution" stipulates that cosmetics registrants or filers must retain samples and records of cosmetics shipped according to regulations. "Public notice related matters of Provisions for the Supervision and Administration of Cosmetics Production and Distribution" (No.140, 2021), which was promulgated on 26 November 2021, requires that, regarding products imported to China from overseas registrants or filers, domestic responsible persons retain samples of each batch of cosmetics. Registrants or filers are responsible for cosmetics. Japan would like to request that China accept that samples do not have to be always

retained in China if the testing system can work immediately when problems with imported cosmetics occur.

2.238. 15. "Administrative Measures on Cosmetic Labelling" stipulates that applications for registration or filing of products as of 1 May 2022 must be adapted to the regulations. It also stipulates that products for which application for registration or filing has occurred before 1 May 2022, must be adapted to the regulations by 1 May 2023. Registrants or filers need detailed rules and guidelines to adapt to the new cosmetic labelling system. Japan would like to request that China provide an adequate grace period of at least one year after promulgation of all relevant regulations. 16. Article 29 of "Specifications for Cosmetics Registration and Filing" requires "Cosmetic Ingredients Safety Information" issued by a cosmetic ingredient manufacturer and registrants or filers must combine information of the raw materials used in cosmetics with "Cosmetic Ingredients Safety Information". Therefore, when registrants or filers change a cosmetic ingredient manufacturer, it is necessary to submit the document again even if the comparability of quality and safety are confirmed by registrants or filers. This causes unnecessary burdens for registrants or filers. Registrants or filers carry out a safety evaluation of the final product based on the quality standard of materials set by themselves and submit the document at the time of registration or filing. It is an excessive requirement to require the submission of Cosmetic Ingredients Safety Information issued by cosmetic ingredient manufacturers. Therefore, in the same manner as international practice, Japan considers that the information of ingredients should be submitted when requested by the NMPA after launch, but not at the time of registration or filing. "Cosmetics Supervision and Administration Regulation" and "Provisions for Cosmetics Registration" require that relevant information on registration and notification management of cosmetics and new cosmetic ingredients be announced to the public. Japan appreciates that during the TBT official meeting in last November China stated that confidential company information will not be disclosed. Japan recognizes that purchasing information related to cosmetic ingredients which are contained in cosmetic formulations, such as the name of each ingredient and its suppliers, is confidential company information. Japan would like to request that China clarify that purchasing information related to cosmetic ingredients is protected as confidential company information and will not be announced to the public.

2.239. The representative of <u>New Zealand</u> provided the following statement. New Zealand acknowledges and supports measures that focus on legitimate objectives, including the protection of human health and safety and we support the concerns raised by Members in this Committee and we would encourage China to ensure that facilitation of trade is considered in the implementation of the regulatory system for cosmetics, and refers China to New Zealand's statement on this trade concern made at the November 2021 TBT Committee, in addition to those preceding it. We would welcome China's response to the concerns raised by New Zealand and other Members in this and other fora.

2.240. The representative of the <u>European Union</u> provided the following statement. The EU would like to support the delegations of Australia, the United States, Korea, Japan, and New Zealand. The EU would like to refer to its earlier statements on this topic, in particular to the statement delivered in the June TBT Committee, as the EU's concerns outlined therein remain unchanged. The main aim of the CSAR is to ensure consumer safety. The European Union supports this objective, however there is an important concern pertaining to the obligation to transmit confidential information on new products and their ingredients to the Chinese authorities. The mandatory disclosure of commercially sensitive information required in the notification and registration process, touching on intellectual property rights (IPR) of companies involved, remains EU's biggest concern. The EU believes that CSAR's requirements go beyond what is necessary to ensure consumer safety and traceability of the ingredients used in cosmetics. It is also diverging from international practice, as such extensive level of information is not required elsewhere in the world for notification and registration purposes.

2.241. Other important concerns of the EU are the following. *Registration of products*: Companies must submit a complete list of raw materials used in the finished product. Supplier of raw materials must submit detailed information on the raw material, including the production process. *Notification for new ingredients*: There are concerns over the amount of information required under the new notification system and potential issues over the disclosure of such information after a certain period. *Efficacy claims*: manufacturers are required to make public a detailed summary of efficacy evaluation, which can reveal business-sensitive information. For certain efficacy claims (sunscreen, skin whitening/spot removal, and anti-hair loss), it is mandatory to use specified Chinese test methods. Such tests must be carried out by specific testing institutions in China. For new efficacies,

if methods are not yet established in China, they must be validated in at least two qualified testing institutions in China to be used to support an efficacy claim in China. Extrapolation of test results between very similar formulations is only allowed under exceptional circumstances (i.e. for colour ranges of a decorative cosmetic, the efficacy test must only be carried out for every one out of five shades). The multiple China-specific requirements for efficacy testing will require significant retesting of products for which the efficacy was already established in a third country. This affects also many thousands of products that already have been placed on the market in China and for which the claim substantiation needed to be completed until May 2022. Significantly, more transition time needs to be given for products already placed on the market prior to May 2022, to allow generating the new required information.

2.242. In response, the representative of <u>China</u> provided the following statement. 1. Safety-related information requirement is a common practices of Members for safety review of health-related products. The required information such as the brief description of production process, production process of raw materials are not subject to government information disclosure. According to the Regulations on the Disclosure of Government Information, authorities are prohibited from disclosing information involving trade secrets and personal privacy, the publication of which 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 business secrets. Cosmetics related regulations also require regulators to protect trade secrets both in the process of reviewing and that of publishing supervision related information. Authorities are not allowed to release trade secret, undisclosed information, only a summary, not the full text of its supporting material is required. The required technical materials of new raw materials only cover the basic aspects, rather than the complete information. The authorities will also strictly protect trade secrets in handling cosmetics registration.

2.243. 2.Regarding the labelling problem. As a matter of fact, the Administrative Measures for Cosmetic Labelling does not require that all contents of the Chinese label and original label should correspond to each other, only requiring that the contents about product safety and efficacy claims indicated in the Chinese label should correspond to those of the original label. The declared efficacy of products is closely related to the efficacy of cosmetic ingredients. In order to prevent the practice of "conceptual addition", which is common in the industry, the Measures for the Administration of Cosmetics Labels stipulates that ingredients with weight percentage not exceeding 0.1% (w/w) should be labelled with "other trace ingredients". They are of very low amount but still have certain effects. They can be declared in the product label upon fulfilling the relevant requirements for efficacy claims. As for the issue of manufacturer location, it is important that relevant information is made known. The cosmetics supervision and administration Regulation clearly stipulates that applicants are responsible for the quality and safety of cosmetics. Measures for the Administration of Cosmetics Labels also require that the corresponding indicating language should be used to mark enterprise information, which would not lead to consumer confusions.

2.244. 3. The Chinese cosmetics inspection method is scientifically verified and internationally used. Inspection method is constantly improved for updated versions. Toxicological safety evaluation is an important means to examine the safety of new raw materials, necessary for protecting the legitimate rights and interests of consumers, to ensure the quality and safety of products. China does not require toxicological safety assessment to be carried out only through animal tests. Alternative methods are also allowed. 4. Requirement for inspection reports issued by accredited inspection institutions is in line with the protection of the legitimate rights and interests of the consumers. Cosmetics used for whitening, sun protection and hair loss prevention are classified as special cosmetics in China. The efficacy evaluation report of such products should be submitted at the time of product registration. Therefore, efficacy evaluation test should be CMA accredited. Inspection institutions could be foreign funded ones. At present, many laboratories of foreign inspection institutions in China have obtained the CMA certification of cosmetics.

2.245. 5. 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 ordinary cosmetics regarding alternative programme of animal test for safety evaluation. For both domestic and imported ordinary cosmetics, toxicological test can be replaced with safety risk assessment once they have obtained quality management system certification issued by

government authorities. For children's cosmetics, at present, as the skin structure and immune system function of growing infants and children are not perfect, safety assessment only may leave some unknown risks. Moreover, safety assessment data available are mainly about ordinary cosmetics. Data about children's cosmetics is scarce. Therefore, China believes that children's cosmetics should be evaluated for product safety through both safety assessment and necessary toxicological tests. 6. The basic principles and requirements in "Good Practice for the Production quality Management of Cosmetics" are consistent with ISO 22716 and internationally adopted requirements, aiming to standardize the production quality management of cosmetics in China, and to ensure the cosmetics safety.

2.1.3.22 Kingdom of Saudi Arabia - Technical Regulation for limiting and restricting hazardous materials in electrical and electronic equipment, <u>G/TBT/N/SAU/1166</u> (ID 666⁶⁷)

2.246. The representative of the United Kingdom provided the following statement. The United Kingdom thanks Saudi Arabia for its continued engagement on notification G/TBT/N/SAU/1166, which sets out their technical requirements for the restriction of hazardous substances in electrical and electronic equipment. We would first like to reiterate our previous encouragement to Saudi Arabia to accept self-declaration as a means of demonstrating product conformity and we refer to our previous November 2021 statement on this. The United Kingdom thanks Saudi Arabia for submitting an addendum notification to the TBT Committee on 10 February 2022 with guidelines and information about new phased implementation dates. We also thank Saudi Arabia for delaying the earliest implementation date to 4 July 2022 and appreciate the guidelines that have been developed to support industry in complying with the measure. It is our understanding that products already present and due to be placed on the market will be able to circulate until 31 December 2023; can Saudi Arabia please confirm if this is correct? And, if so, what measures will Saudi Arabia be taking to implement and monitor compliance with this measure? UK industry have requested clarity on how Saudi Arabia intends to distinguish between products placed on the market before and after the new rules enter into force. We would encourage Saudi Arabia to consider allowing products placed on the market before 31 December 2023 to sell out. The United Kingdom appreciates the constructive engagement to date and we look forward to our continued productive interaction with Saudi Arabia on this matter.

2.247. The representative of the European Union provided the following statement. The EU thanks Saudi Arabia for the bilateral meeting and the information provided therein. The European Union would like to reiterate its concerns regarding the draft Technical Regulations for Restriction of Hazardous Substances ("RoHS Regulations"), notified by Saudi Arabia on 1 December 2020 and adopted in July 2021. The EU would like to refer for details to its comments of November 2021 and to the minutes of the previous TBT Committees. In particular, the EU would like to repeat the invitation to Saudi Arabia to reconsider the requirement of third-party conformity certification, which deviates from common international practice that relies on first-party declaration of conformity. The EU would like to thank Saudi Arabia for the recent confirmation via Addendum (G/TBT/N/SAU/1166/ Add.1), that the application of the RoHS Regulation is postponed by six months (to 5 July 2022) and for the new phased implementation dates for product categories. The EU stresses the importance of granting sufficiently long transition periods, which would ensure a smooth implementation and adaptation for economic operators. The EU appreciates the information on the recently issued guidance to industry, which will have to be examined. We would be grateful if Saudi Arabia could provide the link to or a copy of the guidelines. The EU welcomes the confirmation that conformity assessment bodies not established in Saudi Arabia can be approved by SASO to issue certificates under the RoHS regulation. Any further information on the conditions for this approval would be appreciated.

2.248. The EU highlights the importance of promoting GCC harmonised requirements and their uniform application, as well as the mutual recognition of conformity assessment results in the region, instead of the proliferation of separated national RoHS regulations. The EU kindly invites Saudi Arabia to keep us informed on the timeframe for the adoption procedure of the draft GCC Technical Regulations for the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment, notified to the TBT Committee in March 2018 (<u>G/TBT/N/SAU/1048</u>). The European Union

⁶⁷ For previous statements follow the thread under <u>ID 666</u>.

welcomes any workshop or information session with stakeholders and remains available to further discuss this issue with Saudi Arabia bilaterally.

2.249. The representative of the <u>United States</u> provided the following statement. The United States thanks Saudi Arabia for extending the implementation date for its "Technical Regulation for the Restrictions of Hazardous Substances (RoHS)" by six months, from 5 January 2022 to 4 July 2022, along with a staged implementation based on product category. Further, while we appreciate SASO's willingness to engage with us and other stakeholders regarding this regulation to date, as well as for extending the implementation date, there remains a great deal of confusion on several details associated with the measure. We note that SASO recently provided an official guidance document to clarify the compliance process, which has been a major source of confusion for industry. We are still in the process of reviewing that document and look forward to continuing discussions with Saudi Arabia on any necessary clarifications, for instance does the list of HS codes split up by category in the guidance supersede the list in the legislation, as there are differences. We would also like to highlight that industry also recently raised concerns that it will be required, as part of the requirements for demonstrating compliance, to provide drawings and confidential and proprietary data concerning their products, which are considered among their valuable intellectual property. In fact, in light of the list of intellectual property assets in Annex 3, 2/1(E) which must apparently be disclosed, some US companies are now weighing whether they will continue to sell products in Saudi Arabia or abandon the market entirely. We would appreciate SASO's guidance on this point, and specifically how it intends to ensure that information requirements are limited to only what is necessary to assess conformity, and that any confidential information submitted will be protected from unauthorized disclosure.

2.250. Further, there remain a number of areas on which we have yet to receive clarification from Saudi Arabia. First, we request that Saudi Arabia provide guidance regarding this measure, and outline plans for engagement with trading partners and private sector stakeholders to ensure such guidance is as clear as possible for those who must comply with and enforce the rules, possibly in the form of frequently asked questions (FAQ), as has been done with other WTO Members' RoHS regimes. We also request that Saudi Arabia provide outreach to industry and the conformity assessment bodies to address further questions on the process. Second, we have continued to urge Saudi Arabia to provide clarification of the precise scope of the regulation. The newly released guidance document lists HS codes in the six categories of goods. Can SASO confirm that this list is comprehensive and only those HS codes listed in the guidance document are subject to the conformity assessment requirement? The list of HS codes in the guidelines appears to include categories not listed in the published regulation and some HS codes in the regulation are not included in the guidelines. Please advise which document's list of HS codes should be followed relative to scope of this measure. For example, some of the HS codes in the annex cover products, such as batteries and semiconductors and other electronic component parts that are outside of the scope of categories covered by the final regulation. Further, the definition of hazardous substances refers to radioactive substances, yet none of the regulated substances are radioactive. Can you please clarify the definition of a hazardous substance (vs. radioactive)? Also, there are missing exemptions for certain necessary uses of the regulated substances for products in the monitoring and controlling equipment category. Can you also please clarify when this information will be provided?

2.251. Third, we request further guidance on the process for testing whole equipment and/or critical components of a product. We understand that typically other WTO Members have not asked industry to provide test reports on critical components as such testing requires dismantling the product and destroying its parts. Saudi Arabia's proposed approach, which results in added costs and delays in getting products to market, may be stricter than is necessary to give Saudi Arabia adequate confidence of product conformity. We request that Saudi Arabia provide a process for manufacturers to meet the RoHS requirements without providing test reports for critical components. Fourth, we request that the requirement for suppliers to attach the entire technical file of supporting documentation proving compliance to their products, be modified to instead require a copy of the certificate of conformity from the conformity assessment body, as consumers will not be able to discern compliance from a technical file, and the technical file likely would contain proprietary business information. The United States looks forward to continuing a dialogue with Saudi Arabia, and to providing additional information where needed to address those areas that require further guidance to minimize the trade restrictive impact on industry.

2.252. The representative of <u>Switzerland</u> 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. We reiterate our concerns from previous meetings of the WTO TBT Committee and remain concerned that these requirements may have a negative impact on trade for a wide range of products. We understand the Kingdom of Saudi Arabia's legitimate objective to protect the environment and public health and safety. However, these requirements seem to create unnecessary obstacles to trade: the testing and certification requirements deviate from common international practices which include supplier's declaration of conformity and technical documentations aligned to the appropriate relevant international standard. Furthermore, the implementation of the requirements leads to uncertainties for manufacturers and conformity assessment bodies, such as regarding the scope or the process for testing the products or critical components. We encourage the Kingdom of Saudi Arabia to consider less trade-restrictive alternatives and take international best practices into account. Finally, we encourage the Kingdom of Saudi Arabia to implement clear and transparent guidelines in order to support the implementation of these requirements.

2.253. In response, the representative of the <u>Kingdom of Saudi Arabia</u> provided the following statement. We will reply by uploading our answers in eAgenda by Friday. A technical statement was circulated following the meeting.⁶⁸

2.1.3.23 Indonesia - Government Regulation 28 of 2021 – Implementing Regulation (for the Manufacturing/Industry Sector) to Law No. 11 of 2020 the "Job Creation Act" (ID 724⁶⁹)

2.254. The representative of the European Union provided the following statement. The European Union is concerned by Regulation No. 28 of 2021 and new requirements for Indonesian National Standard (SNI) certification. In February 2021, the Government of Indonesia issued a Government Regulation No. 28/2021. This Regulation is one of the implementing regulations of the Omnibus Law on Job Creation (Law 11/2020) passed last year. Government Regulation 28/2021 aims to increase the competitiveness of Indonesia's national industry and mainly outlines measure related to raw materials. It also introduces new requirements with regard to product certification bodies (Lspros). We understand that the new requirements affect in principle all products subject to SNI certification and it is still very complex to export to Indonesia. Certain sectors appear to be particularly concerned. With regard to the toys sector, articles 38 and 39 create significant challenges. Article 38 prohibits Lspros from using third-party testing facilities. Article 39 stipulates that product certification bodies (Lspros) be Indonesian entities, employ Indonesian citizens, residents of Indonesia to assess product compliance to Indonesian National Standards. Regulatory bodies are now giving this article an overly strict literal interpretation as requiring that every step of the SNI certification be conducted by Indonesian nationals residing in Indonesia, etc. We understand this is both required for scheme 1 (batch testing and pre-shipment inspection) and scheme 5 (factory certification).

2.255. This new approach appears to be implemented despite of no ministerial implementing regulation, which is normally required in the Indonesian regulatory process to implement a Government Regulation. In terms of impact, this means that for batch testing and pre-shipment inspection, samples need to be taken by a Lspro employee/Indonesian resident. Due to COVID-19 restrictions, it was and it is still very difficult for Lspros to send personnel overseas to sample products or to conduct factory audits. As a result, all Lspros have either stopped overseas sampling or stopped overseas certification altogether. In addition, even when international travel would be easier, the new requirements will still add significant costs and delays. The tire industry is also facing major problems. According to our information Indonesia is applying a mandatory certification system for certain spare parts (original and non-original) including tires, safety glazing, rims, primary-batteries and audio/video-components. This implies the audit of the plant where the spare parts are produced (in accordance with ISO 9001) as well as an analysis of the products conducted by Indonesian test institute. This is followed by scheduled conformity of production audits.

2.256. Currently the Indonesian test institute has suspended both the audit of the plants for new certifications, as well as the conformity assessment inspections. The result is that products requiring a new certifications cannot be imported into Indonesia, and those products which already have a certification will be also banned from Indonesia when their respective certifications expire. The European Union would like to understand what measures Indonesia is putting in place to ensure that

⁶⁸ <u>G/TBT/W/768</u>.

⁶⁹ For previous statements follow the thread under <u>ID 724</u>.

EU spare parts can be smoothly imported into Indonesia. In addition, we would like to stress that EU products certified in accordance with United Nations (UN) regulations under the 1958 Agreement have similar or higher levels of road safety and environmental protection performance than those certified in accordance with the Indonesian regulations. Therefore, the European Union would like to invite Indonesia to accept the EU spare parts bearing a UN marking or being accompanied by an UN certificate. The European Union would also like to propose extending the validity of issued Indonesian certificates until Indonesia can resume the conformity of production activities. In addition, Indonesia is encouraged to consider allowing the import of EU original parts, given that original parts have already proven their performance on vehicles in use in Indonesia. The EU notes that the nonimplementation of the recommendations above could result in the exclusion from the Indonesian market of products that are perfectly safe and exceed the Indonesian requirements as regards the safety. Finally, we would like to highlight that new SNI requirements have negative impact also on EU machinery industry. The European Union invites Indonesia to notify to the WTO the implementing regulation to GR 28/2021 before going ahead with its implementation; and to provide adequate time for consultation with the industry considering the sweeping changes at issue. We remain available to discuss the issue also bilaterally.

2.257. The representative of the United States provided the following statement. The United States continues to have concerns, as noted at the last meeting, with the Government of Indonesia Regulation No. 28 of 2021, which is the Implementing Regulation (for the Manufacturing/Industry Sector) to Law No. 11 of 2020 of the "Job Creation Act" (GR28/2021). We again ask that Indonesia suspend implementation of the measure, notify the measure to this Committee, provide a 60-day comment period for stakeholders, and take those comments into consideration before reissuing the measure. We understand that in November of 2021, Indonesia's Constitutional Court ruled the Job Creation Act conditionally unconstitutional and set a two-year period for replacement legislation to be passed. With the implementation of the Job Creation Act apparently on hold, could Indonesia please clarify what impact this will have on the issuance and implementation of Ministry of Industry (MOI) implementing regulations for GR28/2021? We request that Indonesia notify the MOI implementing regulations to this Committee in draft form to allow for stakeholder comment and consideration of those comments prior to finalization. Based on reports from industry, and our review of an unofficial translation of the measure, the regulation appears to mandate conformity assessment bodies use Indonesian citizens domiciled in Indonesia for all conformity assessment. This requirement would effectively negate use of overseas inspection or testing bodies. We again ask Indonesia for a justification for including nationality and domicile as a requirement for product conformity testing. How do these requirements impact the ability to perform conformity assessment?

2.258. Many industries obtain Indonesian national standards (SNI) certification by submitting product sampling for each shipment. At our last meeting, Indonesia confirmed that onsite inspections and sampling can continue only as long as Indonesian nationals are allowed to travel to conduct them. With widespread pandemic-related travel restrictions still impacting much of the world, how does Indonesia envision companies can comply with these requirements? As Indonesia is not allowing for remote factory inspections, companies that rely on factory inspections to obtain SNI certification will be impacted if they have to rely on per-shipment testing. We are concerned that requiring collection of product samples conducted by Indonesian nationals domiciled in Indonesia will effectively halt imports, and already appears to be doing so. The United States observes that similar concerns were actually shared by the Indonesian delegate noted at the November TBT Committee meeting, on an STC related to India's automotive imports (IMS 649): "Indonesia remains concerned that the conformity assessment procedure as required in the document is more restrictive than necessary. The procedure includes 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 visit impossible due to the travel ban and social distancing policy. Therefore, Indonesia urges India to consider the use of remote assessment in conducting factory inspection or any relaxation policy as a mean to facilitate trade and minimize technical barrier to trade, particularly in this difficult time."

2.259. Likewise, with respect to GR28/2021, we regret that Indonesia has not taken into account the current pandemic situation that has made factory visits impossible. Therefore, the United States urges Indonesia to consider resuming the use of remote assessment in conducting factory inspection or any other relaxation of policy as a means to facilitate trade, particularly in this difficult time. We again seek clarification on whether Article 38 requires that conformity assessment bodies must also operate their own testing laboratories for all products required to be certified to SNIs. Industry stakeholders have reported that, in the absence of implementing regulations from the MOI, many

conformity assessment bodies have halted certification for foreign products, resulting in the halt of exports requiring SNI testing per shipment. As companies' SNI certifications based on factory inspection expire, those exports also will be halted because there currently is no means for foreign manufacturers to meet either requirement - factory inspections or per-shipment product sampling. We again urge Indonesia to immediately communicate to Indonesian conformity assessment bodies that certification of foreign product shipments can, and should, continue while MOI prepares the implementing regulations.

2.260. In response, the representative of <u>Indonesia</u> provided the following statement. Indonesia would like to refer to its last statement in TBT November 2021 meeting that all certification process for technical regulations based on SNI in the industrial sector is carried out in accordance with the provisions stated on the related Minister Regulation. All provisions apply equally for both domestic and foreign manufacturers. SNI certifications are conducted through factory inspection and sample are taken on-site by authorized personnel. Indonesia accepts testing result from accredited foreign testing laboratories under the mutual recognition arrangement framework and availability of technical regulation agreement between Indonesia and its country partner.

2.1.3.24 India - Pneumatic tyres and tubes for automotive vehicles, <u>G/TBT/N/IND/20</u>, <u>G/TBT/N/IND/20/Add.1</u>, <u>G/TBT/N/IND/40</u>, <u>G/TBT/N/IND/40/Rev.1</u> (ID 133⁷⁰)

2.261. The representative of <u>Indonesia</u> provided the following statement. The Indonesian Government is extending our gratitude to the Indian Government for holding several bilateral meetings with Indonesia in order to overcome the problems that occur in tyre products from Indonesia, both on the sidelines of the TBT Committee meeting and in the Working Group on Trade and Investment (WGTI) meeting. However, Indonesia regrets that by this time, we have not received an appropriate response and solution to this problem. Indonesia is aware that India has imposed import restrictions on tyre products with certain types and size categories that can be produced by tire manufacturers in India. The policy was implemented shortly after India imposed a temporary import ban on tyre products to India for a period of 6 months as stated in notification no. 12/2015-2020 dated 12 June 2020 regarding Changes in Tyre Import Policy. The implementation of this policy has hampered tyre exports to India, considering that the choice of tyre products that can be exported is highly limited and even has the potential to eliminate market access for imported tyres considering the various types and sizes of tyres produced by India as one of the world's main producers.

2.262. Although there are no official provisions governing the restrictions on the import of tyres, importers are required to make separate statements via electronic mail regarding import restrictions for certain types and size categories which have de facto hampered the export of type products from Indonesia. In addition, Indonesia suspects that there is discriminatory treatment in implementing the said policy, where the policy is applied selectively by targeting certain Member states that have the potential to become competitors and disrupt market access for domestic tyre products. In addition, we also intend to ask for further clarification regarding the application of a royalty policy or a marking fee on tyre products that use the IS Mark. Indonesia perceives that the imposition of the IS Mark marking fee on tyre products to be exported to third countries has the potential to burden businesses and create unnecessary trade barriers to international trade. The imposition of such marking fees has no legal justification and has no relation to the protection of human health, safety or prevention of fraudulent practices. Indonesia views that the implementation of these two policies is not in line with the principle of non-discrimination and has the potential to create unnecessary barriers to international trade as stipulated in Article 2.1 and Article 2.2 of the TBT Agreement. Aligned with this, Indonesia hopes that India may provide further clarification on these two issues and asks India to review the policy to ensure its conformity with the applicable provisions of the WTO TBT Agreement.

2.263. In response, the representative of <u>India</u> provided the following statement. The conformity assessment activities of BIS with respect to product certification are as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. As informed earlier on the same concern, the marking fee is uniformly applicable to all manufacturers, domestic or foreign as per the provisions of this scheme. The marking fee is charged for covering the cost applicable to BIS in carrying out the conformity assessment-related works, which includes administrative overheads, cost of surveillance

 $^{^{\}rm 70}$ For previous statements follow the thread under $\underline{\rm ID~133}.$

including the purchase of market samples and testing charges of the samples drawn from the factory/market.

2.1.3.25 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, <u>G/TBT/N/EEC/264</u>, <u>G/TBT/N/EEC/264/Add.1</u>, <u>G/TBT/N/EU/44</u>, <u>G/TBT/N/EU/571</u> (ID 345⁷¹)

2.264. The representative of the United States provided the following statement. It is incredibly 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 which were submitted to the EU well over 11 years ago. The EU has failed to provide sufficient transparency about this process and has hindered market access for our exporters for over a decade. 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. For the past three years of TBT Committee meetings, the United States has asked the EU to tell us where it is in the process of reviewing the applications. We ask again: Are the applications being actively considered, or have they been put on hold? What is the timeline and process for review? Also, at the last six TBT Committee meetings, we have asked for transparency about the status of other applications so that we can see how our applications compare. We ask again: 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? For pending application, how many of the applications have come from member States? How has the processing of these applications changed, if at all, over the last three years following the adoption of Implementing Regulation 2019/34? Does the EU intend to answer these questions which have been posed repeatedly since November 2019?

2.265. We also have additional questions that have gone unanswered including the following: Could the EU confirm that US producers can continue to use any generic term, such as a grape variety, that is part of a compound term protected as a GI by the EU? For example, could US producers still use the grape variety "Dolcetto," even though the EU protects the compound name "Dolcetto d'Alba?" How do third countries find out about amended changes with respect to EU Protected Designations of Origin (PDO) and Protected Geographical Indications? What is the definition of "generic?" Lastly, will the revised regulation 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.

2.266. The representative of <u>New Zealand</u> provided the following statement. We refer the European Union to New Zealand's statement on this trade concern made at the November 2021 TBT Committee, and those preceding it. We will upload our full statement on eAgenda. A technical statement was circulated following the meeting.⁷²

2.267. In response, the representative of the <u>European Union</u> provided the following statement. The EU understands the continued interest of the United States and New Zealand 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.

 $^{^{71}}$ For previous statements follow the thread under <u>ID 345</u>.

⁷² <u>G/TBT/W/770</u>.

2.1.3.26 China - Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council), <u>G/TBT/N/CHN/1022</u>, <u>G/TBT/N/CHN/1024</u>, <u>G/TBT/N/CHN/1025</u>, <u>G/TBT/N/CHN/1026</u>, <u>G/TBT/N/CHN/1029</u>, <u>G/TBT/N/CHN/1313</u> (ID 428⁷³)

2.268. The representative of the <u>Republic of Korea</u> provided the following statement. The Republic of Korea would like to appreciate China's kind explanations on the revised Regulations for the Supervision and Administration of Medical Devices given in the last TBT Committee meetings of June and November 2021. At the last TBT Committee meetings in June and November 2021, China explained as follows: "The new revision [...] has been released, and took effect on 1 June 2021. The new regulation reasonably sets clinical evaluation requirements, simplifies the review procedures, and further encourages the innovation. Meanwhile, the regulation fully implements the system of registrant, strengthens the responsibility of enterprises and supervision over the whole process of medical devices." Korea fully understands China's explanations and the objective of the revision. However, what Korea requested was clarification on the unclear definition or scope of "qualified testing laboratories" stated in the revised Regulations. Accordingly, Korea would like to once again request China to provide a response on whether internationally accredited test laboratories are included in China's definition of qualified testing laboratories, and further request China to include internationally accredited labs or overseas labs in its definition of qualified laboratories. At the last TBT Committee meeting in June 2021, China responded operational rules including the requested clarifications are being drafted. However, Korea has yet to receive further update from China, and thus requests China to share the current progress of the development of the rules.

2.269. In response, the representative of <u>China</u> provided the following statement. The newly revised Regulations on the Supervision and Administration of Medical Devices came into effect on 1 June 2021. According to article 75 of the Regulations, only the inspection institutions recognized by the certification, accreditation and drug authorities can carry out the inspection of medical devices.

2.1.3.27 China - Registration Fees for Drugs and Medical Device Products (ID 466⁷⁴)

2.270. The representative of the <u>Republic of Korea</u> provided the following statement. As in the previous TBT Committee meetings, the Republic of Korea would like to raise this STC regarding China's Registration Fees for Drugs and Medical Device Products. In the last meetings, Korea repeated its concerns over the difference of registration fees between imported and domestic products. In response, China answered that its registration fees are lower than the global average and there can be minor differences. Korea however would like to reiterate that Korea's concern is about the significant discrepancy in fees, not the higher registration fee, in particular, for imported medical devices. As for Class III medical devices, the fee for imported medical devices is double that of domestic ones. We believe this is not a minor difference even if we take China's rationale from the last meeting into consideration, which is the different cost of the conformity assessment or workload. Moreover, China responded its registration fee is in compliance with common international practices. However, countries such as Korea, the United States of America, Canada, and Australia impose the same amount of registration fees on both domestic and foreign manufacturers. Korea

2.271. In response, the representative of <u>China</u> provided the following statement. First I would like to refer to our previous response to Korea's questions in previous meetings. At present, the pricing authorities are investigating and evaluating the implementation of the registration fee policies and standards for drugs and medical devices, according to the Administrative Measures for Drug and Medical Device Registration Fee Standards, with the support of the National Medical Products Administration.

2.1.3.28 Indonesia - Halal Product Assurance Law No. 33 of 2014 and its implementing regulations, <u>G/TBT/N/IDN/123</u>, <u>G/TBT/N/IDN/131</u>, <u>G/TBT/N/IDN/131/Add.1</u>, <u>G/TBT/N/IDN/134</u>, <u>G/TBT/N/IDN/139</u>, <u>G/TBT/N/IDN/140</u> (ID 502⁷⁵)

2.272. The representative of the <u>European Union</u> provided the following statement. The EU thanks Indonesia for the informative session of 7 March 2022 on the implementation of Halal assurance in

 $^{^{73}}$ For previous statements follow the thread under <u>ID 428</u>.

⁷⁴ For previous statements follow the thread under <u>ID 466</u>.

 $^{^{75}}$ For previous statements follow the thread under $\underline{ID\ 502}.$

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Indonesia. 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 WTO TBT Agreement, Indonesia failed to notify to the TBT Committee the Halal Product Guarantee Law. As regards recent implementing provisions, the EU regrets that, on 6 January 2022, Indonesia adopted Regulation N° 2/2022 on International Cooperation on Halal product assurance (G/TBT/N/IDN/139) before the expiration of the 60-day commenting period at the TBT Committee. In a similar way, the EU stresses that Indonesia adopted Decree 1360/2021 on materials excluded from the Halal certification obligation (G/TBT/N/IDN/140) on 27 December 2021, even before notification to the TBT Committee on 6 January 2022, without respecting the period for comments. The EU encourages Indonesia to notify any relevant technical measures when still in draft form and to provide sufficient time for comments to be taken into account, as provided in Article 2.9.4 the WTO TBT Agreement. In addition, Members are required, in accordance to Article 2.12 of the TBT Agreement, to allow a reasonable interval of no less than six months between the publication of the measure and its entry into force, except if this would be ineffective for fulfilling the legitimate objectives pursued.

2.273. The EU kindly invites Indonesia to provide a written reply to its comments of 12 May 2020 on Regulation 31/2018 on Processed Food Labelling (G/TBT/N/IDN/124). The EU thanks Indonesia for the consolidated written reply of 7 March 2022 covering several Members' comments on the following measures: (i) draft Government Regulation (RPP) 39/2021 on Halal Product Assurance implementing the Omnibus Bill on Job Creation (G/TBT/N/IDN/131); (ii) draft Decree regarding types of products and consumer goods to be Halal-certified (G/TBT/N/IDN/134); (iii) Regulation on Halal fees (G/TBT/N/IDN/138); (iv) draft Regulation on international cooperation on Halal product assurance (G/TBT/N/IDN/139) and, (v) draft Decree on the materials excluded from the Halal certification obligation. The replies are under examination by the EU. The EU stresses the excessive restrictive impact on trade of the adopted Halal law and implementing provisions and invites Indonesia to consider less restrictive alternatives to the current, wide-ranging mandatory Halal certification and labelling, in order to pursue the legitimate objective of ensuring reliable information for consumers without unduly hindering trade flows. Among the main issues of concern for the EU in the Halal Law and implementing measures are 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, the pre-condition of a specific government-to-government mutual recognition arrangement for recognition by Indonesia of foreign Halal certification bodies and certificates would appear unduly complex, represent an excessive burden for economic operators and not allow for smooth trade relations. The EU looks forward to exploring more feasible and agile options. Clarification on transitional provisions for existing certificates would also be welcomed.

2.274. The exclusion of end-products from the coverage of foreign certification and the additional registration requirement for Halal certifications of certain products by foreign bodies also appears to be unjustified, costly and duplicative. In addition, the EU is concerned about the possibility of imposing much higher Halal certification fees for goods and services from foreign business. The EU would also appreciate further clarifications on the criteria used for the list of materials excluded from the Halal certification obligation and the procedure to review the list. The EU stresses the importance of ensuring the continued possibility to place non-Halal products on the Indonesian market and urges Indonesia to review the Halal measures in order to adopt a more trade-friendly approach. Notably, the EU firmly calls upon Indonesia to: limit Halal requirements to food and beverages; avoid the excessively burdensome requirement for mandatory "non-Halal" information as regards non-Halal products; and clarify its approach to international cooperation on Halal and provide for a flexible and pragmatic process for the recognition of foreign Halal certification bodies and acceptance of foreign certificates, building on existing bilateral cooperation and working arrangements on Halal certification. 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.

2.275. The representative of the <u>United States</u> provided the following statement. We note that Indonesia held a video conference earlier this week with BPJPH, and while we appreciated the information, we would have appreciated an opportunity to ask questions to clarify the responses and to discuss our individual concerns with each of the relevant notifications. As our questions were not answered, we again urge Indonesia to continue bilateral engagement with other WTO Members and

industry stakeholders, and we hope to continue these discussions in the days to come. The United States acknowledges 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 since 2015 to ensure that objective is achieved in a way that is consistent with Indonesia's WTO obligations. We refer Indonesia to our previous statement from November's TBT Committee, submitted as Working Document 761, <u>G/TBT/W/761</u>. We hope to receive a response to our many unanswered questions and as such, have not repeated all of them here. Our comments on Indonesia's Notifications on Halal Product Assurance Law No. 33 of 2014 and its implementing measures, including Government Regulation No. 39/2021, are as follows.

2.276. Transparency: We respectfully remind Indonesia of the obligation to notify draft measures to the Committee before they take effect, allow a reasonable time for stakeholder comments, and take such comments into account before draft measures are adopted and implemented. We continue to see a pattern with regard to halal decrees and regulations, whereby measures are finalized without an opportunity for stakeholder comment. For example, we note that while the regulation in G/TBT/N/IDN/139 was notified on 1 December 2021 with a deadline to receive comments on 30 January 2022, the measure was signed into law as Ministry of Religious Affairs Regulation 2 of 2022 on 6 January 2022. Additionally, we have learned that the regulation notified as G/TBT/N/IDN/140 was signed into law on 27 December 2021, as Ministry of Religious Affairs Decree 1360 of 2021, before it was notified to this Committee as a draft on 6 January 2022. By finalizing these regulations before the end of the comment period, or prior to notification, and before stakeholder comments could be received or taken into account, Indonesia has again missed the opportunity to receive valuable feedback from stakeholders on their concerns regarding the measures' impact on trade. We further note that two additional implementing measures of the Halal Law and Government Regulation 39 of 2021 (GR39/2021) that been signed into law without being notified, namely: BPJPH Decree 57 of 2021, which appears to be the ministerial implementing regulation for the Halal Law; and BPJPH Regulation 141 of 2021, which is a fee structure for Halal certification and accreditation. We ask that Indonesia honour its transparency obligations by notifying these measures to the Committee as soon as possible and halting their implementation until stakeholder comments can be taken into account.

2.277. *Government to government MOU*: With regard to Indonesia's most recent notification, <u>G/TBT/N/IDN/139</u>, regarding international halal cooperation, the draft decree, unfortunately, has not provided clarity about the nature or need for a government-to-government MOU. In the US market, the United States Government does not accredit halal certifiers or certify products as halal, but instead halal inspection and certification are carried out by private, US-based, halal certification bodies for both the domestic and export markets. Exporters rely on these US-based halal certifying bodies to certify that all exports conform with Indonesia's halal requirements. The system has functioned this way for decades without issue and we have still not received a justification for why that system should not continue. Under this previous system, US-based halal certification bodies applied for recognition directly with the Government of Indonesia. The <u>G/TBT/N/IDN/139</u> draft Decree appears to contain provisions for overseas non-government certification bodies to enter into a recognition agreement with BPJPH. We ask that Indonesia allow the five US-based halal certifiers to continue to apply for recognition directly without the requirement of a government-to-government MOU.

2.278. Additional requirements: We also understand that with regard to additional requirements, Indonesia's Constitutional Court has recently ruled the Omnibus Job Creation Law conditionally unconstitutional and set a two-year period for replacement legislation to be passed. Can Indonesia please explain how this court ruling will affect the implementation of the Halal Law? We also request that Indonesia elaborate on how GR39/2021 and its related implementing regulations supersede previously instituted measures. For example, MUI maintains a list of ingredients that are deemed to be non-critical to halal product certification, while MORA has notified a separate list of such ingredients in the MORA Draft Decree of the Minister of Religious Affairs Regarding Materials That Excluded From Halal Certification Obligation (<u>G/TBT/N/IDN/140</u>). We urge BPJPH to work with MUI and other relevant government agencies, such as BPOM for cosmetic and food ingredients, to ensure that these lists do not conflict with one another and that manufacturers can easily determine which ingredients are deemed non-critical. We also ask that Indonesia develop a transparent and timely process for industry to petition for the addition of new non-critical ingredients, as such a process could be used to avoid the creation of unnecessary obstacles to trade. We also urge BPJPH to coordinate with other Government of Indonesia Ministries to ensure forthcoming implementing

regulations for the Halal Law do not contradict existing regulations, and ask that Indonesia clearly indicate when and to what extent an implementing regulation supersedes existing regulations.

2.279. We have asked about the certification of services over the course of several years and still have no clear idea of how that will function. We have concerns about the possible requirement that Indonesia intends that all transportation, packing, storage, and delivery services related to food, beverages, cosmetics, and medical devices must be certified halal. Requiring these services to be certified as halal could be problematic and possibly unfeasible for US industry, given the breadth and scope of these services and the lack of clarity from Indonesia about what those requirements might mean. A concern that we have long noted but have yet to receive a sufficient response on is that the halal measures would mandate that halal and non-halal products be separated across the entire supply chain, including storage, transportation, distribution and sales. These requirements will be extremely burdensome and we question their necessity, as product packaging, traceability, and other means are available to ensure the integrity of halal products. The United States requests that Indonesia remove these requirements, as contained within GR 39/2021. Please explain why Indonesia has not worked with industry on developing procedures or requirements by product type, as originally envisioned? For example, requirements for the management of fresh food will likely differ significantly from requirements relating to many of the other products to be certified. Finally, we have noted that requiring each individual business operator to employ a halal supervisor is an overly burdensome requirement raising serious concerns about its impact on international trade. A likely outcome of this requirement is that small and medium-sized enterprises that cannot afford to retain a halal supervisor will instead choose not to do business in Indonesia.

2.280. *Conclusion*: In conclusion, many of the other concerns we have raised at past meetings have not been sufficiently addressed by Indonesia. For example, we have asked questions about: why genetically engineered products are required to be certified by BPJPH when MUI exempted them; justifications for requiring all products to certify as halal or non-halal, when no halal claims are made; requiring colour-coding of haram ingredients on labels; what halal certification services will look like; Indonesia's intended process and timeline for renewing existing accreditations and adding new US-based halal certifiers; and many more for several meetings with no response. To allow US industry time to adjust to these new requirements, and to allow Indonesia time to adequately clarify and answer WTO Members' outstanding questions and concerns, we request that Indonesia postpone commencement of the Halal Law phase-in until Indonesia finalizes all of the relevant implementing regulations related to the Halal Law. We remain committed to working bilaterally with Indonesia to address the aforementioned concerns, and those raised by other Members in this Committee, and to ensure that Indonesia's halal measures do not create unnecessary obstacles to international trade.

2.281. 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 is eager to ensure that our existing halal assurance processes will continue to be recognized when the grace period for Law 33/2014 ends in 2024 and welcomes Indonesia's clarification of this. Australia appreciated the opportunity to provide formal comments on Indonesia's latest Draft Regulation of the Minister of Religious Affairs Regarding International Cooperation on Halal Product Assurance (G/TBT/N/IDN/139), notified to the TBT Committee on 1 December. We look forward to Indonesia's response to our submission and welcome clarification from Indonesia as to whether a halal-specific bilateral agreement is required in order for Australian halal-certifying bodies to be recognized by Indonesia. Australia thanks Indonesia for the Halal Law informative information sessions provided recently. We welcome Indonesia's list of natural products that are exempt from the halal certification requirement, including fresh fruits, vegetables, grains, and dairy. We look forward to further dialogue on the Halal Law to ensure its implementation is no more trade restrictive than necessary.

2.282. The representative of <u>New Zealand</u> provided the following statement. New Zealand would like to thank Indonesia for its ongoing engagement on the implementation of the Halal Assurance Law and associated implementation regulations to date. New Zealand respects Indonesia's desire to increase the robustness of the halal assurances associated with products moving into commerce within Indonesia. However, we are also very interested in working with Indonesia to ensure the halal certification controls and systems operating within New Zealand are recognized without the application of restrictive additional inspection, control or approval processes and associated costs.

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We ask for some clarity on the status of Overseas Halal Certification Bodies who were previously listed with MUI, and the timelines for their registration with BPJPH. Will this registration need to be periodically renewed? Does the same apply for Halal Certification Bodies who were not previously listed with MUI who are now applying to BPJPH? Will Indonesia work directly with those countries with Mutual Recognition Arrangements to list those Halal Certification Bodies that these countries certify meet the agreed criteria and not impose duplicate control, inspection or approval systems or costs? Under Minister of Religious Affairs Regulation 2/2022 on the International Cooperation of Halal Product Assurance, will a Mutual Recognition Agreement between two countries allow foreign Halal Certification Bodies (HCBs) approved by their halal regulatory authority in the country of origin, to certify products without the HCB also being required to accredit directly with BPJPH? Can Indonesia clarify that foreign Halal Certification Bodies in the country of origin are able to certify the halal status of all Raw Material, Additives and End Products as and when required? With regard to the recently-released Ministry of Religious Affairs regulations 748/2021, can Indonesia please clarify both the criteria and the process, including WTO notification and consultation, by which items are added to the appendix listing the type of product that is obliged to be Halal certified? The regulation reads that the head of BPJPH is obliged to include a product on the list if a business actor has applied for Halal certification for a non-listed product. Will there be a WTO-consistent notification and consultation process and an appropriate grace period after products are added to the list that will allow other business actors enough time to apply for Halal certification? Can Indonesia clarify the mechanism by which the updated list will be notified publicly?

2.283. The representative of Canada provided the following statement. Canada appreciates Indonesia's efforts in notifying these measures, however, we would like to remind Indonesia of its WTO transparency obligations to provide trading partners with adequate time and information to comment on a given measure and to ensure that these comments are taken into consideration prior to that measure being finalized. In addition, as per WTO obligations, a 6-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. Canada is concerned that the draft implementing regulation "Decree of the Minister of Religious Affairs of Indonesia Number 2 of 2022" was finalized on 6 January 2022, prior to the closing of the comment period for notification G/TBT/N/IDN/139 on 28 January 2022, during which time Canada sent comments to Indonesia. Similarly, while the comment period for <u>G/TBT/N/IDN/131</u> ended on 12 February 2021, Government Regulation Number 39 of 2021, "Regarding Implementation of Halal Product Assurance", was finalized on 2 February 2021, prior to the end of the comment period. Canada would also like to express its significant concern that Canadian exporters are unable to export halal products to Indonesia, as a Canadian certification body's application for an extension of its accreditation has been pending for six years.

2.284. Canada has followed all relevant requirements and expects to be offered the same opportunity as other Members to have its halal certification body recognized while domestic reforms continue in Indonesia. Canada urges Indonesia to consider how its stated requirement for a Government-to-Government Memorandum of Understanding prior to recognizing foreign halal certification bodies is inappropriate for many WTO Members, such as Canada, where there is no governmental mandate to oversee halal certification. This requirement creates a clear commercial advantage for countries with governmental oversight. Therefore, Canada requests that Indonesia consider allowing reasonable alternatives to the MOU requirement. Additionally, while Indonesia has taken steps to clarify the scope of products that will require halal certification, confusion remains. The only way to be clear about what products require certification is to provide specific HS codes for each product that requires halal certification. Therefore, to avoid unnecessary disruptions to trade, Canada requests that Indonesia provide further clarity on HS Codes for the full suite of agricultural products impacted in its lists of products where halal certification is required. There are also issues of consistency. For example, while we are pleased to see that frozen fish appears to be exempted from the halal requirement, other frozen seafood products are not listed. Could Indonesia explain why frozen fish are exempt but not other frozen seafood, such as crab. Canada has been seeking to engage bilaterally with Indonesia, in particular with the Ministry of Religion's Halal Product Assurance Organizing Agency (BPJPH), for some time. Most recently, officials have been seeking a meeting since the arrival of the new Director of BPJPH in order to clarify the MoU requirement and discuss the Canadian certification body's application and we look forward to a constructive discussion.

2.285. The representative of <u>Switzerland</u> provided the following statement. Switzerland is following this matter with interest and shares the concerns expressed by other Members regarding the Indonesian Halal Product Guarantee Law No 33 of 2014 and its implementing provisions, which

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require mandatory Halal certification and labelling for a large range of products. While Switzerland recognizes Indonesia's legitimate objective to ensure reliable information for consumers related to the halal integrity of certain products, we expect Indonesia to fully meet its WTO obligations. The implementing provisions appear to be more trade restrictive than necessary to ensure that the legitimate objectives are met and the products fulfill the Halal requirements, as prescribed by the Islamic Law. Switzerland is concerned about, among others, the "non-Halal" information requested for non-Halal products or the extension of Halal requirements to products other than food and beverages. We encourage Indonesia to reconsider the respective provisions of its recently adopted regulations. 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. The pre-condition of a government-to-government mutual recognition arrangement for recognition by Indonesia of foreign Halal certification bodies and certificates seems to represent a significant burden for economic operators. The additional registration requirement for Halal certifications of certain products by foreign bodies also appears to be more trade restrictive than necessary. In this respect, we encourage Indonesia to provide flexibility for the recognition of foreign Halal certification bodies and the acceptance of foreign Halal certificates. Switzerland strongly encourages Indonesia to notify any relevant technical measures when still in draft form and to provide sufficient time for comments, in accordance with the WTO TBT Agreement.

2.286. The representative of <u>Chile</u> provided the following statement. The delegation of Chile would like to take this opportunity to thank the representative of Indonesia to the WTO for the invitation to a webinar on Halal regulations last Monday, and echoes the STC raised by the United States and the European Union in view of its concerns over the effects that implementation could have on the trade of Halal-certified products from Chile to Indonesia.

2.287. In response, the representative of Indonesia provided the following statement. Indonesia would like to refer to its statement on the previous TBT meeting in November 2021. In addition, Indonesia has conducted clarification session regarding Halal Product Assurance Implementation on 7 March 2022 inviting WTO Members who have already submitted concerns and enquiries as well as interested stakeholders. Indonesia greatly thanks 153 participants who have joined the session for their time and inputs. Not solely that, BPJPH had also held several hybrid seminars for rebranding and socializing related regulations and policy implementation on halal product assurances, attended by more than 30 embassies from fellow countries, including embassies from the US, Australia, New Zealand, Canada, Switzerland, and Chile; as well as halal certification agencies across the globe. During the session involving WTO Members, Indonesia has provided detailed and thorough information regarding the measures of the following notifications: (i) G/TBT/N/IDN/131; G/TBT/N/IDN/131/Add.1 Government Regulation Number 39 of 2021 Regarding Implementation of Halal Product Assurance; (ii) <u>G/TBT/N/IDN/134; G/TBT/N/IDN/134/Add.1</u> Decree of The Minister of Religious Affairs of Indonesia Number 748 of 2021 regarding Types of Products and Consumer Goods Products Mandatory to be Halal Certified; (iii) G/TBT/N/IDN/138 Regulation of Minister of Finance Number 57/PMK.05/2021 regarding Tariff for Public Services provided by Halal Product Assurance Organizing Agency (BPJPH); and (iv) G/TBT/N/IDN/139 Draft Decree of Minister of Religious Affairs Regarding International Cooperation on Halal Product Assurance; and (v) G/TBT/N/IDN/140 Draft Decree of The Minister of Religious Affairs Regarding Materials Exempted from Halal Certification Obligation. Indonesia once again would like to reiterate its openness and transparency to international cooperation on Halal Assurance System based on the principle of mutual cooperation, mutual recognition, and mutual acceptance in accordance with international regulations and practices.

2.1.3.29 Egypt - Manufacturer Registration System (Decree No. 43/2016 and Decree No. 992/2015), <u>G/TBT/N/EGY/114</u>, <u>G/TBT/N/EGY/115</u> (ID 505⁷⁶)

2.288. The representative of the <u>European Union</u> provided the following statement. The EU would like to inform WTO Members that the registration requirements in Egypt became subject to the Dispute Settlement Procedure DS609 under WTO. The EU will discuss the case exclusively in the framework of that procedure.

2.289. The representative of the <u>Russian Federation</u> provided the following statement. The Russian Federation has raised this issue several times during the meetings of different WTO bodies. Today

 $^{^{76}}$ For previous statements follow the thread under $\underline{\text{ID 505}}$.

we would like to welcome registration decisions made by the Egyptian authorities in respect of Russian exporters. We will follow with interest as a third-party developments of the trade dispute initiated by the EU.

2.290. The representative of <u>Turkey</u> provided the following statement. We want to reiterate our continued concern about Egypt's Decree Number 43/2016, as well as its subsequent amendments and extensions to the manufacturer registration system. First, we would like to thank Egypt for holding the bilateral discussions in Cairo to address the Turkish exporters' concerns over the manufacturer registration system's implementation. However, Turkish exporters continue to face challenges within the implementation of the registration system, including the need for hand delivery of documents during the COVID-19 pandemic, a lengthy registration process, the expiration of registered documents and the cancellation of the companies' registration due to expired documents. We have identified 115 Turkish exporters waiting for the approval, in which GOEIC has not provided any details on the reasons for their lengthy registration period. On the other hand, Turkey is closely monitoring the recently initiated consultations process concerning this measure under the WTO Dispute Settlement Mechanism. In conclusion, Turkey would like to underline its expectations from Egypt to terminate this measure by considering the WTO Agreements' principles and obligations.

2.291. In response, the representative of <u>Egypt</u> provided the following statement. Egypt has indeed entered into consultations in good faith with the EU on this matter as per DS 609; the Russian Federation requested to join the consultations. Egypt would like to stress that it shall continue its positive engagement in the context of the consultations with a view to reaching an amicable mutually satisfactory solution. On the concerns raised by Turkey, I would like to express Egypt's readiness to continue its bilateral exchanges with Turkey to identify the underlying reasons of the issues raised and provide further clarity on the status of the registration of Turkey's factories/companies.

2.1.3.30 India - Mandatory Certification for Steel Products, <u>G/TBT/N/IND/32</u>, <u>G/TBT/N/IND/32/Add.1</u>, <u>G/TBT/N/IND/32/Add.2</u>, <u>G/TBT/N/IND/32/Add.3</u> (ID 224⁷⁷)

2.292. The representative of the <u>Republic of Korea</u> provided the following statement. Korea appreciates India for its explanation at the previous meeting in November last year and its recent decision to postpone the implementation of the Quality Control Order (QCO) on some of steel and steel products. However, we would like to reiterate that Korean companies still have the following difficulties regarding the BIS certification process required for compliance with Steel and Steel Products QCO. Korean companies completed the application for IS 17404:2020 certification in December 2020, and despite the challenges of COVID-19, they have reached the factory audit consultation process thanks to the cooperation of local BIS certification agencies. However, no more follow-up process has been carried out as the visit to Korea was delayed due to differences in opinions between two parties regarding compliance with Korean COVID-19 quarantine guidelines required for factory audits in Korea. As yet, it is possible to meet the domestic demand in India but only for a limited amount of time. Korean steel companies are concerned that failure to obtain BIS certification by May 2022 could bring a steel supply shortage, which might cause a serious disruption in the production capacity of India's industries that demand steel as raw material.

2.293. Therefore, considering the delay in the certification process due to COVID-19 and the facilitation of exports to India, we request that India quickly introduce alternative measures to improve the certification process until the current situation improves, such as exemption from factory-visit inspection, substitution with paper-based audit, or sharing information on the expected implementation schedule for virtual/remote inspection procedure which is currently under review by the Indian Government.

2.294. The representative of <u>The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu</u> provided the following statement. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu remain concerned about the Steel and Steel Products (Quality Control) Order, 2020 on electrogalvanized hot rolled and cold reduced carbon steel sheets and strips (IS 17404:2020). As the IS 17404:2020 entered into force last year, our companies need to finish the mandatory certification procedures to acquire certifications. However, our companies are still facing the difficulties in receiving the on-site inspection visit by BIS due to ongoing impact of COVID-19 and its associated quarantine policies. We appreciate India for considering introducing relevant enabling provisions to undertake virtual/remote inspection in steel sector. We are interested in knowing the

 $^{^{77}}$ For previous statements follow the thread under <u>ID 224</u>.

current status of India's consideration and possible measures and timeline India would adopt. For the purpose of assisting our companies to complete the certification process under this situation, we would like to request India adopt more flexible alternative measures speedily, for instance, granting provisional certificates via virtual inspection and conducting physical factory inspection to issue the formal certificate after the quarantine policies are relaxed. We look forward to a written response and continuing bilateral engagements with India on this matter.

2.295. The representative of <u>Japan</u> provided the following statement. Japan appreciates India's efforts to accelerate its examination procedure in BIS mandatory standards of steel products. We understand all the licences applied before the pandemic were granted. In addition to that, Japan welcomes India's comment at the previous TBT Committee regarding their consideration to introduce relevant enabling provisions to undertake virtual/remote inspection for BIS conformity assessment activities. As the pandemic is continuing in many countries, international human movement is still widely restricted. We encourage India's further consideration and would like to know about the current status and possible timeline for the introduction of such alternative inspection methods.

2.296. The representative of the European Union provided the following statement. The EU would like to support the delegations of Japan, Chinese Taipei, and Korea. India has defined and introduced specific standards and certification requirements for a number of products across sectors that require on-site, in person audits. The Quality Control Orders (QCOs) have protectionist orientation and are sending worrying signals to EU industry, EU investors, and EU member States. Once the QCOs come into force, they cause extra burden and economic cost to the EU industry that has to undergo cumbersome procedures to obtain necessary permissions and/or licences for products already certified under established international standards. Additionally, the QCO on Steel and Steel products require a physical audit by an auditor of the Bureau of Indian Standards (BIS) in order for products manufactured in third-party countries to receive the approval for exports to India. The on-going COVID-19 pandemic and international travel restrictions linked thereto have had negative impact on certification process in India, especially for foreign companies with production facilities outside India. The EU would like to support the introduction of virtual/remote inspection for BIS conformity assessment in the steel sector. Alternative inspection methods are crucial to maintain access to Indian market otherwise; absence of an alternative solution could adversely disrupt supply chains jeopardising businesses of foreign steel manufactures.

2.297. The Steel and Steel Products (Quality Control) Order 2020 targets 145 Steel or Steel products and 7 goods and articles. The QCOs for majority of these products are already in force. However, it remains unclear to the EU which of Quality Control Orders for steel products are already in force. India defers from time-to-time the date of implementation of certain steel products. The EU would therefore, appreciate if India could provide an updated list of steel and steel products for which the QCOs are already in force, together with the list of steel products for which the implementation of QCOs has been deferred. The EU would also like to know whether India plans to further expand the scope of the Steel and Steel Products (Quality Control) Order of December 2020. Finally, does India plan to accept steel and steel products of foreign manufacturers produced in line with internationally accepted standards and prune the list of steel and steel products falling under the QCOs?

2.298. In response, the representative of <u>India</u> provided the following statement. The products under mandatory certification are notified by the concerned Line Ministries (Regulator) of the Government of India through the issuance of Quality Control Orders (QCOs). Gradually all Indian Standard on steels will be covered under the QCO in a phased manner. As per the provisions of the QCO, the products specified therein shall bear a Standard Mark under a valid licence from BIS as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. Under this Scheme, factory inspection is a mandatory requirement for the purpose of grant of licence. Licence to use the Standard Mark on a product is granted after assessing the manufacturing and testing capabilities through factory inspection of the relevant Indian Standard is also established through in-house factory testing or testing at a third-party testing laboratory or a combination of both. At present, there is no provision in BIS (Conformity Assessment) Regulations, 2018, to undertake virtual inspection for conformity assessment activities as an alternative.

2.299. Mandatory BIS certification for steel products is enforced through notification of QCOs to ensure that the quality of steel being manufactured by domestic producers or imported in the country is as per the Indian standards. The implementation of QCOs ensures the availability of quality steel

and steel products to the end-users. It saves the Indian consumers from dumping of spurious and defective steel and steel products. Members are aware that the WTO recognizes the Member's right to implement measures to achieve legitimate policy objectives, such as protecting human health and safety, protecting the environment, preventing unfair trade practices, or national security. The technical regulations/QCOs on steel and steel products have been issued based on such policy objectives. Hence QCOs notified by the government are not trade-restrictive but necessary to fulfil a legitimate objective. As far as possible, date of enforcement of QCOs is not extended from the first date of enforcement. However, due to exceptional cases, if there are any specific requests for extension, they are examined on merit. Factory inspections were on hold earlier due to restrictions on international travel because of the COVID-19 pandemic. At present, the nomination of BIS officers is being considered for carrying out the factory inspection for applications received from foreign manufacturers where the country to be visited is facilitating visits of fully vaccinated BIS officers who are carrying negative RT-PCR test reports, without any restrictions like quarantine and RT-PCR test upon arrival.

2.1.3.31 China - Cybersecurity Law (ID 526⁷⁸)

2.300. The representative of the <u>European Union</u> 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 National Information Security Standardisation Technical Committee (also known as TC260) has released the draft of a short (non-binding) guideline on the identification of "important data" (the Identification Guideline). The concept of "important data" was first introduced by the Cybersecurity Law and has more recently been adopted into the Data Security Law. However, the term has never been comprehensively defined. Under the Data Security Law, regional and sectoral regulators have already been tasked with formulating catalogues of 'important data' for their respective sectors. The Identification Guideline, released on 13 January 2022, is the first step towards implementing this national classification system for "important data". The EU urges China to proceed with these guidelines as soon as possible and take into account the EU comments submitted during the public consultation.

2.301. The EU has taken note of the publication of the Call for Comments on the "(Draft) "Outbound Data Transfer Security Assessment Measures" by the Cyberspace Administration of China (CAC). The movement of information across national borders drives today's global economy. Cross-border data transfers with protection, allow businesses and consumers access to the best available technology and services, wherever those resources may be located around the world. The seamless transfer of informational trade. Companies need to be able to efficiently transfer data across borders in order to respond to customers' needs, deliver goods and services to consumers, process payments and provide customer support. It is essential that regulatory frameworks for data allow companies to compete globally, foster the creation of new business models and ensure a level playing field, with legal certainty and stability, as well as the protection of personal data.

2.302. Conversely, the EU understands that the "Measures for Data Export Security Assessments" would impose broad data and server localization requirements, notably under the umbrella of national security, covering potentially all sectors of the economy. Such constraints could severely limit cross-border data transfers. Also, we are concerned that they put foreign operators at a disadvantage compared to local ones. The scope of some of the provisions remains unclear and it is not possible to determine which types of data and which kinds of transfers would be covered by the measure. Additionally, some of the terms used in the measure are not well defined. While these terms may be defined in other pieces of legislation, the concerns we have raised there would also apply here. For example, those subject to interpretation, in particular, the vague concepts of "important data" and "critical information infrastructure". It would be important to address these issues to ensure legal certainty. The EU urges China to take on board its comments provided during the public consultation.

2.303. The EU has also taken note of the "Critical Information Infrastructure Security Protection Regulation", which is effective as from September 2021. The Regulations provide long-awaited details about how critical information infrastructure operators will be designated and what their

 $^{^{\}rm 78}$ For previous statements follow the thread under <u>ID 526</u>.

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responsibilities will be in order to protect the security of the networks that they build and operate. Since the Cybersecurity Law came into effect in 2017, EU companies have faced uncertainty about whether or not they would be deemed critical information infrastructure operators and therefore face regulatory obligations in data security, procurement, cross-border data flows and other areas. However, the new Regulations do not resolve the overlap between the pre-existing Ministry of Public Security (MPS)-administered system for equipment security, known as the Multi-Level Protection Scheme (MLPS, now in the process of revision to MLPS 2.0) and the critical information infrastructure protection regime. The EU urges China to clarify the mutual links regarding the compliance around the procurement of approved equipment and software for networks at designated levels of sensitivity, many of which would likely also be designated critical information infrastructure. 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.

2.304. The representative of the United States provided the following statement. The United States remains very concerned about China's suite of cybersecurity and cryptography measures. As we have said in prior TBT Committee meetings, this is a major concern for US companies, given China's intertwined requirements for conformity assessment systems for security testing, technical regulations, and a multi-level classification scheme laying out requirements including mandatory standards and testing for the purchase of ICT goods across a wide range of commercial sectors. China's Cybersecurity Law entered into force on 1 June 2017, in spite of serious and long-standing concerns from the United States and many other international stakeholders. Since then, China has continued to develop, and in certain cases, finalize related implementing measures that are sometime general in scope, and sometimes sector specific. We have many concerns regarding China's Cybersecurity Law and related measures, which impose far-reaching, highly trade-restrictive conditions on foreign ICT products through "secure and controllable" requirements, enforced by cybersecurity review regime checks. Such requirements are largely based on a planned update and expansion of the Ministry of Public Security's Multi-Level Protection Scheme (MLPS). As one example, China's 25 January 2018 draft measure, "Information Security Technology - Guidelines for Grading of Classified Cybersecurity Protection," appears to repeat and elaborate upon China's MLPS.

2.305. 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.

2.306. The representative of <u>Japan</u> provided the following statement. Japan continues to have concerns regarding China's "Cybersecurity Law" and would like to refer to the previous statement we made at the last TBT Committee in November 2021. Japan is additionally concerned with the related enforcement regulations. Japan requests that China provide notifications of the enforcement regulation, Japan requests that China provide adequate lead time from the completion of these regulations to the commencement of enforcement, and to implement these measures in a transparent manner.

2.307. The representative of <u>Canada</u> provided the following statement. Canada continues to have significant concerns with China's suite of cybersecurity and cryptography/encryption laws and

related implementing regulations. Among other things, Canada is concerned with the implementing measures multiplication, which creates confusion and complicates businesses' ability to comply with all of them, due to their unclear scope, interaction and adherence to the principles of the TBT Agreement. Besides the draft National Standard on Information Security Technology – Security Technical Requirements of Specialized Cybersecurity Product, which was notified on 21 December 2021, when will the other regulations be notified to the WTO TBT Committee?

2.308. *Critical Information Infrastructure (CII) Security Protection Regulations:* Canada reiterates concerns raised in the November TBT Committee meeting, including the absence of defined criteria operators of CII are to use in assessing a security threat and the lack of a clear commitment to national treatment, MFN treatment or the use of international standards.

2.309. *Cybersecurity Review Measures*: Canada appreciates the clarification of the cybersecurity review's scope to specify it covers data processing activities by "internet platform operators" (rather than "data operators" in the earlier draft) that may affect China's national security. However, besides this clarification, the final version does not respond to many other concerns and suggestions submitted by Canada last July, such as: better clarity regarding what constitutes Critical Information Infrastructure; defined criteria that operators of Critical Information Infrastructure – and internet platform operators – are to use in assessing a security threat; and a clear commitment to National Treatment, MFN treatment and the use of international standards.

2.310. *Draft Regulations on Network Data Security:* Facilitating access to data is critical for innovation, funnels resources to R&D and benefits Chinese consumers. While Canada appreciates the inclusion of a definition for "Important Data", Canada recommends China explicitly list all the laws and regulations under which this definition would apply, including the Cross-border Data Transfer Measures, and ensure no requirement is more restrictive than necessary to achieve a legitimate public policy objective. Canada is of the view that additional requirements on cross-border data transfers, compared to domestic treatment of data transfers (especially regarding articles 32-33 and 35-40), raises significant concerns regarding TBT Agreement, Articles 2.1 and 2.2. In order to facilitate compliance for businesses, Canada seeks China's assurance there will be sufficient coordination between the different regulators and ensure that industry participants are not required to go through different security assessments with multiple regulators. With respect to Article 35 of the draft (i.e. the potential exemption of the outbound data restrictions due to a contractual/personal reason), could China please clarify how the exemption works? To whom and how does a company apply for an exemption? What are the criteria that must be met in order to receive an exemption?

2.311. Draft Measures for Security Assessment of Cross-Border Data Transfer: Canada would be grateful to have more details on how China will ensure respect of National Treatment, given the protection of data that is being transferred outside of China will be under a separate set of rules. How would China be able to ensure that data kept in China has to meet equally stringent requirements? Canada also notes that a number of articles appear to have extraterritorial scope (e.g. Articles 6(3); 8(2); and 9(5)), and condition the sending of data to other jurisdictions on a pre-assessment from Chinese authorities. How would China ensure that no requirement, like those related to "important data" are not more trade restrictive than necessary to achieve a legitimate public policy objective?

2.312. The representative of <u>Australia</u> provided the following statement. Australia continues to have concerns regarding China's Cybersecurity Law and would like to reiterate the previous statement we made at the last TBT Committee in November 2021. We were pleased to make submissions to the Chinese Government as part of public consultations on its cybersecurity framework - including the Personal Information Protection Law and Data Security Law, passed in 2021. As we set out in Australia's submissions, we welcomed a number of revisions to both these draft laws. Nonetheless, Australia still has concerns with the final legislation particularly around extra-territoriality, trade retaliation measures, compliance costs for firms and the overall scope. We remain concerned that provisions in these laws have the potential to create inconsistencies with WTO rules. We note that any measure or counter measure taken under these laws should only be applied consistently with China's WTO obligations. We also continue to remain concerned about the lack of clarity when it comes to definitions, jurisdiction and a number of other fundamental elements, to enable businesses operating in China to fully understand and implement their new obligations. We continue to urge China to take into account the concerns of business and Members in the implementation of these measures and development of future measures. We look forward to continuing to work closely with China on these issues.

2.313. In response, the representative of <u>China</u> provided the following statement. The Cybersecurity Law aims to safeguard China's sovereignty, national security and public interests in cyberspace, and to protect the legitimate rights and interests of citizens, legal persons and other organizations. It does not restrict foreign enterprises, technologies and products from entering the Chinese market, nor does it restrict the lawful, orderly and free flow of data. Since the implementation of the Cybersecurity Law, it has played an important role in safeguarding cybersecurity, safeguarding China's national sovereignty in cyberspace, and protecting citizens' legitimate rights and interests. It has effectively enhanced the awareness of cybersecurity and improved the protection skills on cybersecurity, which provided a security guarantee for the development of the network industry and technology in China.

2.1.3.32 China - Encryption Law of the People's Republic of China by the Office of State Commercial Cryptography Administration (OSCCA) (ID 534⁷⁹)

2.314. 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 have already negatively impacted 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 nondiscriminatory 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, including participation by chipmakers in standardization bodies, including working group 3 of the TC260 and the SCA's own Cryptography Industry Standardisation Technical Committee (CISTC). The EU requests that applications to these bodies be replied to in a timely manner.

2.315. The representative of the <u>United States</u> provided the following statement. We refer to our previously raised statements on this STC.

2.316. The representative of <u>Japan</u> provided the following statement. Japan continues to have concerns regarding China's "Encryption Law" that entered into force on 1 January 2020 and would like to refer to the previous statement we made at the last TBT Committee in November 2021. Japan requests that China's regulation does not hamper foreign companies' activities or market access to China.

2.317. The representative of <u>Canada</u> provided the following statement. As we mentioned at the November meeting of the Committee, Canada provided China with written comments on a draft of China's State Cryptography Administration's cryptography regulations, in September 2020, and continues to look forward to a response. When will these regulations be notified to the WTO TBT Committee? Canada reiterates its request from previous meetings of the Committee, that China consider modifying the regulations and laws related to Encryption and Cryptography, to provide further clarity, transparency and predictability. For example, Canada seeks the definition of terms, clarification that international standards will be used and further precision on the measures' scope. Canada would appreciate China's consideration of its comments and, once again, invites China to notify the draft regulations to this Committee.

2.318. In response, the representative of <u>China</u> provided the following statement. The Law on Cryptography was enforced on 1 January 2020. It clearly stipulates that government agencies 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, import, export, etc. China encourages commercial cryptography technical cooperation based on voluntary principles 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 administration.

 $^{^{79}}$ For previous statements follow the thread under $\underline{\text{ID 534}}$.

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2.1.3.33 China - National Standards on Limits of Volatile Organic Compounds for Furniture, <u>G/TBT/N/CHN/1094</u>, <u>G/TBT/N/CHN/1095</u>, <u>G/TBT/N/CHN/1096</u> (ID 509⁸⁰)

2.319. The representative of the <u>European Union</u> provided the following statement. The European Union would like to refer to its previous statements on Chinese notifications <u>G/TBT/N/CHN/1094</u>, <u>G/TBT/N/CHN/1095</u> and <u>G/TBT/N/CHN/1096</u>. The European Union would like to express concerns over the draft Chinese Volatile Organic Compounds (VOC) standard for furniture "Limit of Harmful Substances of Furniture", which would replace standards notified to the WTO in 2015 (<u>G/TBT/N/CHN/1094</u>, <u>G/TBT/N/CHN/1095</u>, and <u>G/TBT/N/CHN/1096</u>). Despite the collaboration between the European furniture industries and Chinese standardization bodies on a new, improved version of the standard, that would take into account international standards applied in the area of VOC measurements, the draft Chinese standard "Limit of Harmful Substances of Furniture" fails to bring relevant improvements and presents similar concerns as the original text notified to the WTO in 2015. High indoor air quality is essential for the health and wellbeing of European and Chinese consumers. The European Union understands and supports the introduction of standards limiting the emissions of harmful substances from furniture. However, important concerns expressed in the EU's statement in November 2021 remain.

2.320. To recall a few, the EU believes that it is very important to harmonize testing methods. The use of proven standards as a basis should be the reference for all countries and the corresponding testing laboratories. Test methods should be chosen by accuracy and should be science based. The new standard will have an important economic impact on both European and Chinese producers as it will pose a barrier to exports. Furthermore, the requirement proposed in the Chinese draft standard on Individual Volatile Organic Compounds shows an arbitrary choice of thresholds and is not focused on hazardous substances. The draft standard will therefore overestimate the impact of natural substances normally present in wood but underestimate the impact of toxic substances. The EU is of the opinion that only toxicologically relevant substances should be considered as the basis for evidence. To make sure that the standard does not hinder the use of natural wooden materials and water-based coatings, health-based criteria with a focus on individual hazardous substances (not on TVOC) should be applied.

2.321. Additionally, the draft Chinese standard encourages an approach where producers simplify the designs and functionality of the furniture produced for the Chinese market in order to pass the test. The volume-based approach to the testing method used in the draft Chinese standard would make the final emission of the product depend on the design and functions (for example number of drawers) rather than the choice of raw material. A simpler design will limit the choice for Chinese and European design. The EU would like to recall that products made from natural materials and/or with water-based coatings will no longer be available to Chinese consumers. The Chinese draft standard would also pose problems for Chinese furniture manufacturers when exporting to the EU. This would also be the case for manufacturers producing in the EU, because they would then have to use organic solvent-based lacquers to pass the tests. The EU welcomes the change applying to formaldehyde emission, as indicated in the latest version of the standard, dated 21 October. It seems that the standard now follows the internationally approved method of ISO 16000-3 (the DNPH method). The EU hopes that China maintains this approach and that DNPH method remains the chosen way to measure formaldehyde emissions. The EU would like to ask China to share information about the timing for the TBT notification of the new standard.

2.322. In response, the representative of <u>China</u> provided the following statement. Indoor decorating and refurbishing materials - Limit of harmful substances of wood-based furniture (GB18584-2001) specifying the release limit of formaldehyde, is the only ongoing mandatory standard regarding volatile organic compounds in wood furniture in China. Mandatory Standard-Limit of Harmful Substances of Furniture will be released in the near future. It specifies a variety of volatile organic compounds in wood furniture. The types and limits of volatile organic compounds harmonize with the standards and regulations issued by WHO, ISO, or other international organizations.

 $^{^{80}}$ For previous statements follow the thread under <u>ID 509</u>.

2.1.3.34 European Union - Chlorothalonil (pesticide active substance), <u>G/TBT/N/EU/625</u> (ID 579⁸¹)

2.323. The representative of Colombia provided the following statement. Colombia reiterates its concern regarding the measure notified by the European Union (EU) in document G/TBT/N/EU/625 relating to non-renewal of the approval of the active substance chlorothalonil. Despite the many technical and scientific comments submitted during the consultation periods, the regulation under which the marketing approval of the active substance chlorothalonil was not renewed entered into force in May 2020. This decision is already having negative implications and consequences for banana producers in Colombia and has repercussions for an extensive domestic agricultural production chain. In addition, in February 2021, the European Commission set the MRL at the minimum level of detection, a provision that was scheduled to enter into force in 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. Nor has consideration been given to the concerns raised by various Members in this and other settings, and there has been no response either to the calls for dialogue made on a number of occasions. Not only were these measures taken in the absence of sound scientific evidence and in a manner that was inconsistent with international standards, they are also being applied in a discriminatory fashion, as, in practice, their implementation strongly differentiates between domestic producers in the EU and foreign producers. While we recognize the human health and environmental protection objectives involved, these measures are being adopted without any proof that they are indeed the least trade-restrictive means of ensuring an appropriate level of protection. In Colombia, the use of plant protection substances - such as chlorothalonil - is essential in agricultural production for protecting crops against pests and diseases and for maintaining the quality and safety of food products. We therefore once again call upon the European Union to base its decisions on science and to avoid discrimination in the application of these measures.

2.324. The representative of <u>Brazil</u> 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 Health Regulatory Agency has set MRLs for chlorothalonil applied to more than 30 crops. The case of chlorothalonil is particularly harmful towards Brazil's producers of banana, coffee, citrus fruits, papaya, watermelon, among others.

2.325. The representative of <u>Paraguay</u> provided the following statement. This concern and the non-renewal of the approval of chlorothalonil and other substances were already discussed extensively both in this Committee and in the SPS Committee because of the subsequent reduction of MRLs. Paraguay therefore refers to its previous statements and reiterates its cross-cutting concern with regard to the EU's decision not to renew the approval of these substances without a proper risk analysis and without complying with scientific principles. In the specific case of chlorothalonil, this low-risk substance is sold freely in Paraguay and is used in several export products as part of the rotation of substances to avoid pest resistance. It is also the most common alternative for mancozeb, another substance whose approval was not renewed by the EU despite the fact that neither of these substances poses a risk to human health or the environment, if used in accordance with good agricultural practice. As with the trade concerns on other substances and systemic concerns, we reiterate the request to the EU to take into consideration information on pesticides provided by the specialized agencies recognized by the WTO, such as the Codex Alimentarius; reconsider its approach and base its decisions on conclusive scientific evidence and real risk weightings, in accordance with international standards and principles; and ensure import tolerances.

2.326. The representative of <u>Ecuador</u> provided the following statement. Ecuador expresses its thanks and support for the statements of the delegations that have already taken the floor. Ecuador wishes to reiterate its concern in relation to notification <u>G/TBT/N/EU/625</u> on the non-renewal of the approval of the active substance chlorothalonil and document SANTE/10186/2018 Rev 1, through which the European Union (EU) confirms the non-renewal of the approval of the substance.

⁸¹ For previous statements follow the thread under <u>ID 579</u>.

Chlorothalonil is one of the main tools for controlling Black Sigatoka in bananas owing to its effectiveness, low cost and multisite mode of action, meaning that the risk of resistance is low. It is available in a broad range of products, through many suppliers, and is widely available in Ecuador. Controlling Black Sigatoka (Mycosphaerella fijiensis) is the main challenge for banana production in Latin America. To control the disease, strategies to rotate 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 <u>G/SPS/N/EU/394/Add.1</u>, 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.

2.327. 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. The banana sector provides jobs for 2.5 million people. Banana exports generate 2.1 billion in revenue for the country, accounting for 2% of GDP and 35% of agricultural GDP. Furthermore, Ecuador urges the European Union to share whether, where emergency authorizations have been issued for the use of this substance, European Union member countries have notified and justified the application of MRLs that differ from those established in the European Union'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?

2.328. The representative of <u>Costa Rica</u> 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 <u>G/TBT/N/EU/625</u>, relating to the non-renewal of the approval of the active substance chlorothalonil. Costa Rica's concern has been raised during previous meetings of this Committee and is based on the lack of conclusive scientific evidence and the application of a precautionary approach in the processes to renew the marketing approvals, which then affect the establishment of MRLs. This has happened in the case of chlorothalonil, with the Regulation relating to this substance entering into effect in May 2020 despite the many concerns raised in various WTO bodies at both the bilateral and regional level, and at an extremely difficult time for tropical agricultural exporting countries such as Costa Rica, which continue to feel the adverse effects of the pandemic. In this respect, we support the call made by Costa Rica, Colombia and other WTO Members in document <u>G/TBT/GEN/296/Rev.3</u> for the EU to temporarily suspend all review processes of market approvals for plant protection substances, as well as the entry into force of regulations in this area planned for 2020 and 2021, including the non-renewal of the active substance chlorothalonil.

2.329. The representative of <u>Guatemala</u> provided the following statement. Guatemala maintains its position regarding this concern, and we reiterate our comments made at previous meetings on the lack of scientific evidence and the lack of a risk analysis. Chlorothalonil is used on more than 10 crops for domestic consumption and export. This active substance is used as a broad-spectrum and fast-acting contact fungicide. No 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, which have been seriously harmed, and Guatemalan producers and exporters and the economy. Alternative substances to chlorothalonil are: mancozeb, azoxystrobin, pyraclostrobin, sulphur and difenoconazole. The registration of four of these alternative substances was not renewed for marketing in the European Union, and, as a result, MRLs have been reduced to almost zero tolerance, leaving Guatemalan agricultural production with no options that can effectively combat diseases of fungal origin. We ask the European Union to consider the particular circumstances of tropical countries when implementing measures, until it has conclusive studies and has aligned itself with the provisions of the Codex Alimentarius to prevent these measures from becoming more trade-restrictive.

2.330. In response, the representative of the <u>European Union</u> provided the following statement. As explained at previous meetings, the EU proposed not to renew the approval of Chlorothalonil through

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Implementing Regulation (EU) No 2019/67782, 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.⁸³ The conclusion⁸⁴ 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-renewal of 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 to the relevant limits of quantification through Regulation (EU) 2021/155 of 9 February 2021.85 The new values are applicable to all food products since 2 September 2021 (after expiration of a 6-month deferral of the application date that had been granted). As from 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-bycase basis by the "rapporteur" member State and the EFSA. Unless new data would be submitted which would address the concerns raised by EFSA, there will be no further developments in the EU on that substance. As regards the joint Request by several Members 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 position is included in the document of 28 May 2021 with double reference G/SPS/GEN/1814/Rev.2 and G/TBT/GEN/315 circulated in both Committees.

2.1.3.35 European Union - Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR), <u>G/TBT/N/EU/71/Add.1</u>, <u>G/TBT/N/EU/72</u>, <u>G/TBT/N/EU/72/Add.1</u>, <u>G/TBT/N/EU/845</u> (ID 594⁸⁶)

2.331. The representative of <u>China</u> provided the following statement. China thanks to the EU for extending the transition period of the regulations during this special period of COVID-19. In view of the important role of these regulations, China continues to raise concerns. China suggests, during the transitional period of the IVDR, the competent authorities of EU member states could continue to accept FSC applications for IVDD products. The validity of the FSC shall be consistent with the transition period of the corresponding product. FSC is a free sale certificate issued by the competent authority at the request of the manufacturer or EU agency, certifying that the product has been marked CE and is free to circulate in the EU. During the extended IVDR transition period, qualified IVDD products are still in circulation, so it is reasonable to continue to issue FSC for IVDD products during the transition period. During the extended transition period for IVDR, the validity of the FSC shall be consistent with the transition period of the transition period of the FSC shall be consistent with the transition period.

2.332. The representative of the <u>United States</u> provided the following statement. The United States continues to support the development and enforcement of a well-defined medical device regulatory system that assures the safety and performance of medical devices. The United States appreciates the amended transitional provisions adopted by the European Parliament and Council of the European Union last year for a staggered rollout of the in-vitro diagnostics regulation (IVDR). This change will help ensure ongoing patient access to much needed in vitro diagnostic tools. The one-year delay in implementation of the Medical Devices Regulation (MDR) to May 2021, provided some necessary relief. However, we remain concerned about the number of Notified Bodies approved to assess conformity to the MDR, with only twenty-seven Notified Bodies approved as of January 2022. These concerns are particularly acute given the current global health environment, which has limited the ability of prospective Notified Bodies to pursue approval while simultaneously increasing the demand for medical devices.

2.333. We have heard from industry that Notified Bodies are challenged to complete product certification reviews in a timely manner, in some cases creating extensive queues for review completion and delaying manufacturers' ability to comply with the regulation. Given these delays, industry has shared that as they look ahead to 2024, when products must be in full compliance,

⁸² OJ L 114, 30.4.2019, p. 15.

⁸³ <u>http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1489747880535&uri=CELEX:32009R1107</u>.

⁸⁴ EFSA 2018 Conclusion on the peer review of the pesticide risk assessment of the active substance chlorothalonil. EFSA Journal 2018;16(1):5126. <u>https://www.efsa.europa.eu/en/efsajournal/pub/5126</u>.

⁸⁵ OJ L 46, 10.2.2021, p. 5.

⁸⁶ For previous statements follow the thread under <u>ID 594</u>.

some manufacturers are reconsidering whether they can continue to operate in the EU market as they may not be able to certify their products in accordance with the deadlines put forth. These significant delays may also impact European patients who may not have access to life-saving medical technologies as they await certification in the Notified Bodies. Is the Commission considering addressing the lengthy queues for medical devices seeking compliance? If so, how? We hope the Commission will continue to work with the United States as well as stakeholders to address these ongoing challenges with MDR implementation to avoid unintended adverse effects on patients. The United States notes that in recent months, CEN and CENELEC issued a few standards that are harmonized with international standards. The United States appreciates this recent development, and hopes to see this trend continue. We urge the Commission to use international standards where possible to avoid duplicative efforts and additional burdens on manufacturers to comply with regional and international standards.

2.334. We note that in preparation for the implementation of the MDR, the Commission announced in January 2020 that a new nomenclature system, the European Medical Device Nomenclature (EMDN) system would be created to be the basis of the European Database on Medical Devices (EUDAMED). EUDAMED will include a Unique Device Identifier (UDI) module. The EMDN is based on the CND (Classificazione nazionale e internazionali), which is not harmonized with the wellestablished Global Medical Device Nomenclature (GMDN).⁸⁷ 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 70 national medical device regulators to support their activity. The United States uses the GMDN as the basis for our Global Unique Device Identification Database (GUDID). We are concerned that the Commission's selection of EMDN will undermine the interoperability of the two UDI systems (EUDAMED and GUDID) 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 EMDN to GMDN so as to harmonize the UDI systems and reduce duplication for industry. 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 the EU that demonstrates an attempt to map to GMDN. In fact, the EMDN is now available in EUDAMED and there is no option of mapping to GMDN. Could the EU explain what actions it is taking to map EMDN to GMDN?

2.335. The representative of Japan provided the following statement. 1. Japan appreciates the October update of the MDCG Guidance publication plan. At the last TBT official meeting in November 2021, Japan requested that public consultation be carried out prior to the publication of the MDCG, and that the guidance that was published be made mandatory with a transition period. The mapping plan for EMDN (European Medical Device Nomenclature) and GMDN (Global Medical Device Nomenclature) mentioned in the MDCG guidance publication plan was still not available. Japan also requested that a publication schedule be set and executed. Post-marketing surveillance and vigilance were required by the MDR. Though the plan for publication of guidance on post-market surveillance and vigilance has been described, we requested that it be published promptly. Japan requests that the EU continue to consider this matter. 2. Since the MDR was implemented on 26 May 2021, when the MDR was implemented, it has become impossible to ship new products and medical devices with new functions to Europe. At the last TBT official meeting in November 2021, Japan explained that we had received reports from many companies undergoing technical document review that there had been no progress for a long period of time since the start of the review and that it was not foreseeable that the review would be completed and certificates issued by the date of application of the MDR, and that more than one year had passed since the start of the technical document review. Japan would like the EU to investigate the cause of this issue and explain the measures to improve the situation. However, no improvement has been recognized since we received the reports from some companies that it has already taken more than one year and 11 months since the start of technical document review. Japan would like the EU, as a regulatory authority, to continue to investigate the causes and take measures for improvement.

2.336. 3. At the last TBT official meeting in November 2021, Japan stated that the MDR required strict clinical evaluation of Class I, IIa and IIb medical devices. In order to prevent the MDR from becoming more trade-restrictive than necessary, Japan requested that the EU consider simplifying

⁸⁷ The European Commission announced its decision to adopt CND via guidance: <u>https://ec.europa.eu/health/sites/health/files/md_topics-</u> <u>interest/docs/md_emdn_eudamed_nomenclature_en.pdf</u>.

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the clinical evaluation requirements for Class I, IIa, and IIb medical devices in the same way as Japan's premarket certificate or the US 510(k) regulations. Japan request that the EU continue to consider, for instance, the medical devices that are within the moderate risk class or the medical devices using technologies that have already been proven in the market to be exempted from clinical evaluation. 4. Japan welcomes that the Regulation amending a transition period for the IVD Regulation proposed by the European Commission was adopted by the Council of the European Union and the European Parliament on 20 December 2021. Japan recognizes that this will certainly result in an extension of the transition period for three to five years depending on risk classifications of products that need to be certified by the notified bodies. Japan would like to continuously request that the EU provide an adequate transition period. However, considering that the number of products that needs to be certified has increased by eight times with the change from the IVD Directive to IVD Regulation, there are still only six notified bodies conducting certification under the IVD Regulation, while there were 22 such bodies under the IVD Directive. Also, only four guidance documents have been issued as of January 2022. Japan is concerned that the certification of many manufacturers will not be completed under the IVD Regulation by the end of the transition period unless sufficient infrastructure and information needed for the certification are provided, despite the transition period being extended. Japan continuously requests that the EU provide a sufficient number of the notified bodies and guidance documents, as well as providing their timeline in a prompt manner. Japan also request that any new guidance documents issued in the future be subject to a transition period of at least one year, rather than being enforced immediately. 5. As of January 2022, the number of harmonized standards for MDD was 264, whereas the number of harmonized standards for MDR was only 14. Therefore, Japan understands that a large number of harmonized standards for MDR will be published in the future. At the last TBT official meeting in November 2021, Japan stated that the publication plan in the EU Official Journal was not disclosed, and they were instead suddenly promulgated. Japan requested the release of the plan for the development and publication of harmonized standards for MDR and IVDR. Japan requests that the EU continue to consider the publication plan and set an adequate transition period for MDR and IVDR harmonized standard.

2.337. The representative of Australia provided the following statement. Australia also has concerns relating to the implementation by the European Union (EU) of the Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR). This is consistent with the concerns expressed by a number of Members in previous meetings. In particular, we are concerned about continued market access for Australian organizations to the European market given the implementation timeframes for MDR and IVDR, in the context of difficulty accessing appropriately designated notified bodies. This also flows through to the capacity of manufacturers outside Australia to access the Australian market. Under comparable overseas regulator arrangements, Australia allows a range of overseas approvals to support Australian market authorization. This includes extensive use of EU CE mark certification to support supply in Australia. However, if suppliers cannot access notified body services in the short to medium term due to the transition between regulatory systems, or maintain currency of certification for existing medical devices, this impacts access to the Australian market. While this can be addressed by seeking Australian certification, this is an expensive, and potentially prohibitive, regulatory duplication for many stakeholders. Can the EU provide further advice on timeframes and progress of designation of notified bodies, and consideration of possible extensions, in the context transition to the MDR and IVDR.

2.338. We are concerned about the shift to the European Medical Device Nomenclature (EMDN), diverging from the internationally harmonized Global Medical Device Nomenclature (GMDN), creating technical barriers to trade, and potential difficulties for a globally harmonized Unique Device Identifier (UDI) system. Australia is also seeking to implement a UDI system consistent with international norms. The use of the EMDN as the basis for the European Database on Medical Devices (EUDANMED), and GMDN for the USA's Global Medical Device Identification Database (GUDID), in the absence of effective arrangements for interoperability, has potential for creation of barriers to trade and/or significant duplication for industry between various jurisdictions, including Australia. Australia would like to raise awareness of the issues arising from duplicative UDI systems for countries outside the EU and US, and request an update on any work the EU may have undertaken to map EMDN and GMDN systems.

2.339. The representative of <u>Canada</u> provided the following statement. Canada wishes to echo the points raised by other Members regarding the implementation of this measure, and would like to refer to its previous statement made at the TBT Committee in November 2021 as contained paragraph 2.344 of the minutes.

G/TBT/M/86

2.340. In response, the representative of the European Union provided the following statement. As announced in previous Committee meetings, the MDR officially entered into application on 26 May 2021. This new Regulation significantly improves and upgrades the regulatory system for medical devices, aligning further with internationally developed principles by the International Medical Device Regulators Forum (IMDRF) and its predecessor, the GHTF. It is important to remind that the shift between the Directives to the MDR is a gradual one, facilitated by a grace mechanism that allows for medical devices in compliance with the Directives to continue to be in circulation until May 2025, in parallel with MDR certified devices. As regards the IVDR, the Commission continues to assess closely the situation on the ground. In previous TBT Committee meetings, the EU announced that it had become apparent that, due to the additional resources required to address the COVID-19 pandemic, national authorities, health institutions, Notified Bodies and economic operators were not in a position to ensure the proper implementation of the IVDR. With only six notified bodies designated and the focus shifted to pandemic urgencies, it became impossible for manufacturers to conduct the legally required conformity assessment procedures in time. In addition, due to COVID-19 travel restrictions, Notified Bodies were not able to carry out the required on-site audits of manufacturers' premises to verify the manufacturing and other relevant processes. This risks significant disruption in the supply of a multitude of in-vitro diagnostic medical devices (e.g. HIV tests, pregnancy tests or SARS-CoV-2 tests) on the European Union market.

2.341. As such, and as of May 2022, a staggered set of transition periods for IVDs was proposed by the European Commission. The proposed amendment to the IVDR has been since agreed upon by the European Parliament and Council. A measure explaining the adapted transitional provisions was also notified to the TBT Committee. The length of the transition periods depends on the risk class of devices, with shorter transition periods for higher risk devices and longer periods for lower risk ones. In addition, the notified draft proposes a deferred application of the requirements for "inhouse devices", i.e. those made and used within the same health institution. Since our latest update, we have 27 MDR designated Notified Bodies and 6 Notified Bodies under the IVDR, with more following in the pipeline. In addition, and pursuant to a Commission Notice of January 2021 on audits and surveillance assessments under the MDR and IVDR, there is some more flexibility for member States to allow remote audits carried out by Notified Bodies, if the conditions set out within the Notice are met. Given the large subset of additional requirements set out in the new Regulations and the need for both industry and Notified Bodies to adapt to these new requirements, we understand that certification time under the MDR and IVDR is taking longer than certification previously taking place under the Directives.

2.342. Information gathered in the continuous market monitoring conducted by the Medical Device Coordination Group (MDCG) has helped us to understand better the root causes of certain delays. Understandably, it seems that both industry and Notified Bodies are currently in an adjustment period as regards expectations arising from the new requirements, especially those regarding clinical evidence. In certain cases, we also understand that Notified Bodies are requesting follow-up information or testing to be conducted by the manufacturer, so as to ensure the safety of the devices and hence compliance with the new requirements. The turn-around time with the additional requested information by industry sometimes varies, which is inevitably leading to certain delays in original certification timelines. The MDCG will continue to closely monitor the situation on the ground and has established regular contacts with Notified Bodies and industry in this regard. It is important to remind 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 33 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 90 published guidance documents, including several key guidance on the transitional provisions and clinical requirements.

2.343. On standardization, we are happy to report significant progress, with the first publications in the OJEU of references of harmonised standards under the new Regulations taking place in July 2021. The second set was published in January 2022 and a third set is expected in the coming months. We want to reassure you that the Commission will continue to prioritise and encourage the harmonisation of international standards, where possible and appropriate. Furthermore, the expert panels, who have a role in the conformity assessment procedures of certain high-risk products, are officially running and processing applications. The IVD panel is now up and running, having already

delivered a number of opinions. In addition, the registration module of the EUDAMED database was made available in December 2020 and the Unique Device Identification (UDI) registration module went live in September 2021. The remaining three EUDAMED modules will be made available once the system is fully functional. As regards the Unique Device Identification (UDI), allow us to underline the fundamental difference between the UDI and the Nomenclature, which are two topics that 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 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 that 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.

2.1.3.36 Qatar - Ministry of Public Health Circular regarding shelf life for cheese (ID 602⁸⁸)

2.344. The representative of the <u>European Union</u> provided the following statement. The European Union would like to refer again to the Qatar's Ministry of Public Health Circular of 30 May 2019 establishing new import requirements for UHT milk and white cheese that entered into force already in 2019. The scope of these measures was further expanded with Qatar's Council of Ministers instructions issued in August 2021. Regrettably, these measures affected several dairy products exported from the EU to Qatar and the European Union would like to recall the importance of addressing these concerns. During the previous TBT Committee meeting, Qatar stated that this matter is still under consideration by the competent authorities in Doha. The European Union is grateful that we had further constructive exchanges with Qatar on this matter where Qatar signalled to be working on a solution, which is planned to be offered in a near future. The European Union would like to thank Qatar for the constructive bilateral exchanges during the past months and we stand ready to continue to work constructively with Qatar to resolve this important issue in due course.

2.345. In response, the representative of Qatar provided the following statement. Qatar has taken note of the continued concern of the European Union, regarding Qatar's Ministry of Public health circular on quality standards for certain dairy products and thanks the European Union for its interest in this matter. Qatar refers to prior discussions on this matter with the European Union. In particular, during the meeting held on 16 February during which our capital-based colleagues confirmed to the delegation of the European Union the suspension of the Circular in question while awaiting the conclusion of the internal review process. Let me take this opportunity to reiterate that these measures have been adopted in accordance with our international obligations and with a view to ensuring the quality of products available in Oatar. The protection of consumers is of primary importance to the Government of the State of Qatar. We would like to assure Members that the relevant measures apply equally to domestic and imported products and are therefore nondiscriminatory in nature. Furthermore, any impact that such regulations may have on trade will not be more than necessary to contribute to the fulfilment of the legitimate objective of protecting consumers. In this respect, we would like to emphasize that product-specific requirements applied in the State of Qatar do not prevent the importation and sale of any products that meet quality standards and thus do not have a significant effect on trade. This being said, we have listened carefully to the concerns expressed by the European Union today and will again share them with our capital. Also, we remain available to continue our constructive discussion with the European Union and any other interested Members to provide additional explanation where necessary.

2.1.3.37 India - Air Conditioner and its related Parts (Quality Control) Order, 2019, <u>G/TBT/N/IND/74</u>, <u>G/TBT/N/IND/110</u> (ID 598⁸⁹)

2.346. The representative of <u>China</u> provided the following statement. China welcomes the recent decision to defer the implementation of the Air Conditioner QCO to 1 January 2023. However, India

⁸⁸ For previous statements follow the thread under <u>ID 602</u>.

⁸⁹ For previous statements follow the thread under <u>ID 598</u>.

has not taken any measures to solve the problem of factory audits. Therefore, China would like to raise concerns again as follows. 1. China suggests that India implements alternative measures during the pandemic, such as temporary factory audit exemption for a limited period or virtual audit or audits through third-party agencies. It could address or solve the difficulties of physical inspection resulting from international travel restrictions. China would like to suggest a further meaningful delay of the Air Conditioner QCO due to the pandemic. 2. Air Conditioner Import Policy on 15 October 2020, the Ministry of Commerce and Industry of India issued an Amendment in the import policy of items under ITC HS Code 84151010 and 84151090 of Chapter 84 of ITC(HS),2017, Schedule – I (Import Policy). The import policy of air conditioners with refrigerants under HS code 84151010 and 84151090 is amended from "Free" to "Prohibited". China would like to raise concerns as follows: 2.1 China requests India to fulfill its transparency obligations, i.e. notify the TBT Committee in accordance with Article 2.9 of the WTO TBT Agreement, allowing a period of at least 60 days for comments. 2.2 China requests India to explain the scientific basis and necessity of the prohibition for air conditioners with refrigerants.

2.347. In response, the representative of India provided the following statement. The QCO 41/2015-2020 dated 15 December 2020 was necessary to apply standards in reducing risks to human, animal and plant life and health. Besides, it is consistent with India's commitment to the Montreal Protocol. Further, as per the Ozone-Depleting Substances (Regulation and Control) Amendment Rules 2014, the import of air conditioners containing Group VI substances (HCFCs) has been prohibited since 1 July 2015. Presently, the implementation date of Air Conditioner QCO has been extended by one year and will now come into effect from 1 January 2023. At present, there is no provision in BIS (Conformity Assessment) Regulations, 2018 to undertake virtual audits for conformity assessment activities as an alternative. Factory inspections were on hold earlier due to restrictions on international travel because of the COVID-19 pandemic. At present, BIS officers are nominated for carrying out the factory inspection for applications received from foreign manufacturers where the country to be visited facilitates the visit of fully vaccinated BIS officers carrying negative RT-PCR test reports, without any restrictions like guarantine and RT-PCR test upon arrival. Further, sufficient capacity for testing room air conditioners is available in BIS-recognized laboratories. Bureau of Indian Standards, under its laboratory recognition scheme (BIS LRS), grants recognition to laboratories for testing of products as per the relevant Indian Standards. Clause 12 of BIS LRS deals with the recognition of overseas laboratories. The decision regarding recognition of overseas laboratories will be taken by BIS taking into account the MRA (Mutual Recognition Agreement) with the concerned countries.

2.1.3.38 Kingdom of Saudi Arabia - Saber Conformity Assessment Online Platform / Saleem Product Safety Program (ID 615⁹⁰)

2.348. The representative of the <u>European Union</u> provided the following statement. The implementation of the electronic certification system SALEEM through the web-portal SABER remains a concern for the European Union. While we would like to thank the Kingdom of Saudi Arabia for engaging constructively in bilateral talks, and providing some explanations, the difficulties still have a major negative impact on the imports of several products from the European Union to Saudi Arabia. While the conformity assessment requirements differ depending on the sector, several European industries coincide in reporting their overly costly, burdensome and time-consuming nature. The sector of toys is particularly affected. The European Union would like to recall that the main concerns are related to the following issues: request of test reports; selection of representative item; extension of the validity of certificate; and products imported without GCTS (GCC Conformity Tracking Symbol). 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.

2.349. The representative of <u>Switzerland</u> provided the following statement. Switzerland remains concerned over the negative impact of the "Saber Conformity Assessment Online Platform" on bilateral trade with the Kingdom of Saudi Arabia. We would like to support the intervention made by the EU on this matter. The registration and certification process remains non-transparent, complex and time-consuming for our exporters. The industry continues to report that the conformity assessment procedures lead to disproportionate fees and in many cases to unnecessary administrative burden, costs and duplicative requirements. Depending on the sector, strict conformity assessment procedures apply for products considered in their majority to be low risk

 $^{^{\}rm 90}$ For previous statements follow the thread under $\underline{\rm ID~615}.$

products. 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 would appreciate if the Kingdom of Saudi Arabia could ensure that the registration and certification process is not more strict than necessary to give adequate confidence that products fulfil the applicable requirements. Furthermore, we encourage the Kingdom of Saudi Arabia to base the documentation and certification requirements on international standards, to implement clear and transparent guidelines and to ensure that the requirements are applied in an equal and uniform manner. We thank the Kingdom of Saudi Arabia for the useful engagement with our stakeholders on this matter, such as in a webinar organised by the Saudi Standards, Metrology and Quality Organization (SASO) and the Switzerland Global Enterprise (S-GE) last February, and look forward to further cooperation on this matter.

2.350. In response, the representative of the Kingdom of Saudi Arabia provided the following statement. Regarding SALEEM programme, it works through the development of an integrated system of regulations and standards that conform to internationally recognized professional practices by developing a highly efficient system for measuring product safety indicator in the market through mechanisms and procedures that comply with the technical regulations of each product, especially essential requirements for health of human and animals, environment protection, and ensure the effectiveness of the services provided by legislative and regulatory bodies to achieve safety by conformity of those products to SASO Standards. Within the framework of SASO to develop conformity assessment activities (certification, audit and inspection, and testing activities) in the Kingdom of 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, as 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 premarket approach.

2.351. Regarding Saber Platform. 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. Saber is implementing a series of improvements in the user experience in Saber Platform (UX project) and we are committed to keep improving the user experience in the platform. Saber had added the ability for bulk adding products and bulk applying for COC. In addition, Saber now reduced to steps in the platform where after adding your products you can proceed to applying for PCOC. Saber Platform reflects technical regulations, which had been notified to the WTO. In fact, Saber platform is a tool that helps local importers and local manufactories to save time and apply for the conformity assessments scheme and does not add more polices or requirements. The validity of the certificate is one year for the certificate of conformity and three years for the Saudi quality mark as well as the G-Mark. However, the test report can be valid for three to five years if nothing has been changed in the production line or the composite of the product and can be shared with multiple importers. In terms of GSO toy regulation, GCTS tracking symbol must be issued through GSO platform. Once the GCTS is obtained, the shipment certificates can be easily issued through Saber platform. We strongly advise all toys industries to contact the notified bodies according to the GSO Technical Regulation for Toys scheme (listed in Saber platform). In conclusion, SASO is always happy to collaborate and engage with all stakeholders and we look forward to further cooperation on this matter.

2.1.3.39 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), <u>G/TBT/N/IND/68</u>, <u>G/TBT/N/IND/131</u>, <u>G/TBT/N/IND/143</u> (ID 632⁹¹)

2.352. The representative of <u>Canada</u> provided the following statement. Canada continues to remain unclear regarding the objective of India's requirement that toy manufacturing sites be inspected by Bureau of Indian Standards personnel to verify, among other things, production processes and plant layout, and to collect product samples. India has previously stated that its main concern is safety of toys in India and that two thirds of all "foreign" toys in India failed a safety test and 79% failed

 $^{^{\}rm 91}$ For previous statements follow the thread under $\underline{\rm ID~632}.$

electrical inspections. Given this concern, Canada is unclear how inspecting toy manufacturing sites is going to address this concern. Shouldn't India be more concerned that the product meets the health and safety requirements, and not the place of production? Inspecting the assembly line and how the factory looks like is not going to demonstrate that the health and safety requirement of a toy is met. And if the purpose of the factory inspection is in fact product testing, what is India's rationale for not allowing this testing to be done by ILAC accredited labs? The Canadian industry continues to raise great concern with India's compliance requirements for the Quality Control Order. The on-site factory audits and verification testing requirement is onerous, unnecessary, expensive, and virtually impossible to satisfy (even during pre-pandemic conditions). Such audits are also unnecessary and the failure to provide alternatives is inconsistent with international product safety practices such as ISO 17067.

2.353. Additionally, verification testing must be performed by a lab accredited by the Indian accreditation body, only a few of which exist outside of India. In contrast, international safety norms allow product testing to be done by any laboratory accredited to international standards by an accreditation body that is an ILAC-MLA signatory. Further, because costs of the on-site audit, including travel to and from the factory by Indian government auditors must be paid by the manufacturer, the on-site audit requirement treats domestic manufacturers more favourably than foreign ones. We recognize factory inspections have been suspended by the Indian Government at this time because of the pandemic, but our industry continues to voice concerns with the on-site factory audits requirement. India has indicated that they are open to having a reciprocal MRA. However, MRAs would not be a solution for Canada as first, we do not have similar regulatory requirements. Second, MRAs are considered international treaties under Canadian law and are therefore very complex to negotiate, implement, and modify, if needed. And third, MRAs would not address the full extent of Canada's concerns given that several stakeholders have their production located outside Canada, where we can't facilitate the MRA discussions. Canada kindly urges India to consider allowing product testing to be done in the country of manufacture by ILAC accredited labs. Canada looks forward to working with India to ensure access to safe, high quality toys from Canadian firms.

2.354. The representative of China provided the following statement. China is the largest toy exporting country to India, however, many companies in China have suspended exporting toys to India in 2021 due to the impact of the new measure. China raises concerns as follows: 1. It is recommended that in order not to increase the cost of enterprises, India only selects high-risk toy categories for mandatory certification. According to the Toys (Quality Control) Order, 2020, the toys used by children under 14 years of age shall conform to the corresponding Indian standards. All our toy companies exporting to India face repeated testing, factory audits and other burdensome requirements. The cost of the certification is quite high for small and medium-sized manufacturers. During the certification process, an additional USD 10,000 deposit, application fee, annual licence fee, ISI logo fee are required, increasing the cost of the enterprise and causing obstacles to international trade, which is against Article 5.1.2 of the TBT Agreement. 2. It is recommended that the laboratory referred in this Order could include all ILAC-accredited laboratories. The Toys (Quality Control) order 2020 stipulates that the certification is subject to conformity testing from third-party laboratories. We would like to thank India for increasing to 32 accredited laboratories. But currently, the third-party BIS laboratories capable of toy standards IS 9873 and IS 15644 conformity approval, are all located in India. Our company would suffer long periods of audits, which affects the testing efficiency.

2.355. 3. In order not to create unnecessary trade barriers, it is recommended that foreign factories could be allowed to conduct factory audits virtually, and, and extend the transitional period to 1 January 2023. The Toys (Quality Control) Order came into force on 1 January 2021. The toys certification is quite complicated, where factory audits are the precondition for BIS verification. With the international travel restrictions worldwide caused by COVID-19, in-factory audits cannot be carried out as usual, toys certification actually is suspended. As virtual audit is already widely used, it is recommended that virtual audits for foreign factories is allowed. 4. According to Article 5.1.2 of the TBT Agreement, it is suggested that India could cancel the equipment requirements for electric toys and other projects. In October 2020, BIS issued the document 10 Steps to BIS Licence for Toys, while step 4 stipulates that electric toy factories should be with equipment required in IS 15644:2006 Clause 8, 9 and 10. However, expensive and technically demanding equipment is quite burdensome and difficult for small and medium-sized enterprises. Besides, the tests conducted by the abovementioned equipment are often done by third-party laboratories. The equipment requirement is therefore unnecessary and unreasonable.

2.356. Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017-schedule-I (import policy): 5. It is recommended that the Indian government could release the products based on the certificate of conformity. According to newly revised Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017-Schedule-I (Import Policy), samples should be randomly sent to NABL accredited Labs for testing. The clearance may be given by customs until the sample testing is completed. It seriously affected the efficiency of customs clearance and increased the importer's storage costs, which does not comply with Articles 5.1.2 and 5.2.1 of the TBT Agreement. 6. It is recommended that the Indian could accept the results of foreign laboratories accredited by ILAC. Imported toys must be sent to an independent laboratory accredited by NABL in India, which does not comply with Article 6.1 of the TBT Agreement. As NABL in India is a member of ILAC, it is recommended that India could accept the results of foreign laboratories accredited by ILAC.

2.357. The representative of the European Union provided the following statement. The European Union remains concerned about India's Toys Quality Control Order and in particular the certification requirements introduced by the Bureau of Indian Standards (BIS). The EU refers to its previous statement, but would like to highlight today that European industry continues to report the difficulties to work through the Quality Control Order especially because of the factory inspection requirement. In addition, European industry are facing difficulties with India's import policy. This relates to a previous TBT notification (G/TBT/IND/143) that we understood it was replaced by the QCO with regard to the specific import requirements. The European Union would like to invite India to respond to the concerns raised already and we remain available to have bilateral exchanges to find an adequate of this concern.

2.358. The representative of the <u>United States</u> provided the following statement. The United States supports and echoes the statements made by other Members on this STC. In the last four WTO TBT Committee meetings, the United States has urged India to provide a means by which US companies can resume shipments of toys to India. US companies remain unable to ship toys to India because of the Toy Quality Control Order 2020 (QCO). For example, one US company reports it last exported toys to India in the fall of 2020. The QCO makes it effectively impossible to ship toys to India because it requires factory surveillance inspections before a licence to import toys can be granted, but US factories are in locations where the Bureau of Indian Standards (BIS) officials are not yet conducting the required inspections. And this problem appears much larger than just toys, as we heard in November's TBT meeting, where several other STC interventions by Members raised similar concerns for other products. In light of repeated confirmations from India that toy products produced by US-based entities are not the source of safety concerns, we urge India to consider means by which US companies can comply with the QCO without further delaying US companies' exports of toys to India. We have already made our detailed concerns well known in previous statements, and those concerns remain. We therefore urge India to urgently resolve this concern raised by several Members.

2.359. In response, the representative of India provided the following statement. As per the provisions of the QCO, the products specified therein shall bear a Standard Mark under a valid licence from BIS as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. Under this Scheme, factory inspection is a mandatory requirement for the purpose of granting of licence. As per the product certification scheme of BIS, the availability of in-house testing facilities with manufacturers is required to operate a licence. However, BIS has allowed relaxations for toys manufacturers, including permitting sub-contracting of tests to BIS-recognized laboratories. As per the product-specific guidelines for toys, sub-contracting of tests other than physical, mechanical and electrical safety is allowed. Sufficient capacity for testing of toys is available in BIS laboratories and laboratories recognized by BIS under its laboratory recognition scheme (BIS LRS) for testing as per the relevant Indian Standards. Clause 12 of BIS LRS deals with the recognition of overseas laboratories. The decision regarding recognition of overseas laboratories will be taken by BIS taking into account the MRA (Mutual Recognition Agreement) with the concerned nation. The factory inspections were on hold earlier due to the restrictions on international travel because of the COVID-19 pandemic. There is no provision in the BIS Regulations to undertake virtual audits or temporary waiver of factory inspection requirement for conformity assessment activities as an alternative. However, at present, BIS officers are being considered for carrying out the factory inspection from foreign manufacturers where the country to be visited facilitates visits of fully vaccinated BIS officers carrying negative RT-PCR test reports, without any restrictions like quarantine RT-PCR test upon arrival.

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2.1.3.40 Australia - Maturation requirements for imported alcohol (ID 636⁹²)

2.360. The representative of <u>Brazil</u> provided the following statement. Brazil continues to follow closely Australia's proposal to amend current regulations dealing with alcoholic beverages, and we would like to thank Australia for its response in the Committee's last meeting and for its engagement in bilateral talks. In past meetings, we have shared our concerns with Australian technical requirements applicable to cachaça, the Australian Customs Notice N^o 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 two years in wood. Such a requirement does not relate to any quality standard or sanitary requirement applicable to cachaça.

2.361. 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, Pisco and Bourbon. 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, whisky 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 clarify the following points, which could not be 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?

2.362. In response, the representative of Australia provided the following statement. We acknowledge Brazil's continuing interest in Australia's review of maturation requirements for imported alcohol and provide the following update on this matter. Australia remains committed to the review of the legislative framework for the importation of unmatured alcohol products under section 105A of the Customs Act 1901 (Customs Act). We acknowledge that the review process is taking longer than anticipated due to the impact of the COVID-19 pandemic and the legislative complexities associated with this matter. As advised at the last TBT meeting, the Australian Border Force (ABF) initiated a broad consultation process with all relevant stakeholders, including the Brazilian Embassy in Canberra, to review its legislative framework for the importation of unmatured alcohol products under section 105A of the Customs Act. A public consultation paper was circulated, in late 2020, outlining a proposed approach to the legislative amendment. This initial stakeholder engagement has identified possible legislative reform options and highlighted additional considerations associated with the proposed reform model. Subsequent public consultation identified associated complexities. The Australian Government is now reviewing options to resolve this matter. The Australian Government will notify the Committee of any proposed legislative changes to section 105A of the Customs Act and any other changes to alcohol import requirements, in accordance with Australia's obligation under the TBT Agreement once all necessary Australian Government processes have been finalized regarding this review.

2.1.3.41 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 633⁹³)

2.363. The representative of the <u>European Union</u> provided the following statement. The European Union would like to refer to its previous statements on this matter. While the European Union fully

 $^{^{92}}$ For previous statements follow the thread under $\underline{\text{ID 636}}$.

⁹³ For previous statements follow the thread under <u>ID 633</u>.

supports the importance of labelling the presence of animal rennet, the European Union considers that the new certificate requiring that milk products have not been manufactured using animal rennet is not proportionate and not in line with the TBT Agreement. Since most European cheese is traditionally made with animal rennet and the veterinary certificate requires that milk products have not been manufactured using animal rennet, 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. Veterinary certificates are to address sanitary (human or animal) health issues and 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. Therefore, the European Union would ask India to amend the provisions of that veterinary certificate and allow for a label clearly indicating the presence of animal rennet in the cheese and its by-products, as it was previously the case. This label would allow consumers to make an informed choice.

2.364. The representative of <u>New Zealand</u> did not make a statement during the meeting. A technical statement was circulated following the meeting.⁹⁴

2.365. In response, the representative of <u>India</u> provided the following statement. The provision for non-animal rennet in cheese manufacture is not newly introduced in FFSAI regulations. This provision exists in Food Safety and Standards Regulations (FSSR) notified in 2011 and the erstwhile Prevention of Food Adulteration Rules. During a recent revision of the milk and milk product standards in FSSR, these provisions were retained and continue to be a specified requirement. The requirement of a veterinary certificate has been recently aligned with FSSR regarding the prohibition on the use of animal rennet. Hence, FSSAI has not introduced any new condition.

2.1.3.42 India - Order related to requirement of Non-GM cum GM free certificate accompanied with imported food consignment, <u>G/TBT/N/IND/168</u> (ID 651⁹⁵)

2.366. The representative of the <u>United States</u> provided the following statement. The United States once again reiterates its 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 <u>G/TBT/N/IND/168</u>, and a later notified entry-into-force date of 1 March 2021. We have proposed technical cooperation with the Food Safety and Standards Authority of India (FSSAI) on numerous occasions to explore alternatives to this measure. This invitation still stands. <u>G/TBT/N/IND/168</u> stipulates that the "Order is applicable to only food products listed in Annex-I of its Order and does not apply to processed food products in general." Yet, since the Order went into effect in March 2021, FSSAI has used the regulation to limit trade of certain processed products, including for processed products like milled rice where the Order should have no bearing. The United States again urges India to withdraw this requirement, and to engage with trading partners to find a science-based, trade-facilitating alternative.

2.367. 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 Indian requirement goes beyond what is necessary to achieve the stated objective and puts an additional burden and costs on EU exporters. The EU considers that the Order is disproportionate and creates unjustified barriers to trade. India should explain why it considers 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 that 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%. The EU as well as India are both parties to the Cartagena Protocol on biosafety to the Convention on Biological Diversity. 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

^{94 &}lt;u>G/TBT/W/764</u>.

⁹⁵ For previous statements follow the thread under <u>ID 651</u>.

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.

2.368. The representative of Japan provided the following statement. Japan shares the concern that this measure, which requires 24 agricultural products imported by India to be accompanied by a certificate stating that they are not genetically modified origin and do not contain genetic modification, would create unnecessary trade barriers and have negative impacts on agricultural trade between India and other WTO Members. It is regrettable that this measure was enacted in last March, despite the fact that other WTO Members requested India to fully consider the comments and concerns raised to India. In Japan, under domestic laws, the import, distribution, cultivation and other general uses of genetically modified agricultural products for human consumption are subjected to safety evaluations, and agricultural products that are not approved by the evaluation process cannot be imported nor distributed domestically. If certain items that are already under appropriate control in the origin country, requiring those items to be accompanied by a certificate of non-GM origin or GM free is not based on scientific principles or appropriate risk assessment, and this measure can be concluded as more trade-restrictive than necessary. We urge India not to require the attachment of certificates for foods that are properly controlled in the origin country.

2.369. The representative of <u>Australia</u> provided the following statement. Australia thanks India for their ongoing engagement and cooperation regarding the use of Non-GM and GM free certificates. 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 remains concerned with this measure and reiterates that measures should be risk based and no more trade restrictive than necessary. Australia is concerned that aspects of the regulation add unnecessary costs and create an additional regulatory burden on both Australian exporters and Indian importers. Australia suggests India consider adopting an alternative arrangement that can be implemented in a non-trade restrictive way and will gladly work with India on developing a mutually beneficial alternative solution. Australia welcomes and looks forward to India's continued engagement on this issue.

2.370. The representative of Canada provided the following statement. Canada would like to reiterate concerns raised at previous TBT Committee meetings, SPS Committee meetings, and the Council for Trade in Goods regarding the implementation of India's August 2020 Order, which mandates that a non-genetically modified or GM-free certificate accompany imported consignments of 24 imported food products. As detailed in Canada's comments submitted through India's TBT Enquiry Point in October 2020, we are concerned that India's Order will disproportionately impact the ability of GM-producing countries to export to India and unnecessarily restrict international trade. Canada welcomes India's recent decision to accept Canada's attestation for non-GM certification on bean exports. However, Canada continues to encourage India to consider a less burdensome approach to meeting the Order's stated food safety goals. As previously stated, the robust, sciencebased regulatory frameworks developed in countries around the world, including in Canada, should be considered as India assesses 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. Until a satisfactory solution is found and to minimize potential trade disruptions, Canada again requests that India suspend the implementation of this measure and that trade be permitted to continue without a certificate requirement. This would allow for further engagement with Members to discuss and consider an alternate, less trade-restrictive measure to meet India's intended objective. Finally, given the Order's stated objective "to ensure the safety and wholesomeness of articles of food imported into India", Canada reiterates its request that India notify the non-GM Order to the SPS Committee. We remain available and would welcome the opportunity to pursue further discussions on this issue in a bilateral setting.

2.371. The representative of <u>Paraguay</u> provided the following statement. Paraguay reiterates its support for this specific trade concern regarding the Order issued by the Food Safety and Standards Authority of India (FSSAI) requiring imports of food products to have a certificate of non-GM origin. The rules apply to 24 food products, requiring the submission of an official certificate attesting that the imported products have not been genetically modified, but we have not identified the criteria considered by India for the selection of these products. Furthermore, we endorse the comments made by other Members regarding India's failure to submit or identify the implementation of a regulatory impact assessment, scientific evidence or risk analysis underpinning the measure. Moreover, we are concerned that this measure may generate the unjustified assumption that GM foods evaluated and approved on the basis of sound regulatory processes are less safe than non-GM food products. GM products have been subjected to rigorous science-based safety

assessments in line with international standards, guidelines and recommendations to ensure that they are considered as safe as their conventional counterparts.

2.372. The representative of <u>Uruguay</u> 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 reiterate the invitation to the delegation of India to notify this measure to this Organization's SPS Committee. 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. Lastly, we wish to reiterate that we continue to await a reply to the joint note submitted by a number of countries, including Uruguay, in New Delhi in January 2021, 14 months ago.

2.373. The representative of <u>New Zealand</u> did not make a statement during the meeting. A technical statement was circulated following the meeting.⁹⁶

2.374. The representative of <u>Colombia</u> did not make a statement during the meeting. A technical statement was circulated following the meeting.⁹⁷

2.375. In response, the representative of India provided the following statement. The requirement to regulate the import of GM food is not new. It already exists under the Environment Protection Act (1986). This requirement is already notified to WTO and is neither discriminatory nor trade restrictive as it is uniformly applicable to imports from all countries. The FSSAI order on 21 August 2020 made it mandatory for the 24 identified commodities to be accompanied with a Non-GMO origin cum GMfree certificate issued by a competent national authority of the exporting country. On similar lines, India has issued such certificates for its exports to several other countries. The Government of India has authorized Export Inspection Council (EIC) as the nodal agency for issuing Non-GMO certificates for export consignments to other countries. EIC is issuing more than 9000 Non-GMO certificates for the export of primary food crops as well as processed food products for export to several countries. It may be noted that the said Order is not trade restrictive as the consignments of the identified commodities are already being accepted for import to India along with the Non-GM origin cum GM Free Certificate in the prescribed format. Section 7 of The Environment Protection Act (1986) and Rules prescribes that no person shall import or export genetically engineered its organisms/substances or cells except with the Genetic Engineering Approval Committee (GEAC). DGFT Notification No.2 (RE-2006)/2004-2009 dated 7 April 2006 on "Import of Genetically Modified Food" states that import of GMOs/LMOs for food will be governed by the provisions of the Environment Protection Act, 1986 and Rules 1989. GEAC has so far not approved any of the crop varieties of Genetically Modified/Engineered origin listed on the Order mentioned above. The requirement of a Non-GM certificate for import of 24 food crops is an assurance required from Competent Authorities of exporting countries that the food crops exported to India are of Non-GM origin and GM-free. As of date, several trade partners like the US, UK, Australia, Canada, Turkey, Iran, China, EU, including Italy, Germany, France and Thailand, are already providing requisite certificates.

2.1.3.43 Panama - Onions and Potatoes Harvest Life and Sprouting Requirements, <u>G/TBT/N/PAN/86</u>, <u>G/TBT/N/PAN/102</u>, <u>G/TBT/N/PAN/102/Add.1</u> (ID 662⁹⁸)

2.376. The representative of the <u>United States</u> provided the following statement. The United States thanks Panama for making progress on addressing our concerns regarding the duplicative onion nematode testing requirement. Recent developments in Panama have raised significant concerns regarding the predictability of Panama's regulatory regime. Before the November 2021 TBT Committee, Panama delayed entry into force of its potato measure until 1 March 2022. However, on

⁹⁶ <u>G/TBT/W/765</u>.

⁹⁷ <u>G/TBT/W/766</u>.

 $^{^{98}}$ For previous statements follow the thread under $\underline{ID~662}.$

30 December 2021, Panama published the measure and moved the enforcement date back to 17 February 2022, thus impacting US potatoes en route to Panama. For onions, Panama extended the post-harvest window from 75 days to 120 days until 28 February 2022. However, on 6 January 2022, Panama moved the expiration date back to 31 January 2022, also impacting US onions that were already bound for Panama. We were concerned to find that in its updated potato measure, Panama did not take any concerns raised by Members of this Committee into account. The postharvest date window remains in place, as do the prescriptive storage criteria. Although we have raised our concerns and shared technical information with Panama since 2016, Panama still has not explained how these are consistent with any relevant international standards, nor has it provided any technical justification for these requirements. We, again, urge Panama to suspend implementation of the potato and onion measures until Panama has justified the post-harvest date window, storage temperature criteria, and sprouting limits. Such action by Panama would signal to the US and other Members that Panama is serious about addressing our concerns.

2.377. The representative of <u>Canada</u> provided the following statement. Canada would like to thank the US for once again raising this specific trade concern regarding Panama's new quality requirements for fresh potatoes established by the Ministry of Industry and Commerce on 20 February 2020. As a long-standing supplier of fresh potatoes to Panama with year-round exports, Canada continues to share some of the concerns raised by the United States. In our two last interventions at the June and November 2021 WTO TBT Committees, Canada indicated that implementing these new quality requirements could have a direct impact on our ability to export potatoes to Panama. Canada recognizes that Panama has twice delayed the implementation of these measures to allow for further consultations with trading partners. Canada was also appreciative that a bilateral technical meeting was held to address elements of concern on this issue. However, despite this positive engagement, Canada notes that our concerns - including restrictive time limits for storage and marketing, as well as a zero tolerance for sprouting - have not been taken into account by Panama in the latest version of its quality requirements. Canada also notes that these requirements were implemented with little advance notice on 17 February 2022, and much earlier than the previously scheduled entry into force date of 2 April 2022. Finally, we observe that Panama did not notify the WTO until after these requirements had already entered into force. Canada continues to believe that a long-term solution that would provide a more predictable environment for both importers and exporters can be found through further technical dialogue. Until a long-term solution is found on the elements of concern, Canada respectfully requests that Panama indefinitely suspend the enforcement of this new regulation.

2.378. In response, the representative of <u>Panama</u> provided the following statement. My delegation thanks the United States and Canada and notes their concerns, which I will forward to Panama City. Panama has been responding to comments from its trading partners, as evidenced by the extension granted to the entry into force of the amendment for six additional months for potatoes, as well as the various meetings being held in the capital between our delegations. We reiterate our willingness to work with our trading partners and to maintain open communication between authorities.

2.379. The representative of the <u>United States</u> expressed some frustration towards Panama's response. The United States noted that this was Panama's response to our concern after every intervention in this Committee, however Panama has yet to follow up with us. The United States requested that the delegate expedite the response from their capital to follow up before the Committee meeting concludes this week.

2.1.3.44 Republic of Korea - Revision of Safety Conformation Criteria for Textile Products for Infants, <u>G/TBT/N/KOR/678</u> (ID 652⁹⁹)

2.380. The representative of the <u>European Union</u> provided the following statement. The EU would like to thank the Republic of Korea for their engagement on this issue. As a follow-up to the meeting of July last year, the EU has sent contact details of conformity assessment experts to the Korean Agency for Technology and Standards (KATS). The EU requests that KATS provide contacts for the relevant counterparts in order to discuss how best to resolve this issue with the view to having conformity testing, to the specific Korean rules for infant clothing, be performed outside of Korea by internationally accredited laboratories. This would also reduce the environmental impact of shipping tonnes of clothing to Korea for testing.

⁹⁹ For previous statements follow the thread under <u>ID 652</u>.

2.381. In response, the representative of the <u>Republic of Korea</u> provided the following statement. Korea would like to thank the EU for its concerns and comments regarding the "Requirements for Textile Products for Infants" of Korea, and we would like to take this opportunity to respond to the request, which was raised by the EU at this TBT Committee. With regard to the request, KATS (the Korean Agency for Technology and Standards) is in charge, and the EU representative had already requested the matter to this side, so KATS will forward response to the EU representative later.

2.1.3.45 India - Plain Copier Paper (Quality Order) 2020, G/TBT/N/IND/140 (ID 681¹⁰⁰)

2.382. The representative of Indonesia provided the following statement. Indonesia remains concerned on the implementation of Plain Copier Paper (Quality Order) 2020. Since the implementation of the regulation, Indonesia has not been able to export to India due to the strict requirement of factory visit, which remains impossible owed to travel restrictions. India has been a valued partner for the export of paper products, meaning, the absence of plain copier paper exports to India since December 2020 has resulted in considerable losses for Indonesian exporters. Indonesia humbly requests India to establish policies that do not impede trade, but to facilitate imports of products from Indonesia to meet the supply of quality paper products in the Indian market. According to the statement submitted by India delegation during last TBT meeting in November 2021, India mentioned the possibility to establish in-person inspection mechanism as an alternative to factory visit audit. Following this statement, Indonesia asks further clarification on the following matters. 1. Mechanism of implementing in-person inspection and requesting India to notify any policies related to an in-person inspection; 2. In-person inspection allow the use of personnel from foreign conformity assessment bodies who are competent, accredited, and recognized by BIS to carry out inspections based on the scheme established by BIS. Another option is to allow inperson inspection to be carried out by competent quality control officers from the relevant industry under remote supervision of auditors from BIS; 3. Indonesia hopes that the quarantine mechanism applied in Indonesia to prevent the spread of COVID-19 will not become an obstacle for Indian auditors to conduct factory and on-site inspections in Indonesia's region.

2.383. Indonesia urges India to refer to Article 6.1 Agreement of TBT WTO in accepting conformity assessment result. Indonesia, therefore, requests India to accept testing results from accredited conformity assessment bodies under signatory framework of international accreditation when implementing this regulation as a mean to facilitate conformity assessment procedure conducted by conformity assessment bodies in Indonesia. In this regard, a Mutual Recognition Arrangement can take place to ensure that testing results from accredited conformity assessment bodies in Indonesia can be accepted by BIS. Concerning there is no plain copier paper exported during the COVID-19 pandemic due to stringent requirements in the regulation, Indonesia requests India to postpone or provide sufficient transition time to allow industries to comply with the regulation. Indonesia asks India to cooperate in trade facilitation for plain copier paper product.

2.384. In response, the representative of <u>India</u> provided the following statement. Sufficient capacity for testing plain copier paper is available in BIS-recognized laboratories. Bureau of Indian Standards, under its laboratory recognition scheme (BIS LRS), grants recognition to laboratories for testing of products as per the relevant Indian Standards. Accreditation of laboratory as per IS/ISO/IEC 17025 from an accreditation body which is a full member of APAC/ILAC is a prerequisite for recognition under BIS LRS 2020. Clause 12 of BIS LRS deals with the recognition of overseas laboratories. The decision regarding recognition of overseas laboratories will be taken by BIS taking into account the MRA (Mutual Recognition Agreement) with the concerned nation.

2.1.3.46 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), <u>G/TBT/N/SAU/993</u>, <u>G/TBT/N/SAU/993/Rev.1</u> (ID 698¹⁰¹)

2.385. The representative of the <u>European Union</u> provided the following statement. The European Union remains 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 Saudi Quality Mark, the European companies are facing important challenges that has resulted in a de facto quantitative restriction to imports. Main concerns are related to audits; high costs; limited

 $^{^{\}rm 100}$ For previous statements follow the thread under $\underline{\rm ID~681}.$

 $^{^{101}}$ For previous statements follow the thread under $\underline{ID 698}$.

number of certification bodies; unclear audit procedures; and yearly surveillance audits. However, the European Union would like to thank the Kingdom of Saudi Arabia for the constructive bilateral talks on this issue. We remain available to continue the dialogue and we are confident that this concern will be solved in the near future.

2.386. In response, the representative of the <u>Kingdom of Saudi Arabia</u> provided the following statement. Saudi Arabia would like to thank the European Union for raising this matter and for the constructive bilateral meetings, including the meeting this week. As a result of these bilateral meetings, the competent authority in Saudi Arabia is working on a more comprehensive response that involves various elements, and we will reply directly to the EU.

2.1.3.47 Indonesia - Import quota and SNI certification requirements (ID 728¹⁰²)

2.387. The representative of <u>China</u> provided the following statement. SNI certification requirements lead to the delay or even failure of delivery by exporters, increase the cost of international transportation and performance significantly, and cause unnecessary obstacles to international trade. We suggest that: 1. Indonesia should increase the number of SNI accreditation bodies and testing laboratories outside Indonesia, and recognize CB certificates or third-party testing bodies. 2. Indonesia should accept mutual recognition of conformity assessment results through bilateral agreements. 3. Indonesia should lift the restriction that one auditor can only audit one category in one factory at one time; 4. Indonesia should conduct online factory inspections during the pandemic.

2.388. In response, the representative of <u>Indonesia</u> provided the following statement. Indonesia would like to refer to its last statement in TBT November 2021 meeting that all certification process for technical regulations based on SNI in the industrial sector is carried out in accordance with the provisions stated on the related Minister Regulation. All technical regulations based on SNI have also been notified to TBT Committee which provide a commenting period of 60 days. Indonesia remains available for further bilateral engagement with China on this issue.

2.1.3.48 Belgium - Draft law introducing additional security measures for the provision of mobile 5G services, <u>G/TBT/N/BEL/44</u>, <u>G/TBT/N/BEL/45</u> (ID 713¹⁰³)

2.389. The representative of China provided the following statement. China recognizes that WTO Members are legitimately entitled to protect the security of their 5G network. China welcomes any further responses and clarifications from the EU and Belgium and urges Belgium to promptly notify the revised royal decree. For the G/TBT/N/BEL/44, we would like to raise concerns that: 1. It is recommended to use objective and product-based technical standards for risk assessment. The EU's reply did not address China's core concern, i.e. the non-objective risk assessment criteria based on the characteristics of vendors are inconsistent with the TBT Agreement, which provides that a technical regulation shall be an objectively definable standard based on the product characteristics. China would like to point out that there are international standards based on technical criteria in the industry (e.g. the Network Equipment Security Assurance Scheme (NESAS) and Security Assurance Specifications (SCAS) published by Global System for Mobile Communications Association (GSMA), the 3rd Generation Partnership Project (3GPP), the Common Criteria for Information Technology Security Evaluation, and the cybersecurity certification standards set out in EU's 5G cybersecurity certification scheme specified in Regulation (EU) 2019/881). China urges that Belgium comply with Article 2.4 of the TBT Agreement by using internationally recognized technical standards that can objectively assess the product security, or certification methods that are based on international standards as the sole or fundamental assessment criteria for product security in the notified law.

2.390. 2. For Article 105,§4, it is recommended to clarify certain concepts and specify the scope of subjects to which the risk assessment criteria apply. The EU's reply did not address China's core concern on this issue, i.e. the scope of parties affected by the notified law is still not clear. China urges Belgium to specify the scope of "vendor" that may be subject to risk assessment and the method of their designation, and to clarify the relationship between "high-risk vendors" and "high-risk equipment manufacturer" in the notified law. China reiterates that the notified law shall adopt an objectively definable security standard based on the product characteristics, rather than the non-objective risk assessment criteria based on the characteristics of vendors. 3. For Article 105, §4, al.1, it is recommended to specify the procedures to revoke the identification of HRV. The notified

 $^{^{102}}$ For previous statements follow the thread under $\underline{ID 728}$.

 $^{^{103}}$ For previous statements follow the thread under <u>ID 713</u>.

G/TBT/M/86

law does not specify the scope and method where the HRVs are prohibited or restricted, nor does it illustrate the legal basis and the detailed procedures to seek removal of the HRV designation. It appears to be inconsistent with the requirement for the competent authority to administrate traderelated laws and regulations in a uniform, fair and reasonable manner and may constitute discrimination against specific 5G equipment vendors. In this regard, China recommends that Belgium further clarify the specific scope, legal basis and procedures for prohibiting and restricting the HRVs from supplying 5G equipment or services, and specify the path for so-called HRVs to seek removal of its HRV designation with detailed procedural guidance in the notified law.

2.391. 4. For Article 105, §4, al.4, it is recommended to adopt fact-based, objective and fair risk assessment criteria. China's concern is not about whether the notified law complies with the EU Coordinated risk assessment or the EU 5G Cybersecurity Toolbox, but about whether the risk assessment criteria set out in the notified law are objective and impartial. China finds that the risk assessment criteria are discriminatory and vague. For instance, the criterion as regards the extent of interference to the vendor by a non-EU country constitutes discrimination based upon the origin of vendors and discriminates the vendors from non-EU countries. China reiterates that the 5G equipment security shall be assessed based on facts and industry-recognized objective security standards instead of a non-objective risk assessment of the vendors. China urges that Belgium comply with Article 2.1 and 2.2 of the TBT Agreement and other WTO requirements by developing objective, fair and non-discriminatory 5G equipment security standards and measures, taking full consideration of the characteristics and usage of 5G technology and adopting existing industrial good practices.

2.392. 5. For Article 105, §5, it is recommended to provide so-called HRVs with rationales of the assessment and with reasonable remedies. The EU's reply did not address China's core concern. The notified law only allows 5G MNOs to defend against the preliminary results of the risk assessment and to request a hearing. However, the vendors of 5G equipment or services identified as the so-called HRV are not provided with any legal remedies. Given that it is the vendors of 5G equipment or services that are subject to the risk assessment, China proposes that Belgium specify the administrative or judicial remedies for the vendors of 5G equipment or services in the notified law, requiring the competent authority to provide so-called HRVs with rationales and evidence of its decision, and grant vendors the right to defend themselves against unfavourable risk assessment decisions.

2.393. For the <u>G/TBT/N/BEL/45</u>, we would like to raise concerns that: 1. The royal decree as well as relevant regulations and technical standards shall be provided and comply with the principles of fairness, non-discrimination, and transparency on the basis of objective facts and evidence. China suggests the adoption of internationally recognized technical standards that can objectively assess the product security or certification methods that are based on international standards as fundamental assessment criteria for product security, rather than the non-objective risk assessment criteria based on the characteristics of vendors. Regarding Chapter 2 of the notified royal decree, such Chapter prohibits or restricts the 5G mobile network operators from using active elements produced by "high-risk equipment manufacturers" without specific criteria. China would like to point out that there are international standards based on technical criteria in the industry (e.g. the Network Equipment Security Assurance Scheme (NESAS) and Security Assurance Specifications (SCAS) published by Global System for Mobile Communications Association (GSMA) and the 3rd Generation Partnership Project (3GPP), the Common Criteria for Information Technology Security Evaluation, and the cybersecurity certification standards set out in EU's 5G cybersecurity certification scheme specified in Regulation (EU) 2019/881).

2.394. 2. China suggests that Belgium could specify the administrative or judicial remedies for 5G equipment manufacturers affected by the notified royal decree and relevant laws, regulations and technical standards. Chapter 2 of the notified royal decree and the relevant law only allow 5G mobile network operators to defend themselves against the preliminary results of the risk assessment and to request a hearing. However, it does not provide any legal remedies for 5G equipment manufacturers identified as so-called HRVs, nor does it illustrate the method and procedure to lift the HRV designation. China proposes that Belgium could specify the administrative or judicial remedies for 5G equipment manufacturers in the notified royal decree, requiring the competent authority to provide rationales and evidence of its decision and provide the 5G equipment manufacturers the way to defend themselves against unfavorable risk assessment decisions and detailed procedures to remove a high-risk designation, ensuring that the 5G equipment manufacturer identified as so-called HRVs is entitled to apply for removal of the designation. 3. The

royal decree and relevant laws, shall be prepared, adopted, or applied in a manner commensurate to the intended legitimate objectives. Furthermore, they shall not be more trade-restrictive than necessary to fulfil their legitimate objectives. The notified royal decree generally prohibits the use of any active elements produced by "high-risk equipment manufacturer" in specific types of networks. China suggests that different security levels can be applied on the basis of product characteristics and objectively definable product security assessment standards.

2.395. In response, the representative of the <u>European Union</u> provided the following statement. During the commenting period of those notifications, China submitted written comments to which the EU replied on 8 November 2021. The EU would like to clarify that the notified draft (hereinafter "the adopted law") under <u>G/TBT/N/BEL/44</u> was adopted on 10 February 2022 and that no revision of the adopted law is foreseen in the near future. Moreover, the notified draft under <u>G/TBT/N/BEL/45</u> has been substantially revised and will be notified in accordance with the TBT Agreement as a revision with a new commenting period in due course. Moreover, the EU can provide the following specific replies: First, all the criteria on the basis of which a supplier's risk profile is assessed originate from the NIS Cooperation Group's 5G toolbox, except for the following "subfactor": "e) the country the supplier originates from conducts or is involved in an offensive cyber policy". Second, the EU would like to clarify that the adopted law provides that nearly all elements of a 5G network are subject to a safety analysis as per the new Article 105, § 1. In this regard, the risk profile of the supplier of those elements plays an important role in the safety analysis. Finally, the risk profile is assessed on the basis of the factors listed in the new Article 105, § 4, subparagraph 4 of the adopted law.

2.396. The interpretation of the term "supplier" in Article 105, § 4, subparagraph 4, was explained in the latest explanatory memorandum to the adopted law. China comments that the adopted law does not specify to what degree and in what way high risk vendors ("HRV") are forbidden or restricted, nor whether and how the HRV designation can be revoked. If a HRV wants to challenge their high-risk designation they must do so by way of written observations and/or during a hearing (which may be requested by the party applying for a ministerial authorization), and which would follow a refusal. A HRV may also appeal against this administrative legal act before the Council of State (see also the EU's response to the final question). The adopted law and the notified draft under G/TBT/N/BEL/45 do not provide for any list of HRVs. Being designated in that capacity in one case does not automatically imply that the supplier will be considered high risk in another case and vice versa. The supplier's risk profile is assessed for each separate case. Regarding the determination of the supplier's risk profile, the factor of "the likelihood of the supplier being subject to interference from a non-EU country" is justified and explained in the explanatory memorandum to the adopted law. Regarding HRVs, as indicated previously, the criteria for identifying HRVs are provided in Article 105, § 4 of the adopted law and provide the basis of any assessment. As to remedies, a party requesting a ministerial authorization will receive a draft decision and may make written observations and request a hearing, as foreseen in Article 105, § 5, subparagraph 2 of the adopted law. An appeal against the final decision of the Ministers can be lodged with the Council of State. The HRV is able to do initiate this appeal, since Article 19, first sentence of the coordinated Acts on the Council of State provides this can be done by any party who gives evidence of prejudice or of an interest.

2.1.3.49 India - Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order, 2012, <u>G/TBT/N/IND/44</u>, <u>G/TBT/N/IND/44/Add.2</u>, <u>G/TBT/N/IND/44/Add.3</u>, <u>G/TBT/N/IND/44/Add.3</u>, <u>G/TBT/N/IND/44/Add.3</u>, <u>G/TBT/N/IND/44/Add.4</u>, <u>G/TBT/N/IND/44/Add.5</u>, <u>G/TBT/N/IND/44/Add.9</u>, <u>G/TBT/N/IND/47/Add.1</u>, <u>G/TBT/N/IND/47/Add.1/Corr.1</u>, <u>G/TBT/N/IND/47/Add.3</u>, <u>G/TBT/N/IND/47/Add.3</u>, <u>G/TBT/N/IND/47/Add.2</u>, <u>G/TBT/N/IND/47/Add.1</u>, <u>G/TBT/N/IND/47/Add.2</u>, <u>G/TBT/N/IND/47/Add.3</u>, <u>G/TBT/</u>

2.397. The representative of the <u>Republic of Korea</u> provided the following statement. The Republic of Korea appreciates this opportunity to submit comments with respect to the "Electronics and IT Goods (Requirement of Compulsory Registration) Order, 2012", notified to the WTO in October 2020 as <u>G/TBT/N/IND/44/Add.9</u>, and "Clarification regarding coverage of Cameras, Speakers and Microphones used in Automotive sector" announced in July 2021 without notification to the WTO Members. Korea once conveyed a letter of comments from Korean companies to India through the Indian TBT enquiry point on 8 September 2021. However, we have not yet received any reply from India, so we would like to reiterate our earlier comments as follows. As finished cameras for vehicles

 $^{^{\}rm 104}$ For previous statements follow the thread under $\underline{\rm ID~367}.$

were added to the subject of Electronics and IT Goods Compulsory Registration Order (CRO), which is implemented from 1 October 2021, our companies are having difficulties in interpreting the scope of application for "finished products". According to clause (iv.) of the Clarification note (W-47/38/2021-IPHW) issued by the Indian Government on 22 July 2021, finished cameras used in automobiles fall within the scope of CRO. Furthermore, according to "Frequently Asked Questions (FAQ) with respect to products notified under phase V" published online by the Indian Government in February 2021, it is clarified that "the Compulsory Registration Order applies only to the finished goods and not to the spare parts/components used in the manufacturing of the finished goods, unless they are notified separately as independent products under CRO".

2.398. In general, camera modules manufactured by Korean automotive parts companies are items for business-to-business (B2B) transactions that must be installed onto vehicles through additional assembly processes in India, and they are not considered as finished products. Despite recognizing that their products are not finished products, Korean manufacturers requested the Indian Government to provide a clear interpretation of the scope of product coverage in order to faithfully comply with the regulation. But since no response has been received so far, the manufacturers are confused about whether to proceed with the follow-up procedure. If sub-parts in finished products such as camera modules are included under the CRO's scope, follow-up procedures such as approval to use the BIS mark are required, which will burden the industry with excessive cost and delay in export. Regarding the scope of application of the product, Korea would like to enquire to India about the clear definition of "finished cameras being used in automotive", and whether the camera modules for business-to-business (B2B) transactions, and not finished products, fall within the scope of CRO.

2.399. The representative of <u>Canada</u> provided the following statement. Canada would like to reiterate its concerns with this measure and would welcome any further clarification and information that India can provide today to the Committee. Canada notes that India's unwillingness to accept tests performed in accredited foreign facilities is a systemic issue across a range of products. Canada continues to encourage India to adopt IEC standards and to recognize test results from internationally accredited labs. As noted in previous meetings, Canada remains concerned by the CRO 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 other accredited labs.

2.400. In response, the representative of <u>India</u> provided the following statement. Digital Camera, Video Camera and Webcam (Finished Product) are covered under "Electronics and IT Goods (Requirement of Compulsory Registration) Order, 2012 (CRO)" vide Gazette Notification No. S.O. 3429(E) dated 1 October 2020, and the Order came into effect from 1 October 2021. It is clarified that CRO applies only to the finished goods and not to the spare parts/components used in manufacturing the finished goods unless they are notified separately as independent products under CRO. The finished cameras used in the automotive are covered under CRO; however, if they are imported as an integral part of a vehicle, they would not attract CRO provisions. A clarification note vide W-47/38/2021-IPHW dated 22 July 2021 is already issued by the Ministry of Electronics and Information Technology.

2.1.3.50 European Union - Commission Delegated Regulation (EU) 2019/945 on Unmanned Aircraft Systems and on Third-country Operators of Unmanned Aircraft Systems, <u>G/TBT/N/EU/628</u> (ID 585¹⁰⁵)

2.401. The representative of <u>China</u> provided the following statement. China finds that the regulations on tethered unmanned aircraft systems (UAS) still constitute an obstacle to trade, so China would like to reiterate our concerns as follows, and hopes that the EU will actively consider our recommendations. 1. It is recommended that the factor of mechanical strength for the heavier-than-air tethered UAS cable in the EU Regulation 2019/945 should be no less than four times of the maximum take-off mass (MTOM) The requirement for the mechanical strength of the tethered UAS cable is stricter than necessary. The regulation requires ten times by take-off weight, according to assessment by enterprises, four times is enough for safety. It is calculated that the safety factor of mechanical strength of different material cables ten times by the take-off weight is 2.8 - 8.4, which is much higher than the safety factor of all parts of manned civil aviation and general aviation (1.25-1.8). The excessive requirement also leads to a significant reduction of the overall performance. In addition, the backup batteries, automatic return and other technologies are more conducive to

 $^{^{105}}$ For previous statements follow the thread under $\underline{\text{ID 585}}$.

ensure the safe operation of the tethered UAS in terrible weather, air flow and other special conditions.

2.402. 1. China recommends that EU change the extension length limit of category C3 tethered UAS from "50 meters" to "120 meters". We consider the limit of the length of category C3 UAS is too short. With the development of technology, category C3 of tethered UAS has excellent stability and wind resistance. The extension length of 50 meters required by EU regulation, could not meet the needs of customers and limit the development of this type of tethered UAS. Since the regulation limits the flying height of "Open Drones" to 120 meters, and category C3 of the tethered UAS do not have more risks than Open Drones, we suggest that EU consider using the same criteria for both of them.

2.403. In response, the representative of the <u>European Union</u> provided the following statement. Commission delegated Regulation (EU) 2019/945 on unmanned aircraft systems and on thirdcountry operators of unmanned aircraft system and Commission Implementing Regulation (EU) 2019/947 on the rules and procedures for the operation of unmanned aircraft were published in June 2019. Regarding the requirement for the mechanical strength of the tethered UAS cable is stricter than necessary, the factor of 10 is coming from tethered gas balloons certification specifications and takes into account the unmanned aircrafts accelerations, the variability of the tether material and a safety factor. On the extension length limit of category C3 tethered UAS, the EU considers that 50m is the maximum that can be authorized in the open category (low risks operations) as it represents the maximum altitude under which the probability to have manned aircraft operations can be considered as extremely low. This limit is also consistent with the recommendations of the SORA risk analysis.

2.1.3.51 European Union - Hazard-based approach to plant protection products and setting of import tolerances, <u>G/SPS/N/EU/166</u>, <u>G/SPS/N/EU/166/Add.1</u>, <u>G/SPS/N/EU/263</u>, <u>G/TBT/N/EU/383</u>, <u>G/TBT/N/EU/383/Add.1</u>, <u>G/TBT/N/EU/384</u>, <u>G/TBT/N/EU/384/Add.1</u>, <u>G/TBT/N/EU/495</u> (ID 393¹⁰⁶)

2.404. The representative of <u>Australia</u> provided the following statement. Australia would like to thank the EU for its response to Australia's and other Members' concerns raised during the meeting held in November last year. Australia understands that the EU is considering lowering existing MRLs for pesticides no longer approved in its jurisdiction due to environmental concerns - such as some neonicotinoid insecticides – to default values and refusing new requests for import tolerances for these products. By applying EU environmental standards to imported agricultural products, this measure aims to support the EU's ambition to improve environmental objectives globally. While the EU's ambition is commendable, Australia only supports lowering MRLs to default value where a food safety risk has been identified for consumers. Taking into account environmental concerns of a global nature in setting import MRLs, in addition to consumer dietary aspects, introduces arbitrary criteria that are incompatible with current international practice and the EU's obligations under the SPS Agreement. This approach assumes the EU is better placed to assess the environmental impacts of active substances in third countries than the chemical regulators of those countries.

2.405. Furthermore, this approach fails to recognize the efforts of international scientific panels and standard setting bodies - such as the Joint FAO/WHO Meeting on Pesticide Residues and the Codex Alimentarius - in establishing safe and harmonized levels of pesticide residues in agricultural products. 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. To avoid trade disruption, it is imperative that the EU continues to comply with its obligations under the TBT and SPS Agreements when setting MRLs and considering requests for import tolerances. Australia once again requests that the EU respects the conclusions of trading partners' regulators on the environmental impact of chemical substances and limits its aspessment of requests for import tolerances to the consideration of dietary risks. Departing from this approach will result in significant trade disruptions. We remain available to discuss our approach to pesticide regulation with the EU and look forward to continued constructive engagement on this issue.

2.406. The representative of <u>Brazil</u> provided the following statement. Brazil would like to refer to its previous statements regarding STC 393. We emphasize that regulations on endocrine disruptors

 $^{^{\}rm 106}$ For previous statements follow the thread under $\underline{\rm ID}$ 393.

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.

2.407. 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 European Union's (EU) hazard-based regulation for active substances in plant protection products and the setting of import tolerances. Canada does not favour or promote the use of any one production method over another and we share the objective of ensuring that pesticides are used only as necessary. In order to achieve the correct balance for growers, as well as to ensure plant health and minimal waste, farmers need to have access to a wide range of effective and affordable plant protection products, including both chemical and biological options. We have in place an effective regulatory regime to monitor the safe use of chemical solutions when needed, including clear labelling requirements. Using integrated pest management approaches, we support farmers in their own assessment of what is needed according to growing conditions, market demand and other factors. Rigorous regulatory requirements exist, including scientific assessments and monitoring programmes, to ensure the health and safety of consumers where pesticide residues can be a factor, as well the health of the environment. We encourage the EU to take an approach which does not unnecessarily limit the availability of all crop protection tools for growers. Regulatory decisions based on assessments of both hazards and risks for all active substances are the best means to achieve the right balance between grower and consumer safety on one hand and food security and reduced waste on the other.

2.408. The EU has stated that it will be changing how requests for import tolerances are established in the context of their current policy objectives, including the hazard-based cut off criteria and other (unspecified) considerations. Canadian growers and exporters have yet to be convinced of the realworld feasibility, commercial viability and compliance with international obligations of the EU's proposed approach for setting import tolerances when a plant protection product has met the hazard-based "cut-off" criteria. Additionally, the EU has indicated that it intends to consider environmental factors in the establishment of maximum residue limits, which would likely apply to import tolerances as well. Canada would appreciate further information on this approach, including on who will determine what environmental factors will be considered and how these will be scientifically justified in the dietary risk assessment. Canada would also be interested in receiving information regarding upcoming regulatory or policy changes, including any available updates since the last seminar held in Brussels in January 2021, to ensure that unnecessary trade barriers are minimized and that measures are consistent with international trade obligations. Finally, Canada once again requests that the EU consider maintaining MRLs for substances that do not pose unacceptable dietary risks and import tolerances be authorized based on dietary risk alone. 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.

2.409. The representative of <u>Ecuador</u> provided the following statement. My country shares the concerns raised by the Members that have already taken the floor. Ecuador recognizes the importance of protecting human health and the environment; however, we consider that regulatory decisions taken on the basis of hazard-based criteria are inconsistent with international risk-assessment practices. Ecuador urges the European Union (EU) to take into account scientific information emanating from the international specialized bodies recognized by the WTO, such as the Codex Alimentarius, which has relevant information on pesticides. Ecuador also urges the EU to take into account the recommendations of the Committee on Technical Barriers to Trade related to good regulatory 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.

2.410. The representative of <u>Paraguay</u> provided the following statement. Paraguay reiterates its position and refers to its previous statements by stressing the importance of adopting a scientific approach to the regulation of phytosanitary products based on risk and not just on the hazard arising from the intrinsic properties of a chemical. In this regard, Paraguay once again requests that the European Union take into consideration information on pesticides provided by the specialized agencies recognized by the WTO, such as the Codex Alimentarius, reconsider its approach and base its decisions on conclusive scientific evidence and real risk weightings, in accordance with international standards and principles, ensure import tolerances; and, where necessary, provide adequate transitional periods. We echo the concerns and questions of the delegations of Australia and Canada in relation to the MRL-reduction announcements and the non-granting of import tolerance for certain plant protection products owing to environmental concerns.

2.411. The representative of <u>Guatemala</u> provided the following statement. Guatemala remains concerned about the non-renewal of active substances deemed to be potential endocrine disruptors and the decision-making based on the precautionary principle. 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 of an active substance are identified, without considering the characterization of exposure related to product use, thus increasing scientific uncertainty. We would like to express the importance of basing the assessment of active substances for the establishment of import tolerances on risk analysis, particularly for developing countries with tropical climates and thus agro-ecological conditions different from those of the European Union. In addition, geographical location, namely the distance and time needed to export a product to the European Union, is another condition that should be taken into consideration to avoid applying measures that unnecessarily restrict trade.

2.412. The representative of <u>Argentina</u> provided the following statement. Argentina once again reiterates its concern regarding this matter and stresses the importance of ensuring that all Members implement SPS measures based on risk assessments, taking account of the risk assessment techniques developed by international reference bodies. The latter include the principles for establishing pesticide MRLs, as well as the many risk analyses that, over the decades, the Codex Alimentarius has conducted to ensure safety in terms of MRL recommendations for different substances and crops.

2.413. The representative of <u>Costa Rica</u> provided the following statement. As on previous occasions, Costa Rica reiterates its support for the trade concern raised by Australia, Brazil and Canada. Costa Rica is concerned about the hazard-based approach adopted by the European Union, given that, under the multilateral system obligations, all technical requirements must be based on the relevant international reference standard or a risk assessment providing the scientific evidence to support the measure. Costa Rica reiterates its request to the European Union to ensure that the implementation of its regulations is based on the use of risk assessments through the application of criteria supported by sufficient scientific evidence, in line with the commitments established in the TBT Agreement.

2.414. The representative of <u>Chile</u> provided the following statement. The delegation of Chile thanks the European Union for the opportunity to comment on this STC and refers to the statements made by Chile on this subject at previous meetings of the TBT Committee.

2.415. The representative of <u>Colombia</u> provided the following statement. Colombia wishes to reiterate its grave concern regarding the hazard-based approach used by the European Union to establish regulatory measures for plant protection products under which it does not approve or does not renew permits for marketing certain plant protection substances and modifies maximum residue levels. We reiterate that this type of measure needs to be based on risk assessment results and conclusive scientific evidence. We call upon the European Union to use, and base its decisions on, the information provided by international reference bodies such as the Codex Alimentarius. This enables the realities, challenges and needs of developing countries and different geographical areas to be taken into account. We also invite the European Union to review alternative measures that are not more restrictive than necessary to trade, including when adopting measures to protect the environment and human health.

2.416. 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 production, 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 tolerance requests for active substances no longer approved in its territory, taking into account the provisions of the SPS Agreement. Uruguay continues to support any multilateral work undertaken by the Codex Alimentarius to develop a harmonized, risk-based approach that ensures the protection of health, while facilitating international trade in food products. In the meantime, we once again call on the European Union to listen to and address the concerns expressed by a number of Members, and to reconsider its regulatory approach with a view to preventing the unjustified proliferation of barriers to international trade in agricultural products and the serious social and economic consequences of such an approach for other Members, in particular developing and least developed countries, for which the European Union is a key market.

2.417. In response, the representative of the <u>European Union</u> provided the following statement. The European Union thanks 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.

2.418. The EU will take into account environmental aspects when deciding about requests for import tolerances for substances no longer approved in the EU, while respecting WTO standards and other international obligations. Such environmental issues of global concern are, for example, the worldwide decline of pollinators, or the contamination of the environment with bioaccumulative, toxic and persistent chemicals. The European Union intends to address this matter on an incremental basis, considering and reviewing the position of each particular active substance on a case-by-case basis, founded on the best available scientific evidence and ensuring that its measures are not more trade restrictive than necessary to achieve their objective. It is important to note that this new approach will not prohibit other countries to use the pesticide on the crop, as other countries are free to decide on the use of pesticides on their territory. If the harvested crop is destined to be placed on the EU market, it must comply with the Maximum Residue Levels (MRLs) in place in the EU. In addition, applicants have the possibility of submitting additional information to prove that the good agricultural practices included in import tolerance request is sufficiently protective for the environment. The EU would like to draw the attention of the TBT Committee to the thematic session on Trade Facilitative Approaches to Pesticide MRLs, which will take place at the margins of the next SPS Committee meeting on 22 March 2022 and provide further opportunities to discuss this topic. The EU reiterates its commitment to act in full transparency and keep Members duly informed about further developments.

2.1.3.52 Brazil - Draft Ordinance Act N^o. 374, 27 November 2014 (Portaria SDA/MAPA 374/2014) Establishes quality requirements for wine and derivatives of grape and wine, <u>G/TBT/N/BRA/613</u>, <u>G/TBT/N/BRA/613/Add.1</u>, <u>G/TBT/N/BRA/613/Add.2</u>, <u>G/TBT/N/BRA/613/Rev.1</u>, <u>G/TBT/N/BRA/675</u>, <u>G/TBT/N/BRA/613/Add.3</u> (ID 470¹⁰⁷)

2.419. The representative of the European Union provided the following statement. The European Union would like to thank Brazil for notifying the draft Technical Regulation on the identity and quality standards for wines and derivatives of grape and wine and to note that the EU written comments were sent to Brazil on 7 December 2022. The European Union appreciates the recent reply of Brazil announcing a public audience that will provide for further opportunity to review the amended draft regulation. The EU would like to ask about the estimated date for the public audience, when the revised draft regulation will be published and whether Brazil will notify the revised text to the WTO TBT Committee. The European Union would like to recall its main general concerns and refer for details to its written comments. First, the EU would like to kindly ask Brazil to refrain in the ongoing revision from further enlarging the already long list of analytical parameters, many of them diverging from recommendations of the International Organisation of Vine and Wine. To avoid creation of unnecessary obstacles to trade, it is important to clarify that the new parameters do not need to be certified for imported wines and to guarantee that the Brazilian methods of analysis for the new parameters are consistent with OIV recommendations. Second, the EU would like to invite Brazil to aim at resolving in the ongoing revision the longstanding issue of the classification of sparkling wine according to sugar content, which is currently discussed in the OIV, and in the interim, to align with OIV's glucose and fructose method of analysis for the determination of sugar content. As in past TBT Committees, the European Union would like to encourage Brazil to seek international consensus within the OIV framework on issues relevant to our bilateral trade, such as categories of sparkling wines related to sugar content, import documentary evidence and list of analytical parameters for imports. The European Union appreciates the efforts previously demonstrated by Brazil to facilitate the implementation of its wine regulations for importers. However, Brazil is invited to make use to the maximum extent possible of the recommendations of the OIV when revising the relevant technical regulations and to remove the current requirements that are not in line with the OIV standards on identity and quality of wine and on maximum content limits. The European Union is prepared to work bilaterally with Brazil with regard to the ongoing revision, invites Brazil to take into account the EU written comments and looks forward to the opportunity to review the revised draft regulation.

2.420. In response, the representative of <u>Brazil</u> provided the following statement. Brazil would like to thank the European Union for its statement and recall that the Ministry of Agriculture, Livestock and Supply (MAPA) Ordinance No. 346, published on 1 July 2021, opened public consultations regarding a draft regulation that establishes identity and quality standards, as well as complementary rules for labelling and production process of wine and grape-derived wines. In response to the requests from many stakeholders, Brazil extend the time for comments until 7 December, what has been notified as <u>G/TBT/N/BRA/613/Add.3</u>. Brazil appreciates the comments received from the EU and from the US on this notification, which are important to improve the regulation of wine, grapes and their products in Brazil.

2.1.3.53 United Kingdom - Wine labelling and documentation requirements at the end of the Brexit transition period (ID 663¹⁰⁸)

2.421. The representative of <u>Australia</u> provided the following statement. Australia appreciates the engagement with the United Kingdom in this Committee and welcomes the steps taken by the UK Government to remove burdensome requirements such as those for VI-1 forms for all wine imports into Great Britain. However, Australia continues to have concerns over labelling requirements, particularly as they relate to wine exported and transhipped through the UK to the EU. We acknowledge the United Kingdom's response in the previous Committee meeting - that wine marketed in Great Britain can show either a United Kingdom or a European Union imported on the label until 1 October 2022 and that after that date, wine products marketed in Great Britain must bear the details of an importer situated in Great Britain on the label of products. As was raised in the previous meeting, we are seeking flexibility to allow the listing of multiple importers on the label of wine bottles imported into the UK and for multiple destinations, particularly after that grace period ends. We believe it is possible to include a UK importer and importers in other third countries and

 $^{^{107}}$ For previous statements follow the thread under $\underline{ID\ 470}.$

 $^{^{108}}$ For previous statements follow the thread under $\underline{ID 663}$.

still meet regulatory objectives; for example: "For the UK, imported by..." and "For the EU, imported by...". We would like the UK to please clarify whether it would accept labels with a UK and EU importer on the label after 1 October 2022, as this would mean the label still bears the details of an importer situated in Great Britain We want the UK to ensure any labelling requirements are no more trade restrictive than necessary to achieve their objectives and look forward to working closely with the UK on this issue to ensure a mutually satisfactory outcome. Australia welcomes the bilateral engagement we have had to date. We look forward to addressing these issues further in upcoming bilateral engagement, given they remain a major concern for our wine industry.

2.422. The representative of <u>Uruguay</u> provided the following statement. First, my delegation welcomes the adoption of legislation to lift the requirement to submit VI-1 forms for the importation of wine into Britain. Second, Uruguay once again wishes to express its interest in remaining informed of the regulatory requirements and conditions that will apply to the importation of wine into the United Kingdom market from 1 October 2022, in particular with respect to documentation and labelling, and in ensuring that such requirements are the least trade-restrictive possible.

2.423. In response, the representative of the United Kingdom provided the following statement. The United Kingdom welcomes Australia's and Uruguay's continued interest in our wine labelling requirements, and the constructive bilateral engagement we have had with Australia on this topic. As we have said in previous statements on this matter in February, June, and November 2021, for wine imported into Great Britain, our regulations allow for an importer situated in either the European Union or Great Britain to be shown on the label of wine products marketed in Great Britain until 1 October 2022. After that date, the label of wine products marketed in Great Britain must bear the details of an importer situated in Great Britain. We reiterate that we designed the transitional arrangements in close cooperation with the wine industry to minimise the impact on trade as a result of the UK leaving the EU, whilst also taking into account our policy objectives on consumer protection. We take note of Australia's suggestion of allowing individual wine labels to show details of two importers to facilitate sales in different international markets. However, at the moment our rules do not permit this. Rules in this area are complex, falling under both wine and horizontal food labelling laws. They do share the unified aim of protecting the interests of the consumer, providing a clear point of contact should a problem be detected with the wine, and to ensure that information on the label is relevant to the product being offered for sale and is not misleading or confusing for the consumer. The UK Government is in the process of gathering broad evidence from stakeholders on whether the current rules could be refined to further benefit wine producers, traders and the interests and wellbeing of consumers. Wine labelling rules are an area that is under consideration. We remain available for further bilateral discussions with Australia and Uruguay to discuss our regulatory approach. Further details of the wine labelling measures that apply are available on the UK Government website.109

2.1.3.54 European Union - Wine labelling requirements – listing of importers for multiple destinations (ID 659¹¹⁰)

2.424. The representative of Australia provided the following statement. Australia thanks the EU for their engagement to date on this important issue. We nevertheless note this issue remains an ongoing concern and a barrier for industry that relied on shipments between the United Kingdom and the European Union prior to the UK's departure from the EU. We understand that, following the end of the Brexit transition period, the UK has rolled over existing EU wine laws and regulations, meaning wine imported and sold in the UK requires the name and address of a UK-based importer on the label. We understand the same requirement applies to bottled wine sold in the EU. As wine is regularly exported to the EU through the UK, it would be logical to give details of both EU and UK importers on a single label to ensure trade can continue uninterrupted and without additional expense to wine producers. Under EU regulations, we understand that an indication of the "importer" is compulsory for wine imported into the EU (under Regulation No. 1308/2013 and Delegated Regulation 2019/33), to identify the natural or legal person or group of persons importing the wine into the EU. We are supportive of the EU's objective of clearly identifying the business food operator, for example the person assuming responsibility for bringing the wine into circulation in the EU, and not misleading consumers. However, we ask the EU to provide assurance that its labelling requirements are no more trade restrictive than necessary to achieve their objectives.

¹⁰⁹ <u>https://www.gov.uk/guidance/importing-and-exporting-wine</u>.

¹¹⁰ For previous statements follow the thread under <u>ID 659</u>.

2.425. We have stated in previous committees and maintain that the EU allowing an "optional particular" on labels to cover importers in other third countries would be consistent with the EU's objectives, while still clearly identifying the EU importer and person assuming responsibility. For example: statements such as "For the EU, imported by..." and "For the UK, imported by..." would not mislead consumers as regards the business food operator. Australia seeks to understand how the requirements that do not allow this, described by the EU in the last committee meeting, are not unnecessarily trade restrictive. As we raised in the previous Committee meeting, we are also seeking clarity from the EU on whether it is possible to list importers for multiple destinations on the same wine bottle label under current EU Regulations. Further guidance and clarity are important to provide certainty to traders and ensure no interruptions to trade occur. We look forward to working closely with the EU on this issue to ensure a mutually satisfactory outcome as we continue similar discussions with the UK to resolve this issue for wine imported into the UK.

2.426. In response, the representative of the <u>European Union</u> 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 in accordance with Regulation (EU) No 1308/2013¹¹¹ establishing a common organization of the markets in agricultural products and Delegated Regulation (EU) No 2019/33.¹¹² The importer is a natural or legal person or a group of such persons established in the EU assuming responsibility for bringing into circulation non-Union goods within the meaning of Article 5(24) of Regulation (EU) No 952/2013¹¹³ on the Union Customs Code. Any other indication on the label mentioning the entity that brought the wine into another third country before import into the Union could only be acceptable as an optional particular, provided it does not appear in combination with the words "importer" or "imported by (...)" and is not misleading for consumers as regards the business food operator (i.e. the person assuming responsibility for bringing the wine into circulation in the EU). The EU reiterates that it is not possible to list "importers" for multiple destinations on the same wine bottle label.

2.1.3.55 United Arab Emirates - Requirement of G-mark for every toy (ID 702¹¹⁴)

2.427. The representative of India provided the following statement. India has raised this STC in the two previous TBT meetings and is still waiting for a response from the UAE. 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 authorised 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. The G-mark needs to be obtained for each toy as per the extant regulation. This process involves additional procedural requirements; it is also cost-intensive and makes the Indian product uncompetitive when placed in the UAE market. Further, during the conformity assessment, the G-mark Notified Bodies (NBs) frequently request physical samples of all products in a group, not only the representative item. Despite the latest GSO guidance specifying test reports are required for only 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. As per Article 5.1.2 of the TBT Agreement, Members are obligated to 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 stricter or 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. 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 Notified Bodies for all the

¹¹¹ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007, OJ L 347, 20.12.2013, p. 671.

¹¹² Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation, OJ L 9, 11.1.2019, p. 2.

¹¹³ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code, OJ L 269, 10.10.2013, p. 1.

¹¹⁴ For previous statements follow the thread under <u>ID 702</u>.

products in the group. Such insistence is trade-restrictive and renders high costs and difficulties. Besides, it is also inconsistent with Article 5.1.2 of the TBT Agreement.

2.428. The representative of the <u>United Arab Emirates</u> did not provide a response to the concerns raised.

2.1.3.56 Colombia – Good manufacturing practices of overseas production establishments, <u>G/TBT/N/COL/242</u> (ID 697¹¹⁵)

2.429. 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. With less than a year time left for the entry into force of these requirements, the European Union is increasingly concerned about the impact this measure could have on its exports, especially from SMEs, should not all its Free Sale Certificates be accepted. Therefore, the European Union is prepared to continue the bilateral work should there be any need for additional clarifications.

2.430. In response, the representative of Colombia provided the following statement. First of all, we would like to highlight the important work that has been carried out jointly by the health authorities of Colombia and the European Union to clarify various concerns regarding compliance with Ministry of Health Decree No. 162 of 2021. These discussions have focused mainly on the acceptance of certificates of good manufacturing practices (GMP), thus responding to the concerns raised regarding the acceptance of certificates of free sale issued by the European Union authorities. The text issued ensures equal conditions regarding the GMP certificate for domestic producers and producers located outside the national territory, and provides four alternatives for complying with the technical regulation. For the requirement in the case of imported alcoholic beverages, these four feasible options do not disregard the regulations of the country of origin of the parties concerned, meaning that such parties can assess each of the options and apply one of them in order to comply with the Colombian regulations. The health authorities have reiterated that certificates of free sale may be included in option C of the above-mentioned Decree, provided that they comply with the provisions thereof, namely: (i) they are issued by the competent authority, by the accredited certification body or by the authorized third party in the country of origin of the product, and; (ii) they state that the alcoholic beverage and the producer comply with technical control and inspection standards, processes or procedures. Furthermore, Colombia recalls that the deadline for implementing the provisions regarding the requirements for good manufacturing practices is 14 February 2023. The relevant authorities have reviewed the documents provided by the European Union and have expressed their willingness to continue working together to resolve the concerns raised and to find common ground to ensure compliance with this technical regulation. We reiterate our interest in continuing the bilateral work that has been taking place with our health authorities. A technical statement was circulated following the meeting.¹¹⁶

2.1.3.57 Argentina - Requirement of affidavit along with the product certification from a certified body for export of boards derived from wood (ID 696¹¹⁷)

2.431. The representative of <u>India</u> provided the following statement. India has raised this concern in the previous TBT meetings; we thank Argentina for acknowledging the STC and look forward to a detailed reply. 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 <u>G/TBT/N/ARG/342/Add.6</u> dated 22 February 2021 on the proposed draft

 $^{^{\}rm 115}$ For previous statements follow the thread under $\underline{\rm ID~697}.$

¹¹⁶ <u>G/TBT/W/767</u>.

 $^{^{117}}$ For previous statements follow the thread under $\underline{\text{ID 696}}$.

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 product's competitiveness in Argentina. Further, no risk assessment for the additional requirement of an affidavit is shared by Argentina. Hence, prima facie Argentina's requirement of an affidavit in addition to certification requirement appears to be trade restrictive.

2.432. It is also not known what other less trade-restrictive or alternative measures Argentina considered before deciding on the present measure. Given the above, Argentina is requested to not to impose the additional affidavit requirements; and please, respond to the queries submitted by India to its Enquiry Point.

2.433. In response, the representative of <u>Argentina</u> provided the following statement. SCI Resolution No.240/2019 and the amendment thereto, SCI Resolution No. 428/2021, establish three distinct and non-overlapping stages for the fulfilment of technical requirements. In the first stage, an affidavit must be submitted, alongside test reports. In the second stage, proof of initiation of the certification process is needed. In the third stage, a certificate issued by a certification body is required. Argentina understands that India's interpretation is confused or mistaken, as the two stages do not overlap. In other words, the affidavit stage ends once the certification stage takes effect. It should be noted that the "Proof of initiation of the certification process" and "Certification" stages are contingent on recognition by a certifying body and the issuance of an administrative act by the National Technical Regulation Directorate, following which these stages would become effective. In addition, it should be noted that the Argentine Focal Point has no record of the comment submitted by India, and we therefore request that it be resent.

2.1.3.58 Guatemala - Technical Standard 84-2021 for the Sanitary Registration of Repellent Products for External Use in Humans and Spatial Repellent Products (ID 721¹¹⁸)

2.434. The representative of Mexico provided the following statement. The delegation of Mexico refers to Technical Standard 84 - Sanitary Registration of Repellent Products for External Use in Humans and Spatial Repellent Products, the final version of which was published on 28 August 2021 on the website of the Department for the Regulation and Control of Pharmaceutical and Related Products of the Directorate-General of Health Regulation, Surveillance and Control at the Ministry of Public Health and Social Welfare, and of which the Members of this Committee were not notified, overlooking the commitments to transparency in the TBT Agreement. Through this space, we would like to reiterate the concern shared in this forum in November 2021 about toxicity studies for the sanitary registration of repellent products for external use in humans and the need to clarify whether it is possible to use existing or bridging toxicological studies on the formulations, with the aim of reducing the number of studies to be carried out and the costs for importers during the corresponding registration application process. Moreover, we reiterate our request for information on the technical and scientific evidence used to develop this technical regulation, particularly any toxicity studies using animal testing. This is without overlooking how important it is for the Government of Guatemala to observe its transparency commitments, specifically the need for this regulation to undergo a public consultation process, in which the participation of interested third parties is allowed, prior to determining its entry into force. Following the last meeting of this Committee, which took place in November 2021, the delegation of Guatemala stated that it would share the concerns expressed by the delegation of Mexico with the competent authority. We would therefore be grateful for any update it could share with us on this issue. The delegation of Mexico thanks the delegation of Guatemala for giving its consideration to this statement and reiterates its availability to hold bilateral meetings that allow the concerns expressed to be addressed.

2.435. In response, the representative of <u>Guatemala</u> provided the following statement. In this regard, we have been advised that version 1 of this Technical Standard, as identified by the Ministry of Public Health and Social Welfare, was developed due to the need to regulate the marketing of repellents of natural origin, given the health risk that may arise from their inappropriate spatial use, which were not regulated in Guatemala, as evidenced in the purpose and scope of the Standard itself, and which Mexico has surely observed. Guatemala has thus acted in accordance with its Health

 $^{^{118}}$ For previous statements follow the thread under <u>ID 721</u>.

Code (approved by Decree No. 90-97 of the Congress of the Republic of Guatemala), which indicates that repellents comply with the classification of pesticides for domestic use and not with the classification of cosmetics. A product of this nature, if not applied as a repellent, is therefore registered as a pesticide for domestic use, for which other Central American regional regulations exist. Lastly, Guatemala takes note of the reiteration by the delegation of Mexico.

2.1.3.59 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, <u>G/TBT/N/MEX/178/Add.9</u> (ID 608¹¹⁹)

2.436. The representative of <u>Costa Rica</u> 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 are 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 meetings, to indicate the scientific basis or international reference standard used to define the key parameters of the standard in question, and to provide relevant justification for the use of the front-of-pack warning sign as supplementary nutrition information, the scientific basis for setting classification parameters, according to which a product is considered to contain excessive calories, sugar, saturated fats, trans fats or sodium, given that they are not Codex-based.

2.437. 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.

2.438. The representative of <u>Guatemala</u> 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 provided at past meetings. However, Guatemala would like to ask whether the Government of Mexico will issue a supplementary regulation and a clarification on the entry into force planned for April 2021, and whether the use of supplementary labels on front-of-pack labelling is expressly excluded. We recall that CODEX CXS 1-1985, General Standard for the Labelling of Prepackaged Foods, authorizes the use of a supplementary label which fully and accurately reflects the information contained on the original label.

2.439. In response, the representative of <u>Mexico</u> provided the following statement. Given that the concern was raised two days ago, we do not currently have any detailed responses; however, we take note of their concerns and we will respond shortly.

2.1.3.60 Colombia - Food Prioritized for its Sodium Content, Certification Requirements, <u>G/TBT/N/COL/238</u>, <u>G/TBT/N/COL/238/Add.1</u> (ID 609¹²⁰)

2.440. The representative of <u>Costa Rica</u> provided the following statement. First of all, we would like to thank the delegation of Colombia and its capital-based authorities for the constructive meeting and exchange we have had over the last two days to reach a consensus on this issue. However, we wish to reiterate our concern regarding the proposed Colombian Technical Regulation establishing

 $^{^{\}rm 119}$ For previous statements follow the thread under $\underline{\rm ID~608}.$

 $^{^{120}}$ For previous statements follow the thread under $\underline{ID 609}$.

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, 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 continue an open dialogue and 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, as well as the status of this regulation and the potential date of its entry into force. We reiterate our thanks to the delegation of Colombia and we hope to keep channels for dialogue open for these purposes.

2.441. The representative of <u>Guatemala</u> provided the following statement. We reiterate the recognition of the legitimate objective of the Colombian Government to ensure human health, and the efforts made to lower total sodium intake in Colombia in order to reduce hypertension and other related diseases. With regard to the latest report of the Committee on Technical Barriers to Trade, Guatemala thanks the Government of Colombia for providing an explanation of this notification. It is stated that first-party certificates of conformity will be accepted up to 24 months after a certification body is accredited in Colombia, as required by the regulations. Given that this certificate of conformity must be presented for each import, we would like to ask Colombia about steps to be taken should the manufacturing company consistently demonstrate regulatory compliance.

2.442. In response, the representative of <u>Colombia</u> provided the following statement. My delegation will merely make some preliminary points given that this concern was not previously included on the agenda, and we ask the delegations of Costa Rica and Guatemala to please send us their statements. We would simply like to mention that we have taken note of the concerns raised. We must point out to the delegation of Costa Rica that bilateral dialogue is taking place between the relevant authorities and that we send supporting documentation and all relevant explanatory documents to these authorities. We also wish to point out to Costa Rica that this regulation has already been adopted and that our Ministry of Health will contact them regarding the questions they sent us recently.

2.1.4 Reported progress on STCs

2.443. The United States highlighted a recent positive development with respect to Mexico's notification G/TBT/N/MEX/496, the Federal Telecommunications Institute Amendments to the Conformity Assessment Procedure on Telecommunications and Broadcasting. The US thanked Mexico for its collaboration to resolve the concerns raised by the United States and US industry stakeholders. Mexico had notified the draft measure in April 2021 which aimed to amend the conformity assessment procedure on telecommunications and broadcasting. Following its notification, the United States and Mexico held several bilateral discussions on the margins of the TBT Committee and on 27 December 2021 Mexico published in the Official Gazette IFT's modified conformity assessment procedure for the field of telecommunications and broadcasting. After reviewing the latest publication and consulting with industry, the US was pleased to express its appreciation and share its support for the modification made to the procedure. It was the US' understanding that the latest iteration addressed all of the concerns discussed in previous bilateral meetings with Mexico. The United States believed that the bilateral discussions which helped lead to these positive procedural developments showcased the importance of open dialogue and of such meetings. The US thanked Mexico again for its willingness to engage on this topic and from making the changes to procedure, ensuring that trade between their nations was not disrupted.

2.2 Exchange of Experiences

2.2.1 Transparency

2.2.1.1 Chair's report on Informal Meeting (10 February)

2.444. The <u>Chairperson</u> reported on the Committee's informal meeting held on 10 February. At that meeting, she said, she had sought Members' views on how the Committee could organize its work to most effectively address and deliver on the long list of transparency-related recommendations from the Ninth Triennial Review. She noted that the nature of some of these recommendations was

such that they might require more frequent and/or ongoing dialogue and collaboration among interested delegations. Various Members had come forward with concrete suggestions on the general organization of work and on how to advance on specific recommendations (see, for example, <u>G/TBT/W/763</u> form the United States). A number of delegations had suggested that the technical elements of some of the recommendations could first be addressed by a virtual or hybrid working group open to all delegations and then be brought forward for the Committee's consideration.

2.445. In light of this initial exchange among delegations and the strong interest to advance on the recommendations, she had invited delegations to a follow-up meeting to flesh out how the Committee could best organize such a working group. This meeting had been held on 1 March over Zoom. In terms of the format of the working group, there was general agreement that it should be an open, transparent and inclusive group; it could meet in virtual or hybrid format, allowing relevant officials from capitals to participate. The deliberations and any suggestions from the working group would then be reported to the Committee for further consideration and follow up action, as necessary. In terms of how to address some of the specific recommendations, it had been suggested that there could be a step-by-step approach. In some cases, a sub-group of volunteers could undertake some preparatory work and then bring it forward for discussion in the working group. In other cases, the work could start by undertaking a survey on particular practices, or by considering a compilation of existing materials prepared the Secretariat. In terms of specific topics, delegations mentioned the revision of formats; the use of HS codes; timing of notifications and the use of ePing for following up on notifications.

2.446. The Chairperson noted that there was support for holding a first meeting of the working group towards the end of March (or early April) and that work could start on two specific issues: notification formats and use of HS Codes in notifications. To kickstart the discussions, the Secretariat would provide an overview of existing formats and would also provide some information on product coverage in notifications. The Chairperson encourage delegations to participate in the working group and to volunteer to take forward specific topics.

2.447. The representative of the <u>United Kingdom</u> supported the Secretariat's efforts to improve the functioning of the TBT Committee and the implementation of the TBT Agreement. She reiterated her delegation's suggestion, presented at the informal meeting on 10 February, and welcomed further collaboration and work on improving transparency within the TBT Committee.

2.448. The representative of <u>Canada</u> stressed the importance that her delegation attributed to transparency. Canada was particularly interested in the efforts aimed at improving the information available on measures that were being notified – or that were available in a language – *other* than French, English or Spanish. In this context, Canada noted in particular the recommendations 6.29. d. ii. as well as 6.29. e. i. and 6.29. e. ii. (3 recommendations) which Canada believed could also be clustered into one package of recommendations to be dealt with together. Canada thanked the United States for their paper and noted that the US had suggested to have a cluster of issues dealing with notification formats, which was useful. There were also other recommendations dealing with "developing a translation software and use of other tools" in this respect that could be considered. Canada welcomed further work in the Working Group, or even smaller sub-group settings, with the Chair and the Secretariat and other Members to advance on the recommendations.

2.449. The representative of the <u>European Union</u> thanked the Chairperson for the report on the informal meeting of 10 February, and the Secretariat for the continuous work on the integration and upgrade of the online tools. The European Union underlined the centrality of transparency for the Committee. The numerous recommendations in this regard made by the Members during the Triennial Review confirmed its importance. The EU reaffirmed its commitment to proceed with dedicated work on transparency, including dedicated subgroups, as this was likely to improve efficiency and progress. The EU intended to come forward with some further elements by writing in due course and remained available to engage with other Members.

2.450. The representative of <u>Singapore</u> noted that her delegation had, on several occasions, expressed support for the transparency initiatives and emphasized the importance of transparency and notifications in the TBT Committee. Singapore was supportive of the discussions that the Committee had at the informal meeting, including the idea of the creation of a working group, or even sub-groups to advance on specific work; Singapore would actively participate in such work.

2.451. The representative of <u>Australia</u> supported the points made by other Members on the importance of transparency for the TBT Committee, and the WTO more broadly. Australia commended the work of the Secretariat on improving transparency as this underpinned the operation of the rules-based trading system. Recent efforts regarding the release of a beta version of the notification portal was a good example.

2.452. The representative of <u>Switzerland</u> expressed support for initiatives increasing transparency and the establishment of sub-groups and working groups on specific topics related to transparency. He commended the integration of the existing online tools; Switzerland was supportive of these initiatives – they contributed to the goals of the TBT Committee, including the implementation of core principles and procedures under the TBT Agreement. The tools enabled Members to engage with each other in an effective way. Regarding the recommendation on the handling of comments, and the sharing of comments on replies from notifications, Switzerland was pleased to see that an increasing number of Members had started to use the online tools to share information related to comments and replies. Switzerland remained open to further engagement on these topics.

2.453. The <u>Chairperson</u> said she would follow-up shortly with a Communication on next steps.¹²¹

2.2.1.2 Integration and update of online tools

2.454. The <u>Secretariat</u> said that the objective with the integration of online tools (the TBT and SPS Information Management Systems, TBT and SPS Notification Submission Systems and ePing) was to improve the services on offer to Members and to strive towards a single-window platform to assist delegations in their engagement with the WTO on TBT (and SPS) matters. At the same time, the Secretariat was keen to ensure that the new platform continue to serve all stakeholders involved, including the private sector, and facilitate dialogue among them. This effort was also in line with one of the 9th Triennial Review Recommendations on transparency calling on the Secretariat to work towards a centralized platform. The Secretariat reported that the new platform would go live on 28 March, it is currently available <u>here¹²²</u>.

2.455. The representative of the United States thanked the Secretariat and the team in the Central Registry of Notifications (CRN) at the WTO for its hard work over the last several months in consolidating the many online tools for TBT followers into the pilot ePing platform. The United States appreciated the updates shared with Members regarding the development of the consolidated system, as well as the opportunity to test, provide feedback and observations on the ePing pilot platform. The USA TBT Enquiry Point staff, other US Government stakeholders and some of the US most actively engaged private sector stakeholders explored the pilot version of the new ePing platform during the testing phase. The US delegations then summarized the feedback received by type of stakeholder, government, private sector and shared it with Secretariat colleagues. The US had also shared feedback on TBT features with SPS colleagues for awareness and for coordination purposes. When the US noticed a few glitches in the new pilot during testing, the US delegation had informed the Secretariat resulting in guickly acknowledgment and remedies, where possible. The new Notification Submission System, like the current TBT NSS, was user-friendly and intuitive. The interphase for searching notifications was very different from the previous one so it would take some time for stakeholders to familiarize themselves with this. However, the US had no doubt that the US delegations and its Notification Authority would adapt, and the US appreciated the benefits from the enhancements available in the new ePing platform, especially as the WTO adjusted the system based on the feedback shared with delegations testing the system.

2.456. The representative of the United States also informed the Committee that the US delegation had begun using the current ePing systems so that other Members would know when the US had provided comments on another Member's notification made to the TBT Committee. This was practice that the US had now incorporated into its inter-agency procedures.

2.2.1.3 Covid-19-related Notifications (Update)

2.457. The <u>Secretariat</u> provided an update on new <u>COVID-19 related notifications</u> submitted to the TBT Committee. Since the beginning of the pandemic (in March 2020), WTO Members had submitted a total of 192 COVID-19 related TBT notifications (this represented more than 40% of all

¹²¹ The communication was subsequently circulated as <u>ICN/TBT/11</u>.

¹²² https://epingalert.org/

COVID-related WTO notifications to date). During 2021, more than 70 notifications related to COVID-19 had been submitted by Members, mostly during the months of March, April and May. Since the last TBT Committee meeting, between 10 November 2021 and 9 March 2022, a total of 11 COVID-19 related TBT notifications had been submitted. These were submitted by Brazil, Canada, Colombia, Ecuador, Japan, Kenya, the Philippines, and Chinese Taipei. The notifications covered a range of products, including COVID-19 antigen test kits and other in-vitro diagnostics, human immunoglobulin, UV Radiation-emitting and Ozone-generating medical devices, vaccines, and flocked swabs. The notified measures broadly related to emergency authorization and other conformity assessment procedures to streamline access to medical goods, new regulatory requirements for medical goods, as well as other regulatory flexibilities adopted due to the pandemic.

2.2.1.4 Article 15:2 - Statements from Members

2.458. The <u>Chairperson</u> noted that the TBT Committee's 2021 Annual Review, circulated on 2 March 2022 in document <u>G/TBT/47</u>, contains, amongst other information, details on Members' statements of implementation. This information is also available through the TBT IMS. The Committee took note.

2.2.2 Conformity Assessment Procedures

2.459. The <u>Chairperson</u> referred to the Elements Paper circulated in document <u>JOB/TBT/438</u> (31 January 2022) and the discussion that took place at the 10 February 2022 informal meeting of the Committee. At that meeting, Members had been of the view that the paper was a good basis for the Committee's further work to develop non-prescriptive practical guidelines for conformity assessment procedures (hereafter "the Guidelines").¹²³ At that point, some Members had provided specific comments. The floor was opened for a discussion of the comments received to date and any other interventions Members wished to make.

2.460. The representative of the <u>United Kingdom</u> (<u>JOB/TBT/440</u>) noted, in general, that the Elements Paper provided a very helpful basis for work. Where possible, however, the paper could have stronger wording. For example, it was suggested that the word "requesting" should be replaced by "requiring" in para. 3.8 of the Elements Paper (see <u>JOB/TBT/440</u>, p.2, for more detail). The UK also suggested some minor adjustments to the international standards and accreditation section, which were mainly about clarity and perception. The UK remained flexible and willing to discuss the proposed changes with other Members.

2.461. The representative of <u>Australia</u> (<u>JOB/TBT/442</u>) said that the Elements Paper was consistent with the suggestions and information provided in its proposal. Australia supported non-prescriptive guidelines that allowed flexibility to innovate and select conformity assessment procedures that aligned with Members' needs, circumstances, and regulatory objectives. Australia supported evidence-based procedures that considered the context and met international obligations. Australia was of the view that the Elements Paper reflected this approach. One key suggestion from Australia was for a new paragraph to highlight the significance of supply chain traceability issues in conformity assessment, especially in modern transnational and digital markets. This, Australia said, was also a reflection of the recently held thematic session discussion on digital solutions where Members had shared experiences on supply chain and digital solutions for supply-chain traceability (see <u>G/TBT/GEN/324</u>, dated 28 March 2022).

2.462. Regarding the UK's proposal on para. 3.13 (see <u>JOB/TBT/440</u>, p.2), Australia stated that their preference was to support and retain the original text rather than the UK's proposed alternative text. The effect of the UK's alternative text was to recommend accreditation as *the* approach for qualifying conformity assessment bodies; Australia was of the view that the original wording recognized the fact that, while accreditation was a recommended approach, it was not the *only* one. Australia supported accreditation in its own conformity assessment procedures but recognized that there were legitimate circumstances where regulators could choose *not* to use accreditation. This also aligned with Australia's position that the conformity assessment guidelines should be non-prescriptive and allow for flexibility in Members' domestic practices. More specific comments were contained in Australia's submission (<u>JOB/TBT/442</u>).

¹²³ <u>G/TBT/41</u>, para. 4.17.b and <u>G/TBT/46</u>, para. 4.18.a.

2.463. The representative of <u>South Africa</u> (<u>JOB/TBT/443</u>) appreciated that the Elements Paper was meant to facilitate Members' work in preparing the non-prescriptive practical Guidelines to support regulators in their choice and design of appropriate and proportionate conformity assessment procedures – and that South Africa's proposal was, to a certain extent, reflected in the Elements Paper. However, South Africa made a few observations for Members' consideration.

2.464. South Africa said that Section 3.5 of the Elements Paper, on "acceptance of results", needed to deal with the matter related to Certificates of Free Sale (CoFS). This practice might not be consistent with the WTO TBT Agreement and could lead to unnecessary technical barriers to trade. CoFS required a government of an *exporting* Member to confirm: (i) that exported good was freely available in the market of the exporting Member, and (ii) that an exported good conformed to applicable standards and technical regulations of the exporting Member. This raised a few challenges. As Members requiring CoFS to accompany exports were on the rise, work on the Guidelines was an opportunity to discipline the requests for CoFS in terms of Article 5 of the WTO TBT Agreement. An additional issue was that the government of the exporting Member was required to assume conformance of the product instead of the economic operator - this seemed to suggest that the government assumed product liability. South Africa stressed that CoFS was seen as an additional certificate that duplicated conformity assessment activities already undertaken by the economic operators. This was burdensome to economic operators and led to unnecessary technical barriers to trade. CoFS was unique and a special case in the context of CAP. South Africa therefore proposed that Members requesting CoFS replace it with technical regulations and conformity assessment procedures that were consistent with the WTO TBT Agreement. In this vein, South Africa proposed an amendment of para. 3.14 of the Elements Paper (<u>JOB/TBT/443</u>, p.2).

2.465. The <u>United States</u> (<u>JOB/TBT/444</u>) said that the Elements Paper was a good basis for the Committee to develop a very constructive guideline paper. The United States had three types of comments: comments from US regulators; comments from conformity assessment experts; and, comments from the point of view of good regulatory practice (GRP).

2.466. Regarding the comments from regulators, the US comments reflected an interest to include the "right to regulate". The United States had included comments and corrections related to this issue which were consistent with the TBT Agreement – suggesting accurate alignment with TBT Agreement language, relating back to technical regulations. The US regulators also had a concern about the use of the term "proportionality", as this was a term of competition law that raised multiple questions. This deserved discussion; for now, the US had suggested the deletion of the term from the text. Regarding good regulatory practice (GRP), comments related back to "notice and comment" and were intended to make the document more accurate and correct. With respect to conformity assessment, US experts had looked at clarity in language, particularly making sure that the ISO standards and the CASCO toolbox were accurately reflected. The United States wanted to make sure that the language was broad enough to include suppliers' declaration of conformity (SDoC). In some cases, the text appeared to be only considering certification, some language had therefore been corrected. And there needed to be recognition that there was private sector participation in the conformity assessment system. In this regard, there was a comment with respect to conformity assessment private actors and the US wish for open competition and markets for these actors.

2.467. The representative of <u>Malaysia</u> (<u>JOB/TBT/445</u>) was of the view that the Elements Paper provided a very good draft for Members' use. Malaysia's comments were on section 3.4: in the context of impartiality, independence and trust, the example of accreditation bodies and conformity assessment bodies was indispensable. Therefore, Malaysia was proposing a few changes to the text in para. 3.12 (<u>JOB/TBT/445</u>, p.1), and also had a comment on the section on Transparency and consultation, in para. 3.18 (<u>JOB/TBT/445</u>, p.2).

2.468. The representative of <u>Mexico</u> noted that her delegation's comments would be circulated shortly. (Mexico 's comments were subsequently circulated in <u>JOB/TBT/452</u>.)

2.469. The representative of <u>Colombia</u> considered that the Elements Paper was comprehensive, thorough and a good basis for work. Colombia had the following preliminary comments. First, Colombia attached importance to the *degrees* of risks referenced in the document; in this regard, Colombia considered that moderate- and mild-risks also needed to be referred to – not only low- or high-risks. Second, it was important, the representative of Colombia said, to go into more depth in the section on market surveillance, and the new tendency for the use of digital methods for conformity assessment. These elements could be reflected in the section on strategic planning. Some

of this had been discussed during the recent thematic session discussion on digital solutions for conformity assessment (see <u>G/TBT/GEN/324</u>, dated 28 March 2022). Colombia also said that more information about the use of international recommendations and the importance of cooperation amongst assessment bodies could be provided. For instance, there could be more references to methods pertaining to acceptance of results of conformity assessment, or mutual recognition. In the section on strategic planning, or the section concerning risk assessment, Colombia said it would be relevant to refer to surveillance and the future vision of regulators to identify emerging risks in advance, such as those linked to climate change, or other issues. (Colombia's comments were subsequently circulated in <u>JOB/TBT/446</u>.)

2.470. The representative of <u>Brazil</u> thanked the Secretariat for their efforts in preparing this Elements Paper and hoped to be able to contribute comments as well.

2.471. The representative of <u>New Zealand</u> supported the approach taken; the development of the Guidelines would add a valuable resource to the Committee's work. She asked if the Secretariat would compile the edits made by Members into one document to help with the review process.

2.472. The <u>European Union</u> thanked the Secretariat for the Elements Paper, and Members for explaining their comments. The EU was of the view that the Elements Paper represented a sound basis on which to advance the discussion of the Guidelines. As had been evident in the thematic sessions (on both accreditation and digital solutions, see <u>G/TBT/GEN/324</u>), the guidelines would have a key role in helping regulators identifying elements of conformity assessment they could use in designing appropriate and proportionate procedures. At the time of the meeting, the EU was working on concrete suggestions, including on some useful aspects that had emerged from the discussions on digital solutions. The EU was of the view that the paper and the exchanges so far marked substantial progress. The EU was of the view that Members should have regular discussions in order to achieve a constructive result. (The EU's comments were subsequently circulated in <u>JOB/TBT/455</u>.)

2.473. The representative of <u>India</u> thanked the Secretariat for the Elements Paper that was being considered in capital. He noted that it could be helpful if the Secretariat could provide a continuous compilation of the comments made by countries for comparison and/or analysis. The representative of India also asked how the guidelines would fit into the TBT Agreement. He suggested that Members could perhaps develop the Elements Paper based on good practices so that the work would become more substantive.

2.474. The <u>Chairperson</u> said that the exchange had been very useful, and that there was good momentum. On process, she suggested that delegations provide any further written comments by 13 April 2022 and that the Committee meet again to discuss the Guidelines in informal mode on 27 April. She encouraged delegations to come forward with written comments as these would further enrich the document. The Secretariat would continue to circulate any comments received so that Members could consider them ahead of the informal meeting.¹²⁴

2.475. The <u>Moderators</u> for the thematic sessions provided their reports. The thematic session on Accreditation¹²⁵ was held on 8 March in the morning; the moderator¹²⁶'s report is contained in <u>G/TBT/GEN/323</u>. The Thematic Session on Digital Solutions¹²⁷ was held on 8 March in the afternoon and the moderator's¹²⁸ report is contained in <u>G/TBT/GEN/324</u>.

2.476. The representatives of the <u>United States</u> and <u>India</u> thanked the moderators for their reports and skill in moderating the sessions. The representative of India noted that there had been plenty of information to absorb during the morning sessions (on accreditation) and that eleven interventions had perhaps been too much for one session.

¹²⁴ The Chairperson's subsequent communication confirming the dates is contained in <u>ICN/TBT/11</u>.

¹²⁵ <u>https://www.wto.org/english/tratop_e/tbt_e/tbtts_e/tbtts080322am_e.htm</u>

¹²⁶ Mr. Hélio Silva (Brazil).

¹²⁷ <u>https://www.wto.org/english/tratop_e/tbt_e/tbtts_e/tbtts080322pm_e.htm</u>

¹²⁸ Mr. Warren Merkel (United States).

2.2.3 Other Decisions and Recommendations

2.477. The <u>Chairperson</u> noted that, under this agenda item, Members had the opportunity to raise any matter relevant to follow-up on Committee Decisions and Recommendations, including those contained in the Ninth Triennial Review (<u>G/TBT/46</u>), or any other previous Committee decisions and recommendations (<u>G/TBT/1/Rev.14</u>).

2.478. On COVID-19, the Chairperson reported on discussions that had taken place at the 10 February informal meeting. She noted that the Committee could consider initiating its work on COVID-19 and future pandemic preparedness (G/TBT/46, para. 8.4): several Members had taken the floor to encourage the Committee to start work to examine and compile best practices. In this respect, there had been a suggestion from Members that the Secretariat could provide the Committee with information on the work of the Committee to date since the start of the pandemic. This could then serve as a reference point for further work. The Chairperson invited the Secretariat to prepare such a background reference document.

3 TWENTY-SEVENTH ANNUAL REVIEW

3.1. The <u>Secretariat</u> introduced the Twenty-Seventh Annual Review of the Implementation and Operation of the TBT Agreement under Article 15.3, contained in document <u>G/TBT/47</u>. The Committee <u>took note</u> of the report.

4 TECHNICAL COOPERATION ACTIVITIES

4.1. The representative of the <u>United States</u> drew the Committee's attention to a update contained in document <u>G/TBT/GEN/322</u>.

4.2. The <u>Secretariat</u> reported on a new capacity building initiative: the "Transparency Champions Programme". In an effort to respond to growing demands for technical assistance in the TBT area, the Secretariat intended to launch an innovative and comprehensive capacity building programme on transparency. This programme, it was explained, will offer selected government officials an opportunity to advance their participation in the TBT transparency mechanisms and assume the role of champions for transparency. Each cohort will benefit from a six-month programme, involving inperson and virtual modules, as well as ongoing support from the Secretariat, mentors and their peers. Tangible results from the programme will be shared via the Committee as well as other communication channels, such as social media. The ultimate goal of the programme was to raise awareness on the importance of transparency and create a global community of transparency practitioners/champions. The Secretariat noted that, given the synergies and the momentum created by the AfCFTA, the programme would start with a pilot segment for participants from Africa, to be followed by subsequent regions to reach participants globally. The TBT Section would work closely with the SPS Section in the Secretariat to run parallel programmes with a common approach.

5 OBSERVERS

5.1 Updates

5.1. The representative of <u>UNECE</u> noted that it had launched the world's largest repository of standards mapped to the UN Sustainable Development Goals. The "Standards for SDG Portal" had been developed under the Working Party 6 on Regulatory Cooperation and Standardization Policies (WP.6) and currently contained maps of over twenty thousand standards of a dozen major standards development organizations and also provided over forty case studies demonstrating how standards had contributed to attaining the SDGs in certain countries. The Portal could help governments identify technical standards, business standards, guidance documents, recommendations, and conventions that were available and that could be used to help achieve the 17 goals of the 2030 Agenda. The <u>Portal¹²⁹</u> was part of a larger project run by the UNECE Working Party 6 which included work on gender-responsive standards and e-learning training on topics such as Conformity Assessment and Market Surveillance. The UNECE intended to update the TBT Committee on other aspects of this project after they had been completed in June 2022.

¹²⁹ <u>https://standards4sdgs.unece.org</u>

5.2. The representative of <u>BIPM</u> provided a report that can be accessed <u>here¹³⁰</u>.

5.3. The representative of the <u>Codex Alimentarius Commission</u> provided an update contained in document <u>G/TBT/GEN/325</u> and on the <u>Codex Website</u>.

5.4. The representative of <u>OIML</u> provided contained in <u>document G/TBT/GEN/327</u>.

5.5. The <u>Chairperson</u> also drew the Committee's attention to information provided by other observers, including the <u>IEC¹³¹</u>, <u>ISO¹³²</u> and <u>UNIDO.¹³³</u>

5.2 Pending Requests

5.6. The <u>Chairperson</u> noted that an updated list of observers, including pending requests, was contained in document <u>G/TBT/GEN/2/Rev.17</u>. Document <u>RD/TBT/1/Rev.9</u> provided an updated compilation of the original communications received by the WTO from the various bodies that had sought observer status in the TBT Committee and whose requests were still pending. The Chairperson noted, regarding the pending request, that she had no information that would lead her to believe that the situation had changed from where the Committee stood at the last meeting. She therefore suggested that the Committee revert to this matter when Members had had the time to further consult among themselves.

5.7. The representative of Turkey reiterated her delegation's support for the Standards and Metrology Institute for Islamic Countries (SMIIC)'s application for observer status in the TBT Committee. SMIIC, Turkey explained, is an affiliated institution of the Organization of Islamic Cooperation (OIC), and, of its 43 members, 33 are also Members to the WTO while 8 are observers. However, since the SMIIC's application to the TBT Committee in 2017, no progress had been made. The Members' negotiations regarding the pending requests had been limited to continuous announcements of "no consensus under this agenda item". Annex 3 paragraph 4 of WT/L/161, the Guiding rules of Observers Status for International Intergovernmental Organizations clearly specified that each application for observer status shall be examined on a case-by-case basis. Furthermore, the document also clearly stated that the requests for observer status would be considered while taking into account factors such as nature of work of the organization concerned, nature of its Membership, the number of WTO Members in the Organization, among other factors. Moreover, the delegation of Turkey pointed out, the document G/TBT/1/Rev.14 titled Decisions and Recommendations adopted by the WTO Committee on Technical Barriers to Trade since 1 January 1995, clearly stated that it has been decided to ensure timely consideration of the requests for observer status and to discuss best practices for Observers' participation in meetings of the TBT Committee. In this regard, Turkey invited the TBT Committee to evaluate each application on its own merits, on a case-by-case basis, and in a timely manner in accordance with this guidance. Turkey expressed its readiness and willingness to be part of any effort that might be meant to resolve the bottlenecks in the evaluation process.

6 ELECTION OF CHAIRPERSON

6.1. The <u>Chairperson</u> 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 at a later stage.

7 OTHER BUSINESS

7.1. The <u>Secretariat</u> noted that due to the scheduling of MC12, the TBT Committee had to reschedule next meetings to the week starting 11 July. The Secretariat intended to organize a half-

 130 https://www.bipm.org/documents/20126/42177518/2022-March+BIPM+Liaison+Report+to+WTO+TBTC.pdf/a33fe9d2-959e-97a9-dd88-a1dd55f5aea9?t=1647006743982

¹³² G/TBT/GEN/326.

¹³¹ iec wto tbt report 2022 feb a4 lr 0.pdf

¹³³ <u>G/TBT/GEN/328</u>.

day symposium to discuss the value of the Committee's work on regulatory bottlenecks and the global economy in the morning of 14 October 2022.

8 DATE OF NEXT MEETING

8.1. The <u>Chairperson</u> recalled that, due to the 12th Ministerial Conference being held in June, the dates of the next regular meeting of the Committee had to be changed. The next regular meeting of the Committee would now take place on 13-15 July 2022 and would be preceded with Thematic Sessions on Transparency on 12 July (in the morning), and on Regulatory Cooperation between Members (MSMEs) (in the afternoon).