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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING 8-10 NOVEMBER 2023

CHAIRPERSON: MS. ANNA VITIE

Note by the Secretariat¹

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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.

1 ADOPTION OF THE AGENDA

1.1. The <u>Committee</u> adopted the agenda contained in <u>WTO/AIR/TBT/27</u>.

1.2. The representative of <u>Ukraine</u> informed the Committee about Ukraine's activities in 2023 concerning technical regulations. Despite enduring significant human and economic losses, along with the intentional destruction of critical civilian infrastructure due to Russia's war of aggression, Ukraine had maintained its commitment to adopting national standards aligned with international and European requirements. This was in an effort to approve and review technical regulations and conformity assessment procedures, aiming for a holistic approach in standardisation and metrology, and striving to ensure the transparency of their TBT measures.

1.3. The representative of the <u>Russian Federation</u> requested a point of order.

1.4. The <u>Chairperson</u> asked for Ukraine to be allowed to finish its intervention.

1.5. The representative of the <u>Russian Federation</u> requested the floor to explain its reasons for raising a point of order. He noted that the Committee had recently approved the meeting agenda, including an item (Item 2) on the implementation and administration of the agreement, which encompassed STCs, exchange of experiences, and other matters. He cited the annotated agenda which stipulated that under Item 2(c) "other matters", delegations wishing to raise any other matter relevant to the implementation and administration of the Agreement would be invited to do so. Russia was of the view that the Ukrainian statements about relevant activities in the field of technical regulations should be addressed under Item 2(c) under "Other Business". He reminded the Chairperson of her duty to ensure that discussions adhere to the agreed agenda and the terms of reference of the Committee. He said that Rules of Procedure provided that Chairperson can and should interrupt speaker if their remarks are irrelevant for the agenda item and/or terms of reference of the Committee.

1.6. The <u>Chairperson</u> thanked the Russian Federation for its input and asked Ukraine to continue its intervention.

1.7. The representative of <u>Ukraine</u> emphasized Ukraine's ongoing efforts to adopt and harmonize national standards with international and European requirements, approve and review technical regulations and conformity assessment procedures, and ensure a comprehensive approach in standardization and metrology, all while maintaining transparency under martial law conditions.

1.8. In 2023, Ukraine persevered with the review of national standards, adopting over 46,000 standards, the majority of which were international standards adopted nationally. They also approved numerous technical regulations in line with New and Global Approach Directives and worked to preserve and maintain their national measurement standards system. Ukraine included numerous Calibration and Measurement Capabilities in the International Bureau of Weights and Measures database. Despite Russia's full-scale invasion, Ukraine became an Associate Member of the European Association of National Metrology Institutes (EURAMET) and terminated its involvement with the European Cooperation of national metrological institutions (COOMET).

1.9. Moreover, Ukraine sustained its metrological activities with 76 authorized verification laboratories and 165 technical committees for standardization operating across various economic sectors, including 12 bodies responsible for conformity assessment in metrology and 71 accredited bodies conducting full conformity assessments in different regions.

1.10. The National Accreditation Agency of Ukraine's accreditation is recognised as equivalent to that of over 80 countries within relevant international and European organisations. However, due to ongoing military actions by Russian forces, certain regional research centres in Ukraine could not resume their work, while others faced continuous attacks.

1.11. Ukraine continued to strive for infrastructure restoration and harmonization of international standards, viewing them as vital for future recovery. Through technical regulation and quality infrastructure enhancement, Ukraine sought to promote its goods and services internationally, develop export capacity, and engage in global markets and events. The representative expressed gratitude for international support in technical regulation and quality infrastructure, the removal of

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trade barriers, and business cooperation aimed at recovery and reconstruction. Ukraine began implementing a comprehensive e-Restoration Programme and the Digital Restoration Ecosystem for Accountable Management (DREAM) for transparent construction management. In the ongoing conflict, Ukraine remained committed to informing the WTO about its measures related to technical regulations, submitting numerous notifications and responding to member queries on TBT issues.

1.12. In conclusion, the representative thanked international partners for their support during these challenging times and urged WTO members to take necessary steps to limit Russia's capability to wage war, highlighting the extensive destruction and suffering caused by the conflict and its detrimental impact on the multilateral trading system.

1.13. The representative of the <u>European Union</u> expressed approval of Ukraine's endeavours to integrate into the EU internal market, highlighting Ukraine's close collaboration on standardization and adherence to EU technical regulations and quality infrastructure. The EU also commended Ukraine for its dedication to the World Trade Organization (WTO) duties, as evidenced by its continued submission of notifications and responses to inquiries amidst the conflict. The European Union strongly condemned Russia's unprovoked and unjustified military actions against Ukraine and the illegal attempted annexation of Ukrainian regions by Russia. They underscored that such actions gravely breach international law, compromise global security and stability, and are characterized by increasing evidence of war crimes and systematic destruction of civilian infrastructure. The EU demanded an immediate cessation of Russian hostilities, the withdrawal of its troops, and respect for Ukraine's territorial integrity and sovereignty, affirming steadfast support for Ukraine for the duration of this conflict.

1.14. The representative of the <u>United States</u> echoed the European Union in commending Ukraine for its unwavering commitment to the work of the WTO. The US reiterated its strong denunciation of Russia's brutal and unwarranted aggression towards Ukraine. The US held Russia solely accountable for the immense loss of life and suffering in Ukraine, as well as the escalating threats to global food security, which affect developing nations acutely. The US pledged ongoing support for Ukraine's valiant efforts to defend its sovereignty, maintain its territorial integrity, and safeguard its citizens. The US urged Russia to immediately halt the conflict.

1.15. The representative of the <u>United Kingdom</u> reaffirmed the country's steadfast support for Ukraine, aligning with the sentiments previously expressed by other colleagues. They acknowledged the wide-reaching impact of Russia's continued aggression and its illegal invasion, which is felt globally and within the multilateral trading system. The UK commended Ukraine's courage and resilience in advancing its work related to the Committee under such dire circumstances. The UK, along with its allies, pledged to continue highlighting the significant global repercussions of Russia's actions for as long as necessary.

1.16. The representative of <u>Canada</u> commended Ukraine's ongoing engagement with the Committee's work and its commitment to the multilateral trading system and the rule of law, even under hostile conditions. Canada unequivocally condemned Russia's illegal and unjustified invasion, viewing it as a blatant violation of international law and the rules-based international order. Canada assured its unwavering support for Ukraine and its people and vowed to utilize trade mechanisms to aid Ukraine in rebuilding its economy and society. Canada reiterated its call for Russia to immediately halt all hostile activities against Ukraine.

1.17. The representative of <u>Australia</u> thanked Ukraine for the update provided to the Committee and recognized the challenges Ukraine faces in meeting its WTO obligations amidst the conflict. Australia welcomed Ukraine's efforts to adopt standards consistent with international standards, maintain adherence to the TBT Agreement, especially meeting transparency and notification obligations, and its continued commitment to international cooperation in metrological and accreditation matters. Australia restated its strong condemnation of Russia's invasion, which they deemed a gross breach of international law, including the Charter of the United Nations, and reaffirmed its support for Ukraine's sovereignty and territorial integrity, urging Russia to stop its aggression and withdraw from Ukrainian territory.

1.18. The representative of <u>New Zealand</u> continued to denounce Russia's aggression and stressed the importance of accountability for the atrocities in Ukraine. They commended Ukraine's proactive steps to maintain the functioning of its technical regulation systems despite wartime disruptions.

New Zealand highlighted Russia's significant disruption of global production and trade, particularly as a result of its attack on a key food producer and the destruction of civilian infrastructure. They underscored the severe negative effects of Russian actions on both Ukraine's and the global economy. New Zealand stood in solidarity with Ukraine, supporting its sovereignty and territorial integrity, and joined in calls for Russia to cease its war.

1.19. The representative of <u>Switzerland</u> strongly condemned Russian military aggression against Ukraine, calling it a severe violation of international law and an infringement on Ukraine's sovereignty and territorial integrity. Switzerland demanded that Russia comply with international obligations, reverse its actions, withdraw its troops, and contribute to de-escalation, while urging all parties to adhere to international law, including humanitarian law.

1.20. The representative of <u>Japan</u> addressed the situation in Ukraine, expressing a firm condemnation of Russia's aggression and attacks on Ukrainian civilian infrastructure and cities. Japan, as the only nation to have suffered from atomic bombings, categorically rejected Russia's nuclear threats and any potential use of nuclear weapons. Japan called on Russia to halt its aggression, withdraw its forces immediately from Ukraine, and adhere to Ukraine's internationally recognized borders. Japan committed to continue imposing severe sanctions on Russia and providing significant support to Ukraine in collaboration with the international community.

1.21. The representative of the <u>Republic of Korea</u> thanked Ukraine for its ongoing efforts to ensure transparency in the WTO regarding national standards and TBT matters. Korea joined the international chorus in strongly condemning Russia's armed invasion of Ukraine and affirmed that Ukraine's sovereignty, territorial integrity, and independence must be upheld.

1.22. The representative of the Russian Federation reiterated the obligation of the Chairperson to moderate discussions to ensure adherence to the agenda, rules of procedure and terms of reference of the Committee. He noted that noted that according to the Rules of Procedure, the Chair should interrupt if remarks are not pertinent to the agenda item or the Committee's terms of reference. He cited Article 13 of the TBT Agreement, which stipulates that the Committee's purpose is to consult on matters related to the operation of the Agreement or its objectives. The representative expressed concern that recent interventions deviated from these mandates, resulting in a misuse of the delegates' time. The representative of Russia invited those delegates who were interested in the special military operation conducted by the Russian Federation in Ukraine to follow the work of relevant UN bodies, where Russia shared in detail information on the root causes of the operation as well as insights regarding current phase of the operation. He emphasised that interventions that were made by a number of delegations under this agenda item aimed to justify illegitimate unilateral trade restrictive coercive measures with extraterritorial effect introduced against Russian exports. Such measures were a reason for the disruption of global supply chains, increased energy costs, cost of freight and insurance that led to growing price level across the world. Russia underscored that all additional costs due to thousands of unilateral trade restrictive coercive measures were passed on to global consumers. It was further noted that wide scale economic repercussions in the world could have been avoided if the WTO Members that had taken the floor under this item had not breached basic WTO obligations.

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Specific Trade Concerns (STCs)

2.1.1 Withdrawn concerns

2.1. The <u>Chair</u> reported that the following STC had been withdrawn from the agenda at the request of the concerned Members:

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

2.1.2 Reported progress

2.1.2.1 Peru - Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA (ID 618²)

2.2. The representative of <u>Brazil</u> welcomed the Peruvian Government's response to the previously expressed concerns over labelling requirements issued in the Manual of Advertising Warnings approved by the Supreme Decree 012-2018-SA and amended by Supreme Decree 015-2019-SA. Brazil commended the Peruvian endeavour to ensure the highest health standards that help better inform consumers while realigning its labelling requirement with the Codex. Through the joint effort of the different bodies in both countries, the Peruvian Government had managed to promote internal measures to allow the use of stickers to insert warnings on the labels of food and beverages aimed at children, in line with international studies on the topic. The success in the negotiations ultimately showed the importance of the work developed in the WTO, especially TBT, to overcome barriers to trade and strengthen mutually beneficial commercial ties among nations while promoting high regulatory standards.

2.3. The representative of <u>Costa Rica</u> thanked the Government of Peru and its Permanent Delegation in Geneva for their efforts and drew attention to the prevailing spirit of dialogue and transparency between both parties since this trade concern, relating to the Supreme Decree prohibiting the use of adhesive labels for foods, was raised in the Committee on Technical Barriers to Trade. On 1 July 2023, the Supreme Decree was amended and published in the Official Journal, making it applicable indefinitely, and was notified to this Committee in document <u>G/TBT/N/PER/97/Add.5</u>, acknowledging that the objectives of protecting public health and informing consumers can be achieved by using adhesive labels, while adhering to Codex Alimentarius guidelines. Costa Rica therefore withdrew this trade concern from the agenda of the Committee on Technical Barriers to Trade, while reaffirming the role that this body plays in spurring dialogue and building bridges to eliminate unnecessary barriers to trade, and thanking the Government of Peru for the bilateral engagement to date.

2.4. The representative of <u>Paraguay</u> joined the interventions made by Brazil and Costa Rica regarding STC 618 and thanked Peru for its efforts in bringing this standard into compliance and accepting the use of additional labelling as a sufficient mechanism to achieve the legitimate objectives. Paraguay thanked Peru and noted that thanks also to the work of this Committee, the STC had been resolved.

2.5. The representative of the <u>United States</u> added its support for the positive development in STC 618. Peru's actions had definitely improved the situation for US exporters.

2.6. The representative of the <u>European Union</u> welcomed the latest development and permanent solution to this longstanding concern which emphasized the importance of dialogue within the WTO TBT Committee in addressing technical barriers to trade. The EU thanked Peru for their cooperation and commitment to addressing such matters in the WTO TBT Committee.

2.7. The representative of <u>Chile</u> joined others in thanking the delegation of Peru for the progress made in this specific trade concern, and indicated that it would not be supporting the STC at this meeting, in view of the reported developments.

2.8. The representative of <u>Peru</u> thanked Brazil, Costa Rica, Paraguay and other delegations for withdrawing the specific trade concern relating to the Manual of Health Warnings in the framework of Law No. 30021 on the promotion of healthy eating among children and adolescents. In this regard, on 1 July 2023, Supreme Decree No. 017-2023-SA entered into force, amending paragraphs 8.3 and 8.5 of section 8 of the Manual of Health Warnings, in the framework of the aforementioned Law. The use of labels or indelible marking on the front side of the product label is therefore permitted indefinitely. The Committee was duly notified of this in writing through document <u>G/TBT/N/PER/97/Add.5</u>. Accordingly, while reiterating its appreciation for the withdrawal of the STC, Peru reaffirmed its commitment to refrain from preparing, adopting or applying technical regulations that may create unnecessary obstacles to international trade.

 $^{^{2}}$ For previous statements follow the thread under ID <u>618</u>.

2.1.2.2 Mongolia - Draft Law on controlling the circulation of alcohol beverages, and fight against alcoholism (ID 730³)

2.9. The representative of the <u>United Kingdom</u> thanked the delegation of Mongolia for the progress seen in relation to its concerns on the draft law for controlling the circulation of alcohol beverages, and fight against alcoholism. The UK had met bilaterally with Mongolia several times and welcomed the amendments made to permit the application of tax stickers in tax bonded warehouses. The UK believed this had now reduced the trade restrictiveness of this measure and addressed its concerns in the TBT space. The representative hoped for continued collaboration with Mongolia in order to address concerns which sit in the remit of other committees and thanked Mongolia for their engagement, appreciating the opportunity to draw attention to the good work that can be undertaken in this Committee in order to reduce barriers to trade.

2.10. The representative of the <u>European Union</u> thanked Mongolia for their clarifications and support and reported that this issue had been resolved.

2.1.2.3 United States - United States - Chapter 173-337 of WAC, safer products restriction and reporting (ID 787⁴)

2.11. The representative of the <u>Republic of Korea</u> stated that it was withdrawing from STC ID 787 – United States – Chapter 173-337 of WAC, safer products restriction and reporting.

2.1.2.4 Kingdom of Saudi Arabia - Electrical Clothes Dryers Energy Performance Requirements and Labelling (ID 605⁵)

2.12. The <u>Chair</u> reported that the delegation of the Republic of Korea had informed the Secretariat of some positive developments with respect to this STC, which was now indicated as resolved.

2.1.2.5 Kingdom of Saudi Arabia - Air Conditioners - Minimum Energy Performance, Labelling and Testing Requirements for Low Capacity Window Type and Single-Split (ID 668⁶)

2.13. The <u>Chair</u> reported that the delegation of the Republic of Korea had informed the Secretariat of some positive developments with respect to this STC, which was now indicated as resolved.

2.1.2.6 Kingdom of Saudi Arabia – Electrical Clothes Washing Machines – Energy and Water performance Requirements and labelling (ID 619⁷)

2.14. The <u>Chair</u> reported that the delegation of the Republic of Korea had informed the Secretariat of some positive developments with respect to this STC, which was now indicated as partially resolved.

2.1.3 New Specific Trade Concerns

2.1.3.1 India - Draft Food Safety and Standards (Alcoholic Beverages) Amendment Regulations, 2023, <u>G/TBT/N/IND/271</u> (ID 805⁸)

2.15. The representative of <u>Mexico</u> provided the following statement. The delegation of Mexico refers to the Draft Food Safety and Standards (Alcoholic Beverages) Amendment Regulation, 2023, notified to Members of the Committee on Technical Barriers to Trade in document <u>G/TBT/N/IND/271</u>, and refers to the communication sent by the Government of Mexico to the Government of India on 4 August 2023. In this connection, the delegation of Mexico would like to express the following concerns and requests: The draft Regulation excludes drinks made from wine and beer from the definition of ready-to-drink/low alcoholic beverages, which could contravene Article 2.2 of the TBT Agreement, by creating an unnecessary obstacle to the trade in such products. The Government of

⁶ For previous statements follow the thread under ID <u>668</u>.
⁷ For previous statements follow the thread under ID <u>619</u>.

 $^{^{3}}$ For previous statements follow the thread under ID $\underline{730}$.

 $^{^{4}}$ For previous statements follow the thread under ID <u>787</u>.

⁵ For previous statements follow the thread under ID $\underline{605}$.

⁸ For previous statements follow the thread under ID <u>615</u>.

India is therefore requested to provide the technical and scientific evidence underpinning the definition of ready-to-drink/low-alcoholic beverages proposed in the Regulations. Furthermore, the Regulation could hinder trade for third-country producers wishing to export ready-to-drink/low-alcoholic beverages, as it imposes a maximum limit of 8% of alcohol by volume (ABV), which would impede market access for new products.

2.16. India is therefore requested to provide the technical and scientific evidence underpinning the decision to set the maximum alcohol content of ready-to-drink/low-alcoholic beverages at 8% ABV. In addition, India is requested to provide the technical and scientific evidence or the international standards underpinning the decision to set maximum limits with respect to the physico-chemical specifications to be met by alcoholic beverages marketed in India. Lastly, the delegation of India is kindly requested to clarify whether the specifications for "country liquors" are applicable to imported liquors, and to provide a response to the comments submitted by the Government of Mexico during the public consultation period on the Regulation. The delegation of Mexico thanks the delegation of India for giving its consideration to this statement.

2.17. The representative of the <u>European Union</u> provided the following statement. The EU would like to thank India for notifying this measure allowing thus other WTO Members to make comments in writing, discuss them, and take these comments and discussions into account. The EU provided its comments on 1 September; however, it did not yet receive any reply from India to the questions raised therein. Therefore, the EU would like to reiterate its comments as follows. The draft Food Safety and Standards (Alcoholic Beverages) Amendment Regulations, 2023, add the category of "ready-to-drink beverages" and while the EU welcomes the Indian authorities' objective to provide ready to drink beverages (RTDs) with a legal framework, the EU has concerns regarding the proposed definition, particularly: (i) the range for the content of alcohol, (ii) ingredients, and (iii) the recognition of nitrogen as a permitted additive for RTDs.

2.18. First, as regards the definition, it does not seem to be in line with international standards and could create unnecessary barriers to trade, as defined by the Article 2.2 of the TBT Agreement. Namely, limiting RTDs to beverages having less than 8.0% of alcohol ABV will have the effect of excluding a significant part of the RTDs range from the Indian market. The proposed limit of the alcohol content of RTDs is not in line with the Codex Alimentarius in which RTDs are included in the Food Category 14.2.7 (Aromatized alcoholic beverages) and which specifies that "most of these products contain less than 15% alcohol", and not 8% as proposed in the Indian Regulation. The Codes, actually, recognize that some traditional non-standardized aromatized products may contain even up to 24% alcohol. Therefore, the EU suggests deleting the proposed maximum 8% ABV level for RTDs, or increasing it to at least 15% ABV, in order to align the definition with Codex and ensure that imported products will not be excluded from the Indian marketplace. Second, the list of ingredients that can be used to produce RTDs appears to be too restrictive and would exclude many RTDs produced by third countries to be marketed in India. For instance, RTDs can be mixtures of different spirit drinks categories (vodka and liqueur), or mixtures of a spirit drink and wine (liqueur and white wine). According to the Codex Alimentarius, RTDs are defined as prepared cocktails and "mixtures of liguors, ligueurs, wines, essences, fruit and plant extracts, etc.". Hence, the EU suggests amending the proposed definition, in order to align it with Codex and to allow the addition of any alcoholic beverage to produce RTDs.

2.19. Third, the proposed definition does not explicitly allow the use of liquid nitrogen for RTDs, whereas Codex Alimentarius does so. The EU therefore suggests amending the definition to allow the use of nitrogen in RTDs to avoid creating a barrier to innovation. Lastly, the EU invites the authorities of India to clarify whether "ready-to-drink" and "low-alcoholic beverage" must both be stated on the label or whether they can be stated in a mutually exclusive manner. The EU kindly asks the authorities of India to review the entire definition of RTDs and align the draft Regulation to Codex, unless there are objective justifications for such deviations, which the EU would like India to provide information on. With regard to nitrogenated beer, the EU welcomes the acknowledgement of "nitrogenated" or "nitro" beer. Nevertheless, the EU notes that the proposed amendment in Column No 8, table 3 in Article 1(8) does not mention the category "nitro beer", but merely "strong". The EU suggests that the alcohol bands be broadened, so that beers with alcohol content lower than 5% ABV are also recognized as "nitro" beers. The EU suggests a "nitro beer" category with "strong" and "regular" columns mimicking the approach taken for the existing beer and draught beer categories. Furthermore, to be able to accommodate "nitro" beers with lower carbonation levels, the carbon dioxide ranges should be amended as 0.75-3.6 v/v. With climate change policies requiring initiatives for decarbonation, the availability of further lower ranges will grow. Their prohibition from

the Indian market would not be justified from both brewing science and environmental perspectives. The EU would be grateful if the above-mentioned comments could be taken into account and replied to before adoption of the notified draft.

2.20. In response, the representative of <u>India</u> provided the following statement. We thank Mexico, European Union for their interest in India's regulation titled "Draft Food Safety and Standards (Alcoholic Beverages) Amendment Regulations, 2023". We are currently examining the statements made.

2.1.3.2 Argentina, Uruguay - Draft Resolution No.02/23 -MERCOSUR Technical Regulation on definitions relating to alcoholic beverages (except fermented beverages), their raw materials and manufacturing processes (Repeal of GMC Resolution No.77/94)), G/TBT/N/ARG/444; G/TBT/N/URY/85 (ID 806⁹)

2.21. The representative of Mexico provided the following statement. The Mexican delegation refers to draft Resolution No.02/23 - MERCOSUR Technical Regulations on definitions relating to alcoholic beverages (except fermented beverages), their raw materials and manufacturing processes (Repealing GMC Resolution No.77/94), notified to the members of the TBT Committee in documents G/TBT/N/ARG/444 and G/TBT/N/URY/85. We also refer to the communication sent by the Government of Mexico to the Government of Argentina on 10 August 2023, containing comments on the MERCOSUR Regulations. We would also like to say that, while the Government of Mexico recognizes the efforts of MERCOSUR trading partners to keep technical regulations up-to-date, particularly the regulations of ever-changing industries such as the alcoholic beverage industry, it is important to ensure that elements of previous regulations that remain in force are taken into account when updating technical regulations, in order to maintain trade flows. In this connection, the delegation of Mexico would like to know why the definition of teguila is not included in the Regulations, considering that it is included in the regulations to be repealed. Failure to consider tequila as an (unfermented) alcoholic beverage could contravene the principle of proportionality, stipulated in Article 2.2 of the TBT Agreement, as it creates an unnecessary barrier to trade by modifying existing trade conditions. Lastly, the delegation of Mexico requests the delegation of Argenting provide a reply to the comments submitted by the Government of Mexico during the public consultation period on the Regulations.

2.22. In response, the representative of Argentina provided the following statement. First, as provided by the draft MERCOSUR Technical Regulation notified by Argentina, the aim of this Regulation is to update the harmonized definitions of alcoholic beverages (except fermented beverages), their raw materials and manufacturing processes, which were agreed upon several years ago at the MERCOSUR level under GMC Resolution No. 77/94. The fact that the new proposed Regulation does not include the definition of the term "Tequila" (which, to date, has been included in GMC Resolution No. 77/94) should not be interpreted as an obligation to eliminate this term from the national legislations of the four States Parties of the bloc. Put simply, the term "Tequila" will no longer have a harmonized definition at the MERCOSUR level, and, as in other cases, each MERCOSUR State Party shall be free to include a definition of the term in its national legal system. In the case of Argentina, this facilitates the implementation of what was agreed at the 6th Meeting of the Argentina-Mexico Commission on Economic, Trade and Investment Affairs, held in Buenos Aires on 19 May 2023. At that meeting, Argentina undertook to begin taking the necessary steps to grant recognition of the appellation of origin "Tequila", within the framework and subject to the outcome of bilateral negotiations between Argentina and Mexico on a new Additional Protocol to Economic Complementarity Agreement No. 6 (ECA No. 6). Eliminating the term "Teguila" from GMC Resolution No. 77/94 is precisely what will enable the advancement of the procedure being carried out at the national level to comply with this bilateral understanding. This procedure is well under way and is expected to come to completion soon by way of internal consultation. In this regard, withdrawing the term "Tequila" will in no way impede trade; rather, the withdrawal seeks to pave the way towards facilitating the negotiation of the 17th Additional Protocol to ECA No. 6. With regard to the comments shared by the Government of Mexico during the public consultation period for the Regulation, we wish to report that consultations with the relevant bodies are under way, and feedback will be provided as soon as possible.

2.23. In response, the representative of <u>Uruguay</u> provided the following statement. Uruguay would like to thank Mexico for its interest in Draft Common Market Group (GMC) Resolution No. 02/23:

 $^{^{9}}$ For previous statements follow the thread under ID <u>806</u>.

MERCOSUR Technical Resolution on definitions relating to alcoholic beverages (other than fermented), their raw materials and production process (Repeal of GMC Resolution No. 77/94). In this connection, the relevant draft Technical Regulation was notified by Uruguay to the WTO in document G/TBT/N/URY/85 on 1 August 2023, with a 60-day consultation period, in fulfilment of the transparency obligations under the TBT Agreement. During this period, Uruguay received comments from several WTO Members, including Mexico. The comments received continue to be analysed internally as part of the process of reviewing these draft regulations, which have not yet been approved or incorporated into the legal system of any of the MERCOSUR States parties. With regard to the scope of the harmonized rules within MERCOSUR, these reflect the points on which technical agreement exists between MERCOSUR States parties. As indicated by the Argentine delegation, the fact that an alcoholic beverage is not included in the draft GMC Resolution does not preclude MERCOSUR member States from regulating it through domestic legislation. In this regard, Uruguay hereby notifies that it is working on a complementary decree, which will regulate aspects not addressed in draft GMC Resolution No. 02/23 and will be notified to the WTO in fulfilment, again, of the transparency obligations under the TBT Agreement. It is regrettable that the Mexican delegation has decided to immediately raise a specific trade concern with the WTO TBT Committee when, in our view, there are no objective reasons for doing so, and this point could have been satisfactorily clarified through bilateral dialogue between the capitals or in Geneva. In future, we invite the Mexican delegation to use existing bilateral channels in this regard.

2.1.3.3 European Union - Regulation (EU) 2023/1115 of the European Parliament and of the Council on the making available on the Union market and the export from the Union of certain commodities and products associated with deforestation and forest degradation and repealing Regulation (EU) No 995/2010 (ID 807¹⁰)

2.24. The representative of the <u>United States</u> provided the following statement. The United States believes that this is a technical regulation as it regulates product characteristics for derived products and it includes conformity assessment procedures in its due diligence requirements. As such, the United States believes this measure is within the scope of the TBT Agreement and should be notified to the TBT Committee. As a leader in addressing deforestation, the United States has been committed to conserving critical ecosystems and addressing drivers of global deforestation since the early 1900s. Based on this experience, the United States emphasizes that deforestation is a global issue that requires cooperative approaches by national competent authorities and civil society organizations rather than unilateral action. For this reason, the United States has strong concerns with the EU's unilateral approach in this space. Specifically, we are deeply concerned that the EU's approach may not be well-calibrated to effectively address root causes of deforestation and that it may adversely impact trade by imposing significant costs and burdens to global supply chains without providing measurable benefits to curb global deforestation. While we are still evaluating the full impact, it is our understanding that the EU's regulation will add billions in costs for a variety of industries, in both markets, and potentially complicate supply chains without producing a sufficiently tangible benefit to the global fight against deforestation from each affected industry or market.

2.25. We understand that the regulation has been formally adopted and published in the EU's Official Journal; however, additional work must be done to develop the country benchmarking methodology and implementing guidance for Member States. We request continued consultations between our technical experts to discuss ways this regulation can be better calibrated to address global deforestation and avoid imposing undue burdens on any producers that a party can demonstrate do not contribute to global deforestation. Given that this regulation is expected to have a significant impact on international trade, the United States respectfully requests that the EU delay implementation of this regulation, notify the regulation to the WTO TBT Committee, provide adequate time for stakeholder comment, and take those comments into account before implementing the final regulation. The United States looks forward to further technical dialogue on this regulation.

2.26. The representative of <u>India</u> provided the following statement. India is concerned with European Union's "Regulation on deforestation-free products" (Regulation (EU) No. 995/20102) ("Regulation"). The EU's omission to notify the Regulation to the Committee on Technical Barriers to Trade ("TBT") raises serious questions with respect to the compliance with the TBT Agreement. India believes that the Regulation would have a disproportionate impact on countries with agrarian economies that have significantly large population and vast tracts of forest land. Though the

¹⁰ For previous statements follow the thread under ID $\underline{807}$.

Regulation claims to contribute to the achievement of the Sustainable Development Goals ("SDG"), it is noted that the Regulation would, in fact, have an adverse impact on the achievement of other SDGs such as "no poverty" (SDG1), "zero hunger" (SDG2) and "reduced equality" (SDG10). The EU has failed to disclose the scientific basis on which it has selected the seven "relevant commodities" and the evidence to demonstrate that the targeted seven products pose a high risk to deforestation. Additionally, the retroactive cut-off dates and the burdensome due diligence processes, including annual reviews, are some of the specific concerns that would affect the trade in the relevant commodities between India and EU. The EU has unilaterally introduced a three-tier risk assessment system under which every country would be assessed and categorised into High, low or standard risk countries. No objective criteria have been disclosed for the risk assessment model. There is a high risk that the risk assessment could turn out to be highly subjective.

2.27. Further, EU shall not be the sole arbiter of the efforts of other Members for reducing the environmental impact of deforestation activities. The provision relating to cooperation with third countries is vague and lacks any substantive methodology for implementation. India is concerned that the Chapter relating to the country benchmarking system and cooperation with third countries confers an unreasonable amount of discretion to the Commission to assess the risk level of countries, without any accountability or transparency. India believes that the cumbersome implementation mechanism provided in the Regulation does not address the policy objectives sought to be achieved. The due diligence obligations in the Regulation apply to operators that "place a relevant commodity in the Union market". The burden on an operator would increase manifold for collecting data conducting due diligence, assessing the risk, providing information to the competent authorities in the EU market, maintain the data for a period of five years, etc. There are legitimate concerns that even the exporters/producers that follow "deforestation-free" agricultural practices may be denied access to the Union market if the "operators" in the Union market (to whom the exporters/producers supply their products) are unwilling to comply with the due diligence requirements. The ban on "placing a product in the Union market" unless they are "deforestation-free" appears to be excessive, and India is concerned that the EU has made insufficient attempts to consider less-trade restrictive alternatives to meet its objectives. India urges EU not to implement the Regulation before arriving at a consensus with trading partners on the definitions, scope of products covered, cut-off date, due diligence, risk assessment, etc.

2.28. The representative of Colombia provided the following statement. First, Colombia would like to state that it shares the objectives of reducing deforestation and forest degradation at the global level, as part of its efforts to promote sustainability and combat climate change. Nevertheless, we are concerned that the implementation and enforcement of this measure could become barriers to trade for some exports, even when these exports bear little or no relation to deforestation. I say this because some key Colombian export sectors, such as cattle, cocoa, coffee, palm oil, rubber and soy, would be required to provide a due diligence statement to demonstrate that they are deforestation-free. In this context, there are concerns about implementing the measure because there could potentially be multiple models of the due diligence statement, and certification that already takes such risks of deforestation into account could lose its relevance. On the other hand, this Regulation does not take into account local circumstances and capacities, national legislation and certification mechanisms in developing producer countries. It is clear that the European Union's "one-size-fits-all" model, based on due diligence and traceability, disregards the varying local conditions, imposing high costs on exporting nations, producers and consumers. The most harmful effects of this Regulation stem from excessive administrative tasks related to geolocation, traceability requirements, certification and customs procedures. We therefore agree with the United States that deforestation is a global problem that requires a cooperative approach rather than unilateral action. Lastly, I would like to reiterate that Colombia values environmental objectives and is committed to efforts aimed at combating deforestation and defending multilateral commitments, of course under the principle of common but differentiated responsibility. We are also ready to engage in constructive dialogue in order to strike a balance between conservation objectives and trade needs. We therefore call for a detailed and objective revision of the Regulation to ensure that it complies with WTO principles and obligations and for consideration of less restrictive alternatives that could achieve the desired goal without creating unnecessary barriers to international trade.

2.29. The representative of <u>Paraguay</u> provided the following statement. Paraguay reaffirms its commitment to environmental objectives and principles. In particular, we are at pains to stress our commitment to combating deforestation and forest degradation. However, we are concerned about how European legislation addresses these issues. Paraguay thanks the European Union for the information session held during Environment Week, the circulation of document <u>WT/CTE/GEN/30</u>,

the recent publication of a document with frequently asked questions, and the bilateral discussions. However, concerns persist, as evidenced by Members' concerns and queries, as seen from the number of questions submitted in the various bodies of this Organization, including the General Council. This Regulation and other unilateral measures that supposedly have environmental objectives and a clear impact on trade are being discussed in several bodies of this Organization, including the General Council. The EU has already announced that it will organize a new information session at the next meeting of the Committee on Trade and Environment. We thus hope that the EU will be able to respond to the questions and concerns raised in one of these forums, as what Members need is a dialogue and for their concerns to be taken into account, not a unilateral presentation on EU measures. Allow me, Chair, to conclude my statement by calling on the EU once again to engage in "effective cooperation and meaningful dialogue with its partners in the areas of trade and sustainable development to jointly address the impact of EU legislation and its implementing instruments, including providing support to facilitate trade". In addition, I would like to let you know that, together with other Members, we will forward written questions on this measure to the EU within the framework of the Committee on Trade and Environment.

2.30. The representative of <u>Canada</u> provided the following statement. Canada would like to thank the US, India, Colombia and Paraguay for raising this specific trade concern. Canada shares the EU's desire to address deforestation globally and recognizes the scope and scale of what the EU is undertaking regarding deforestation free supply chains. However, Canada is concerned that some of the compliance measures proposed in this regulation will result in barriers to trade for Canadian exports of several important products, even though they are at low risk of having stemmed from deforestation. Based on information provided thus far by the European Commission, it seems clear that, in particular, the geo-location requirement provided for in the Regulation will be unworkable for many Canadian exporters, particularly for composite or bulk products such as paper, soy beans, or wood pellets. While we respect the aims of the regulation, and understand the desire for traceability, we ask that the EU consider a more flexible approach to meeting some of these compliance objectives. We also ask the EU to consider delaying the entry into force of this Regulation given the large number of uncertainties around how the Regulation will be enforced, and the country benchmarking process. We further call upon the EU to notify the measure to the TBT Committee and allow the appropriate time for Members to provide comments. Reducing unnecessary and unintended effects on trade, particularly when sourcing agricultural and forest products that originate from countries with well-managed, stable forest area, is critical at this time of global economic uncertainty. To that end, it is imperative that complex requirements such as those included in the Regulation are well thought through and feasible.

2.31. The representative of <u>Australia</u> provided the following statement. Australia wishes to add its voice to the concerns raised by other Members. Australia shares international concerns about the global rate of deforestation and its impacts on climate and biodiversity. Australia supports measures that address global deforestation and forest degradation and is committed to halting and reversing net forest loss and land degradation by 2030 as a signatory to the Glasgow Leaders' Declaration on Forests and Land Use and the Forests and Climate Leaders' Partnership. Nevertheless, Australia, like many countries, uses specific definitions derived from internationally agreed terms and adapted to national circumstances, considering factors such as tree height and canopy cover. The one-size-fits-all definitions used in the regulation do not consider Australia's unique forest ecosystems. Australia is concerned that the use of satellite imagery to develop the EU Forest Observatory will not accurately reflect the status of Australia's forests. Added to which, there is an alarming lack of clarity and detail around the methodology applied to the country risk rating system that will be used to determine each country's risk rating. Australia asks the EU to provide opportunities to verify the data on Australia's forest status in the map being built by the Commission. Australia is willing to assist and provide information to the EU as required.

2.32. Furthermore, Australia and other WTO Members are concerned the EU's deforestation measures are more restrictive than necessary and create unnecessary barriers to international trade, creating a costly and time-consuming compliance burden. Noting this regulation has been adopted and will apply from 30 December 2024, Australia is concerned about the limited compliance timeframe until entry into force of the regulation. Australian producers and exporters of affected commodities and products will need to develop fit-for-purpose traceability systems to record and transfer geolocation data throughout their supply chains to meet the requirements of the regulation. This will be complex, costly and time intensive to achieve; added to which, some derived products captured in the regulation such as leather for example are already in production. Australia requests the EU provide specific guidance for producers and exporters of affected commodities and products

by the first quarter of 2024. Australia notes the EU is developing guidelines for implementation of the regulation by member States. Australia requests information on the regulatory approaches to be taken by member States, including the process for review in the event of detained consignments, be provided to third countries as soon as possible. Australia further seeks clarification from the EU on the role of the European Commission in overseeing the implementation of the regulation by member States and how the European Commission will resolve disputes between an exporter and the member State border authority.

2.33. The representative of Brazil provided the following statement. Brazil also manifests its support for the STC raised by the United States, India, Colombia and Paraguay, regarding the Regulation (EU) 2023/1115 of the European Parliament and of the Council. The EU's "one-size-fits-all" approach, implemented through this model of due diligence and traceability, ignores the different local conditions and will inevitably impose immense costs on exporting and importing countries alike, as well as on producers and consumers. While these costs are certain, we consider that the legislation, by itself, will bear no positive impact on deforestation rates and may even produce other adverse effects, such as increased poverty, diversion of resources, and hindrance of the attainment of SDGs. Smallholders are especially vulnerable to the EUDR and require special support. The EU should acknowledge the efforts made by developing countries to improve their livelihood and sustainability practices as well as the significant challenges faced by them regarding limited access to financing schemes, new technologies and technical training and assistance. Smallholders may end up being excluded from international value chains not because they have deforested their land but due to their inability to show compliance with the stringent requirements imposed by the EUDR. That would unfairly deprive smallholders of an important source of income and livelihood, and even impact their ability to adopt sustainable practices. We call, therefore, on the Commission to formulate clear and detailed implementing acts and guidelines that include differentiated compliance and due diligence regimes for commodities and products originating from smallholders in developing countries, considering that EU SMEs will be granted more flexible treatment.

2.34. In conclusion: 1. The EU should work to repair this legislation, or, at a minimum, aim to mitigate its more harmful impacts through implementation guidelines that adequately value the current, as well as developing local sustainable practices in agricultural value chains, and avoid trade disruption including the excessive administrative burden related to the geolocation and traceability requirements, certifications, and customs procedures. 2. We reiterate our commitment to the SDGs and to multilateral environmental agreements and goals. Given our shared objectives and the need to work together to tackle global challenges, we call on the EU to engage in effective cooperation and meaningful dialogue, with its partners in the areas of trade and sustainable development to jointly address the impact of EU legislation and its implementing instruments, including providing support to facilitate trade.

2.35. The representative of <u>Peru</u> provided the following statement. Peru would like to thank the delegations of the United States, India, Colombia and Paraguay for having submitted the specific trade concern regarding the EU regulation on deforestation-free products for discussion in this Committee. In this regard, we would also like to share our concern over this regulation, considering its potential impact on trade flows in products that fall under its scope, especially in those chains involving small-scale producers. In the case of Peru, exports of the products covered by the regulation form a significant share of Peru's agricultural exports to the world. It is a major supplier of such products, based on high quality and sustainability standards. Palm oil, cocoa, coffee and timber value chains have been growing and the European Union is one of our top markets. Thousands of small-scale producers (200,000 for coffee and 90,000 for cocoa, for example) are involved in these chains. This is why policies that impact products like these have major repercussions for exports from our country overall and, ultimately, for our economy, affecting thousands of producers whose livelihoods depend on the sale and export of such goods.

2.36. We understand that the measure includes conformity assessment procedures and lays down product characteristics. However, the transparency procedures established by the Agreement on Technical Barriers to Trade have not yet been followed. Furthermore, we are concerned that there are still many aspects of this European regulation that remain unclear or require supplementary regulations. This means that the actual time frame that operators and agents within these value chains have to make the necessary adjustments for compliance will be far shorter than the 18-month time frame for implementation established by the regulation. By way of example, the EU regulation does not specify what documents operators will require for exporters to be able to prove that their products are deforestation-free and that they comply with the legal parameters established. The

time frames for all the procedures envisaged by the regulation are also not specified, which will result in significant discretion and ambiguity in their implementation, potentially affecting trade. Moreover, this regulation appears to favour European Union member States and nationals over third countries given that it establishes a time frame of six months for EU members to only provide notification of the competent authorities responsible for complying with the obligations under the regulation, while third countries are expected to implement complicated processes within 18 months, including in relation to traceability, geolocation and the monitoring of agricultural chains involving hundreds of thousands of producers. Furthermore, it establishes a special time frame of 24 months to implement the regulation in SMEs within the bloc, whereas MSMEs and small-scale producers from third countries that are suppliers to the chains will have to comply with all the requirements within the aforementioned 18-month time frame.

2.37. In addition, countries will be assigned a deforestation risk rating, the specific criteria and methodology for which have not been communicated to the countries affected. In this respect, if the rating is based on general indices and does not take into account the specific circumstances that may arise in each country, it could have a negative effect on producers and exporters from low-risk areas, putting them at a disadvantage in relation to like products from other countries. Peru is committed to addressing the threat of climate change, global warming and deforestation. However, we believe that, in order to do so, unnecessarily trade-restrictive measures must be avoided. We cannot lose sight of the fact that among the main drivers of deforestation are poverty and the lack of options for generating income, which the opportunities offered by international trade can address. This is especially true for the products within the scope of the European regulation, which in Peru's case have also served as alternatives for illicit crops such as coca leaf. To conclude, we believe this regulation should be implemented only once an in-depth discussion on the matter has been held in a multilateral setting, there is clarity on the requirements and time frames laid down, and there is enough certainty to resolve any issues its implementation may cause, without creating unnecessary obstacles to trade.

2.38. The representative of <u>New Zealand</u> provided the following statement. New Zealand appreciates the opportunity to comment on the EU's Deforestation Regulation. While we, like others, share the desire to eliminate unsustainable deforestation, and to halt and reverse global forest loss, we remain unconvinced about the effectiveness of the EU's approach. We are also deeply concerned about the significant impact of the EU's implementation of these deforestation regulations on global trade. We are particularly concerned at the high implementation costs of this approach, including for those countries that maintain sustainable forestry systems and practices and for exporters whose production systems are not linked to unsustainable deforestation. We also hold a systemic concern about the prescriptive nature of the measure and the disregard for local conditions of production. New Zealand believes that a more effective approach would involve WTO Members working together collectively in this House, rather than through contributing to the proliferation of unilateral initiatives which cause trade disruption and risk fragmenting the international trading system. We encourage Members to collaborate, including at the WTO, to consider how trade facilitation and other trade levers can be used to address global challenges such as deforestation.

2.39. The representative of Argentina provided the following statement. Argentina would like to thank the United States, India, Colombia and Paraguay for including this item on the agenda. Argentina is convinced that the European legislation can be improved in order to adequately reflect local circumstances, national legislation and certification mechanisms in developing countries. We strongly believe that a fair and collaborative approach is always more constructive when implementing "one-size-fits-all" solutions. Indeed, we advocate a collaborative approach to addressing global challenges such as climate change, loss of biodiversity and pollution, while recognizing the specificities of our country and developing countries. The Argentine Republic reiterates its commitment to the 2030 Agenda for Sustainable Development, its goals and multilateral environmental goals. In this context, we believe that our efforts and achievements as regards the sustainability of national agri-food systems deserve fair recognition. Given our role as partners of the European Union in multilateral environmental forums and the World Trade Organization (WTO), we hope that the directives for the implementation of the legislation and risk assessment are developed by the European Commission through cooperation and consultation. In particular, we believe that in this process, the European Commission has the opportunity to consider the challenges that a unilateral regulation like the Regulation on deforestation-free products (EUDR) poses to developing countries, especially to their small producers, which is an issue that was not taken into account in the drafting of the Regulation. We therefore value dialogue as a means of ensuring recognition of the environmental achievements of our agri-food system, which is supported by national regulations and certification systems that merit adequate consideration. We urge the European Union to enter into, continue or deepen dialogue to address the concerns of the Members involved.

2.40. The representative of the <u>Russian Federation</u> provided the following statement. This is to echo concerns raised by other delegations on the EU deforestation regulation as the regulation is of strong concern to Russia as well. We set out our position multiple times on this regulation in other WTO working bodies, including in CTG and CMA.

2.41. The representative of <u>Panama</u> provided the following statement. Panama wishes to echo the statements made by previous speakers. Panama also shares the environmental objectives of combating deforestation as set out in the Regulation. However, we wish to express our deep concern about this standard, as it is having an impact on trade and creating a great deal of uncertainty in my country. We hope that the EU can respond to the questions and concerns submitted by Members in this Committee and in other forums of this Organization. We need a constructive dialogue to address our concerns.

2.42. The representative of <u>Indonesia</u> provided the following statement. Indonesia would like to thank for the opportunity to comment on this agenda item. At the outset, we want to join others in voicing our deep concern regarding the unfolding development of the EU deforestation policy. In this regard, despite its well intention, we are still of the view that there are some aspects in the regulation that we need to carefully consider prior to its implementation in December 2024. In particular, we need to carefully consider the negative impacts that such policy will bring to the trade of agricultural products as well as to the small-holder farmers. Moreover, we are of the view that tackling the deforestation issues will require more intensified cooperation instead of creating unnecessary trade barriers. The last thing we need at this point is unilateral trade measures under the disguise of protecting the environment, which undermine the system and pose a significant threat to developing Members and LDCs. At the same time we are not sure how the impacts of this policy will actually create differences in our common efforts of preventing deforestation. We urge the EU to continue their open dialogue and outreach activities, especially those involving producing countries, on this issue We also seek the possibility of amending such legislation to take into account this growing valid concern from Members.

2.43. The representative of <u>Guatemala</u> provided the following statement. We thank the United States, India, Colombia and Paraguay for including this item on the agenda. Guatemala shares the objectives of reducing deforestation at the national and global levels. However, applying these measures in the absence of clear procedures and guidance creates greater uncertainty for producer-exporters. A number of concerns have arisen, however, as these measures may constitute an unnecessary barrier to trade, creating excessive costs for several Guatemalan export sectors and particularly small producers. Producers are making every effort to achieve sustainable production and comply with the requirements set out in international standards. However, these requirements may not be compatible with the conditions and realities of rural areas that are not associated with sustainable production. Our concern is that a one-size-fits-all model is being applied without recognizing trading partners' geographical differences and conditions, particularly those in developing countries. We ask that the European Union consider a more flexible approach commensurate with the realities of its trading partners, and engage in dialogue with its trading partners.

2.44. In response, the representative of the <u>European Union</u> provided the following statement. Regulation (EU) 2023/1115 of the European Parliament and of the Council (On the making available on the Union market and the export from the Union of certain commodities and products associated with deforestation and forest degradation and repealing Regulation (EU) No 995/2010) was published in the EU Official Journal on 9 June 2023, entered into force twenty days later, and it shall fully apply from 30 December 2024. The EU considers this Regulation to be outside the scope of the definition of a technical regulation within the meaning of Annex 1 to the WTO TBT Agreement. For this reason, the EU did not notify this Regulation to the WTO TBT Committee. The Regulation 2023/1115 does not "lay down" or otherwise prescribe, positively or negatively, "product characteristics". The Regulation only refers to conditions that have to be met before placing the products on the EU market or exporting products from the EU market, in its Article 3, which reads: "Relevant commodities and products may be placed or made available on the Union market, or exported from the Union market only if all the following conditions are fulfilled: (a) they are deforestation-free; (b) they have been produced in accordance with the relevant legislation of the country of production; and (c) they are covered by a due diligence statement as laid down in Article 4(2)."

2.45. The definition of "deforestation free" is provided in Article 2 (13): "Deforestation-free' means: (a) that the relevant commodities and products, including those used for or contained in relevant products, were produced on land that has not been subject to deforestation after 31 December 2020, and (b) that the wood has been harvested from the forest without inducing forest degradation after 31 December 2020;". Nevertheless, the EU has been extremely transparent and forward leaning on this Regulation. The EU informed the WTO Committee on Trade and Environment on several occasions, most recently on 12 June 2023, and before, in March this year and in October last year. Furthermore, the EU is proactively engaging with the WTO Members through information sessions it hosts, the next one to be organized on 15 November alongside the WTO Committee on Trade and Environment. The EU will continue to engage in this dialogue with other WTO Members in the future.

2.46. The representative of the <u>United States</u> provided the following statement. (In rebuttal to the EU's argument that the Deforestation-Free Products Regulation does not lay down product characteristics or their related processes or production methods, and is therefore not a TBT measure): The United States disagrees with the EU's position regarding the TBT Agreement's definition of technical regulation. The United States notes that operators will be required to exercise due diligence requirements prior to placing relevant products on the EU market, and it appears that these due diligence requirements will be used by the EU to determine those relevant requirements in the regulation are fulfilled. Specifically, Article 15 of the regulation describes how EU competent authorities will examine mandatory due diligence statements to determine that the relevant requirements in the regulation are fulfilled.

2.1.3.4 Chile - Regulations on consumer information and advertising in relation to alcoholic beverages, <u>G/TBT/N/CHL/625</u>, <u>G/TBT/N/CHL/625/Add.1</u>, <u>G/TBT/N/CHL/625/Add.3</u>, <u>G/TBT/N/CHL/625/Add.4</u>, (ID 808¹¹)

2.47. The representative of <u>Mexico</u> provided the following statement. The delegation of Mexico refers to the Regulations on consumer information and advertising in relation to alcoholic beverages (Regulations relating to Articles 40 *bis* and 40 *ter* of Law No. 19.925), notified to the members of the TBT Committee in document <u>G/TBT/N/CHL/625</u>. In this connection, the Government of Mexico stresses that it agrees that providing clear and precise information to incentivize informed consumer decision-making is important; however, some aspects of the Regulations could create an unnecessary obstacle to international trade in alcoholic beverages. Specifically, the delegation of Mexico would like to voice the following concerns and requests regarding the labelling requirements laid down in the Regulations. Article 3 on warning pictograms could contravene Article 2.2 of the TBT Agreement, as it imposes additional and unnecessary requirements, given that many Mexican alcoholic beverages currently exported to Chile already bear warning pictograms that are recognized and used internationally.

2.48. Therefore, and with a view to avoiding consumer confusion and additional costs for producers due to labels solely for alcoholic beverages exported to Chile, it is requested that the Chilean Government continue to accept the warning pictograms and messages currently in use. Furthermore, Article 4 defines the minimum dimensions and proportions of the warning labels on packaging. These labelling regulations would mean that certain alcoholic beverages of Mexican origin would be unable to comply with the specifications under Article 4. In that regard, the delegation of Mexico would appreciate clarification as to whether the minimum dimensions and proportions required for the warning labels are mutually exclusive. In addition, Article 11 establishes energy value labelling requirements for alcoholic beverages, but fails to take into account the standard serving size of many distilled spirits. This could create confusion among consumers concerning their energy intake. Mexico therefore requests the usual energy information for distilled spirits be allowed to be declared. Lastly, Article 12 lays down the provisions regarding energy value information on the labels. However, using a text box for energy information, together with the pictorial warnings, would take up most of the space on the label. We therefore request the Government of Chile reassess the font size for the energy information text box. The delegation of Mexico thanks the delegation of Chile for giving its consideration to this statement.

 $^{^{11}}$ For previous statements follow the thread under ID <u>808</u>.

G/TBT/M/91

2.49. In response, the representative of Chile provided the following statement. The delegation of Chile appreciates the comments made by Mexico regarding the aforementioned Regulations. It should be noted that Decree No. 98 of the Ministry of the Interior and Public Security was published in the Official Journal on 7 July 2023, approving the regulations of Articles 40 bis and 40 ter of Law No. 19.925, as amended by Law No. 21.363, published in August 2021. The Decree incorporates warnings on the negative health effects of alcohol into packaging, regulates advertising and establishes requirements to include the calorie count on labels of alcoholic beverages marketed in Chile, whether produced domestically or imported from third markets. The Regulations were duly notified to the WTO Committee on Technical Barriers to Trade on 9 March 2023, following which several comments and concerns were received from the members of this Committee. Chile has fully complied with the commitments of the WTO TBT Agreement in this case and has even made additional efforts to give all members the opportunity to review and comment on the draft Regulations. On 10 May, additional time was granted to receive comments, as notified under Addendum 1. Subsequently, we replied to the comments, and the replies were notified under Addendum 2 on 18 July 2023. Following 75 days of international public consultation, members were informed of the publication of Decree No. 98 on 18 July under Addendum 3. Lastly, the Manual on Graphic Standards for Warning Messages and Energy Labelling on Alcoholic Beverages was published under Addendum 4 on 8 November. Most of the suggestions and comments were incorporated into the Decree, and a staggered entry into force of the provisions was carried out, with a time frame ranging from 12 to 36 months from the publication of the Decree in the Official Journal. This led to the creation of regulations that strike a balance between complying with consumer rights on access to information on the health risks of potentially harmful alcohol consumption behaviours and ensuring the least possible impact on international trade. Nevertheless, the specific questions submitted by the delegation of Mexico in this Committee shall be duly referred to the Ministry of the Interior and Public Security, which is fully prepared to provide further clarifications as required.

2.1.3.5 Philippines - Implementing Guidelines of the Philippine Energy Labeling Program for Clothes Washing Machines (ID 809¹²)

2.50. The representative of the <u>Republic of Korea</u> provided the following statement. On 23 October 2023, Korea submitted comments regarding the "Implementing Guidelines of the Philippine Energy Labeling Program for Clothes Washing Machines" (hereinafter Implementing Guidelines) through the TBT Enquiry Point and received a reply from the Philippines on 31 October. Korea thanks the Philippines for its quick and detailed response, which resolved some of our industry's concerns. Out of the five issues covered in the previous letters, there is one inquiry left to be further addressed, which Korea would like to communicate through this STC. Regarding the testing conditions for automatic clothes washing machines, Korea requests that the Philippines clarify whether the reference programme for reference washing machine can be decided by the manufacturer or there is a separate guidance under the regulation. If there is specific programme for the reference machine, Korea requests that the programme be identified from Annex E and F of PNS IEC 60456 for each washing machine type (e.g. Automatic/Manual washing machines, Front loader, Top loader with built-in heater, Top loader without heater, etc.)

2.51. In response, the representative of the <u>Philippines</u> provided the following statement. We would like to thank Korea for its interest on the implementing guidelines of the Philippine Energy Labelling Program for clothes washing machines. The Philippines would like to clarify that for automatic Clothes Washing Machines, the reference program is based on the manufacturer's instructions, which is the standard program set by the manufacturer consistent with the Specific Guidelines for the Conduct of Verification Testing (Section 1.5.3.1) in the Philippine Energy Labelling Program (PELP) Implementing Guidelines for Clothes Washing Machines. In cases where the manufacturer's instruction is not available, the reference program to be used shall be based on the available program of the tested unit that is most suitable. This must also be aligned with the parameters specified in Annex E and F of the Philippine National Standard IEC 60456:2013, whichever may be applicable. In addition, please be informed that the Philippines Department of Energy is in the process of updating the Implementing Guidelines for Clothes Washing Machines. Comments from stakeholders will be taken into consideration.

 $^{^{12}}$ For previous statements follow the thread under ID <u>809</u>.

2.1.3.6 India - Medical Textiles (Quality Control) Order, 2023, <u>G/TBT/N/IND/287</u> (ID 810¹³)

2.52. The representative of <u>Indonesia</u> provided the following statement. Indonesia would like to thank India for its notification related to the Medical Textiles (Quality Control) Order 2023 as <u>G/TBT/N/IND/287</u> on 3 July 2023 to the TBT WTO Committee. Referring to the notifications, the India Ministry of Textiles has issued six standards regulations on textiles export products, where the products must be certified according to Indian Standards and the manufacturer is required to undergo certification by the Indian Standards Bureau (BIS) under Foreign Manufacturer Certification (FCMS), before the product is allowed to enter the Indian market. Related to the implementation of the regulation, Indonesia had sent enquiries seeking clarification and explanation on the legitimate objective of this Quality Control Order. However, India responded that this regulation has been enacted on 27 September 2023 and India has not provided any explanation regarding Indonesia's concerns. India also did not notify the addendum to the WTO TBT Committee Secretariat regarding the implementation of this Quality Control Order.

2.53. In this regard, we would like to seek further clarification on the following matters: (i) Legitimate objective of the Quality Control Order. As we understand that the aim of this provision is to increase standard and quality of medical textiles in India, but the requirement of certification and the inclusion of Standard Mark to the six products would be unnecessary obstacle to trade and increasing cost for the companies engaged in the international trade with India. (ii) Related to sample testing on Sanitary Napkin and Disposable baby diapers products, we seek possibility to have the skin irritation testing to be carried out in Indonesia, considering to minimize the testing cost. (iii) How the process of determining the product certification body in terms of compliance with these standards. (iv) Regarding the audit process, please explain whether it should be done for every shipment product or one time audit that is valid for a certain period of time. Indonesia Ministry of Health (MOH) as regulator for those products, conduct only one time audit that is valid for five years as the requirement for market authorization licence. (v) The production of Indonesia Sanitary Napkins and Disposable baby diapers from raw material to finish products, has been integrated to comply with the standards issued from MOH. In addition, the probability of contact with human hands was very small so that the level of hygiene is guaranteed. If the sample testing is carried out by testing the cleanliness aspect whether it is not contaminated or not contaminated due to direct contact with humans, we assume that testing the cleanliness aspect is not needed. (vi) The transition time of the regulation is insufficient for producers to be able to meet the requirements set out in the QCOs. With a large number of regulated products, the need for physical testing, and the factory inspection requirements at production sites, we are concerned about the possibility of queues and backlogs of product certification applications coming into the BIS, which could slow down the certification process and hinder the export process. In this regard, we request India to postpone the implementation of this QCO at least 12 months after promulgations. (vii) Indonesia suggest India open the option of international recognition for conformity assessment results and/or conformity assessment bodies (inspection bodies) from the country of origin to speed up the audit and certification process and also reduce the cost of certification. Indonesia also urges India to notify the stipulated technical regulations to the secretariat, in accordance with Article 2.9.2 of the TBT Agreement.

2.54. In response, the representative of <u>India</u> provided the following statement. BIS certification scheme is basically voluntary in nature. However, for a number of products compliance to Indian Standards is made compulsory by the Central Government under various considerations viz. public interest, protection of human, animal or plant health, safety of environment, prevention of unfair trade practices and national security. For such products, the Government of India directs mandatory use of Standard Mark under a Licence from BIS through issuance of Quality Control Orders (QCOs). The requirement of Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization is an optional requirement for disposable (non-reusable) sanitary napkins as per IS 5405:2019 and for reusable sanitary pad/sanitary napkin/period panties as per IS 17514:2021. However, for Disposable Baby Diaper as per IS 17509: 2021 it is a mandatory requirement. These standards prescribe that the manufacture shall ensure that raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use and prescribe methods for detection of biocompatibility. The product specific guidelines (i.e. product manuals) issued by BIS for these products, which are available on BIS website www.bis.gov.in, specify that conformity of raw materials to the standard may be established through supplier's test certificate, test report of

¹³ For previous statements follow the thread under ID $\underline{810}$.

BIS recognized/empanelled lab or any other NABL accredited lab or through in house testing. Foreign Manufacturers can apply for BIS certification under BIS Foreign Manufacturers Certification Scheme (FMCS).

2.55. The process broadly involves submission of application by the manufacturing unit, examination of application and on-site factory audit by BIS Certification Officer during which assessment of the capability of the manufacturer to manufacture and test the product according to the Indian Standard is done, testing of the product as per the standard is witnessed in the factory and sample(s) of the product are drawn for testing in BIS lab or BIS recognized/empanelled lab as per the Indian Standard. Decision for grant of certification is taken based on the application, factory audit and the lab test results. Details of BIS Foreign Manufacturers Certification Scheme (FMCS) are available on BIS website www.bis.gov.in. BIS certification is granted to the concerned manufacturing unit for one or two years initially and can be renewed subsequently for up to five years. The requirements of the concerned Indian Standards as follows, shall apply IS 5405:2019 – for disposable (non-reusable) sanitary napkins, IS 17514:2021 - for reusable sanitary pad/sanitary napkin/period panties, IS 17509:2021 – for Disposable Baby Diaper.

2.56. These can be accessed from BIS website www.bis.gov.in standards or https://standardsbis.bsbedge.com/. The Indian Standards are developed by technical committees that are representative of various stakeholders having interest in the relevant subject of standardization under the scope of such committees through a process of consultation so that views of all are given due consideration and a consensus is evolved in formulating a standard. The stakeholders involved in national standardization can broadly be categorized as industry, consumers/users, technologists (R&D and Scientific institutions, academia, individual subject experts etc.) and government departments/regulators. There is possibility of contamination of product due to raw material, storage, handling, transportation, production environment, and packaging. Accordingly, hygiene testing requirements have been prescribed for sanitary pad and baby diaper to ensure the quality of product. The implementation timeline for the aforementioned QCO is as follows A) for Sanitary Napkins, Baby Diaper and Reusable sanitary pad sanitary napkin period panties. For Small & Micro Enterprises (SME) -1 October 2024, For Others - 1 April 2024. B) For Shoe covers, Dental bib/ Napkins and Pillow Covers – 7 April 2024. As regards the proposal for consideration of international recognition for conformity assessment results as well as conformity assessment bodies, such provisions can be made only under the provisions of Government to Government Mutual Recognition agreement (MRA) with interested countries with the approval of Central Government.

2.1.3.7 United States - Energy Conservation Program: Test Procedure for Commercial and Industrial Pumps, <u>G/TBT/N/USA/980/Rev.1/Add.1</u> (ID 811¹⁴)

2.57. The representative of <u>China</u> provided the following statement. The US Department of Energy proposes that pumps that operate at 960 to 1440 rpm or are designed to operate with 6-pole motors would be tested with a nominal speed of 1200 rpm. Cavitation during testing represents the result of the actual operation. Therefore, the test results are still valid. However, testing a 6-pole motor or pump with a design speed between 960-1440 rpm at a rated speed of 1200 rpm will significantly increase the testing burden and cost. Moreover, due to limited testing conditions, the test results are not stable, and the test results obtained from the deceleration experiment can also be converted to a rated speed of 1200 rpm by pump affinity laws. According to Article 2.2 of the <u>WTO/TBT</u> Agreement, "Members shall ensure that the formulation, adoption, or implementation of technical regulations do not create unnecessary obstacles to international trade in purpose or effect" and consider reducing unnecessary testing costs and improving the stability of test results, China suggests that the US adopt commonly used methods in the motor testing industry and add the option of a speed reduction test for manufacturers to choose from.

2.58. In response, the representative of the <u>United States</u> provided the following statement. As we discussed in our bilateral meeting with China this morning, we are hearing these comments for the first time so it is hard to respond substantively when we are getting them at the last minute, but the United States appreciates the comments submitted by China on the measure on 7 June 2022. The United States took into account all comments received during the open comment period and

 $^{^{14}}$ For previous statements follow the thread under ID <u>811</u>.

responded to each substantive comment when we issued the final rule. Those replies are publicly available at Federal Register, Volume 88 Issue 57 (Friday, 24 March 2023) (govinfo.gov)

2.1.3.8 European Union - Mandatory Batch Testing of Pharmaceutical Products (ID 812¹⁵)

2.59. The representative of <u>India</u> provided the following statement. India is concerned about present EU norms that require analytical testing of each and every batch of the imported consignment at the port of destination and only after the confirmation of satisfactory results the consignment is allowed to reach the market. This procedure delays the product reaching the market by 2-3 months. Other developed countries allow the consignments based on company's certification. It has been repeatedly suggested that analytical testing could be conducted randomly and self-certification of analysis by the exporter could be accepted similar to what is done in other countries so as to avoid dual testing of each medicinal/pharma consignment.

2.60. In response, the representative of the European Union provided the following statement. At the outset, the EU would like to inform Members that the measure that India is raising has been in place for over 20 years as the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use has been adopted in November 2002. Article 51 para 1. point b) of this Directive provides that member States shall take all appropriate measures to ensure that the qualified person is responsible for securing that each production batch has undergone, in a member State, a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products, in accordance with the requirements of the marketing authorization. This means that each batch of products imported from outside the EU has to be re-tested in the EU for obvious public health reasons and that this cannot be replaced by the acceptance of batch testing certificate issued in India and based on tests performed in India. To accept batch testing certificates without re-testing the products in the EU, the Commission would first need to evaluate and confirm that India's regulatory framework applicable to medicines and their active substances exported to the EU, as well as the respective control and enforcement activities, ensure a level of protection of public health equivalent to that of the EU. That is not the case as currently there is regrettably no technical cooperation on the quality of medicines with India. This cooperation would be the pre-requisite for such an evaluation and, in a distant future, a possible mutual recognition of each other's regulatory framework and the respective control and enforcement activities applicable to medicines, which could ultimately lead to the recognition of batch testing certificates.

2.1.3.9 Mozambique - Regulation on standardization and conformity assessment, decree No. 8/2022 of 14.03.2022 (<u>G/TBT/N/MOZ/17</u>) and Conformity assessment procedure of imported products for mandatory control during customs clearance of 16.08.23 (not notified) and Ministerial Diploma No. 98/2023 establishing taxes on products to be exported to Mozambique of 14.07.2023 (not notified), <u>G/TBT/N/MOZ/17</u> (ID 813¹⁶)

2.61. The representative of the European Union provided the following statement. The Decree No. 8/2022 of March 14th that defines the framework for standardisation and conformity assessment was notified by Mozambique under G/TBT/N/MOZ/17. This decree is lying down the general framework, and we did not have specific comments at the time. Several subsequent measures, recently adopted, further detail the way this decree will be implemented. There is the Conformity Assessment Procedure of Imported Products for Mandatory Control during Customs Clearance, dated 16 August 2023. This one details the procedure for conformity assessment for imported products. In our view this should have been notified to the WTO, as a standalone notification or as an addendum to the earlier notification, so that Members would have had the possibility to comment. Furthermore, there is the Ministerial Diploma No. 98/2023: it establishes taxes and dates from 14 July 2023. It is a further clarification of the two measures already mentioned and it should also have been notified. We understand the entry into force took already place on 1 November 2023. It seems that the new conformity assessment program has replaced a pre-shipment inspection. A certificate of conformity can only be issued by one company (Intertek) and must occur prior to shipment for goods to be cleared by Customs at Mozambican Ports and Borders. For this certificate, the exporter needs to pay a percentage-based fee per consignment. This new system seems to be largely equivalent to the earlier one and is very cumbersome for our industry. We see different

¹⁵ For previous statements follow the thread under ID <u>812</u>.

¹⁶ For previous statements follow the thread under ID $\underline{813}$.

problems with these three measures that are all linked. Mozambique should have notified the whole package to the TBT Committee to provide for a proper consultation. Then there is a different treatment foreseen for domestic and imported products. We would like to get additional information about how the same domestic products are being treated, both concerning conformity assessment procedures and the related fees.

2.62. The TBT Agreement (Article 5.1) provides that conformity assessment procedures should be prepared, adopted and applied so as to grant access to suppliers of like products originating in other Members under conditions no less favourable than those accorded to suppliers of like products of national origin, in a comparable situation. We furthermore wonder why the fees are ad valorem based. Why would the value of the imports be a problem? Such a fee must be related to the service rendered not to the value of the imported products. The conformity assessment procedures for the respective products create an unnecessary obstacle to international trade as the procedures seem more strict than necessary to give Mozambique adequate confidence that products conform with the requirements set out in technical regulations. In this respect some aspects of the procedures need to be clarified, like whether there is any possibility for importers to avoid repeating the conformity assessment procedure for any shipment to Mozambique, which seems to be unnecessarily burdensome in particular for less risky products. Mozambique should accept EU certificates that are based on the same international and EU standards and done by ILAC laboratories as many countries are doing world-wide. We would be grateful if Mozambique could reply to our questions and notify the two outstanding measures to WTO.

2.63. In response, the representative of <u>Mozambique</u> provided the following statement. My delegation would like to thank the EU for raising this issue. In 2022, the Mozambican government approved Decree no. 8/2022, of 14 March, which establishes the Conformity Assessment Programme (CAP) for products imported into Mozambique to guarantee compliance with the technical standards and regulations in force in the country. The fees to be applied in the implementation of the CAP were approved by Diploma Ministerial n.98/2023 of 14 July. Mandatory conformity assessment begins on 1 November 2023 for the products on the list -ANNEX 2, which is also available on the National Institute for Standardisation and Quality (INNOQ) website. The Decree n. 8/2022 of 14 March, has been notified to the World Trade Organization and has the code <u>G/TBT/N/MOZ/17</u>, 1 June 2022 and is also available only in Portuguese version on the INNOQ, IP website. Unless otherwise indicated, the TBT Agreement states that technical regulations, conformity assessment procedures and technical standards must be notified. However, with regard to Diploma Ministerial no. 98/2023, of 14 July, which approves the fees to be charged for the conformity assessment programme for products imported into Mozambique, this document has not been notified to the WTO for the reasons mentioned above, but it is available on the INNOQ, IP website.

2.64. Regarding to the fees: The ARTICLE 2 (Incidence), the Diploma Ministerial n.98/ 2023, of 14 July, determine: The fees for CAP implementation services shall be charged to exporters in the country of origin of the products and are set out in Annexes I and II to this Ministerial Diploma, as follows. Category A: Occasional exporters and/or used products - % Ad Valorum (As per FOB value) a. 0.50%, Minimum Fee (USD) b. 250,00, Maximum fee (USD) c. 2750,00. Category B: Frequent exporters – a. 0.45% b. 250 Usd c. 2.750 usd. Category C: Exporter/Manufacturer with high frequency volumes – a. 0.25% b. 250 Usd c. 2.750 Usd. Category D: Verification in Mozambique of a product that does not have a certificate of conformity – a. 0.80% b. 500 Usd c. 5.000 Usd.

2.1.3.10 Ecuador - Proposal for a Regulation on the labelling of processed and packaged foods for human consumption (ID 814¹⁷)

2.65. The representative of <u>Mexico</u> provided the following statement. The delegation of Mexico refers to the Republic of Ecuador's Proposal for a Regulation on the labelling of processed and packaged foods for human consumption. In this connection, the Government of Mexico stresses that it agrees that providing clear and precise information to incentivize informed consumer decision-making is important; however, it is necessary to ensure that technical regulations comply with the principles of the WTO TBT Agreement on as wide a basis as possible. In this regard, the delegation of Mexico would like to voice the following concerns and requests. Article 3 of the Regulation includes a general definition of alcoholic beverages, but this definition does not cover fermented or prepared alcoholic beverages, to provide greater certainty about the application of the

 $^{^{17}}$ For previous statements follow the thread under ID <u>814</u>.

Regulation, to establish a level playing field for all alcoholic beverages and not to be more traderestrictive than necessary, in accordance with Article 2.2 of the TBT Agreement. Chapter VI of the Regulation lays down the alcoholic beverage labelling provisions. It is important that warning symbols can be included anywhere on the label and not necessarily on the front-of-pack label, which would make it easier to bring the labels into line with the various provisions of other countries and with the recommendations of the World Health Organization and the Organisation for Economic Co-operation and Development, in accordance with Article 2.4 of the TBT Agreement. Lastly, the Government of Ecuador is requested to notify this draft Regulation to the WTO TBT Committee, in accordance with the commitment to transparency, pursuant to Article 2.9.2 of the TBT Agreement, so that comments on the Regulation may be submitted in writing. The delegation of Mexico thanks the delegation of Ecuador for giving its consideration to this statement.

2.66. In response, the representative of Ecuador provided the following statement. Ecuador wishes to report that, in March 2023, the Inter-Ministerial Committee on Quality adopted the road map submitted by the Ministry of Public Health of Ecuador, which is overseeing the preparation of the "Draft Regulation on the labelling of processed and packaged foods for human consumption". The road map sets out the transparency obligations assumed by Ecuador as a Member of the World Trade Organization and as part of its trade agreements. In this regard, the road map adopted by the Committee covers: Internal consultation: This is for the regulatory improvement process, relating to the publication of the draft regulation and the summary of the regulatory impact analysis on the Ecuadorian Standardization Service (INEN) website for 20 days to receive technical suggestions and comments from regulated domestic entities, the integrated public health network, consumers and civil society, among others. The internal consultation process was announced on 26 August 2023 to this end. Circulation for internal consultation: The document was shared with regulated domestic entities, the integrated public health network, consumers and civil society, among others. The comment period ran from 4 to 25 September 2023. At the request of regulated domestic entities, the internal public consultation period has now been extended to 23 October 2023, as reflected on the INEN website. External consultation: Once the comments received as part of the internal consultation have been reviewed, the notification will be submitted through the WTO ePing system pursuant to the Agreement on Technical Barriers to Trade, and a 60-day comment period will be accorded. The recommendation contained in document G/TBT/35/Rev.1 will be taken into consideration for this purpose.

2.67. Formal adoption process for the draft technical regulation: A reasonable interval will be allowed between the publication of technical regulations and their entry into force, pursuant to the TBT Agreement. *Final notification:* The final version of the technical regulation will be notified through the WTO ePing system. The Ministry of Public Health has now requested circulation of the draft regulation. At present, comments received from various public and private sectors are gradually being analysed in order to proceed with the notification of the draft regulation in accordance with the TBT Agreement, so that stakeholders can submit written comments through the WTO TBT Enquiry Point once Ecuador has notified the draft to the WTO. Lastly, it is important to mention that a period of more than six months has been established for the draft regulation's entry into force to allow stakeholders reasonable time to implement it.

2.1.3.11 Thailand - Notification of the Committee on Labels, entitled Determination of Products Containing Lasers as Label-Controlled Products; Draft Notification of the Committee on Labels, entitled Determination of Personal Computer and Computer Device as Label-Controlled Goods, <u>G/TBT/N/THA/667</u>, <u>G/TBT/N/THA/684</u>, <u>G/TBT/N/THA/684/Add.1</u> (ID 815¹⁸)

2.68. The representative of the <u>United States</u> provided the following statement. The United States thanks Thailand for providing the opportunity for stakeholders to comment on "Determination of Products Containing Lasers as Label-Controlled Products" (<u>G/TBT/N/THA/667</u>) and "Determination of Personal Computer and Computer Device as Label-Controlled Goods" (<u>G/TBT/N/THA/684</u>). U.S. industry submitted comments on <u>G/TBT/N/THA/667</u> in September 2022 and on <u>G/TBT/N/THA/684</u> in December 2022. We understand that the final version of these two notifications were published in the Royal Gazette recently. However, we remain concerned that the proposed labelling requirements may have the effect of creating unnecessary obstacles to international trade. We would welcome an update from Thailand regarding what steps Thailand has taken to consider stakeholder

 $^{^{\}rm 18}$ For previous statements follow the thread under ID $\underline{\rm 815}.$

comments on the two notifications. The previous concerns we flagged for Thailand largely pertained to the failure to reference two widely accepted international standards.

2.69. First, the "Determination of Products Containing Lasers as Label-Controlled Products" had an unclear scope and did not consider the risk of the lasers or differentiate their categories. US industry requested that Thailand consider referencing IEC 60825-1:2014, a widely accepted international standard, to address the safety of different laser products and provide appropriate safety labelling. Can Thailand clarify if it took this comment into consideration in the final? We have also heard reports that the final measure now requires labels to indicate the product's "date of expiry" or "best before" date, which was reportedly not in the draft version of the measure. It is unclear to us how a date of expiry is relevant within the context of ICT equipment. We request that Thailand explain the legitimate regulatory objective it is attempting to fulfill with this requirement.

2.70. Second, US industry is concerned that the "Determination of Personal Computer and Computer Device as Label Controlled Goods" also does not align with relevant international standards. In this regard, US industry notes the benefits of Thailand aligning classifications, safety warnings, and documentation requirements with international safety standard IEC 62368-1:2023 and considering adoption of voluntary consumer information for some content. US industry encourages the acceptance of e-labelling as a voluntary option, due to the amount of information requested and the limited space for physical labels. We welcome an update on how Thailand considered these comments in the final regulation.

2.71. Finally, particularly in light of these concerns, we also request that Thailand consider extending the implementation period to a minimum of one year to allow a reasonable interval between the publication of the regulations and their entry into force. Manufacturers need sufficient time to revise their labelling to comply with these new requirements. While the regulations provide 120 days for implementation, according to US industry, a minimum of one year is needed to allow a reasonable interval for manufacturers to adapt their global supply chain of products or methods of production in scope to the new requirements. We thank you for your consideration of this matter. We greatly appreciate the information we've received from Thailand to date, and remain open to continuing a bilateral dialogue with Thailand to address these concerns.

2.72. In response, the representative of <u>Thailand</u> provided the following statement. Thailand would like to thank the United States for their comments and statement. As we have not received any information regarding these specific concerns from the United States in advance, we would appreciate it if the written statement is provided. We, therefore, will refer the concerns to the competent authority in capital and respond in due course via your enquiry point. Thailand also welcomes further bilateral dialogue with the United States to address the concerns raised.

2.1.4 Previously raised concerns

2.1.4.1 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 678¹⁹)

2.73. The representative of the <u>United States</u> provided the following statement. The United States submitted comments on <u>G/TBT/N/MEX/465/Rev.1</u> on 3 May 2022, and has not received a response. The United States remains concerned about the scope and implementation of the measure. Could Mexico provide a timeline for when it will respond to WTO Members' comments? Please provide an update on the status of this measure and an estimated timeframe of when the revised measure will be notified to the WTO. In November 2022, Mexico shared that the measure was in the final stage of review by Mexico's Ministry of Economy legal team. The United States reiterates its request that Mexico consider allowing fatty acid analysis to be voluntary rather than mandatory. Currently, there are no internationally well-accepted biomarkers to differentiate milk fat from all vegetable fat, and there are no relevant internationally accepted testing methods available for this type of analysis.

2.74. The United States is concerned this measure may conflict with the ongoing redrafting of the corresponding cheese standard. How will Mexico harmonize the 2019 update to the NOM-223 cheese

 $^{^{19}}$ For previous statements follow the thread under ID $\underline{678}.$

standard, with the NOM-223 cheese CAP versions developed through 2020–2021, and an expected update to the NOM-223 cheese standard? Once finalized, will implementation of the measure move forward based on Mexico's Quality Infrastructure Law or the law it replaced, the Federal Law on Metrology and Standardization? We request that Mexico provide an outline of the different roles that each Ministry will play in the monitoring, compliance, and verification activities listed in the draft measure. We continue to have several significant concerns and questions about this measure's scope and implementation and request that Mexico indefinitely delay implementation or implement no earlier than 1 November 2024.

2.75. The representative of <u>Australia</u> provided the following statement. Australia would like to reiterate its concerns stated at previous TBT Committee meetings that Mexico's measure notified as <u>G/TBT/N/MEX/465</u> and associated revision appears discriminatory and more trade restrictive than necessary. Australia recognizes the original objectives of the proposed measures and welcomes the review of the procedure considering Mexico's international commitments. Australia appreciates that Mexico's competent authorities are still in the process of analysing the comments received with respect to this measure. Australia kindly asks Mexico to advise on expected timeline to answer these important questions. We look forward to receiving Mexico's reply to our comments on its revised notification and an update for the release date of the new version of the procedure for public consultation.

2.76. The representative of <u>New Zealand</u> provided the following statement. New Zealand welcomes the opportunity to again speak in support of this specific trade concern raised by the United States. New Zealand considers that the conformity assessment procedures that Mexico has set out for cheese under NOM-223 are more trade restrictive than necessary, with some aspects of the conformity assessment procedure creating unnecessary obstacles to international trade and likely to cause difficulties for New Zealand exporters. We support the request for Mexico to consider less trade-restrictive alternatives to the measures. We look forward to receiving a response from Mexico to the concerns raised, and an update on the status of any revised version of the Conformity Assessment Procedure.

2.77. In response, the representative of <u>Mexico</u> provided the following statement. The Government of Mexico wishes to thank the United States, Australia and New Zealand for their statements and reiterates that the authorities of the Ministry of Economic Affairs and the Ministry of Agriculture and Rural Development are currently at the stage of reviewing the 164 comments received from domestic and foreign stakeholders during the consultation period. The Government of Mexico will report its results to the delegations concerned and all WTO Members once this revision has been concluded. It is also vital to reiterate that this process is carried out in accordance with the provisions of the WTO TBT Agreement, as well as the agreements related to the FTAs to which Mexico is party.

2.1.4.2 European Union - Chemical strategy for sustainability (implementation of the European Green Deal) (ID 690²⁰)

2.78. The representative of the <u>Russian Federation</u> provided the following statement. We are requesting to incorporate into minutes our intervention in its entirety made over previous Committee meeting on this item as our concern hasn't been addressed by the European Union. Once again, it is worrisome that the EU link fulfilment of its transparency commitments with the reasons not related to the WTO. Transparency is the important pillar of this organization which has been acknowledged by the EU on multiple occasions. It is unfortunate that the EU's actions run counter its words.

2.79. Statement from June 2023 meeting, in full.²¹ The Russian Federation would like to reiterate its concern on the European chemical strategy for sustainability. In December 2022, the European commission published the Recommendation for safe and sustainable chemicals, which contains classification of hazardous properties and their influence on human health and environment. However, the classification is based upon the REACH Regulation which lacks of laboratory and epidemiological data or the scientific justification. The EU keeps imposing unilateral trade restrictions under the umbrella of European green deal despite the rules of the WTO. None of the questions that have been asked in the Committee since June 2021 on that strategy have been answered. We urge the EU to provide responses on the questions raised during the previous TBT Committee meetings. Moreover, it is worrisome that the EU link fulfilment of its transparency commitments with the

 $^{^{\}rm 20}$ For previous statements follow the thread under ID $\underline{690}.$

²¹ G/TBT/M/90, para. 3.451.

reasons not related to the WTO as they have been refusing to engage on the issue. Transparency is the important pillar of this organization. The EU acknowledged its importance on multiple occasions. It is unfortunate that the EU's actions run counter to its words.

2.1.4.3 Canada - Proposed Prohibition of Certain Toxic Substances Regulations, 2022, <u>G/TBT/N/CAN/673</u> (ID 753²²)

2.80. The representative of the Republic of Korea provided the following statement. Following Canada's notification on 18 May 2022 as G/TBT/N/CAN/673, Korea submitted comments to Canada regarding the "Proposed Prohibition of Certain Toxic Substances Regulations" in July 2022 and also raised STCs in the previous Committee meetings of March and June 2023, requesting to postpone and reconsider the regulation. While Korea appreciates Canada's responses to our comments, relevant Korean industries remain concerned about the proposed restriction of DBDPE, so Korea would like to reiterate those concerns. DBDPE, known for its outstanding and cost-effective flame-retardant features, is used as an intermediate material in various industrial sectors such as in the manufacture of electrical and electronic products, automobiles, construction equipment vehicles, agricultural machinery, etc, replacing the once commonly used but now restricted decaBDE. Korea supports Canada's endeavours to protect the environment and its policy initiatives aimed at realizing such efforts. Nevertheless, if the restriction on DBDPE is enforced without taking into account the availability of its alternatives, there are concerns that such measures would not only be more traderestrictive than necessary but also put human safety at risk. Korea acknowledges that the proposed regulations provide temporary exemptions for electrical and electronic products, vehicle parts and pellets or flakes used in manufacturing wires and cables. Nevertheless, if no adequate alternatives were found by the end of the exemption period, consumer safety risks would increase significantly due to the absence of flame-retardants or the low flame-retardant quality in products.

2.81. Korea would like to note in this regard that several Korean companies have tested a range of non-bromine flame retardants in efforts to develop alternatives to DBDPE. However, they have encountered challenges such as reduced efficiency in the manufacturing process and product quality deterioration (including surface whitening, water spots, ammonia odour, corrosion, etc). As of now, there seems no viable replacement for DBDPE. Moreover, the U.S. Environmental Protection Agency (EPA) and the European Chemicals Agency (ECHA) have not imposed risk management measures on DBDPE. Neither the Stockholm Convention nor the Great Lakes Water Quality Agreement (GLWQA) has listed DBDPE as a prohibited substance. Consequently, Canada is the only country to adopt a restriction on DBDPE, one that is overly stringent compared with prevailing international standards. Therefore, Korea requests that Canada conduct a comprehensive evaluation of product safety and carefully assess the impact on the relevant industries before enforcing the DBDPE restriction. Korea also recommends Canada postpone the regulation indefinitely, even beyond the temporary exemption periods, until alternative flame retarding materials (or methods) matching DBDPE in terms of cost and performance are developed for manufacturers' use.

2.82. The representative of <u>China</u> provided the following statement. China suggests suspending the prohibition of DBDPE for the following reasons. Firstly, the proposed regulation does not contribute to fulfilling a legitimate objective. The scientific evidence on DBDPE shows that DBDPE is essentially unreactive and will not form, even under photolysis, potentially toxic substances. DBDPE as such is of low toxicity to mammals and aquatic organisms. The release of DBDPE into the environment does not lead to exposure to persistent and bio-accumulative products. The assumption to prohibit DBDPE is that it would, once exposed to the environment, transform into toxic and bio-accumulative products is scientifically untenable. The prohibition of DBDPE and of products containing DBDPE does, therefore, not contribute to such a legitimate objective as protecting the Canadian environment or the Arctic ecosystem and its indigenous peoples. Secondly, the technology to replace DBDPE is not well-proven and it takes quite a long time to finish such a replacement. Also, if product manufacturers are forced to use alternatives not well proven, it will undermine the fireproof performance of the products and jeopardize consumers' lives and property. Thirdly, DBDPE is different from DecaBDE. A major reason why DBDPE is listed as a hazardous substance is that DecaBDE is used as a surrogate for DBDPE in hazardous assessment, and this is problematic. US National Academies of Sciences (NAS) released a study report in 2019, holding that OFRs used in consumer products cannot be made a hazardous assessment as a single group; instead, they should be sorted into 14 subgroups based on chemical structure, physicochemical properties, and predicted biologic activity. It is noteworthy that in the study, NAS grouped DBDPE and DecaBDE into separate

 $^{^{22}}$ For previous statements follow the thread under ID $\underline{753}$.

subclasses. Fourthly, currently there is no precedent in the world to control DBDPE particularly. The evaluation on DBDPE is pending under EU REACH. It is better to have a further assessment on DBDPE, not only a hazardous assessment but also an assessment of replacement feasibility and industry impacts.

2.83. The representative of Japan provided the following statement. Japan appreciates Canada's comments at the last TBT Committee meeting in June that the final regulation is to be published in summer 2024, that "the proposed Regulations provide time-limited exemptions for parts and products of certain industrial sectors, such as the automotive sector and electronic and electrical equipment", and that Canada thinks alternatives including non-chemical-based ones can be used. Also, Japan recognizes that the same description regarding the timing of publication of the final regulation is written in the TBT notification (G/TBT/N/CAN/673/Add.1) published on 11 August 2023. However, Japan continues to have concerns regarding the proposed DBDPE restriction in the draft revision of the Regulations, especially its impact on industries and citizens' lives in Canada. DBDPE is widely used in various categories such as EEE, automobiles, aircraft, medical equipment, industrial equipment, social infrastructure equipment, agricultural machinery, industrial machinery, construction machinery and industrial vehicles as an alternative for decaBDE, which is a brominated flame retardant that has been internationally prohibited. DBDPE has not been restricted by international conventions or in other countries or regions.

2.84. Although Canada commented that alternatives including non-chemical-based ones can be used, currently there is no alternative flame retardant available, including a non-chemical-based one, which is equivalent to DBDPE in many applications. Therefore, the period of exemption proposed in May 2022 is not sufficient for developing alternatives to DBDPE and completing substitution through the entire supply chain. Accordingly, it is highly likely to have significant and serious effects on the trade and distribution in Canada of the various types of equipment noted above. In particular, medical equipment and industrial equipment are important not only for supporting Canadian industries and infrastructure but also for the impact they have on citizens' lives in Canada. Therefore, we reiterate our request for setting a sufficient grace period for the examination and introduction of DBDPE alternatives through conducting additional stakeholder consultations and deliberate consideration. Canada concluded that DBDPE has a risk to cause adverse effect on the environment and indicates contribution to the protection of the Canadian environment and wildlife as the main objectives of DBDPE restrictions.

2.85. We understand the objectives of the regulations, however, according to Japanese industries, DBDPE contained in products is rarely released to the environment during its intended use and poses a very low risk of harmful effects on humans and the environment, including wildlife. Further, the screening assessment published by Environment and Climate Change Canada elaborates this as follows: "OECD (2009) identifies potential volatility to atmosphere from service life for generic OFRs in plastics, estimated at 0.05% over lifetime for indoor or outdoor use; however, this generic value may be an overestimate for a very low volatility OFR like DBDPE. Environmental release of the substance from plastic polymers via leaching is considered possible, albeit low. The potential release of OFRs from plastics during service life to water is estimated at 0.05% over lifetime if the substance is for indoor use or 0.16% over service life for outdoor use (OECD 2009). The large majority of DBDPE containing products would be enclosed or used for indoor use; the release rate of 0.05% is therefore most applicable and may likely be an overestimate since contact with water is not expected." Considering the information mentioned above, we would appreciate if Canada would indicate its rationale that the scope of the Regulations includes DBDPE contained in products. Based on the above, in order to ensure that the draft revision of the Regulations would not be more trade restrictive than necessary to achieve its legitimate objectives, Japan would like to request the following points to Canada: 1) To conduct a more thorough risk assessment for the effects of DBDPE contained in articles on human health and the environment, 2) to take into account consistency with risk assessment results from other countries and regions, and 3) to re-examine the necessity of restrictions on DBDPE in articles and a grace period for such through conducting a practical feasibility study on alternatives to DBDPE and additional stakeholder consultations.

2.86. In response, the representative of <u>Canada</u> provided the following statement. We thank Members for their comments. Canada would like to reaffirm that since the Chemicals Management Plan (CMP) was launched in 2006, Canada has taken a robust approach to risk assessment to determine whether a substance presents or may present a risk to the environment or to human health. Decisions are based on a weight-of-evidence approach and precaution to determine the potential risk posed by a substance. As previously stated, all information received by the Government

of Canada, including studies on transformation for DBDPE, have been carefully evaluated and considered as part of the weight of evidence. The screening assessment considered analogue evidence for certain characteristics of DBDPE for which limited information was available. Selection of analogues was based on scientific judgement and followed the internationally-recognized Guidance on Grouping of Chemicals, Second Edition , published by the Organisation for Economic Co-operation and Development (OECD). A number of comments were received on the proposed DBPDE provisions, during the 75-day comment period. Comments and concerns from all stakeholders are being considered in the development of the final regulations, expected to be published in summer of 2024 at the earliest, as was communicated in the Canadian TBT notification <u>G/TBT/N/CAN/673/Add.1</u> on 10 August 2023. A Regulatory Impact Analysis Statement (RIAS) will be published with the final Regulations and will include a summary of the comments received, along with how they were considered in the development of the final Regulations.

2.87. In terms of international action, Canada understands that other Members have assessed or are currently assessing DBDPE, and have signalled prioritization in the development of risk management measures, including restrictions. Canada does not specify alternative flame retardant substances for industry in the proposed measure. It is contingent upon industry to identify and transition to appropriate alternatives. Flame retardants such as DBDPE are generally used to meet performance-based flammability requirements. These performance-based requirements do not specify which chemical flame retardants need to be used; rather they may require a product or component to pass a laboratory test such as a cigarette smoulder or open flame ignition test (ASTM 2014). Using chemical flame retardants such as DBDPE in their products is one means through which companies can achieve flammability requirements for their products. Alternate substances, as well as non-chemical-based alternatives, may also be used to replace the use of DBDPE as a flame retardant in various applications. We remain open to discuss the Members concerns bilaterally.

2.1.4.4 China - Recommended National Standard (GB/T) for Office Devices (Information security technology – Security specification for office devices) (ID 761²³)

2.88. The representative of Japan provided the following statement. Japan understands that this draft national standard was recently subject to public comment procedures to seek outside opinions. Regarding this draft national standard, Japan has expressed concerns in various committees, including WTO/TBT Committee, that the provisions requiring the development and production of multifunction devices and printers within China may violate WTO agreements, including Article 2.1, Article 2.2, and Article 5.1.2 of the TBT Agreement and the China Accession Protocol. It is noted that the current draft national standard does not include such provisions. Although we understand that discussions and procedures will proceed toward the establishment of this national standard, we continue to request that it not include content which discriminates between domestic and foreign countries and content which could lead to de facto requests for technology transfer. In this regard, the provisions of this draft national standard still pose concerns about leakage of trade secrets and technology depending on the content of information supplied by providers of office equipment for security testing of such equipment. For example, this draft national standard requires the provision of materials related to the supply chain, materials related to third-party technology, and materials related to the manufacturing processes of office equipment, but these materials may include information related to trade secrets and sensitive technologies. This may violate Article 5.1.2 of the TBT Agreement. We request that the design and operation of security tests including these points be consistent with international agreements which China has concluded, including the WTO Agreement. Finally, Japan submitted opinions regarding this draft national standard based on the public comment procedure, and we would like to ask China to consider the content of those opinions.

2.89. The representative of the <u>Philippines</u> provided the following statement. The Philippines shares the concerns of Japan on China's Recommended National Standard for Office Devices. We would like to restate our previous concerns that complying with China's new regulations on the security and protection of critical information infrastructure presents an additional challenge for Philippine exporters. We again request China to notify the draft measure and to provide information on the dates for the submission of comments.

2.90. In response, the representative of <u>China</u> provided the following statement. From 25 August to 24 October 2023, the Recommended National Standard Information Security Technology—

 $^{^{23}}$ For previous statements follow the thread under ID <u>761</u>.

Security specification for office devices was publicly solicited for comments on the websites of SAC and TC260. 234 comments were received, mainly from the Japanese Embassy in China, Epson, Fuji, Toshiba, Canon, etc. The opinions mainly involve the adjustment of supply chain security management requirements and the refinement of evaluation methods. Currently, the editor team is studying and handling them. As far as we know, the current document does not involve the requirements for critical information infrastructure operators and office equipment components to be developed and produced in China. We will keep following this standard.

2.1.4.5 United States - Chapter 173-337 of WAC, safer products restriction and reporting, <u>G/TBT/N/USA/1958</u> (ID 787²⁴)

2.91. The representative of <u>China</u> provided the following statement. China is pleased to note that the new rule released by Washington State Department of Ecology on 31 May 2023 has adopted the suggestions of Members. However, China notes that the new rule still restricts the use of intentionally added organohalogen flame retardants (OFRs) in some external enclosures for indoor EEE products and implements a new reporting requirement for OFRs used in casings and enclosures for some outdoor EEE products. Firstly, China suggests the US should not control OFRs as a family. US should specify which OFR subgroup or which specific OFR to be restricted based on scientific assessment not only in hazard but also in the technical feasibility of alternatives as well as impacts on the industry. There are a total of over 100 types of OFRs, and no more than 10 types are restricted currently. US National Academies of Sciences, Engineering, and Medicine (NASEM) released a study report in 2019, pointing out that OFRs used in consumer products cannot be made a hazardous assessment as a single group; instead, they should be sorted into 14 subgroups based on chemical structure, physicochemical properties, and predicted biologic activity, and then they should be assessed not only in hazard but also in the technical feasibility of alternatives as well as impacts on the industry. Secondly, China suggests US should postpone the implementation of OFR restriction and reporting for one year based on the current timeline in the new rule. It usually takes a circle of two or three years to complete the replacement of a flame retardant from material formulation development to downstream users' confirmation of the market's stability feedback. If product manufacturers are forced to use alternatives not well proven, it will undermine the fireproof performance of the products and jeopardize consumers' lives and property. Currently, the earliest implementation of OFRs restriction will take place on 1 January 2025, only 1.5 years away from 1 July 2023, the effective time of the new rule.

2.92. The representative of Japan provided the following statement. Regarding the restrictions on organohalogen flame retardants (OFRs) in plastic external enclosures of consumer electrical and electronic equipment (EEE) (hereinafter referred to as "OFR restrictions") for an implementation program (known as "Safer Products for Washington") of Chapter 70 A. 350 RCW, US-State of Washington Law, Japan appreciates the comments of the US Government at the last <u>WTO/TBT</u> Committee meeting in June that the final rule was published and posted on TBT notification (<u>G/TBT/USA/1958/Add.1</u>) on 31 May 2023, and that the final regulatory analysis and related information were provided on the website for the program. Japan's industrial associations submitted their comments to the Washington State Department of Ecology (DoE) during the three rounds of public comment continued to express its concerns at the last Committee meeting and would like to express its concerns again taking into account the final regulation.

2.93. We appreciate that the final regulation on the OFR restrictions limits the scope of prohibition effective from January 2025 to TVs and displays with a screen area larger than 100 square centimeters or 15.5 square inches, and the effective dates for other products were postponed by one year. However, the final regulation still prohibits all OFRs contained in plastic external enclosures of consumer EEE for indoor use excluding medical devices on the grounds of a potential exposure to human and the environment although an appropriate risk assessment has not been conducted yet. OFR refers not to a single substance but is a generic term for all organohalogen flame retardants, whose number is said to be in the thousands to the tens of thousands or more. OFRs are commonly used in EEE plastic external enclosures to prevent the start of or spread of fires, and to protect human lives. Also, we have been informed by Japanese industries that there is little release of OFRs from consumer EEE plastic external enclosures used as intended and that the risk of adverse effects on human health and the environment is extremely low. If the OFR restrictions were to be implemented in a hasty manner, many products which are distributed as compliant products in other

 $^{^{24}}$ For previous statements follow the thread under ID <u>787</u>.

countries may be hindered to be distributed in not only the State of Washington but also the entire United States, and in addition to seriously affecting many industries, many citizens in the United States would be at a huge disadvantage.

2.94. The DoE states in the Final Regulatory Analysis issued in May of 2023 that "The law defines safer as 'less hazardous', not 'less risky'. Including a risk assessment or exposure assessment would not meet the definition of safer." as a justification for not conducting a risk assessment. In addition, during the hazard assessment for OFRs, the DoE concluded that all OFRs were hazardous using the results for only 22 OFRs that are thought to be potentially hazardous. However, we believe that the measure of concluding that all OFRs are hazardous based on the evidence regarding merely 22 examples out of the thousands to tens of thousands of such substances for which an assessment was concluded without conducting the minimum necessary risk assessments and the fact that this OFR restrictions which uniformly prohibit all OFRs contained in plastic enclosures of consumer EEE would be put into effect despite the fact that such a law has never been implemented in any other US State, jurisdiction, or international convention, may be grounds for the assertion that these actions are more trade restrictive than necessary. Moreover, the DoE has asserted that several non-halogen flame retardants are available as alternatives to OFRs. However, it is not guaranteed that such alternatives can be used with the equivalent flame retardancy or reliability to OFRs currently used for consumer EEE plastic external enclosures, and it will take time to undertake such an assessment.

2.95. Based on the above, while we understand that the regulatory objectives, which are to protect human health and the environment, we are concerned that the OFR restrictions would be more trade restrictive than necessary to fulfill the objectives. Japan would like to request that the United States implement the following points in order for the OFR restrictions to be consistent with Articles 2.2 and 2.12 of the TBT Agreement. 1) to conduct a more thorough risk assessment on the impact on human health and the environment posed by OFRs contained in EEE plastic external enclosures and to make their intended measures consistent with the regulations in other countries and regions, 2) based on the results of the risk assessment, to identify the CAS Registration Number of the targeted OFRs, narrow the scope of the EEE to be regulated, and 3) to carry out a practical feasibility study on the alternatives, conduct public consultations and invite and consider stakeholders' opinions and reconsider the necessity of OFR restrictions for EEE and an appropriate grace period.

2.96. In response, the representative of the <u>United States</u> provided the following statement. The United States has offered Japan and China opportunities to meet bilaterally with the State of Washington and I hope they will take us up on that offer. The United States appreciates the comments submitted by China, Japan and Korea in response to this notification. The final measure was published 31 May 2023, as <u>G/TBT/N/USA/1958/Add.1</u>. Visit the Safer Products for Washington rulemaking webpage for information about this rulemaking and to review the supporting documents. These include the Final Regulatory Analyses, the Concise Explanatory Statement, the Rule Implementation Plan, and the SEPA Determination of Non-significance.

2.1.4.6 European Union - Proposal for a Regulation of the European Parliament and of the Council on shipments of waste and amending Regulations (EU) No 1257/2013 and (EU) No 2020/1056, <u>G/TBT/N/EU/893</u> (ID 783²⁵)

2.97. The representative of <u>Indonesia</u> provided the following statement. Indonesia would like to thank the European Union for its response to Indonesia's enquiry regarding notification <u>G/TBT/N/EU/893</u> - Proposal for a Regulation of the European Parliament and of the Council on shipments of waste and amending Regulations (EU) No 1257/2013 and (EU) No 2020/1056 (COM (2021) 709 final) ("the proposal"), and we are still reviewing the document which was received on 31 October 2023. Indonesia is aware about the EU intention reflected in the notified draft which are to establish greater legal clarity and pursue harmonization in transboundary shipments of waste that additionally include measures to address illegal waste shipments. While ensuring environmental protection, reduce the risks to human health, the proposal is ultimately designed to contribute to the circular economy by easing shipments of waste for reuse and recycling both within EU as well as globally. Nonetheless, Indonesia is keen to highlight the TBT Agreement's provision, which states that actions attempted to accomplish legitimate objectives are presumed not to create unnecessarily obstacle to international trade. Indonesia shares the same commitment in accordance with environmental preservation which incorporates the need to increase the implementation of circular

 $^{^{25}}$ For previous statements follow the thread under ID <u>783</u>.

economy, reduce greenhouse gas emissions and achieve Net Zero Emissions. Related to waste management, Indonesia has set targets that need to be achieved gradually where 100% of waste in Indonesia is targeted to be well managed and 30% of them through 3R approach by 2025.

2.98. Moreover, Indonesia also pursues to reduce GHG emissions from waste sector by 40 million tonnes CO2e with its own efforts and up to 43.5 million tonnes CO2e with the help from other countries by 2030.²⁶ These ambitions are equipped with various legal instruments to ensure the enforcement, for instance Presidential Regulation No.97/2017, Waste Management that are oriented towards handling plastic waste, Ministry of Environment and Forestry Regulation No. P.75/2019 on Roadmap of Waste Reduction by Producer, Ministry of Environment and Forestry Regulation No.19/2021 on Guidelines on management of hazardous waste and non-hazardous waste, and environmental standards that harmonize with the international provisions. In addition, we emphasize the importance of recognizing environmental regulations and environmental standards that are also implemented and adopted by other WTO Member countries that have also implemented aspects of international environmental rules such as: Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal; Stockholm Convention on Climate Change; The Paris Agreement; Montreal Protocol on substances that deplete the ozone layer.

2.99. Indonesia ratified and implemented its obligations under the multilateral environmental agreements as regards the relevant reporting obligations thereof. Law (UU) No. 19 of 2009 on the Ratification of the Stockholm Convention on Persistent Organic Pollutants²⁷, Law No. 11/2017 on the Ratification of the Minamata Convention on Mercury²⁸, Law No. 16/2016 on the ratification of the Paris Agreement to The United Nations Framework Convention on Climate Change²⁹, Presidential Decree No. 61 of 1993 on the Ratification of the Basel Convention on The Control of Transboundary Movements of Hazardous Wastes and Their Disposal³⁰, Presidential Regulation No. 129 of 2022 on the Ratification of the Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer, Kigali, 2016³¹, Presidential Regulation No. 47 of 2005 on the Ratification of the Amendment to The Basel Convention on The Control of Transboundary Movements of Hazardous Wastes and Transboundary Movements of Hazardous Wastes and Their Disposal³².

2.100. For that, Indonesia will highly appreciate if the EU could consider it to be "broadly equivalent" to the EU conditions underpinning the environmentally sound management of waste. Referring to the above perspective, and in order to minimize potential technical barriers to trade due to the upcoming implementation of the EU WSR, Indonesia is open for collaboration with EU in addressing the objective of the proposed regulation. We intend to invite EU to provide information on the progress of the current regulatory discussion and the estimated time for its ratification which is currently underway in the EU, including in terms of registering as The List country. This is important as part of the preparation efforts of WTO Member countries to possibly study the technical and implementation instructions of the EUWSR.

2.101. The representative of <u>Türkiye</u> provided the following statement. We would firstly like to thank the EU for their cooperation. We have had a chance to meet with the EU delegation on the margins of the November 2022 TBT Committee meeting bilaterally. That said, we still have concerns regarding this regulation and we would like to state them today. In fact, Türkiye shares the stated EU objectives with this regulation of supporting the transition to a green and circular economy. However, we believe that the monitoring and inspection requirements and measures envisaged in the draft for waste shipments of especially recycled raw materials of certain industries go beyond the stated legitimate environmental objectives. In this regard, we believe that the trade restrictive nature of these measures might be incompatible with EU's international commitments. First of all, the draft lacks clear conditions for "monitoring of export and safeguard procedure" and for the inspection requirements of the importer facilities. These might lead to restriction of waste exports; and might impose additional burden and costs on importers while creating technical barriers to trade. Secondly, the draft legislation does not distinguish potentially hazardous waste streams such as mixed plastic waste from secondary raw materials being used as a raw material of certain industries.

²⁶ <u>https://unfccc.int/sites/default/files/NDC/2022-09/23.09.2022</u> Enhanced%20NDC%20Indonesia.pdf

²⁷ https://peraturan.bpk.go.id/Details/38639/uu-no-19-tahun-2009

²⁸ https://peraturan.bpk.go.id/Details/53614/uu-no-11-tahun-2017

²⁹ https://peraturan.bpk.go.id/Details/37573

³⁰ https://peraturan.bpk.go.id/Details/62396/keppres-no-61-tahun-1993

³¹ https://peraturan.bpk.go.id/Details/230496/perpres-no-129-tahun-2022

³² https://peraturan.bpk.go.id/Details/42626/perpres-no-47-tahun-2005

This approach undermines the benefit of trade in certain secondary materials, which contribute to low emission production and thus boost global circularity.

2.102. In this sense, we believe the draft legislation may endanger the supply of raw materials for third countries' recycling facilities, hampering the already functioning circular economy in these countries. For instance, taking into consideration that 53.4 % of the ferrous scrap, 52.8 % of non-metal waste is imported from the EU, Turkish recycling industry and steel production is highly dependent on the supply received from the EU. On the other hand, it is important to underline that under the Paris agreement, it is part of an international collective effort to reduce the carbon emissions significantly. Therefore, global cooperation is significant in this regard. Furthermore, Basel Convention and related OECD Decision already set the rules for transboundary movements of hazardous waste. In this sense, this draft regulation might be inconsistent with Article 2.4 of the TBT Agreement. In that respect, Türkiye would like to ask information to the EU on the negative environmental impact justifying the need for the implementation of additional requirements in the draft. What constitutes the basis for imposing certain measures to monitor and when necessary restrict trade of ferrous scrap and non-metal non-hazardous waste for environmental protection concerns? Furthermore, Türkiye has been harmonizing relevant EU legislation with regards to waste management. Facilities in Türkiye that manage, recycle and import waste are already subject to licensing and auditing requirements. Therefore, the requirements foreseen by the legislation will bring additional burden for our facilities. In that respect, Türkiye would like to ask whether similar additional monitoring and auditing requirements will be introduced for the EU member States as well.

2.103. In response, the representative of the European Union provided the following statement. The European Union (EU) would like to thank Indonesia and Turkiye for their interest in the "Proposal for a Regulation of the European Parliament and of the Council on shipments of waste and amending Regulations (EU) No 1257/2013 and (EU) No 2020/1056 (COM(2021) 709 final)." We have recently replied to the questions received. As indicated in the notification form, this notification was made for transparency purposes and does not prejudge the Union's position as to the applicability of the TBT Agreement.³³ The volume of exports of waste from the EU is considerable (33 million tonnes in 2020) and has substantially increased in the last decade (+75% since 2004). Waste shipped across borders can generate risks for human health and the environment, especially when not properly controlled. The notified draft, in line with the EU's commitments under the European Green Deal, the Circular Economy Action Plan and the Zero Pollution Action Plan, aims to ensure that the EU does not export its waste challenges to third countries, seeks to tackle illegal waste shipments and seeks to contribute to the circular economy by facilitating shipments of waste for reuse and recycling in the EU. The EU welcomes that Indonesia indicates that it also shares the importance of a transition to a green and circular economy and the management of waste in an environmentally sound manner. The EU reiterates that the notified draft does not prohibit international shipments of waste.

2.104. In order to avoid that exported waste emanating from the EU harms the environment or public health in countries outside of the EU, the notified draft includes provisions designed to ensure that the export of waste from the EU only takes place when there are sufficient guarantees that this waste will be managed in an environmentally sound manner in the country of destination. Waste treated in the EU is already subject to strict rules designed to protect the environment and human health. Waste treatment facilities in the EU are in addition subject to inspections and enforcement measures by national competent authorities in the EU member States. In this context, the notified draft includes provisions which are designed to ensure that waste exported outside the EU is managed in the countries of destination in conditions that are "broadly equivalent" to EU conditions to underpin the environmentally sound management of waste. It therefore aims to achieve the EU's environmental and public health objectives by ensuring there is a coherent regulatory approach to waste treated in the EU and waste exported from the EU to third countries. When assessing "broad equivalence", full compliance with requirements stemming from EU legislation shall not be required, but it should be demonstrated that the requirements applied in the third country of destination ensure a similar level of protection of human health and the environment than the requirements stemming from EU legislation.

2.105. The principle that all waste should be managed in conditions that are "broadly equivalent" to EU conditions when exported outside the EU is already reflected in the current EU legislation on

³³ The notified draft was also notified to the Environment Committee on 2 June 2022.

waste shipments.³⁴ The notified draft is designed to ensure that the provisions on "broadly equivalent conditions" are made fully operational, and is intended to overcome persisting implementation difficulties associated with the lack of clear criteria on this point in the current Regulation. In that respect, the notified draft is necessary to secure compliance with the EU's regulatory regime for waste management. The EU reiterates that the notified draft does continue to distinguish between hazardous and "green-listed waste" relating to the applicable respective procedures for such wastes, but that it considers as well that the environmental objectives can only be met if the requirements relating to the environmentally sound management of waste apply to all types of waste exported from the EU. This principle is reflected in the existing legislation. In that respect, the EU notes that "green-listed waste" can also potentially cause environmental damage if not managed in an environmentally sound manner, are laid down in the notified draft.

2.1.4.7 European Union - The PFAS Restriction Proposal under the Registration, Evaluation, Authorisation and Restriction of Chemicals (ID 798³⁵)

2.106. The representative of the <u>Republic of Korea</u> provided the following statement. Korea appreciates this opportunity to convey the following comments and concerns from our industries on the Perfluoroalkyl and Polyfluoroalkyl Substances Restriction Proposal under the REACH Regulation, currently under consultation by the European Chemicals Agency. Due to the gravity of the issue, Korea had raised an STC at the previous TBT Committee meeting and submitted a formal letter via the Enquiry Point before the release of a draft regulation, requesting (1) clarification of the scope of the regulation and the provision of implementation guidelines on test methods and reference values for PFAS, (2) exclusion for specific uses and substances, and (3) transition and grace periods tailored to industries and specific applications. It is understood that Korean companies and associations representing the industries submitted comments to the ECHA in September. Korea requests that the EU fully consider and appropriately reflect those industries' concerns and opinions, including those already filed for the ECHA public consultations and those that will be submitted through the WTO TBT Enquiry Point.

2.107. The representative of Japan provided the following statement. Continuing on from the previous Committee meeting of June 2023, Japan would like to express its concerns about the proposal to newly restrict perfluoroalkyl compounds and polyfluoroalkyl substances (PFASs) under the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation, published by the European Chemicals Agency (ECHA) in March this year. Since many PFASs are used in a wide range of sectors in which no alternative substance has been identified, a full ban on the use, trade, and so forth encompassing all PFASs would be extremely trade restrictive. Japan understands the regulatory objectives of protecting human health and the environment. However, the proposed restriction, which would introduce a uniform restriction on the use, trade, and so forth of all PFASs, including PFASs that have not been proven to pose unacceptable risk and PFASs that pose less risk depending on their uses, would be inconsistent with Article 2.2 of the TBT Agreement, as the proposed restriction lacks sufficient scientific and rational basis and is more trade restrictive than necessary to fulfil the regulatory objectives. We believe that the EU will provide a sufficient grace period in accordance with Article 2.12 of the TBT Agreement when introducing the proposed restriction, but in light of the above and based on our understanding that more than 5,600 comments have been submitted to ECHA, we would like to request that the EU appropriately consider and examine the comments submitted by industries and other stakeholders, and limit the scope of the restriction to an appropriate range for the objectives of the REACH regulation, namely the protection of human health and the environment.

2.108. In response, the representative of the <u>European Union</u> provided the following statement. The EU would like to thank Japan and Korea for raising the issue of a possible PFAS restriction under EU REACH legislation. Pollution from PFAS (per- and polyfluoroalkyl substances) is a serious human health and environmental concern, considering the large number of cases of soil and water contamination across Europe - including drinking water. At the same time, PFAS are needed in critical applications, for example in the digital and energy sectors (e.g., semiconductors, electrolysers and membranes for green hydrogen production). Within the framework of the REACH Regulation, five

³⁴ Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste; OJ L 190, 12.7.2006, p. 1–98 - <u>https://eur-lex.europa.eu/legal-</u> content/EN/TXT/?uri=CELEX%3A02006R1013-20210111&gid=1670254090535

³⁵ For previous statements follow the thread under ID <u>798</u>.

national authorities (from the Netherlands, Germany, Denmark, Sweden and Norway) have proposed a broad ban with some derogations on the use of PFAS. This proposal is currently undergoing an independent scientific assessment in the European Chemicals Agency (ECHA) Scientific Committees. As part of this assessment, the ECHA's Scientific Committees will also carefully consider the need for derogations for specific applications. Of course, the EU will notify the measure to the TBT once it has a legal proposal ready.

2.1.4.8 China – Packaging requirements for Edible Agricultural Products, <u>G/TBT/N/CHN/1715</u> (ID 804³⁶)

2.109. The representative of the <u>Philippines</u> provided the following statement. We thank China for notifying this proposed measure on packaging requirements for edible agricultural products. While the objective of the draft regulation could contribute to waste reduction which may positively impact food business operators in the Philippines, we would like to request for the English version of the proposed regulation to determine whether the requirements could be potentially more trade restrictive than necessary.

2.110. The representative of <u>India</u> provided the following statement. India would like to reiterate its previous concern as we await China's response to the previous statement. India notes with concern China's Notification No. <u>G/TBT/N/CHN/1715</u> dated 3 February 2023 related to Packaging requirements for Edible Agricultural Products. India finds the packaging requirements as restrictive and excessive. India requests China to provide the detailed scientific assessment underlying the determination for various parameters including - number of packaging layers, inter-space ratio and weight ratio, as specified in the proposed standard. Further India requests China to provide rational for limiting the cost of packaging at 20% of the sale price of the product. India also requests China to indicate the objective sought to be achieved through the proposed standard and how the proposed measures help in fulfilling the objective.

2.111. In response, the representative of China provided the following statement. With the consumption upgrading of fresh edible agricultural products, the problem of excessive packaging of fresh edible agricultural products such as excessive packaging layers, large gaps, and high costs has gradually become prominent. In order to promote the green development of agriculture, strengthen the management of the whole chain of commodity excessive packaging, and standardize and guide the appropriate and reasonable packaging of fresh edible agricultural products, The Chinese government has issued a mandatory national standard for "Limiting Excessive Packaging of Commodities for Fresh Edible Agricultural Products". 1. Scope of application. This standard applies to the sales packaging of fresh edible agricultural products such as vegetables (including edible fungi), fruits, livestock and poultry meat, aquatic products, and eggs, excluding logistics protective packaging and functional products such as cooling, gas regulation, and moisture protection. According to Article 25 of "the Standardization Law of the People's Republic of China", products and services that do not meet mandatory standards shall not be produced, sold, imported, or provided. Therefore, the import of fresh edible agricultural products for domestic sale needs to meet the requirements of this mandatory national standard. 2. Judgment criteria. The main criteria of the standard are the packaging void ratio, the number of packaging layers, and the packaging cost, and the excessive packaging in the standard refers to the packaging of fresh edible agricultural products that exceed the requirements of these indicators. The main technical criteria include three aspects.

2.112. Firstly, the upper limit of 10%-25% package void ratio is set for fresh edible agricultural products of different categories and different sales packaging quality. For the sale of goods with only one layer of packaging, the packaging void ratio is not limited. Secondly, it is to stipulate that vegetables (including edible fungi) and eggs should not exceed 3 layers of packaging, and fruits, livestock and poultry meat and aquatic products should not exceed 4 layers of packaging. In the calculation process of the number of packaging layers, the net/net cover loaded with the whole fresh edible agricultural products, the combination of two materials, and the drawer type combination packaging are counted as one layer; Simple bundling ropes, labels, labels, padding, spacers, padding, cushioning, body-fitting packaging, and heat-shrinkable film attached to sales packaging are not considered as one layer. When calculating, the packaging directly in contact with fresh edible agricultural products is the first layer, and so on, the outermost packaging is the N layer, and N is the number of layers of the packaging. Thirdly, it is clear that the ratio of packaging cost and sales price of most fresh edible agricultural products does not exceed 20%. For strawberries, cherries,

 $^{^{36}}$ For previous statements follow the thread under ID $\underline{804}$.

bayberries, loquat, livestock and poultry meat, aquatic products, and eggs whose sales price is more than 100 yuan, the limit ratio is not more than 15%. The cost of packaging to some extent reflects whether the packaging is excessive. According to the investigation of the packaging of agricultural products in the Chinese mainland market, part of the agricultural products have excessive packaging phenomenon. Therefore, this standard limits the packaging cost of fresh edible agricultural commodities in order to minimize the waste and environmental pressure caused by excessive packaging. The sales packaging included in the packaging cost includes: packaging materials, bags, net bags/nets, net covers, bundling, padding, small tools, free gifts of non-fresh edible agricultural products, and so on. And excluding cooling, gas regulation, moisture and other fresh-keeping function supplies. The cost of sales packaging refers to the contract price of sales packaging. If no contract is signed, the actual transaction price shall prevail. The sales price of the commodity refers to the sales contract price of the commodity. If no contract is signed, the actual transaction price shall prevail, and it is the highest price of the batch to which the commodity belongs.

2.113. 3. Transitional arrangement. The transition period between the release date and the implementation date of the mandatory national standard "Limiting Excessive Packaging of Commodities for Fresh Edible Agricultural Products" is six months. Considering that after implementation, some fresh edible agricultural products produced or imported before the implementation date will continue to be sold, in order to avoid waste, Part VII of this standard provides that fresh edible agricultural products produced or imported before the implementation date of this document may be sold until the end of the shelf life. From the date of implementation, packaging of fresh edible agricultural products that do not meet the requirements of this standard is not allowed in the Chinese market. 4. Supervision and management of standard implementation. The supervision and administration department of the mandatory national standards for "Limiting Excessive Packaging of Commodities for Fresh Edible Agricultural Products" is the State Administration for Market Regulation of the People's Republic of China.

2.1.4.9 United Arab Emirates - Technical Requirements for Electric Vehicle, <u>G/TBT/N/ARE/572</u> (ID 796³⁷)

2.114. The representative of <u>China</u> provided the following statement. The seven Gulf GCC countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE, and Yemen) carry out uniform GCC certification for automotive products, and GSO conducts uniform testing and certification according to GSO standards, and mutual recognition within GCC members. However, there are repeated tests and repeated certifications on electric vehicle crash items. For example, the UAE crash standards directly quote the GSO standards. However, in terms of certification, the UAE requires that electric vehicles must apply for the UAE local vehicle certification certificate, and in the certification process, UAE officials require witness crash certification tests. In addition, Saudi Arabia also requires electric vehicles to apply for a local Saudi Arabian vehicle certificate, and Saudi Arabian officials are also required to witness the crash certification tests. At the same time, in terms of other member states applying for GCC vehicle certificates, in the GCC certification process, GSO officials are also required to witness the crash certification tests. However, the crash regulations and test methods adopted by the UAE, Saudi Arabia and Gulf GCC are the same, and the implementation of such crash tests requires the following resources: 2 complete vehicles and 2 body-in-white, and the certification cost is about 1 million RMB. If the vehicle certificates for three markets are applied for separately, the required resources are three times, that is, 6 vehicles, 6 bodies-in-white, the certification cost is about 3 million RMB, and the witness test time of government officials in the three markets needs to be booked 3-6 months in advance, resulting in an increase in the certification cycle of at least 3 months. Article 6.1 of the WTO/TBT Agreement stipulates that "Whenever possible, the results of conformity assessment procedures in other Members are accepted." GCC itself is an integrated market with a uniform conformity assessment procedure, and each member state shall recognize the results of the GSO conformity assessment, which means the repeated test and repeated certification violate the principles of the GSO organization itself. Therefore, China suggests that the UAE, Saudi Arabia, and other GCC countries uniformly recognize the electric vehicle crash witness test report and GCC certification according to the GSO standard, so as to avoid repeated tests and repeated certifications for the same item, which can reduce unnecessary obstacles to trade.

2.115. The representative of the <u>Philippines</u> provided the following statement. We thank the United Arab Emirates for notifying this measure, and to better assess the potential effects of this regulation,

 $^{^{37}}$ For previous statements follow the thread under ID $\underline{796}$.

the Philippines would like to request the UAE to provide a list of products (in HS codes) that will be covered by these proposed technical regulations for Electric Vehicles.

2.116. In response, the representative of the <u>United Arab Emirates</u> provided the following statement. We have conveyed the message to the capital. We will get back to China as soon as we receive any response thereof. A technical statement was circulated following the meeting.³⁸

2.1.4.10 European Union - Proposal for a regulation on horizontal cybersecurity requirements for products with digital elements, <u>G/TBT/N/EU/936</u> (ID 795³⁹)

2.117. The representative of <u>China</u> provided the following statement. Thanks for the EU's prompt response to our comments and concerns in the initial phase. Taking into account the most recent legislative advancements of CRA, we would like to raise the following concerns: 1. European Parliament version Recital 34a indicates high-risk vendors (HRV) and its assessment criteria. It is recommended to remove them; if not possible, it is advised to adopt objective, fair, clear, and proportionate criteria based on technology for assessing suppliers and the supply chain. The evaluation criteria used ambiguous wording, such as "close links" between suppliers and non-EU countries. These standards lack objectivity compared to objective cybersecurity technical standards, which makes the application of standards uncertain. It is suggested to remove the wording of high-risk suppliers from the draft regulation. To enhance cybersecurity, countries should establish cybersecurity standards based on technology neutrality to manage, test, verify and audit relevant suppliers. There are widely recognized international standards in the field of supply chain security, such as ISO/IEC 27001 and ISO28000; these can be utilized to ensure and evaluate supply chain security.

2.118. 2. European Parliamentary version of Chapter 2 2/13/3, Chapter 5 5/41/8&5/43/1& 5/45/1A, Council & Parliamentary version Recital 33: Each article emphasizes "non-technical risk factors". It is recommended to clarify the scope of "non-technical risk factors", and relevant factors should be based on validated, transparent, non-discriminatory and proportionate criteria. The aforementioned formulation allows for the influence of non-technical factors on the withdrawal or recall of certain products, thereby impacting market access to the EU and EU members. Given that the precise scope of these non-technical factors remains undefined in current provisions, we concern over potential misuse leading to trade protection restrictions and violations of the principle of most-favoured-nation and national treatment. 3. The Parliamentary version of Chapter 1 1/6/5 requires that highly critical products must obtain a level "high" certification pursuant to Regulation (EU) 2019/881, such as EUCC high level, within 12 months after the adoption of its relevant delegated act. Furthermore, it is recommended to extend the certification period to 36 months. At present, the EUCC in (EU)2029/881 certification scheme is being issued, while the formulation of EUCS/EU5G/EUXX and other certification schemes is still ongoing. Furthermore, most member States currently have only one certification body, which fails to meet the demands for a large number of highly critical product certifications. Based on an in-depth investigation into the status quo of the international CC certification, it has been found that the average certification cycle for high-grade CC certification exceeds 12 months.

2.119. 4. Parliament version 2 2/10/6 outlines the various factors manufacturers should consider when determining the support period for vulnerability patches, as well as providing multiple methods to inform end users of the support period. Firstly, it is recommended to incorporate "the impact of the vulnerability" when determining the support period. Since different levels of vulnerability have varying impacts on different areas, the "impact of the vulnerability" should be a crucial factor in considering the maintenance cycle. Secondly, it is recommended not to set mandatory requirements for the method of informing end users, the method provided in the text serves as mere examples. 5. Parliament version chapter 2 2/10/6: this article outlines the security updates shall remain available for a minimum duration of 10 years. It is advisable not to impose any limitations on the duration and instead refer to point 4 in the parliament version above, allowing the manufacturer to make a decision based on various factors. 6. For Parliament version Chapter 2 2/11/1a, it is recommended to add exception scenarios. The severity and impact of the vulnerability may vary, therefore it is suggested that article (c) include a provision for exceptional circumstances based on the "one month" requirement for submitting the final report. Specifically, the manufacturers can

³⁸ <u>G/TBT/W/779</u>.

 $^{^{39}}$ For previous statements follow the thread under ID <u>795</u>.

submit an extension application to the supervisory authority after a comprehensive assessment of vulnerability severity and impact.

2.120. 7. Parliament version Chapter 2 2/11/4 stipulates that manufacturers shall notify product users about identified vulnerabilities and security incidents that may impact product safety. It is recommended to clarify the definition of product users. In many cases, due to the resale or sale of products through local channels, the manufacturer cannot know all the information of end users, which results in the failure of notification obligation. Please clarify whether importers, authorized representatives, and distributors should also be considered as users. 8. For ANNEX I 1/(3), it is recommended to further clarify the requirements. Due to the unpredictability of vulnerability occurrences, there remains an uncontrollable time gap between the execution/completion of product conformity assessment and its release into the market. In some cases, vulnerabilities may even be discovered while the product is already in transit. Manufacturers face challenges in enforcing this requirement. Therefore, it is recommended that vulnerability treatment of post-conformity assessment for products should adhere to the requirements specified in Chapter 2 2/11/1a of the draft regulation. In addition, it is recommended to add a definition of "known exploitable vulnerabilities" in Chapter 1, Section 1/3.

2.121. 9. Parliament and Council version of ANNEX I 2/(1) requires vulnerabilities and components contained in the identification and recording of products, including drafting software bills of materials in common and machine-readable formats that cover at least the top level of product dependencies. It is advisable to eliminate the requirement for providing software bills of materials. Considering that the legislative intent of regulations is to inform users about security vulnerabilities, it is essential for these regulations to clearly outline the requirements for achieving vulnerability management objectives without specifying the specific means and methods. Furthermore, in the realm of technical standards, research on bill of materials is still in its nascent stage, lacking a consensus on its application. If misused, it could potentially expose software supply to more precise security attacks and subsequent incidents. Therefore, Article 7 of ANNEX V should also be simultaneously removed. 10. Regarding ANNEX I 2/(4), It is recommended that the disclosure of vulnerabilities should not be comprehensively public and instead support the adoption of a parliamentary version for description. 11. Regarding ANNEX I 2/(8), it is recommended that the upgrade cost of product software should comply with both supply and demand contracts as well as industry practices, rather than mandating free upgrades. Additionally, it is advised to support the adoption of parliamentary versions for description. 12. For ANNEX III, it is recommended to support the Council's version of the Critical Product Category I & II list, which takes into account the cybersecurity risks associated with products.

2.122. The representative of the <u>Philippines</u> provided the following statement. We thank the EU for notifying this proposed measure. The regulation will cover a wide range of products ranging from computers and laptops, smartphones and tablets, and cloud-based services. To better assess the potential effect on our exports, the Philippines would like to request the European Union to provide a list of products (in HS codes) that will be covered by the Horizontal cybersecurity requirements under the draft Cyber Resilience Act (CRA).

2.123. In response, the representative of the <u>European Union</u> provided the following statement. The EU would like to thank China and Philippines for the comments they provided on the Proposal for a regulation on horizontal cybersecurity requirements for products with digital elements. The EU takes note of detailed comments provided by China today, and as regards comments provided by Philippines the EU would like to note that in its Article 3 the Proposal for a regulation on horizontal cybersecurity requirements defines "products with digital elements" as "any software or hardware product and its remote data processing solutions, including software or hardware components to be placed on the market separately". The definition is to be as comprehensive as possible, in order to minimise cyber risks, in environments where products are increasingly connected and hence hackable. Examples of such products include laptops or smartphones, products which are part of the Internet of Things thanks to digital connectivity features that are built in or added to them (smart refrigerator, smart TV, smart printers, connectable machinery equipment), as well as microprocessors, operating systems or firewalls.

2.1.4.11 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 393⁴⁰)

2.124. The representative of Australia provided the following statement. Australia remains concerned about the significant uncertainty surrounding the mechanisms for setting import tolerances for substances falling under the hazard cut-off criteria, without adequate consideration of actual or anticipated exposure to the substance. We consider that reduction of allowable residues in imported products to the limit of determination would impose a de facto ban on the usage of those products in trading partners should they wish to export to the EU. For example, the primarily hazardbased assessment of mancozeb - and associated lowering of maximum residue limits (MRLs) to the level of quantification - removes safe use of these products by Australian farmers where there is limited availability of alternatives. Australia maintains that the use of food residue limits to pursue domestically set environmental policy outcomes in third countries is inappropriate as it does not account for variations in risk stemming from differences in pollinator species, environmental conditions and chemical use practices around the world. The Australian pesticides regulator - the Australian Pesticides and Veterinary Medicines Authority (APVMA) - must consider impact on offtarget species in its assessments of products for registration. The APVMA's decisions consider the specific practices and settings of Australian farms and Australian environmental conditions. Accordingly, Australia requests that the EU maintain MRLs for substances that do not pose unacceptable dietary risks and import tolerances be authorized based on dietary risk alone. Australia reiterates its position from previous meetings about the importance of adopting a risk-based approach for regulating plant protection products rather than considering only the potential for harm due to the intrinsic properties of a chemical. We remain available to discuss our approach to pesticide regulation with the EU and look forward to continued and constructive engagement on this issue, including in the SPS Committee.

2.125. The representative of Kenya provided the following statement. 1. Kenya reiterates her previous position on this Specific Trade Concern. 2. Kenya takes note of the EU's response given in the June 2023 TBT Committee meeting. The reference made by the EU are guidelines from European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA). However, there is need to cross reference to other international guidelines issued by CODEX Alimentarius Commission and International Plant Protection Convention (IPPC), as well as other scientific literature. 3. The EU's proposed measure is on Hazard-based approach to plant protection products and setting of import tolerances whereas in the response issued in the June 2023 TBT Committee meeting, the EU bases their assessment on risk analysis principles on a case-by-case basis which is subjective. A wholistic approach to risk analysis consistent with CODEX guidelines should be adopted for purposes of consistency and predictability. 4. Adoption of the Hazard based system by the EU has the potential to create unnecessary barriers to trade by limiting the availability of plant protection products. This is deemed to be inconsistent with Article 2.2 of the TBT Agreement. In addition, Technical Regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. 5. Kenya reiterates that a Risk Based Approach is the best international practice that meets the intended objective. 6. The proposed measure would be deemed to be in contravention of Article 12.3 of the TBT Agreement which requires that "Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country members". 7. Kenya requests EU to withdraw this measure.

2.126. The representative of <u>Costa Rica</u> provided the following statement. Costa Rica wishes to express its gratitude for the opportunity to raise this trade concern once again, as it is genuinely concerned about the hazard-based approach adopted by the EU when setting its import tolerances for products coming from trade destinations outside of the EU bloc. Under the obligations of the multilateral system, all technical requirements are to be aligned with an international reference standard or a risk assessment providing the scientific basis for the measure. Costa Rica once again urges the EU to ensure that the application of its regulations is based on risk assessments that meet

 $^{^{40}}$ For previous statements follow the thread under ID <u>393</u>.

criteria supported by sufficient scientific evidence, in accordance with the obligations set out in the TBT Agreement.

2.127. The representative of <u>Brazil</u> provided the following statement. Brazil would like to refer to its previous statements regarding STC 393. Brazil understands that the European approach to limiting the use of pesticides is more trade restrictive than necessary and disregards risk analysis in the process of adopting this regulation. Regulations on endocrine disruptors must be established according to sound scientific principles and taking into account all available data. Previous EU's responses have been limited to indicating which EU regulations are the basis for the analyses and conclusions in this matter. Recalling that the TBT Agreement provides that measures must be based on the best available scientific evidence and not just on the national (or communitary) regulations themselves, Brazil would like the EU to present scientific evidence that would support such measures.

2.128. The representative of <u>India</u> provided the following statement. India remains concerned about the significant uncertainty surrounding the mechanisms for setting import tolerances for substances falling under the hazard cut-off criteria. We consider that reduction of allowable residues in imported products to the limit of determination would impose a de facto ban on the usage of those products in trading partners. As stated previously, such a hazard-based approach would not improve public health or environmental protection, but may have adverse consequences for sustainable agricultural production due to the removal of crop protection tools from the market, despite their established safety in use. India reiterates its position from previous meetings about the importance of adopting a risk-based approach for regulating plant protection products rather than considering only the potential for harm due to the intrinsic properties of a chemical.

2.129. The representative of <u>Ecuador</u> provided the following statement. We recognize the importance of protecting human and environmental health. However, we consider that regulatory decisions taken on the basis of hazard-based criteria are not consistent with international risk-assessment practice, given that there is no consideration of exposure. The precautionary approach has resulted in approvals of active ingredients increasingly being withdrawn for lack of data and MRLs subsequently being reduced to the minimum detection limit. Furthermore, there is some concern about the EU's policy of establishing MRLs and import tolerances for active substances that are no longer approved in the EU. Establishing MRLs for these active substances at predetermined limits could have negative implications for trade by affecting the importation of products in the EU. This could have a major negative 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. Ecuador urges the EU to take into account scientific information emanating from the international specialized bodies recognized by the WTO, such as the Codex Alimentarius, which has relevant information on pesticides.

2.130. 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. When risk analysis studies carried out by the European Food Safety Authority (EFSA) determine that a result is inconclusive as regards the potential impact on health, the EU, owing to its precautionary principle, establishes the maximum residue limit at the analytical detection level. Ecuador calls on the EU to recommend that the EFSA conduct more in-depth studies in order to obtain conclusive information that supports the ban or reduction of MRLs. Lastly, Ecuador urges the EU to establish a simpler and more expeditious process for the application of import tolerances, similar to that of emergency authorizations for member countries.

2.131. The representative of <u>Argentina</u> provided the following statement. We would like to thank the delegations for including this trade concern on the meeting agenda and request that Argentina's support be put on record. Argentina once again reiterates its concern and stresses the importance of ensuring that all Members implement measures based on risk assessments, taking account of the risk assessment techniques developed by international reference bodies, including the principles for the establishment of maximum residue levels for pesticides, as well as the many risk analyses that, over the decades, the Codex Alimentarius has conducted to ensure safety. Argentina joins the other delegations and 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.

2.132. The representative of <u>Paraguay</u> provided the following statement. Paraguay reiterates its position and refers to its previous statements, while stressing the importance of adopting a scientific risk-based approach to the regulation of plant protection products, instead of basing it solely on the hazard arising from the intrinsic properties of a chemical. In this regard, Paraguay once again requests the European Union to take account of 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 the relevant international standards and principles. Paraguay also asks that, where necessary, the EU provide sufficient transitional periods and establish science-based import tolerances with streamlined mechanisms, such as those for emergency authorizations.

2.133. The representative of Uruguay provided the following statement. Uruguay thanks Costa Rica, Australia and Kenya for including this specific trade concern on the agenda. Uruguay supports the comments made by the other delegations and reaffirms its systemic trade concern relating to the EU's use of a hazard-based approach, instead of an approach based on comprehensive scientific risk assessments, to the adoption of regulatory decisions authorizing active substances used in plant protection products, and setting import tolerance levels for substances that fall below the cut-off or exclusion criteria established in Regulation No. 1107/2009. We reiterate the need to base such decisions on conclusive scientific evidence, gathered from an assessment of the actual risks, to avoid imposing unjustified restrictions on active substances that are still important components of pest management systems and are used safely. 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. As usual, Uruguay continues to support any multilateral efforts undertaken by the Codex Alimentarius to develop a harmonized, risk-based approach to the treatment of plant protection products and MRLs for foods that would protect health and, at the same time, facilitate international trade. In the meantime, we once again urge the EU to listen to and address the concerns expressed by many Members, and to reconsider its regulatory approach in order to avoid the unjustified proliferation of barriers to international trade in agricultural products.

2.134. In response, the representative of the European Union 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 Commission Regulation (EU) No 2018/605.⁴¹ This is complemented by a quideline by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), providing more details on how to interpret these criteria.⁴² Plant protection products and residues in or on those products are regulated in the EU by Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005. Both Regulations are complementary and are implemented in a coordinated manner to avoid risks and hazards for humans, animals and the environment in the use of plant protection products. Environmental protection is foreseen in the EU Regulatory framework, and this is applicable to pesticide residues. When taking risk management decisions, all the factors relevant to the matter under consideration shall be taken into account, as foreseen by the relevant EU legislation.⁴³ This includes environmental factors when read together with Article 11 of the Treaty on the Functioning of the European Union requiring that "Environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting sustainable development." 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 authorized in the EU, due to the so-called "cut-off" criteria in Regulation (EC) No 1107/200944 on plant protection products. As previously explained, the European Union decided to follow the

⁴¹ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33.

⁴² https://doi.org/10.2903/j.efsa.2018.5311

⁴³ Regulation (EC) No 396/2005 and Regulation 178/2002.

⁴⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309 24.11.2009, p. 1.

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 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. During the thematic session on Trade Facilitating Approaches to Pesticide MRLs, in the margins of the SPS Committee of 22 March 2022, the EU provided an overview of the methodology used in EU for pesticide residues risk assessment.⁴⁵ The EU reiterates its commitment to act in full transparency and keep WTO Members duly informed about further developments.

2.1.4.12 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/134</u>, <u>G/TBT/N/IDN/138</u>, <u>G/TBT/N/IDN/139</u>, <u>G/TBT/N/IDN/139/Add.1</u>, <u>G/TBT/N/IDN/140</u>, <u>G/TBT/N/IDN/140/Add.1</u>, <u>G/TBT/N/IDN/157</u>, <u>G/TBT/N/IDN/161</u>, <u>G/TBT/N/IDN/162</u>, <u>G/TBT/N/IDN/163</u>, and <u>G/TBT/N/IDN/164</u> (ID 502⁴⁶)

2.135. The representative of the European Union provided the following statement. The European Union reiterates its serious concerns on the Indonesian Halal Product Assurance Law No 33 of September 2014 and its implementing provisions. Mandatory Halal certification and labelling would be required for a very wide range of products to be placed on the Indonesian market, which would result in significant obstacles to EU trade with Indonesia. In particular, the EU is concerned about Indonesia's stance and policy that disregard the EU's principle of single market, despite repeated calls from the EU. The single market has enabled EU-based halal certifiers in any EU member State to certify companies from other EU member States. The EU invites Indonesia to consider less restrictive alternatives to the current, wide-ranging mandatory Halal certification and labelling, 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 are the "non-Halal" information requested for non-Halal products and the planned extension of Halal requirements to products other than food and beverages. In this respect, the EU stresses the importance of ensuring the continued possibility to place non-Halal products on the Indonesian market. Furthermore, 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 of foreign Halal certificates by Indonesia. It is also crucial that all companies have the possibility to certify their product via a foreign Halal certification body well in advance of the mandatory deadline i.e. foreign Halal certification bodies to be accredited at least a year before the mandatory deadline. The EU reiterates its willingness to continue further discussion and cooperation on Halal issues with Indonesia, with the aim of finding a practical way forward and solve trade concerns.

2.136. The representative of the <u>United States</u> provided the following statement. The United States remains interested in working with Indonesia to ensure implementation of Indonesia's Halal Product Assurance Law is achieved in a way that is consistent with Indonesia's WTO obligations. Unfortunately, many of our long-standing concerns remain unanswered. We again refer Indonesia to our statements and concerns from previous WTO TBT Committee meetings, as well as outstanding questions submitted as <u>G/TBT/W/761</u> and ask Indonesia to respond to all questions and concerns laid out in the Working Document and past statements. We remained concerned about the continued pattern with regard to halal decrees and regulations, whereby measures are finalized without providing an opportunity for stakeholder comment. In fact, just last week, on Thursday, 2 November Indonesia notified six halal related measures, four of which appear to have been adopted and entered into force months before being notified, including: <u>G/TBT/N/IDN/161</u>, <u>G/TBT/N/IDN/162</u>, <u>G/TBT/N/IDN/163</u>, and <u>G/TBT/N/IDN/164</u>.

2.137. Furthermore, it appears that Presidential Decree Number 6 of 2023 on Halal Certification for Drugs, Biological Products, and Medical Devices (PD 6/2023) entered into force in January 2023, nearly six months prior to being notified as <u>G/TBT/N/IDN/157</u>. We refer Indonesia to the comments submitted by the United States Government and US industry stakeholders through the Enquiry Point before the comment deadline in September 2023. We invite Indonesia to comment on how it took stakeholder comments into account given that the Decree had already entered into force. Many of our concerns with PD 6/2023 echo our previously raised concerns: First, there is a lack of clarity

⁴⁵ <u>https://www.wto.org/english/tratop_e/sps_e/thematicsession220322_e.htm</u>

 $^{^{46}}$ For previous statements follow the thread under ID <u>502</u>.

about what products require certification, the definition of animal ingredients and their derivative products, and what materials are classified as "haram" or forbidden. Second, this regulation creates Indonesia-specific halal certification requirements that apply to products that have not been subject to mandatory halal certification requirements previously, such as cosmetics and services. In the absence of existing international standards, will Indonesia intend to develop new, Indonesia-specific, halal standards for these products? If so, can Indonesia share information about those standards? Third, the duplicative labelling requirements will create confusion for consumers and will be costly and challenging for companies, both foreign and domestic, to implement. Finally, Indonesia continues to require halal certification for a variety of services in this regulation, including processing, packaging, and storage, but has yet to adequately engage stakeholders or provide clarity on the necessity of that requirement. Industry remains concerned about how to comply with such requirements.

2.138. In addition to PD 6/2023, can Indonesia confirm what implementing regulations are forthcoming and what is the expected timeline for notification? Will there be other industry-specific implementing regulations, for example related to halal certification for cosmetics or services? We again urge Indonesia to notify these regulations when drafts become available, before they take effect, and to take stakeholder comments into account before the draft regulations are adopted and implemented. In early 2022, Indonesia issued Presidential Emergency Regulation No. 2 Year 2022 (Perppu No 2 Tahun 2022), which appears to modify several provisions in the Halal Product Assurance Law. As previously asked, does Indonesia intend to notify this measure to this Committee, given that it may have a significant effect on international trade? We also remain concerned about the lengthy process for accrediting halal certifying agencies, and that agencies may not be accredited in time before the certification requirements are implemented starting in 2024. Please provide an update on how Indonesia is addressing this concern. We remain committed to working 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. We therefore look forward to an update on what Indonesia is doing to address the concerns that have been raised in this Committee, and to respond to the specific questions raised today.

2.139. The representative of <u>Australia</u> provided the following statement. Australia welcomes ongoing discussions on the Indonesian Halal Product Assurance Law No.33 of 2014 (Halal Law). Australia encourages Indonesia to continue to facilitate an open and transparent dialogue with its trading partners that allows foreign businesses and their valued Indonesian importers to remain adequately informed of the Halal Law's implementation. Australia appreciates recent engagement with Indonesia's Halal Product Assurance Organizing Agency (BPJPH) and Indonesia's commitment to work bilaterally with Australia on the implementation of the Halal Law. Australia welcomes further opportunities to engage with BPJPH on a number of technical matters relating to the implementation of the Halal Law. This includes the process and timeframes for accreditation of Australian halal certifying bodies, clarification on how Australia's existing halal assurance processes will continue to interact with Indonesia's regulations when the grace period for the Halal Law ends in 2024, and additional updates from Indonesia on products that do not require halal certification under the Halal Law. We welcome further dialogue on the Halal Law to ensure its implementation is clear and no more trade restrictive than necessary.

2.140. The representative of the <u>Philippines</u> provided the following statement. We share the concerns raised by the European Union, the United States, Australia, Switzerland, and Canada on Indonesia's Halal Product Assurance Law No. 33 of 2014. We acknowledge the legitimate objective of Indonesia for the mandatory Halal certification of products to prevent deceptive practices and strengthen consumer protection. Following our statement at the June meeting, the Philippines reiterates our request for Indonesia to provide the HS codes for products and CPC for services sectors that will be covered by the mandatory certification. We note that the Philippines and Indonesia had started laying the groundwork for a possible Memorandum of Understanding with Indonesia's Halal Product Assurance Agency in 2021, allowing for the recognition of Halal accreditation bodies between our two countries. We look forward to revisiting these discussions with Indonesia at the soonest possible time.

2.141. The representative of <u>Canada</u> provided the following statement. Canada welcomes recent bilateral engagement between Canadian and Indonesian competent authorities on this matter and we look forward to this engagement continuing in a constructive fashion. Nevertheless Canada would once again like to join other Members in expressing its concerns with Indonesia's Halal Product

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Assurance Law no. 33 of 2014, and its implementing regulations, as it continues to represent a barrier to Canadian exports of halal products to Indonesia. While Canada supports Indonesia's objective to provide Indonesian consumers the assurance that they have access to products that are certified as halal through a rigorous and recognized process, the broad scope of the measure, as well as the lack of predictability and clarity on its implementation, remain problematic. We refer Indonesia to our statements from previous WTO TBT Committee meetings. Canada thanks Indonesia for notifying Presidential Decree Number 6 of 2023 regarding Halal Certification of Medicines, Biological Products and Medical Devices as G/TBT/N/IDN/157. However, once again, we note that while the measure was notified on 11 July 2023, with a 60-day comment period, it came into force on 19 January 2023. Could Indonesia please provide clarity as to how such an approach to transparency is in line with Indonesia's obligations under the TBT Agreement, in particular, can Indonesia explain how WTO Members' comments can be taken into account in the development of a technical regulation when the measure has already been adopted and entered into force six months before? Could Indonesia provide additional information on whether a halal certification body for food/beverages/beef slaughter will be authorized to certify halal certification for drugs, biological products, and medical devices? Are there specific requirements for the halal certification body, such as the halal certification body must have a Moslem pharmacist/medical doctor as the halal assessor? Further, could Indonesia provide information on when industry-specific implementing regulations will be developed? Canada thanks Indonesia for recently notifying six measures related to halal certification, referred as G/TBT/N/IDN/159 to 164. Canada will be reviewing these measures and trusts that any comments it submits will be taken into consideration in the final measure. However, we understand that some of these measures have already entered into force despite Indonesia providing a comment period. We once again urge Indonesia to abide by its transparency obligations under the TBT Agreement.

2.142. The representative of <u>Norway</u> provided the following statement. I first would like to thank the EU and United States for raising this issue. As underlined in our earlier interventions under this issue, Norway recognizes Indonesia's objective of providing its consumers with access to products which are certified as halal. Norway would like to note that the notified regulations are included in different regulations. It is therefore not easy to get a complete overview of the framework. We are further concerned by the uncertainty with regard to products which are listed as exempt from halal certification, as it is hard to deduce which products are exempt on the basis of the described categories. Indonesian authorities have confirmed that seafood is considered as halal. But if understood correctly, Norway questions why for instance non-slaughtered, wild caught frozen fish which has not undergone processing must be certified as halal. Norway requests Indonesia to provide more detailed information about the exemption procedures and product categorisation. Norway finds that the total extent of these measures place excessive burdens on economic operators and foreign governments and create barriers to trade. We look forward to further cooperation with Indonesia in order to find solutions in the seafood sector which secure the least trade restrictive framework possible.

2.143. The representative of <u>Switzerland</u> provided the following statement. Switzerland shares the concerns expressed by other Members regarding Indonesia's Halal Product Assurance Law No. 33 of 2014 and its implementing regulations, which require mandatory halal certification and labelling for a wide range of products. In particular, we stress the importance of the recognition of foreign Halal certification bodies and the acceptance of foreign certificates. In this context we kindly ask Indonesia to confirm that Comprehensive Economic Partnership Agreements are accepted as government-to-government agreements under the Indonesian Halal Law. We thank for the recent notification of several decrees containing clarifications and guidelines in connection with halal certification. We will analyse these in detail and get back to the Indonesian enquiry point in case of guestions and further comments.

2.144. In response, the representative of <u>Indonesia</u> provided the following statement. Indonesia would like to thank the European Union, the United States, Australia, Philippines, Switzerland, and Canada for their continues interest on Halal Product Assurance Implementation in Indonesia. Indonesia as the biggest moslem country in the world, should ensure a reliable information regarding halal integrity of products that is consumed or used by people through Halal Certification mechanism and labelling. It is also referred to the Al-Quran and Al Hadiths as guidance, in accordance to Islamic Law or Syariah. Mandatory halal certification applied not only to foreign business actors, but also domestic producers. Indonesia stressed that non halal products can still be distributed in Indonesia as long as they meet the requirements states in the halal regulation, including the inclusion of non-halal information in the form of images, signs or writing. Non-halal information is not only made

by written text "non-halal" label at the product packaging, but it can also show by images/other signs which essentially becomes a means of communicating information between business actors and consumers that the products are not halal. This obligation to include non-halal information is carried out independently/self-declared and does not go through a registration process.

2.145. The mechanism to obtain halal certificates for imported products is implemented through 2 mechanisms, such as: Direct halal certification in Indonesia through BPJPH certification procedures and requirements; or Halal Certification by its country foreign halal certifications bodies which has been recognized and listed by BPJPH. The recognition of foreign halal certification bodies, will be conducted by halal accreditation and/or conformity assessment of foreign halal certification bodies in accordance with provisions of statutory regulations, halal standards and sharia Law applied in Indonesia. (Please refer the Guideline for Accreditation And/or Conformity Assessment of Foreign Halal Certification Bodies, notified as <u>G/TBT/N/IDN/159</u>). Foreign Halal Certification Bodies can certify the final products depends on the scope of foreign halal certification bodies' competence. The competence scope will be decided from assessment result according to the competency of the resources of the agency (internal and external resources), the number of halal auditors and the existence of sharia boards.

2.146. Indonesia previously has notified to the WTO TBT Committee, the derived regulations related to halal certification, to ensure all stakeholders understand the certification process in Indonesia, such as: Mandatory Halal Certification Stages of Implementation and labelling information, GR 39/2021 (notified as G/TBT/N/IND/131, G/TBT/N/IND/131/Add.1). Products category that are mandatory to be halal certified as listed in Minister of Religious Affairs Regulation No. 748 of 2021 (notified as G/TBT/N/IND/134, G/TBT/N/IND/134/Add.1). Regulation of Minister of Finance Number 57/PMK.05/2021 regarding Tariff for Public Services provided by Halal Product Assurance Organizing Agency (BPJPH), Ministry of Religious Affairs (notified as G/TBT/N/IND/138). International Cooperation on Halal Product Assurance, Minister of Religious Affairs Number 2 of 2022 (notified as G/TBT/N/IDN/139 and G/TBT/N/IDN/139/Add.1). Products category or material which are not necessary to be halal certified as listed in Minister of Religious Affairs Regulation No. 1360 of 2021 (notified as <u>G/TBT/N/IND/140</u>, <u>G/TBT/N/IND/140/Add.1</u>). Currently, Indonesia has also notified the implementation regulations of halal certifications: Draft Decree of Halal Product Assurance Organizing Agency No.___ of 2023 Regarding the Determination of General Services Rates of BPJPH, (notified as <u>G/TBT/N/IDN/161</u>). Decree of The Head of Halal Product Assurance Organizing Agency No. 20 of 2023 Regarding the Criteria for Halal Product Assurance System, (notified as <u>G/TBT/N/IDN/162</u>).

2.147. The Presidential Decree Number 6 of 2023 regarding Halal Certification of Medicines, Biological Products, and Medical Devices (notified as <u>G/TBT/N/IND/157</u>), regulates provisions for products in the form of medicines, biological products, and medical devices originating from non-halal materials and/or the method of production are not yet halal. It should be highlighted that medicines, biological products, and medical devices originating from non-halal materials or materials are not yet sourced from halal sources still can be circulated and traded in Indonesia by including Non-Halal Information on the products. If medical devices do not contain animal elements, it does not need to be certified halal and can still be circulated in Indonesia. The mandatory implementation stages of halal certification in medical devices will be forced with a maximum time of 17 October 2039. This transition time is considered sufficient for domestic and foreign business actors to prepare the requirements for halal certification. With regard to the implementation of halal international cooperation regulations, it is clearly mentioned that the mutual recognition and acceptance will be based on bilateral agreement between 2 countries, which is Indonesia and partner country.

2.148. The halal certificate should only be issued for business actors from its origin country foreign halal certification bodies. The international halal cooperation should follow the availability of a G-to-G MoU between Indonesia and its country partner. Based on the statutory provision, Indonesia does not apply cross-country and cross-border certification in terms of mutual recognition and mutual acceptance of halal certification. It is important to mention that fish products are including to seafood products that is considered as halal. Indonesia never issued regulations requiring fish to be slaughtered first before consumed. In accordance with regulations, the fresh, frozen, dried and salted fish and fishery products are exempt from halal certification obligations. But if fish and fish products are undergone further processing treatment, then it should be halal certified. Indonesia understands that the HS code is needed to facilitate trade and transparency, therefore BPJPH has prepared regulations regarding The Establishment of Harmonized System Codification of Types of

Products that are Required to be Halal Certified in Food and Beverages, notified as G/TBT/N/IDN/160). Lastly, Indonesia looks forward to further cooperation and open dialogue with WTO Member to ensure that halal certification will not become unnecessary barrier to trade.

2.1.4.13 China - Cybersecurity Law (ID 526⁴⁷)

2.149. The representative of the European Union provided the following statement. The EU would like to refer to its statements at previous TBT Committees with regard to the Cybersecurity Law⁴⁸, the Data Security Law⁴⁹ and related legislation and standards. The concerns raised in those previous statements remain and have already had a severe negative effect on business confidence. Uncertainty remains around key legal and regulatory definitions, including, but not limited to, critical information infrastructure operator⁵⁰, online platform operator, network products and services, industrial data, important data, core data and data transfer. This in turn gives rise to uncertainty for foreign companies as to which legislation is applicable to them. In addition, there is an overlap between the scope of application of the Critical Information Infrastructure Security Protection Regulation⁵¹ on the one hand and the Multi-Level Protection Scheme (MLPS) 2.0⁵² on the other. The uncertainty resulting from this overlap is exacerbated by the fact that the Regulations on Cybersecurity Classification Protection⁵³ have not yet been finalized, and that many regulatory requirements originally addressed only to critical information infrastructure operators are being expanded to cover Level 3 networks under the MLPS. The EU therefore urges China to distinguish between the compliance obligations - especially with regard to product and service procurement applicable to critical information infrastructure on the one hand, and to networks above MLPS Level 3 on the other, so as to ensure that these two sets of obligations are distinct.

2.150. The Cybersecurity Review Measures⁵⁴ continue to give rise to considerable uncertainty. The triggers for security review of network products and services are defined extremely broadly and the reviews themselves have proven to be opaque and potentially lengthy. It also remains unclear what exactly the consequences are when a review is failed, in particular for downstream customers. The EU requests that China notify draft implementing measures of the Cybersecurity Law, including but not limited to product and service catalogues for testing and certification, and any sectoral implementation to the WTO. The EU remains highly concerned about the Outbound Data Transfer Security Assessment Measures and their implementation. There is uncertainty regarding the triggers for assessment, such that they may potentially be triggered by normal cross-border commercial activity. The assessment process is proving to be lengthy and burdensome, giving rise to considerable uncertainty. The opacity of the assessment process makes it impossible to ascertain whether assessments are not conducted in a non-discriminatory manner. Assessments have led to de facto rejections of many essential cross-border data transfers for foreign companies. The "necessity" criterion for data transfers during the assessment process appears to be interpreted in a very narrow manner. The EU is particularly concerned that these measures put foreign operators at a disadvantage compared to domestic ones.

2.151. In addition, there are considerable concerns regarding the protection of trade secrets during the assessment process. The EU notes the draft Regulations on Regulating and Facilitating Crossborder Data Flow⁵⁵ and requests China to respond to the comments received on these draft regulations from the EU and European industry. The EU also continues to be concerned about the lack of clarity surrounding the sectoral scope of application of the Measures for Data Security Management in Industry and Information Technology (for Trial Implementation). The EU calls on China to clarify key legal and regulatory definitions and apply them in as narrow a manner as possible. The EU calls on China to clarify the necessity criterion applied in cross-border data transfer security assessments and apply it in as broad a manner as possible. The EU furthermore calls on

⁵⁰ 关键信息基础设施的运营者

 $^{^{47}}$ For previous statements follow the thread under ID <u>526</u>.

⁴⁸ 网络安全法

⁴⁹ 数据安全法

⁵¹ 关键信息基础设施保护条例

⁵² 网络安全等级保护制度

⁵³ 网络安全等级保护条例, also translated as "Multi-Level Protection Scheme Regulation"

⁵⁴ 网络安全审查办法

⁵⁵ 网络数据安全管理条例 (征求意见稿

China to minimise regulatory overlap. In particular, the EU encourages China to define sectoral catalogues of important and core data as soon as possible and ensure that they are aligned. In general, the EU calls on China to implement its legislation in a non-discriminatory manner, respecting the principles of transparency, proportionality, necessity and technology neutrality, and to ensure adequate protection of intellectual property.

2.152. The representative of the <u>United States</u> provided the following statement. 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. Our numerous, long-standing concerns are clearly laid out in our past statements to this Committee and remain unaddressed. We will therefore refer the Committee to our previous statements.

2.153. The representative of Japan provided the following statement. Japan continues to have concerns about the Cybersecurity Law and its subordinate regulations. In September 2022, the draft amendment to the Cybersecurity Law was published, and Japan has submitted its comments. Japan would like to request that China take them into account. In particular, Article 65, which has been changed in the draft amendment, stipulates penalties for critical information infrastructure operators who use network products or services that have not undergone or passed a "cybersecurity review." We understand that the Cybersecurity Review Measures stipulate the procedures, required documents, and required number of days for this cybersecurity review. However, some points remain unclear, such as the specific scope of network products, which may create unnecessary obstacles to the market entry of relevant foreign vendors and service providers. Japan requests that the above unclear points be clarified and that the cybersecurity review be operated in a manner consistent with especially Article 5 of the TBT Agreement. We also have comments regarding the Cross-border Data Transfer Security Assessment Measures which came into effect in September 2022, the Cybersecurity Multi-Level Protection Scheme which was published for public consultation in 2018, and the Security Certification Specifications for Cross-border Processing Activities of Personal Information which were published in December 2022, as subordinate regulations of the Cybersecurity Law or Personal Data Protection Law.

2.154. 1) Japan submitted comments on the Cross-border Data Transfer Security Assessment Measures during the public consultation period. While the Measures define "general data", "critical data", and "core data", they do not provide objective and specific criteria for classification of such data. In February 2022, the Information Security Technology Critical Data Identification Guideline was submitted for public consultation, and in September 2022, the Information Security Technology Network Data Classification and Grading Requirements were submitted for public consultation. Japan would like to request that China clarify whether China intends that the classification criteria for general data, critical data, and core data will be defined appropriately in these national standards. 2) Japan submitted its comments on the Cybersecurity Multi-Level Protection Scheme during the public consultation period in 2018. We continue to have concerns about the unclear terminology, for example, the difference between "network operator" and "network service provider," and the consistency of national standards referred to in the Cybersecurity Multi-Level Protection Scheme with Articles 2 and 5 of the TBT Agreement. At the previous TBT Committee meetings, China has stated that the process was in the drafting phase. Japan would like to request that China provide information and that a transparent system be established.

2.155. 3) With regard to the Security Certification Specifications for Cross-border Processing Activities of Personal Information, these standards require personal data processors who engage in cross-border processing activities of personal information to establish a personal data protection agency and to assess the impact of personal data protection on activities in which personal information is to be provided to foreign recipients. These obligations will have a significant impact on foreign businesses that have a high need to provide personal data outside of China, and may hinder the smooth facilitation of business activities depending on their specific nature. Since predictability is important from a perspective of business, Japan would like to request that the opinions it has submitted for public consultation be taken into consideration, and that transparent implementation is ensured.

2.156. The representative of <u>Australia</u> provided the following statement. In past statements Australia has noted its concerns with China's Cybersecurity Law and related laws, including the Personal Information Protection Law and Data Security Law. As we set out in Australia's submissions

to China's consultation on the then proposed laws, we welcomed a number of revisions to both these draft laws. Nonetheless, Australia still has concerns around extra-territoriality, trade retaliation, compliance costs for firms and the overall scope. These concerns have still not been addressed. We remain concerned about the lack of clarity when it comes to definitions, jurisdiction and a number of other fundamental elements. 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 note the release of China's draft Regulations on Standardizing and Promoting Cross-Border Data Flows, and will closely observe their development and impact on the operating environment for businesses. We welcome the opportunity to provide comments on draft measures.

2.157. The representative of Canada provided the following statement. Canada welcomes the Cyberspace Administration of China's recent draft Provisions on Regulating and Facilitating Cross-Border Data Transfer; issued on 28 September 2023 for public comments. We encourage China to finalize the draft provisions as soon as possible and, in relation to cross-border data transfer, to take further actions to: (i) reduce the regulatory compliance burden, and (ii) provide increased transparency, for businesses operating in China. In addition, Canada would like to refer to its statements at previous TBT Committees and continues to have significant concerns with China's suite of cybersecurity and cryptography/encryption laws, and related implementing regulations. The multiplication of implementing measures 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, namely: the Critical Information Infrastructure (CII) Security Protection Regulations; the Draft Regulations on Network Data Security; the Measures on Security Assessment of Cross-Border Data Transfer; the Measures on the Standard Contract for the Cross-Border Transfer of Personal Information; the Practical Guidance of Cybersecurity Standards—Technical Specifications for Certification of Cross-border Handling of Personal Information; and the Implementation Rules of Personal Information Protection Certification. Canada would like to urge China to recognize the concerns that have been raised by Members on these measures since 2017 and reiterate our longstanding request for notifications of these measures.

2.158. In response, the representative of <u>China</u> provided the following statement. Since its implementation in 2017, the Cybersecurity Law has provided strong legal protection for safeguarding cyberspace sovereignty, national security, and public interests, and protecting the legitimate rights and interests of citizens, legal persons, and other organizations. At the same time, in order to adapt to the new situation, the "Administrative Penalty Law", "Data Security Law", "Personal Information Protection Law" and other laws have been revised, formulated and implemented in 2021. In order to coordinate and connect the Cybersecurity Law with newly implemented laws, improve the legal liability system, and further ensure network security, it is planned to amend the Cybersecurity Law. At present, relevant Chinese departments are further revising and improving the law based on opinions from various parties.

2.1.4.14 China - Encryption Law of the People's Republic of China by the Office of State Commercial Cryptography Administration (OSCCA) (ID 534⁵⁶)

2.159. The representative of the <u>European Union</u> provided the following statement. The EU would like to reiterate its concerns relating to the Cryptography Law⁵⁷ and related legislation. The EU remains concerned about the wide scope of the law. These concerns have already negatively impacted business confidence. We note in particular that the Law does not recognize China's commitment that the cryptography regulation would only apply to products whose core function is providing encryption.⁵⁸ The EU remains concerned about the Commercial Cryptography Administrative Regulations and its implementation, which often goes beyond the Cryptography Law. Particular concerns are: the wide scope of the regulations; the insufficient safeguards for the protection of intellectual property; the imposition of pre-market and export controls; unclear requirements around testing and certification; turning voluntary certification requirements into de facto market access prerequisites; the imposition of national security reviews; the use of domestic standards; and the lack of meaningful access to Chinese standards development organisations. The EU welcomes that the published final version of the Commercial Cryptography Administrative Regulations limits security assessment, and product testing and certification to critical information infrastructure operators. However, given the newly introduced Article 41 of these regulations, the

⁵⁶ For previous statements follow the thread under ID 534.

⁵⁷ 中华人民共和国密码法, also translated as 'Encryption Law'.

⁵⁸ The so-called "Year 2000 Clarification" by the State Cryptography Administration (SCA).

EU is concerned that similar requirements may re-appear for other operators in other legislation, in particular the Regulations on Cybersecurity Classification Protection, which is still pending release. The EU calls on China to ensure that legal and regulatory requirements are non-discriminatory, do not favour specific technologies, do not limit market access and do not lead to forced transfers of intellectual property. The EU urges China to guarantee the possibility for foreign companies to participate on an equal footing with domestic companies in the market for cryptographic products. Additionally, the EU urges China to provide effective access, including the right to vote and to lead standards drafting, for foreign companies to standardisation bodies, in particular Technical Committee 260 and the Cryptography Industry Standardisation Technical Committee (CISTC).

2.160. The representative of the <u>United States</u> provided the following statement. The United States will support other Members' interventions and refer to its statement on the Cybersecurity Law.⁵⁹

2.161. The representative of <u>Japan</u> provided the following statement. Japan continues to have concerns about the Encryption Law, which came into effect as of 1 January 2020. The Encryption Law contains an article that prohibits requests for disclosure of source code, etc. We would like to request that China prohibit the disclosure requirement of algorithms as well as source code. Japan would like to request that the operation of this law not be more trade restrictive than necessary in accordance with Article 2.2 of the TBT Agreement, and that it not impede the activities of foreign companies in China or their entry into the Chinese market.

2.162. The representative of <u>Canada</u> provided the following statement. Canada would like to refer to its statements at previous meetings of the TBT Committee with regard to China's Cryptography (Encryption) Law and Regulations on the Administration of Commercial Cryptography

2.163. In response, the representative of <u>China</u> provided the following statement. The law came into force on 1 January 2020. It clearly stipulates that the governments at all levels and relevant competent departments shall follow the principle of non-discrimination, and treat all the organizations equally including foreign-invested enterprises that engage in commercial cryptography research, production, sales, service, import and export, etc. China encourages commercial cryptography technical cooperation on a voluntary and commercial basis in the process of foreign investment. Administrative agencies and their staff are prohibited from forcing any transfer of commercial cryptography technology by administrative means.

2.1.4.15 European Union - Transitional periods for MRLs and international consultations, <u>G/TBT/N/EU/682</u>, <u>G/TBT/N/EU/683</u>, <u>G/SPS/N/EU/360</u> (ID 580⁶⁰)

2.164. The representative of <u>Kenya</u> provided the following statement. Kenya reiterates her previous position on this Specific Trade Concern. 1. Kenya raised this as a Specific Trade Concern in the previous TBT Committee meetings and continues to have concerns over the same issue. 2. Kenya takes note of the EU's response given in the June 2023 TBT Committee meeting on the Transitional periods for MRLs and international consultations. 3. The transitional periods for MRLs established by EU are short and do not take into account the needs and adaptive capacities of developing countries which is inconsistent with Article 12.3 of the TBT Agreement. The transition periods clearly need to be longer. 4. Kenya therefore calls for a review of the transitional periods. 5. Kenya will also continue these discussions in the SPS committee.

2.165. The representative of <u>Colombia</u> provided the following statement. These two topics have been raised several times in this Committee because no solutions have yet been found as regards appropriate transitional periods, nor is it clear how comments submitted by Members in international consultations have been taken into account. The problem is exacerbated when maximum residue levels and import tolerances are reduced or totally withdrawn and the transitional period to adapt to new conditions is completely insufficient for exporters in non-EU countries – hence the pressing need to extend such transitional periods to allow time to properly adapt to new legislation. It is worth remembering that access to international markets is essential to the livelihoods of thousands of rural families, especially since the European Union is one of the top markets for producers of bananas, coffee and exotic fruits, among other products. We therefore call on the European Union to consider the comments made before implementing new measures regarding the level of detection for an active ingredient, conduct comprehensive risk assessments before establishing a new maximum

⁵⁹ China - Cybersecurity Law (<u>ID 526</u>).

 $^{^{60}}$ For previous statements follow the thread under ID <u>580</u>.

residue level and ensure that transitional periods are sufficiently long. Otherwise, we will end up in a situation with measures that unnecessarily restrict and impede trade because they go beyond what is necessary to fulfil the objective being pursued. We therefore invite the EU to follow the recommendations for good regulatory practices, according to which rules should be based on clear and objective information, and open dialogue with stakeholders, transparency and reduction of market distortions are promoted, to the benefit of not only developing countries but also the multilateral trading system, which has already been hit hard by this and other measures.

2.166. The representative of <u>Costa Rica</u> provided the following statement. Costa Rica reiterates its support for this trade concern and repeats its request for an extension of the transition periods for compliance with the new tolerances established for agrochemical inputs. The approval for their use has not been renewed and the impact that they have on agricultural production in our country and others around the world is very significant. The usual period granted by the EU, around six months, still does not provide enough time to replace an agrochemical being used. As a result, there is a need to assess the possibility of longer transition periods for fruit and vegetable producing and exporting countries.

2.167. The representative of the <u>United States</u> provided the following statement. The United States continues to have concerns with the European Union's (EU) practices related to the reduction of pesticide maximum residue levels (MRLs). We have, in several meetings of this Committee, noted that following the restricted approval or non-renewal of many active substances in the EU, the EU has subsequently reduced or withdrawn MRLs, including those based on Codex limits or import tolerances, without finalizing a risk assessment. The United States continues to request that the EU follow science- and risk-based processes, and that the EU complete science-based risk assessments based on a full body of evidence, prior to reducing or withdrawing pesticide MRLs. The United States has also taken note of recent EU MRL reductions to levels well below the EU's current, default limit of determination (LOD) of 0.01 ppm. The United States is concerned that EU's efforts to lower MRLs to levels ranging from 0.001 ppm to 0.005 ppm may be more trade restrictive than necessary to meet the EU's human health objectives. The United States is concerned that such reductions to MRLs can have negative effects on agricultural trade and can create trade disruptions from inaccurate residue analytical results, cross-contamination, or other reasons outside of a farmer's or exporter's control.

2.168. The United States has also previously shared concerns regarding the European Union's enforcement of MRLs. We ask the European Union to consider alternate and more flexible approaches to the enforcement of changes to MRLs. A more flexible approach can support our shared goals of enhancing global food security in the least trade restrictive manner possible while still protecting consumers. We request the EU extend the transition periods for MRLs where the EU has not identified risks to consumers based on dietary exposure based on completed risk assessments. The United States, along with many third country producers, have expressed the need for lawfully produced food products to have sufficient time to move through the channels of trade, including products with long shelf lives. The EU's policy of enforcing MRLs at the time of importation for imported goods rather than at the time of production, as currently applied to the EU's domestic agricultural products, causes disruptions in trade destined for the EU market. The United States requests that MRLs for all products, both domestic and imported, be enforced based on the MRLs in place at the date of application of the pesticide. This would resolve the inconsistency of enforcement of MRLs for agricultural goods produced inside and outside the EU.

2.169. The United States also expects the EU to take WTO Member comments into account prior to finalizing its draft measures. The United States has observed that the period of time between the WTO comment submission period and European Commission voting on draft regulations on active substance renewals and MRLs can be brief. We look forward to discussing with the EU the possibility of finding additional opportunities for third countries to provide data and other analysis in advance of the formal WTO notification comment period. This would facilitate the ability of the EU to take a full body of available evidence into account prior to finalizing an MRL decision. Lastly, we ask the EU to retain existing MRL levels while import tolerances are under consideration. Recent EU regulation states that import tolerance applications will be considered on a case-by-case basis dependent upon meeting its definition of "environmental criteria." However, the lack of predictability that results from the consideration of import tolerance requests on a "case-by-case" basis unnecessarily increases uncertainty for farmers globally and limits farmers' ability to protect crops from pests and diseases.

2.170. The representative of <u>India</u> provided the following statement. India would join the concerned raised by other WTO Members on the international consultation processes and planned transition periods related to the MRL setting procedures as adopted by the European Union (EU). In previous reply, EU has failed to address the concerns raised by the members. The EU has reiterated its existing processes without considering how it plans to modify its processes to take into account the concerns raised by the Members. India requests EU to address substantively the concerns of the Members.

2.171. The representative of <u>Canada</u> provided the following statement. Maximum residue limits (MRLs) regulations were developed to mitigate unnecessary trade barriers. However, these measures can unintentionally become unnecessarily trade restrictive and impede trade when a country imposes a sudden MRL deletion without giving its trade partners sufficient time to adjust. To that end, Canada would like to reiterate its concern with the EU's approach to transition periods for MRLs. Canada is of the view that the EU's approach does not acknowledge the reality of international agricultural supply chains such as the time required to ship product, multi-year inventory and extensive shelf life. At a time when ensuring food security is of high concern, Canada urges the EU to extend transition periods for MRLs for its trading partners taking into account the need for exporters to adapt to new requirements.

2.172. 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. Brazil stresses the importance of assuring reasonable transition periods - between the publication of technical regulations and their entry into force - regarding MRLs. 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.

2.173. The representative of Ecuador provided the following statement. Ecuador is extremely concerned about the "transition periods" granted by the EU for implementing its measures relating to the non-renewal of the approval of substances and the reduction of tolerances. In order to establish reasonable transition periods, it is necessary to consider harvesting periods and the times when agrochemicals are applied. Farmers need more time to adapt to MRL requirements, as it takes at least 10 years on average to develop or register a new phytosanitary pest-control product, and this is when new alternatives have already been identified. We therefore urge the EU to consider an adequate period – at least 5 years – to enable developing countries to adjust their production to the new conditions established in the European regulations. The extension for applying the measures has also been requested given that their implementation makes it necessary to find alternative measures that do not affect the price of agricultural products, and because of the need to minimize the impact of the reduction of agricultural production in the country, as it is important to bear in mind that according to data in the study carried out by the United States (USITC - Global Economic Impact of Missing and Low Pesticide Maximum Residue Levels), it is estimated that the strategies applied by the EU, in a middle-of-the-road scenario, would lead to the prices of agricultural products increasing by around 50% and a 4% decline in global agricultural production, which would have a huge impact on the country's economy.

2.174. It is clear that the regulations on the prohibition of the use and the withdrawal of the compounds are of an internal nature for EU member countries; however, bearing in mind that the next step is to review and modify the MRLs for these compounds, which, in some cases, involves reduction to the level of detection, this would mean that the restriction on their use would also be reflected in exporting countries. This leads Ecuador to urge the EU to consider the comments of third countries before resolving to reduce the minimum detection level of an active ingredient, particularly when it is key for the control of pests or diseases typical of tropical and subtropical climates, with conditions that differ from those of the European region. Ecuador is aware that the EU allows its farmers to request emergency authorizations so that, in certain special situations, they can use active substances that have already been banned in the European market. For Ecuador, it is important to know whether, where emergency authorizations are issued for the use of such substances, EU member countries have notified and justified the application of MRLs that differ from those established in the EU's existing MRL regulations. We would also like to know how the EU monitors whether the member State that has received an emergency authorization for the use of prohibited substances is complying with the existing MRL regulations and how it verifies, in the case

of non-compliance with the MRL regulations, that the products containing the prohibited substances have not been marketed in other EU member States.

2.175. The representative of <u>Argentina</u> provided the following statement. We would like to thank the delegations that included this concern on the Committee's agenda and we would be grateful if Argentina's support could be put on record. We once again reiterate our concern about the EU policy of removing import tolerances for substances that are no longer used in the EU, which is clearly a more restrictive measure than necessary and goes beyond the acceptable level of risk set by the EU. The approach taken by the EU to establish transitional periods for MRLs is inappropriate and does not take into account the needs and adaptive capacities of third countries. The transition period clearly needs to be longer, and Argentina therefore once again calls for a review of the transition periods.

2.176. The representative of Uruguay provided the following statement. Uruguay wishes to thank Costa Rica, Colombia, the United States and Kenya for including this item on the agenda. Firstly, my delegation reiterates the call for Members to take regulatory decisions based on internationally accepted standards, or to present conclusive scientific evidence when it is strictly necessary to deviate from those standards to meet their legitimate aims, in accordance with the relevant WTO Agreements. On this matter, considering harvest seasons, the stages at which plant protection products are applied, and the time needed to develop and register alternative substances, the transitional periods established by the EU in the regulations amending the MRLs for active substances are, in practice, mostly insufficient to make the necessary adjustments to production and to ensure that agricultural products, in particular processed or frozen products, comply with the new, amended MRLs. Any changes should be gradual, and a reasonable period of time should be granted in order to raise awareness in the production sector and among technical advisers, and to make available effective substitutes for the active ingredients for which the MRLs are to be reduced. It is inappropriate to make abrupt changes to the rules in the middle of a harvest season, considering the impact this may have on the marketing of the affected products. In this regard, Uruguay urges the EU, when taking decisions to reduce MRLs for active substances used in agricultural production by other Members, to provide sufficient transitional periods to make the relevant adjustments, reaffirming that more than six months are needed to adapt. Lastly, Uruguay reiterates the concerns expressed regarding how the EU's international consultation process on MRLs works in practice and urges that the EU delegation respond to the requests made by Colombia, Paraguay, Guatemala and Uruguay at the March 2023 meeting of the TBT Committee for further information on how, and to what extent, the EU has taken into account the comments of other Members in its regulatory process, and provide examples of instances where the EU has modified its original proposals in response to comments or information received from third countries.

2.177. The representative of <u>Paraguay</u> provided the following statement. As with STC ID 393, we urge the European Union to reassess its approach and, where MRL reductions are duly justified, provide adequate transition periods that take into account the realities of the production processes and the geography, including distances, of its trading partners. With regard to the international consultations, we thank the European Union for the notification of the measures. However, we repeat our question to the European Union about how the comments submitted by Members at different stages of the consultation process are taken into account. We would also like to know whether there are cases in which regulatory changes or adjustments have been introduced using the information submitted by stakeholders during the consultation process. In many cases, the limited time between the end of the comment period and the approval of the drafts without amendments leads us to believe that these notifications and comment periods are mere formalities, and comments are not intended to be, and are in fact not, taken into account.

2.178. In response, the representative of the <u>European Union</u> provided the following statement. The European Union would like to thank the WTO Members for raising this issue. The EU has provided detailed information on transitional periods for Maximum Residue Levels (MRLs) at previous TBT Committees, since March 2019 until June 2023. The EU considers that measures lowering MRLs due to concerns for human health, fall under the remit of the SPS Committee and should be discussed in that context. Nevertheless, we would like to also inform Members of the TBT Committee that all measures taken on MRLs in the EU are based on a scientific risk assessment carried out by both an evaluating EU member State and the European Food Safety Authority (EFSA) and using the most up-to-date science and evidence available. Obviously, science is under continuous development with new data and risk assessment methodologies becoming available. Therefore, the EU has the procedures in place to review any measure at any moment, if this is necessary. Contrary to measures

lowering MRLs, all measures concerning non-approval or restriction of active substances used in plant protection products in the EU and a limited number of very specific measures lowering MRLs due to environmental issues of global concern (e.g. clothianidin and thiamethoxam) are notified to the TBT Committee. These measures do not have direct consequences on SPS related matters. In the interest of transparency and, further to requests by some Members, when notifying these measures under the <u>WTO/TBT</u> notification system, the EU additionally informs the SPS Committee of the submission of those notifications.

2.179. 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 in those cases. The EU 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. In the interest of efficient proceedings in both Committees and, in line with the respective Agreements, the EU would invite Members to raise matters on approvals of active substances and measures dealing with MRLs in view of environmental issues of global concern exclusively in the TBT Committee, while matters relating to MRLs for pesticides due to human health concerns should be raised exclusively in the SPS Committee. Issues concerning transitional periods for MRLs should therefore generally be raised at the Committee to which the original notification was made, which would be, in most cases, the SPS Committee.

2.180. The representative of <u>Paraguay</u> provided the following statement. I would simply like to thank the European Union for its comments on how the comments received by the appropriate channels are taken into account, and to reiterate that it would be useful to have information on how these comments are taken into account and examples of when regulatory changes or adjustments have been made on the basis of those comments.

2.1.4.16 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 594⁶¹)

2.181. The representative of <u>China</u> provided the following statement. China has very specific suggestions to EU's regulation on medical devices. 1. It is recommended to clarify the regulatory requirements of original equipment manufacturer (OEM) and original design manufacturer (ODM), and issue relevant guidance for OEM and ODM as soon as possible. OEM and ODM are effective modes for technical exchanges between enterprises and for market promotion, as well as well-established production modes with technology and management systems. However, the EU has not expressly mentioned the relevant regulatory requirements of OEM under MDR, nor has it issued any relevant guidance. At present, different notified bodies have different regulatory requirements for OEM and ODM, which causes great troubles and obstacles for manufacturers.

2.182. 2. It is recommended to revise the current MEDDEV 2.7/1 rev 4 guidance or issue MDCG clinical evaluation guidance under the MDR regulatory system in order to provide systematic and specific guidance for clinical evaluation: (1) Specific guidance on the clinical evaluation of medical devices to which MDR 61 (10) applies, such as determination of the suitability of this pathway of a medical device and identification of clinical endpoints (especially safety endpoints), etc. (2) Specific quidance for clinical evaluation of well-established technologies (WET) devices, such as the determination of mature technology devices (including the application for the WET list, selection review, and release mechanism), the significance of non-Class III/non-implantable WET devices, and the clinical data requirements for such devices, etc. (3) Specific guidance on the requirement that "the device uses the SAME materials or substances in contact with the same human tissues or body fluids for ..." in point 3 of Annex XIV to MDR. For example, where "materials or substances shall be the SAME", what level of similarity does it refer to? Can different requirements be established for different types of devices? (4) Requirements for high-quality post-market clinical follow-up (PMCF) survey, for example, whether ethical review is required, and the requirements and prerequisites for conducting a high-quality PMCF survey for different categories of medical devices; (5) Explicit requirements and exemptions for post-marketing clinical tracking (PMCF) for different categories of medical devices. (6) Application of real-world data (such as device registry) and clinical data trial outside the EU in clinical evaluation; (7) How to calculate and present the benefit-risk ratio in data analysis; (8) Contents and requirements of clinical development plan (CDP); (9) Definition of

 $^{^{61}}$ For previous statements follow the thread under ID <u>594</u>.

"undesirable side-effects", as well as the association and difference between undesirable side-effects and clinical risks; (10) Definition and significance of benchmark device. 3. It is recommended the EU official could establish a consultation channel to respond to common consultation questions from manufacturers, and other relevant parties regarding the implementation of MDR regulations, serving as the corresponding regulatory basis for reducing the time of product certification and promoting access efficiency.

2.183. The representative of Japan provided the following statement. Japan appreciates the implementation of Regulation (EU) 2023/607 revising the MDR and IVDR on the extension of transitional measures and the removal of distribution deadlines. However, there are issues to be addressed in the MDR and IVDR as described below, and we request the following improvements. 1. MDR. The MDR requires rigorous clinical evaluation assessment even for relatively low-risk Class I, IIa and IIb medical devices. However, this may be more trade-restrictive than necessary to achieve legitimate objectives. In order to ensure that the regulations do not become more trade-restrictive than necessary, Japan continues to request that the EU simplify the requirements of the assessment similar to the Japanese pharmaceutical certification and the US 510(k) regulations, taking into account the promotion of international harmonization in regulations. For example, clinical evaluation could be simplified for medical devices with a medium or low risk using technologies that have already been proven on the market. 2. IVDR. The (EU) 2023/607, dated 15 March 2023, enables companies to supply devices that meet certain conditions. However, Japan is deeply concerned that the conformity assessments for many manufacturers will not be completed by the deadline. Therefore, Japan would like to request that the transition period for the IVDR be re-extended until at least the end of 2027 or the end of 2028 or beyond, as was done for the MDR.

2.184. 3. MDR and IVDR. 3.1 Japan welcomes the publication of guidance in line with the MDCG Guidance Publication Plan. However, Japanese manufacturers have informed us that the requirement to conform to guidance without a transition period is a factor in the prolonged conformity assessments. As we requested at the previous TBT Committee meetings, we continue to ask that public consultation be carried out prior to the publication of MDCG guidance, that newly published MDCG guidance has a transition period of at least one year, and that MDCG guidance be used for reviews by notified bodies after the transition period has elapsed. We appreciate the publication of guidance MDCG 2022-21 on Periodic Safety Update Reports (PSURs) on post-marketing surveillance; however, this guidance states that guidance on trend analysis will be issued separately, but it has not yet been issued. We request the guidance on trend analysis to be issued promptly as it is necessary to build the process for the implementation of the PSURs. 3.2 In some cases of conformity assessments by notified bodies, the need for conformity may be required even though the harmonized standards of MDR and IVDR are published in the EU Official Journal immediately before the conformity assessments. We request that an appropriate transition period be established for harmonized standards in accordance with Article 5.9 of the TBT Agreement.

2.185. The representative of Australia provided the following statement. Australia refers to its previous statements made in the TBT Committee and notes the recent decision by the European Parliament to extend transition timeframes for the European Union Medical Device Regulations (EU MDR). Australia welcomes this extension as it will allow additional time and increased capacity to access appropriately designated notified bodies to transition medical devices to the new regulatory framework. The EU MDR impacts both Australian manufacturers accessing European markets, but also impacts access to Australian markets given common reliance on European conformity assessment certification to support marketing approval in Australia. We still remain concerned about misalignment of components of the EU MDR with international guidance for certain medical devices which may result in trade barriers and burden to manufacturers who also supply their products to other countries including Australia. Australia also reiterates concern about the European shift to the European Medical Device Nomenclature (EMDN) currently being developed, diverging from the internationally developed Global Medical Device Nomenclature (GMDN). Australia is concerned about the issues this may create for a globally harmonized Unique Device Identifier (UDI) system resulting from use of EMDN in Europe, in contrast to use of GMDN in a range of other jurisdictions. Australia continues to be concerned about the absence of effective arrangements for interoperability (such as a mapping of EMDN and GMDN codes), given the potential for duplication for industry, and impact on information sharing in monitoring and responding to safety concerns for patients.

2.186. In response, the representative of the <u>European Union</u> provided the following statement. The EU thanks the WTO Members for their comments on the Medical Devices Regulation (MDR) and in vitro Diagnostic Medical Devices Regulation (IVDR). As announced in previous Committee

meetings, the MDR officially entered into force on 26 May 2021. It is important to underline that the shift between the Directives to the MDR is a gradual one, facilitated by transition periods that allow for medical devices in compliance with the Directives to continue to be in circulation until May 2024, in parallel with MDR certified devices. As regards the IVDR and as of May 2022, a staggered set of transition periods for IVDs was proposed. 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. One of the revolutionary changes introduced by the two new regulations include fit for purpose classification rules, reinforced notified body requirements and higher clinical evidence thresholds. These changes were deemed necessary in order to respond to a number of failures in the system and prevent future crises putting patients at serious risk. Regarding notified bodies, we are glad to report that their number is constantly growing. As of today, we now have 40 MDR designated Notified Bodies and 12 Notified Bodies under the IVDR. With the amendments to extend the transition period for MDR and IVDR compliance, the EU believes that the situation has improved, and that notified body capacity has been alleviated as well. Nevertheless, the preparedness of medical device manufacturers remains essential and working towards early compliance will be essential to avoid bottlenecks in the system.

2.187. On the question of SME access to notified bodies, the EU has put in place a number of nonlegislative measures in order to encourage availability of notified body capacity to deal with new applications as well as applications submitted by SMEs. Continuous monitoring of these measures is ongoing and frequent discussions with notified bodies entail the assessment of those activities. On Nomenclature, the EU maintains the need to separate the discussions from those related to Unique Device Identification (UDI). While the UDI system used in the EU is based on internationally agreed principles, the Nomenclature, also known as the language of use is 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 has been based on the need for a sensibly structured nomenclature that is transparent, open, fully accessible for the public, and downloadable for free. There are currently no other nomenclature systems offering those characteristics. The EU maintains that the choice of language and dictionary for medical devices i.e., the nomenclature does not constitute a barrier to trade. The EU is fully determined to ensure 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.

2.1.4.17 European Union - Non-renewal of the approval of the active substance mancozeb, <u>G/TBT/N/EU/712</u>; <u>G/TBT/N/EU/797</u>, <u>G/SPS/GEN/1494/Rev.1</u> (ID 627⁶²)

2.188. The representative of <u>Kenya</u> provided the following statement. Kenya reiterates her previous position on this Specific Trade Concern on the Non-renewal of the approval of the active substance Mancozeb. 1. Kenya raised this as a Specific Trade Concern in the previous TBT Committee meeting and continues to have concerns over the same issue. 2. Kenya takes note of the EU's response given in the June 2023 TBT Committee meeting on nonrenewal of the approval of the active substance Mancozeb. 3. The non-renewal of the approval of the active substance Mancozeb. 3. The non-renewal of the approval of the active substance Mancozeb and EUs response on the restrictive use of Mancozeb under the EU Chemicals legislation (REACH) is likely to be discriminatory. This will restrict Kenya's products from accessing the EU market which is deemed to be inconsistent with Article 2.1 of the TBT Agreement. 4. The active substance Mancozeb is an important molecule in pest control in Kenya. Mancozeb containing products are used in the agriculture sector for the control of a wide range of fungal diseases found in the tropics. Its use is critical in the flower industry, which is a leading sector in terms of the Kenya's GDP and also employs thousands of Kenyans thus impacting livelihoods.

2.189. 5. Mancozeb has been an important molecule in relation to fungal pathogens control on a number of vegetable crops including French beans, potato, tomato, onions among others. 6. There are no available alternatives to offer multisite fungicide for control of early and late blight on the above crops, which cause annual yield losses of up to 60-70% on the 4.5-5.5 million metric tonnes (USD 1.9 Billion) of potato, 560,000 metric tonnes (USD 333 Million) of tomato respectively produced in Kenya for local consumption. 7. Mancozeb has a multi-site contact activity which is a key aspect for resistance management. 8. Kenya wishes to raise this STC since the measure is deemed to be more trade restrictive than necessary contrary to Article 2.2 of the TBT Agreement. 9. The proposed measure would be deemed to be in contravention of Article 12.3 of the TBT Agreement which

 $^{^{62}}$ For previous statements follow the thread under ID <u>627</u>.

requires that "Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members". 10. Kenya requests the European Union to review and withdraw this Regulation.

2.190. The representative of Colombia provided the following statement. Colombia is aware of the importance of foods free from excess pesticide residues that comply with international safety recommendations. However, the ban on active substances such as mancozeb, clothianidin, thiamethoxam and chlorothalonil, and the subsequent non-renewal of the approval of these substances, are hitting our country's agricultural export sector hard. While our health authorities are going to great lengths with the productive sectors to explore alternatives to meet the requirements, the search for substances to replace those that have been banned or whose approval is being modified requires time and investment, especially when potential alternatives are also becoming scarcer owing to changes to phytosanitary regulations in the European Union. A typical example of this, but not the only one, is the limited availability of an alternative to mancozeb, on account of similar substances, such as chlorothalonil, being banned in the European market. In this context, it is vital that the non-renewal or modification of approval for active substances takes into account production processes and methods in countries that could be affected. Failing to do so would violate Article 2.2 of the TBT Agreement, which stipulates that technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective. Failing to do so also seems to violate Article 12.3 of the TBT Agreement, which states that account should be taken of the special financial and trade needs of developing countries, with a view to ensuring that regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports. In this regard, we agree with arguments presented in this Committee expressing the need for the European Union to bring maximum residue levels into line with the levels established within the framework of the Codex Alimentarius and to treat farmers in third countries no less favourably than it does European farmers. We therefore invite the European Union to seek out and support solutions that would allow our agricultural producers to continue meeting the European demand for food, to the benefit of not only developing countries but also the multilateral trading system, which has already been hit hard by this and other measures.

2.191. The representative of <u>Costa Rica</u> provided the following statement. We thank the delegations that support this trade concern and echo their statements. Costa Rica once again wishes to reiterate its concern regarding the draft Implementing Regulation notified by the EU in <u>G/SPS/N/EU/384</u>, under which approval for the use of mancozeb would not be renewed. We will keep this concern on the TBT Committee's agenda and will support the proponents of this concern given this measure's impact on our exporting agricultural sector and small products.

2.192. 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, and present a few requests. As previously stated, mancozeb is a substance whose use is approved for many different crops by the Brazilian Health Regulatory Agency. 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. It is particularly important for the management of fungicide resistance to control soybean rust. 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. In light of the insufficient transitional period granted by the EU, such crops could not have their treatments changed in time for exportation to the EU market before the entry into force of the regulation. Brazil regrets that European authorities have not established transition periods that were adequate to the production cycle of the affected crops. 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. In this sense, Brazil asks the EU to align MRLs with limits established under the framework of Codex Alimentarius, to consider less trade-restrictive alternatives that would also safeguard its legitimate policy objective and to grant a treatment for Brazilian farmers no less favourable than that granted to European farmers. Finally, Brazil would like to request any available updates on this matter, considering that the scientific opinion on MRLs for dithiocarbamates presented concludes that all MRL proposals derived by EFSA are indicative and still require further analysis by risk managers.

2.193. The representative of Paraguay provided the following statement. This concern and the non-renewal of the approval of other 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 European Union's decision to not renew the approval of these substances without a proper risk analysis and without complying with scientific principles. The arguments in favour of the use of this substance have not changed either, and these are shared by the European Union, or at least by several of its members, who consider them sufficient to provide emergency authorizations. We therefore request that the statement made by my delegation at the March meeting be recorded in the minutes. I would like to reiterate that Paraguay and other Members have raised a series of questions about this and other measures. In Paraguay's case, these questions will be recorded in the minutes, since they were mentioned in our statement at the March meeting. We hope that the European Union can provide full responses. I believe that Paraguay and several other Members have been showing flexibility in terms of time by shortening our interventions in the room. However, if we continue to receive insufficient responses, we will have to revert to the practice of reading full statements and adding new matters to unaddressed questions and concerns, which will mean that, before long, we will need a whole week just to discuss trade concerns.

2.194. Statement from March 2023 meeting, in full.⁶³ There are some new developments that we would like to discuss, but have yet to receive answers to the questions we have submitted. This is the same statement that I delivered at the previous meeting, hoping for different results and full answers from the EU to the questions submitted in the SPS Committee and in this one. This concern and the non-renewal of the approval of other 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.

2.195. The arguments in favour of the use of this substance have not changed either, and these are shared by the EU, or at least by several of its members, who consider them sufficient to provide emergency authorizations, as follows: - the lack of available alternatives to protect against some pests; - the importance of mancozeb to avoid problems with resistance and, in general; - the production and financial losses caused by some pests that only this substance can combat effectively. With regard to these emergency authorizations, we have already heard the EU say that the measures are only in place for 120 days, but we recall that there is no limit to the number of times that they can be renewed.

2.196. We see, for example, how many of the emergency authorizations for mancozeb are given for approximately the same annual period (roughly June to September or October), probably linked to the threshold of humidity and warm temperatures that increase the prevalence of some of the fungi that are effectively and safely controlled by substances like mancozeb. Imagine, how much more often these thresholds are reached in subtropical countries like Paraguay with climatic conditions very different from those of the European Union. We have also heard the EU explain that emergency authorizations are not intended to facilitate trade, unlike import tolerances, but we have not received answers to repeated written questions on the specific mechanisms used to grant emergency authorizations and to ensure that products with temporary MRLs are kept within the borders of the authorizing member, and on the consistency between these authorizations and alleged concerns about the use of these substances. Here we note not only the discrimination that exists in practice between EU producers and trading partners but also an inconsistency between the legitimate objective pursued and the actions taken to achieve it."

2.197. Furthermore, we have heard that, although emergency authorizations are granted by EU members, the EFSA reviews them if it considers that they are not properly justified. However, we note that even in cases where the EFSA considers that an emergency authorization is not properly justified, there are no restrictions on new emergency authorizations, which continue to be approved by the same members for the control of the same pests on the same crops for which the EFSA concluded that the use of the substance was not properly justified. Paraguay shares the objectives that the EU seeks to meet 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, which do not exist in this case, as

⁶³ <u>G/TBT/M/89</u>, paras. 2.223-2.227.

the EU agrees by granting emergency authorizations to its members. We reiterate our question on how the Members concerned by the process can participate in the analysis that the EFSA is conducting on the MRL for mancozeb; on the current status of the analysis, since an outcome was expected in the first half of 2022; and on how comments submitted by Members will be taken into account.

2.198. We are also seeking detailed responses to the queries regarding emergency authorizations that were raised in the SPS Committee and were not satisfactorily answered with the statement that it "is the responsibility of the EU member States", who are also WTO Members in their own right and to whom we should address questions if we receive no responses. Lastly, we cannot fail to recognize the extraordinary efforts that the EU is making in the bilateral/plurilateral and multilateral spheres, including through dual notifications (TBT/SPS). However, what my country and my country's producers need is not a unilateral explanation of the measures but a frank dialogue that allows the legitimate demands we are making to be met while at the same time achieving the EU's legitimate objectives in the least trade-restrictive way possible, in compliance with the rules and principles of the multilateral trading system.

2.199. The representative of <u>Argentina</u> provided the following statement. We would like to thank the delegations that included this specific trade concern on the Committee's agenda. Argentina continues to share the general concern over the hazard-based approach used by the EU as regards regulating pesticides, without identification of risk, which is an unnecessary technical barrier to trade. In the case of mancozeb, this is a broad-spectrum fungicide used for growing fruits, vegetables and extensive crops. Although Argentina shares the EU's concern over strengthening the protection of human health and the environment, we would once again like to underline the importance of complying with Articles 2.2 and 2.4 of the TBT Agreement to ensure that technical regulations are not more trade-restrictive than necessary to fulfil a legitimate objective. We are particularly concerned by the number of substances banned by the EU Commission, which has been increasing with each passing day. This situation may have serious consequences for various WTO Members, particularly developing countries, whose populations and economies are highly dependent on agricultural exports. It is therefore crucial for the EU to use a risk assessment approach in the analysis of these regulatory changes and to have conclusive scientific studies to determine the various aspects that may affect human health and the environment.

2.200. The representative of Uruguay provided the following statement. Mancozeb is an active substance that is authorized and routinely used in many countries, such as Uruguay, where it is used safely to control diseases and major pests in various products in the domestic fruit and vegetable sector, such as apples, pears and citrus fruits. In that connection, we share the concerns and requests expressed by other delegations, particularly in view of the possibility that, as a result of the ongoing dithiocarbamate review process, the EU will significantly reduce the corresponding MRLs, even to the limit of detection, without having any conclusive scientific evidence that substantiates such a decision in line with the SPS Agreement of the WTO. In this regard, we would appreciate an update on the status of the review process for these substances, including the predicted date for the presentation of the EFSA scientific opinion on dithiocarbamates, as well as the expected time frame for any notification to the SPS Committee regarding the relevant MRLs. In this context, like other Members, Uruquay recalls the importance of taking due account of international standards, quidelines and recommendations, and scientific information produced within the framework of international standard-setting bodies recognized in the WTO, such as the Codex Alimentarius; the obligation to open consultation periods that may serve as effective instances of regulatory cooperation between Members; and the need to grant reasonable transition periods if an amendment to the MRLs is finally decided.

2.201. The representative of <u>Ecuador</u> provided the following statement. Ecuador wishes to reiterate its concern regarding notification G/TBT/N/EU/712 on the non-renewal of the approval of the active substance mancozeb. Mancozeb is a fungicide used throughout the world for a wide range of strategic crops, many of which are produced by Ecuador and imported into the European Union (EU). This compound is crucial for pest management because, due to the tropical climate in countries like Ecuador, pest behaviour follows patterns that are very different from those prevailing in countries with four seasons such as those in the EU. Prohibiting the use of mancozeb could have a very significant economic impact on small-, medium-, and large-scale producers in Ecuador, as well as on consumers in the EU. In Ecuador's view, it is vital that studies concerning the renewal of active substances be based on scientific evidence and conclusive data, and not only on the precautionary principle. Ecuador therefore urges the EU to take into consideration the relevant scientific

information emanating from international specialized agencies recognized by the WTO, such as the Codex Alimentarius, showing that mancozeb does not produce adverse effects in humans, experimental animals or wild life at concentrations below those at which effects would be expected as a result of systemic toxicity.

2.202. EFSA decided not to renew the approval of the active ingredient mancozeb, classifying it in "toxic for reproduction" category 1B, and considers it to be an endocrine disruptor in humans and non-target species; however, given the reproductive toxicity hazard profile of mancozeb, it would be more appropriate to classify it in "toxic for reproduction" category 2, or even to refrain from classifying it. Furthermore, the EU has notified in document G/TBT/N/EU/996 of 20 July 2023, the non-renewal of the approval of the active substance metiram. Like mancozeb, Ecuador is concerned that substances belonging to the same group are being banned for use in the EU, which will trigger a reduction in their MRLs. For these reasons, Ecuador calls upon the EU to consider alternative measures that are less trade-restrictive, given that the few options for multi-site fungicide control (chlorothalonil) are being restricted and alternative substances that enable existing trade to continue have not been identified; to base its measures on conclusive studies and not on the precautionary principle alone; and to establish adequate transition periods for the registration of alternative substances, in view of the current shortage of tools available to control pests.

2.203. The representative of <u>Panama</u> provided the following statement. I wish to thank the delegations that placed this concern on today's agenda. As at every meeting of this Committee, the SPS Committee and the Council for Trade in Goods, Panama reiterates its concern at the non-renewal of these substances, particularly mancozeb. The active substance mancozeb is vitally important for my country's main crops. On account of its particular mode of action, it is irreplaceable in the control of black Sigatoka, the main pest in tropical crops. There is currently no other active ingredient on the market that can replace mancozeb; this leaves our industry deprived of sanitary tools and thus seriously affects Panama's exports to the EU. Panama shares the legitimate objective pursued by the EU, but this objective must not be more trade-restrictive than necessary. Panama therefore reiterates its request for the EU to reconsider its regulatory approach and take into consideration the relevant scientific information, such as the Codex Alimentarius.

2.204. In response, the representative of the European Union provided the following statement. The EU provided detailed explanations on this issue in previous TBT Committees. The non-renewal was based on a scientific assessment conducted under the EU Plant Protection Products Regulation 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. For advice on alternatives to Mancozeb, the EU pesticides database⁶⁴ is publicly available and contains information on all active substances, their approval status, and their main purpose (e.g., fungicide, insecticide or herbicide). Independently of the situation under the EU Plant Protection Products Regulation, use restrictions of Mancozeb have been introduced under the EU Chemicals legislation (REACH⁶⁵), following the classification of the substance as CMR (carcinogenic, mutagenic or reproductive toxicant) 1A or 1B under that same Regulation. As regards maximum residue levels (MRLs), the EU would like to inform Members that EFSA – as is usual practice for MRL assessments – follows a risk-based approach. EFSA has recently published a new risk assessment⁶⁶ reviewing the MRLs for dithiocarbamates. This review takes into consideration residues of mancozeb along with those of other substances belonging to the same group (dithiocarbamates), as they are reported under a common residue definition, as carbon disulfides (CS2). It also considers existing Codex MRLs along with import tolerances, while taking into account background levels of CS2 due to naturally occurring sulphur compounds. Based on EFSA's opinion, risk managers commenced discussions and regulatory work on the review of those MRLs in autumn 2023.

⁶⁴ <u>https://ec.europa.EU/food/plant/pesticides/eu-pesticides-db_en</u>

⁶⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

⁶⁶ <u>https://www.efsa.europa.eu/en/efsajournal/pub/7987</u>

2.1.4.18 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>. <u>G/TBT/W/774</u> (ID 632⁶⁷)

2.205. The representative of China provided the following statement. 1. For the Toys (Quality Control) Order, 2020: Firstly, according to Article 3 of the Toys (Quality Control) Order, 2020, the mandatory certification has involved a large range of toys (all toys products or materials) used by children under 14-year-old including swing and slide, etc. It is recommended that Indian can manage toys according to their risk level by conducting mandatory certification on toys of higher risk and exempting toys of other risk levels. Secondly, the BIS issued the document of 10 Steps to BIS License for Toys on its official website, it requires that factories producing electronic toys should be equipped with the instruments specified in IS 15644:2006 Articles 8, 9 and 10. However, the instruments needed by some of tests are expensive with high technical requirements, which are difficult for small and medium-sized enterprises to equip. In addition, those tests are usually done by third-party laboratories. This requirement that the instrument should be provided by factory itself is unnecessary and unreasonable. According to the TBT agreement 5.1.2, it is recommended that the Indian could cancel the factory equipment requirements for electric toys and other projects. 2. For Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017- Schedule-I (Import Policy): According to Article 2 of the newly revised Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017- Schedule-I (Import Policy), samples of imported toys should be randomly sent to NABL accredited Labs for testing in the process of clearance. The samples would be released after the test is qualified, which seriously affected the efficiency of customs clearance and the cost of the importer's storage. It is recommended that Indian could exempt the port test for accredited toys.

2.206. The representative of the European Union provided the following statement. The EU remains deeply concerned by the increasing number of Quality Control Orders (QCOs) issued by India across many sectors. The EU would like to recall that the majority of QCOs introduced by India appear to have a protectionist orientation and consequently raise questions regarding their compliance with the WTO's TBT Agreement obligations. The EU is particularly concerned by the fact that QCOs usually prescribe India-specific standards where international standards already exist. The EU would like to remind India that Article 2.4 of the WTO TBT Agreement requires Members to use international standards, where they exist, as basis for their technical regulations, except, when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems. Furthermore, QCOs prescribe mandatory conformity assessment procedures that are more restrictive than necessary to fulfil their legitimate objective. They cause extra burden and economic cost to the EU industry as a result of unnecessarily cumbersome procedures, including mandatory factory inspections, sample testing in Indian laboratories, to obtain necessary permissions or licences for products already tested and certified under established international standards and schemes. There is no provision for a streamlined process on the basis of existing certification from any international body.

2.207. The EU remains concerned with the visible trend towards establishing mandatory domestic standards in India that deviate from international ones for a growing number of products in various sectors. The EU also notes that India is failing to notify many of these measures as required under Articles 2.9 and 5.6 of the WTO TBT Agreement. The European Union remains concerned about India's Toys Quality Control Order (QCO) (<u>G/TBT/N/IND/131</u>) and the certification requirements introduced by the Bureau of Indian Standards (BIS). The EU would like to refer to its previous interventions on this STC. The European industries indicate that the QCO remains challenging and the process is still very burdensome and complex. In addition, a major concern is related to the fact that the import policy (<u>G/TBT/N/IND/143</u>) is applied on top of the QCO. One of key issues for the EU toy industry are the challenges in understanding by the BIS of the complexity and velocity of toy manufacturing. For example, when a factory is being audited, only the limited number of items being produced in that moment are taken as samples and sent for testing, and then included in the factory licence. However, all other toys produced in that factory at a later stage also need to be included in that licence, which is a burdensome process as for foreign manufacturing sites this has to be done via paper-based applications, whereas local manufacturers can do it online.

 $^{^{67}}$ For previous statements follow the thread under ID <u>632</u>.

2.208. Moreover, given that companies are producing a huge variety of items over the year with constant innovation, the requirement to add each new SKU (Stock keeping unit) coming from an audited factory can cause huge delays in importing new items and should rather be replaced by an online application, in order to guarantee a level playing field with local manufacturing. According to the EU, the application process should be simplified with less documentation needed and electronic versions of documents should also be accepted for review. This would include extending the same online system as Manakonline to foreign manufacturers to submit the inclusion applications, which allows for easy access, status information, and reference needed for customs clearance. Given that the on-line application for licence is only accessible to domestic toy manufacturers results in more burden and delays for foreign manufacturers. The EU would like to point out that the time taken to process the applications (between the submission of the application and the nomination of an auditor), which is currently two months in average (and sometimes up to almost two years for overseas manufacturers) should be reduced to one month to enhance the efficiency of the application process.

2.209. As concerns the preparation of audits, the EU would like to propose to stipulate a statutory timeline for every stage of audits, as this would give better visibility regarding the start and end point, increase transparency in the process and eventually benefit not only the applicant to obtain the licence in a timely manner but also the BIS to keep track of the applications. Moreover, overseas audits should be allowed to be outsourced and carried out by 3rd party auditors, in particular for licence renewals, in order to speed up the process. In order to improve the auditing process itself a set time limit for the issuance of licences should be provided as well as additional resources and trainings for auditors, including check-lists and a standard procedure. The EU would also like to have more clarity as regards the procedure of licence renewal. The EU welcomes the increased transparency of the process, but would like to understand whether a longer renewal period is granted to companies that specifically ask for it? To ensure the continued effectiveness of the Indian toy safety and quality regime under the QCO, the European Union would like to ask once more that the Indian government considers removing the current possible duplication of tests for QCO and at customs level under the DGFT notification for BIS certified products. According to recent information, the EU understands that currently only the QCO is applicable and the previous regime is no longer in force. This would mean that there is no need of additional testing at customs anymore. However, the EU would welcome a formal confirmation of this understanding. The European Union invites India to address the concerns raised and to alleviate the requirement for factory audits overseas. The European Union remains available to have bilateral exchanges to find an adequate solution.

2.210. The representative of <u>Canada</u> provided the following statement. Canada would like to thank China and the EU for raising this STC and support the points and issues they raised regarding this measure. Canada would further like to reiterate that, as we stated in previous TBT Committee Meetings, the objective of India's quality control orders across many sectors, including toys, remains fundamentally unclear. Canada notes that India continues to avoid addressing Canada's and other Members' issues and questions in its responsive statements in the recent TBT Committee meetings. Canada would once again ask that India provide a substantive response to Members and stakeholders questions and concerns.

2.211. In response, the representative of India provided the following statement. Bureau of Indian Standards (BIS) is carrying out physical inspections for applications received from foreign manufacturers, where the country to be visited is facilitating the visit of fully vaccinated BIS officers without the requirement of quarantine. Bureau of Indian Standards, under its Laboratory Recognition Scheme (BIS LRS), grants recognition to outside laboratories for testing of products as per the relevant Indian Standards. The Laboratory Recognition Scheme is governed by provision under section 13(4) of BIS Act, 2016 and Rule 32 of BIS Rules, 2018. These statutory provision confers upon BIS, powers to recognize any laboratory in India or outside India for carrying out testing of samples in relation to Conformity Assessment and such other functions as the Bureau may assign to it. Clause 12 of BIS LRS details the complete procedure of recognition of foreign laboratories. The decision regarding recognition of foreign laboratories will be taken by BIS taking into account the MRA (Mutual Recognition Agreement) with the concerned nation. BIS LRS is available on BIS website www.bis.gov.in under "laboratory services" tab. As on date, there is no pending application from any Outside Laboratory located outside India seeking recognition from BIS in compliance to the provisions of LRS. For EU - Six licences for toys have been granted to foreign manufacturers in the countries of EU. There are two applications pertaining to toys for which audits have been completed and are under process. For China - There are 161 applications from China for which inspections are pending. Audits to factories located in China could not be carried out due to reasons as intimated earlier.

2.1.4.19 India - Quality Control Orders for Chemical and Petrochemical Substances,			
<u>G/TBT/N/IND/116</u> ,	<u>Ġ/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/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> ,	<u>G/TBT/N/IND/175</u> ,
G/TBT/N/IND/176,	<u>G/TBT/N/IND/177</u> ,	<u>G/TBT/N/IND/186</u> ,	G/TBT/N/IND/187,
G/TBT/N/IND/191,	G/TBT/N/IND/193,	<u>G/TBT/N/IND/199</u> ,	G/TBT/N/IND/201,
G/TBT/N/IND/202,	G/TBT/N/IND/203,	<u>G/TBT/N/IND/204</u> ,	G/TBT/N/IND/205,
G/TBT/N/IND/206,	G/TBT/N/IND/208,	G/TBT/N/IND/215,	G/TBT/N/IND/219,
G/TBT/N/IND/220,	G/TBT/N/IND/221,	G/TBT/N/IND/223,	G/TBT/N/IND/224,
<u>G/TBT/W/774</u> (ID 630 ⁶⁸)			

2.212. The representative of the <u>United States</u> provided the following statement. In the last nine WTO TBT Committee meetings, the United States has raised concerns about India's enactment of mandatory quality control orders for chemical and petrochemical products. We understand that India has started notifying mandatory, India-specific quality-control standards for the 76 chemicals discussed during India's Department of Chemicals and Petrochemicals (DCPC) March 2023 consultation with several industry stakeholders. We refer to our previous intervention on the 76 chemicals and reiterate our request for clarification on the rationale behind mandating compliance to standards developed by the Bureau of Indian Standards (BIS) for these substances, as opposed to encouraging voluntary compliance, recognizing other international standards, or including reference to international standards in the BIS standards? Additionally. we understand that in September 2023, India provided another three-month extension of the Polyethylene Material for Molding and Extrusion (Quality Control) Order (Polyethylene QCO). The United States understands from industry that there are still delays in securing BIS inspection and certification for facilities under the Polyethylene QCO and that industry will not be able to comply with India's requirements until these mandatory facility inspections take place.

2.213. Further, we have received some reports that, despite having raised concerns about Polyethylene QCO's burdensome requirements, India may have issued additional new requirements for repacking units to obtain a BIS licence, thereby making it even more difficult for traders to comply. Can India please confirm and provide additional information about these new requirements, and notify the requirements to the WTO? We refer to our previous interventions on the Polyethylene QCO and ask that, if India is to continue to mandate foreign facility inspections, implementation of the quality control order be delayed until India is able to complete the required inspections. Lastly, we remain interested in the questions submitted in <u>G/TBT/W/774</u> in November 2022. When can Members expect a response from India to the questions contained in that document?

2.214. The representative of <u>Indonesia</u> provided the following statement. Indonesia shares the concerns expressed by the delegations of the United States of America, and Canada regarding India's Notifications <u>G/TBT/N/IND/220</u>, <u>G/TBT/N/IND/221</u>, <u>G/TBT/N/IND/223</u> and <u>G/TBT/N/IND/224</u> regarding the implementation of the (Quality Control) Order for Acid Oil, Coconut Fatty Acid, Lauric Acid, and Palm Fatty Acid. Indonesia noticed that the aforementioned QCO has come into force since 24 October 2022. While producers maximize their effort to comply to the QCO provisions, the large number of regulated products, the need of physical testing, and the factory inspection requirements at production sites, are remained to be Indonesia's concerned. Reflecting implementation of other QCOs where queues occurred and backlogs of product certification applications coming into the BIS, that slow down the certification process and hinder the export process. In this regard, Indonesia urges India to consider postponing the implementation of the QCO until adequate infrastructure for its implementation is ensured, thereby not creating trade barriers in the future. Indonesia is of that view that the option of international recognition for conformity assessment result and/or conformity assessment bodies (inspection bodies) from the country of origin not only speed up the audit and certification process, but also reduce the cost of certification. For that, Indonesia encourages India

 $^{^{68}}$ For previous statements follow the thread under ID <u>630</u>.

to accept conformity assessment results issued by foreign conformity assessment bodies (inspection bodies) under the MRA/MLA and accreditation framework.

2.215. The representative of <u>Canada</u> provided the following statement. Canada would like to thank the US and Indonesia for raising this STC as we similarly continue to have concerns over the approach taken by India to make mandatory the use of Indian Standards on the regulation of a series of chemical substances. Canada continues to remains of the view that the notification process followed by India to inform interested parties of its "Quality Control Orders" (QCO) is problematic, and that several systemic issues persist with respect to the QCO framework across many sectors. Most notifications from India with respect to QCO chemicals and petrochemical substances lack clarity and transparency with respect to substantive information and timelines for implementation. In Canada's view, the approach to such notifications, goes against the spirit of the transparency provisions in the TBT Agreement. Canada urges India to engage constructively in this Committee on issues raised by many Members on the QCO framework, including those contained in document <u>G/TBT/W/774</u> of November 2022, and to ensure that the implementation of the orders is conducted in a manner consistent with India's WTO TBT obligations.

2.216. In response, the representative of <u>India</u> provided the following statement. Chair, the process of standards development of Bureau of Indian Standards (BIS) is aligned with accepted international best practices that are based on the core principles of openness, transparency, impartiality and consensus. While formulating Indian standards, it is an integral part of the standard formulation process to analyse the relevance of the existing international standards (ISO, IEC or even other standards) for Indian situation in accordance with the Code of Good Practice of the WTO-TBT Agreement and as a policy. BIS always tries to align Indian Standards with International Standards where available and to the extent possible, keeping in consideration the specific climatic, environmental conditions and technological development in the country. Around 88% of Indian Standards, for which corresponding ISO and IEC standards are available, are harmonized with their ISO/IEC counterparts. Several extensions have been granted for the QCO orders on chemicals and petrochemicals based on the feedback received from stakeholders. These include QCOs on products like Ethylene Vinyl Acetate Copolymers, Polyethylene Material for Moulding and Extrusion, Polyester Continuous Filament Fully Drawn Yarn, Polyester Partially Oriented Yarn, Polyester Industrial Yarn, 100 Percent Polyester Spun Grey and White Yarn (PSY).

2.1.4.20 India – Draft Food Safety and Standards (Import) Amendment Regulation, 2020, <u>G/TBT/N/IND/180</u>, <u>G/TBT/N/IND/237</u> (ID 667⁶⁹)

2.217. The representative of the European Union provided the following statement. The European Union would like to thank India for the guidance provided so far on how facilities should be registered. However, the EU would still refer to its previous statements on this measure and reiterate some of the concerns raised at previous TBT Committee meetings. Even though no trade disruption has occurred until now, the EU remains concerned about the possible disruption to trade in the future associated to delays in listing registered facilities, given the absence of any specific criteria to define the risks associated to the listing or delisting of facilities, which may go beyond the India legislation, and given the fact that there are different authorities in India regulating imports of the same products, the EU would like to kindly ask India to: Provide written guidance on how to maintain the list of facilities updated; Provide details about the risk assessment India performed as a basis for the requirements about the registration of facilities; Clarify the modalities related to audits in the exporting countries, inspections of facilities, border checks and health certificates associated to the registration of foreign food manufacturing facilities, if and when these requirements will be made mandatory by the authorities of India; Consider a sufficiently long transition period before restricting imports based on the registration of facilities, and avoid that facilities that have not yet been registered in the India's Registration of Foreign Manufacturers (ReFoM online system) due to administrative errors, cannot export; Consider avoiding that the competent authorities of the export countries sign more than one certificate with regard to the same sanitary measure; and Notify to both the WTO TBT and SPS Committees the above-mentioned modalities and guidance, to ensure full transparency and timely follow-up by all the competent authorities, producers and exporters. The EU would like to repeat its request to India to notify these amendments and future measures related to the registration of food manufacturing facilities also to the WTO SPS Committee.

⁶⁹ For previous statements follow the thread under ID <u>667</u>.

2.218. The representative of the <u>United States</u> provided the following statement. The United States remains concerned with India's facility registration measures, notified to the WTO TBT Committee as G/TBT/N/IND/180 and G/TBT/N/IND/237. We note that, thus far, trade has continued uninterrupted for US products since this measure was implemented. However, we note that additional guidance is needed in writing as to how the measure will be implemented by India, including information regarding the treatment of shipments from unregistered facilities that enter ports in India, for exporters and exporting authorities to comply with the measure. For greater clarity, could India please provide a list of HS Codes for products subject to these facility registration requirements so that their scope is clearly understood by all parties? In addition, we would be interested to know how India's new registration system has led to any demonstrative change or improvement in food safety oversight. Furthermore, the United States remains concerned with India's draft measure, Food Safety and Standards (Import) Amendment Regulation, 2020 (G/TBT/N/IND/180). The draft measure 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 still concerned about the lack of information regarding the scope of this proposed technical regulation and are concerned about its consistency with the TBT Agreement. The United States hopes that India will provide any scientific and technical information that is used to determine the specific "risk" for food product categories; as well as information on audit processes. We look forward to receiving further information and clarification from India on these two concerning measures.

2.219. The representative of <u>Japan</u> provided the following statement. Japan would like to express its concerns regarding India's Order related to requirement to register foreign food manufacturing facilities. Although ten months have passed since Japan submitted lists of food manufacturing facilities in accordance with the Order on 10 October last year, India has not yet registered some of the facilities on the list. Japan would like to request India the following: Specify the HS codes for the designated food categories subject to the Order: milk and milk products; meat and meat products including poultry, fish and their products; egg powder; infant food; and nutraceuticals; Clarify the details on how to apply for the registration of foreign food manufacturing facilities; Clarify the procedures following our submission of Japan's answers to the food safety assessment questionnaire for the evaluation of regulatory food control systems over milk and milk products; Respond to the unanswered questions posed by Japan; and Notify the Order under the SPS Agreement as well because one of the objectives of India's Order is to protect human health or safety.

2.220. The representative of <u>Canada</u> provided the following statement. Canada would like to once again reiterate concerns 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, which has been implemented as of 1 February 2023. It remains unclear what criteria would be used to determine the level of risk for food products imported into India, and what circumstances would instigate an audit or an inspection of a foreign manufacturing facility. Canada remains concerned with the measure's 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 barriers to trade. Canada thanks FSSAI for its prompt registration of Canada's food manufacturing facilities and publication of list of establishments. However, a number of questions still remain regarding the requirements and we look forward to India's response to Canada's comments letter dated 12 January 2023. Canada continues to reiterate 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.

2.221. In response, the representative of <u>India</u> provided the following statement. FSSAI vide Order No. F. No. TIC/B02/2/2022- IMPORTS- FSSAI, dated 10 October 2022, notified that the registration of foreign food manufacturing facilities falling under Milk and Milk Products, Meat and Meat Products including Poultry, Fish, and their products, Egg powder, Nutraceuticals, Foods for Infant Nutrition and manufacturers desirous to export such article of food to India shall register with the Food Authority before exporting to India. The registration has been made mandatory from 1 February 2023. The competent authorities of the exporting countries have to provide the list of existing manufacturers and of those who are intending to export milk and milk products to India as per the notified format in the order to <u>import@fssai.gov.in</u>. Based on the list provided by the competent authority of exporting country, the registration of such facilities will be done by FSSAI on its ReFoM portal. The listing/registration of the Foreign facilities is available on FSSAI website.

So far the total of 3,012 facilities have been registered from 47 countries including USA, EU member States. Further, FSSAI is also flexible to do addition/deletion in the existing list, if requested by the member States. By listing /registration of facilities, FSSAI is creating a database, which may be used for devising Risk Management System for food import in the country. As per Food Safety and Standards (Import) Regulation, 2017, inspection of Foreign Food manufacturing facility is not mandatory for all facilities and may be done as deemed necessary. The trading partners will be informed, as and when, such requirements hold.

2.1.4.21 European Union - Draft EU Batteries Regulation (implementation of the European Green Deal), <u>G/TBT/N/EU/775</u> (ID 685⁷⁰)

2.222. The representative of the Republic of Korea provided the following statement. The Korean government appreciates the opportunity to deliver its comments related to 'Regulation (EU) 2023/1542 of the EU of 12 July 2023 concerning batteries and waste batteries. Korea would like to express our gratitude to the EU for reviewing Korea's comments made in the previous TBT Committee meetings and bilateral meetings in 2022 and 2023 and an official letter submitted last August. In particular, Korea wishes to thank the EU for its response to our August inquiry on 1 November, which provided some relief to the industry's concerns. However, there remain unresolved concerns within relevant Korean industries regarding Article 11 of the Battery Regulation, on the "removability and replaceability of portable batteries and LMT batteries". Korea would like to underscore the following requests. First, Korea requests that the EU provide appropriate exemptions and detailed guidelines regarding battery replacement tools and cycles for products without any specific replacement requirements, such as Wearable devices, Watches, etc. Second, paragraphs 6 and 8 of Article 11 set forth requirements that portable battery (or LMT battery) for appliance should be readily substituted by another compatible battery without performance degradation or impediment by software. Korea requests that the EU, at the very least, allow a simple warning (e.g. "The battery is not compatible with the device") to be displayed by the software, if the substitute battery does not meet the requirements originally designed by the appliance manufacturer.

2.223. The representative of <u>China</u> provided the following statement. Firstly, regarding the calculation method of carbon footprint: the regulation specifies the carbon footprint in Chapter 2, Section 7, Appendix II, and sets a maximum threshold for the full life cycle carbon footprint. However, it is currently difficult for the EU to conduct a fair and scientific assessment of the carbon footprint of batteries based on the data. China believes that conducting carbon footprint calculations for battery products should be based on a scientific and reasonable foundation. In addition, according to the principle of "shared but differentiated responsibilities" in the United Nations Framework Convention on Climate Change, if the EU sets a maximum threshold for carbon footprint, it will inevitably conflict with international rules. To facilitate the implementation of the "carbon footprint threshold", it is recommended that the EU publicly disclose the plan and progress of the development of carbon footprint calculation methods, and allow other members to participate in the discussion of the development of carbon footprint calculation methods. Given China's accumulated experience in carbon footprint calculation methods to make the relevant methods more scientific and effective.

2.224. Secondly, regarding supply chain due diligence: the regulation stipulates a supply chain due diligence plan in Chapter 7, Section 48. This investigation is authorized by the EU to conduct supply chain due diligence in other markets, which will involve issues of sovereignty and business secrets, inevitably posing security risks to trade. Regarding supply chain due diligence, China appreciates the European side's willingness to consider China's suggestions and evaluate the relevant provisions in the draft regulations one by one. China believes that maintaining communication and dialogue is an effective way to resolve differences. China is willing to maintain continuous communication with the EU on this issue and conduct discussions with relevant European experts to develop a more scientific and reasonable solution. Thirdly, regarding the issue of "separate registration is required for initial sales in member states": the regulation says in Chapter 8, Section 55, Paragraph 2 that "when manufacturers first sell batteries in different member states' markets, they should submit separate registration applications to each member state." Given that the current EU member states do not have unified requirements for manufacturer registration, separate registration will cause an unnecessary burden to enterprises. Regarding the issue of "separate registration is required for initial sales in member states", China appreciates the efforts to simplify the registration requirements

 $^{^{70}}$ For previous statements follow the thread under ID <u>685</u>.

within the EU. However, enterprises still report the phenomenon of duplicate registration in member states. China suggests that the European side establish a unified registration platform, which not only reduces the burden on enterprises but also facilitates regulation.

2.225. Fourthly, regarding the certification of battery recycling components: the regulation stipulates sustainability and safety requirements for battery carbon footprint and recycling components, but it doesn't specify whether cobalt, lead, lithium, or nickel must be obtained from the EU market or can be obtained from the place of origin. If it can be recovered from the origin, it is suggested that the EU explain the certification process of cobalt, lead, lithium, or nickel recovered from the origin in the EU. Fifthly, regarding the carbon footprint and algorithm of batteries: the Annex II Carbon Footprint specifies the use of the climate module in the EU Product Environmental Footprint (PEF) method to calculate the carbon footprint of battery products. However, ISO has released ISO14067:2018 Greenhouse gases - Product carbon footprint - Quantitative requirements and guidelines. According to Article 2.4 of the WTO TBT Agreement, "Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued". We hope the EU can explain the reason why ISO 14067 and other relevant international standards were not used as rules for calculating the carbon footprint of battery products. Lastly, regarding carbon labelling requirements: the regulation requires battery products to obtain carbon labels in order to enter the EU market. We know that the most fundamental method to achieve carbon neutrality is the adjustment of industrial structure and technological progress. In order to prevent and reduce "carbon leakage", it is suggested that the EU consider providing technical assistance to the main producing areas of imported batteries (such as China) in accordance with Article 11 of the TBT Agreement to reduce carbon emissions during the production process; At the same time, it is recommended that the EU maintain open communication channels with other Members regarding the carbon footprint certification system and conformity assessment system.

2.226. The representative of the <u>Russian Federation</u> provided the following statement. The Russian Federation would like to reiterate its statements made at the previous TBT Committee meetings with regard to the Regulation of the European Parliament and of the Council concerning batteries and waste batteries. Since June 2021, the EU delegation has been requested to provide clarification on specific scientific justification of proposed measure, relevant international standards which had been the basis for the regulation provisions, in particular, for the maximum level of carbon footprint over the lifecycle of batteries, minimum level of certain recycled materials, as well as additional restrictions on the use of cobalt, lithium and nickel. The EU was also requested to share information if less trade restrictive measures to stimulate recycling of nickel, lithium, cobalt, copper and lead were considered rather than such administrative measure as minimum level of recycled materials in the battery. None of the requests has been addressed.

2.227. In response, the representative of the European Union provided the following statement. The EU would like to thank China and Korea for their comments on the proposal for an EU Batteries Regulation. The proposal has recently been adopted as Regulation (EU) 2023/1542 in July 2023. The EU would like to reiterate that, on Article 11 on removability and replaceability of portable batteries and light means of transport batteries, preparatory work on the guidelines is still ongoing. The replaceability of such batteries is important for consumers, and derogations can only apply when this is required to ensure the safety of the user and the appliance. As for the timetable regarding the implementation on carbon footprint calculation methodology, the situation on batteries for electric vehicles is very advanced thanks to the work that was already carried out by stakeholders in the past. The Joint Research Centre of the European Commission has recently published their recommendations, which will serve as the basis for the further process on the delegated act, along with feedback of stakeholders. The EU intends to notify a draft to TBT in the coming months. The EU will also engage with stakeholders on other parts of the implementation of the Regulation, both for further legal implementation and for additional guidelines. Finally, the EU considers that the regulation is not more trade restrictive than necessary to fulfil its legitimate policy objectives, taking into account the risks that non-fulfilment would create.

2.1.4.22 European Union - Withdrawal of the approval of the active substance alphacypermethrin, <u>G/TBT/N/EU/770</u>, <u>G/TBT/N/EU/908</u> (ID 694⁷¹)

2.228. The representative of <u>Kenya</u> provided the following statement. Kenya reiterates her previous position on this STC where EU has proposed new regulations withdrawing the approval of the active substance alpha-cypermethrin. 1. Kenya raised this as a Specific Trade Concern in the previous TBT Committee meeting and continues to have concerns over the same issue. 2. Kenya takes note of the EU's response given in the June 2023 TBT Committee meeting and looks forward to the report of the review currently being conducted by European Food Safety Authority (EFSA)

2.229. The representative of Brazil provided the following statement. Brazil would like to express its concerns related to European notification G/TBT/N/EU/770 regarding the Commission Implementing Regulation proposal to withdraw the approval of the active substance alpha-cypermethrin. Alpha-cypermethrin is registered in Brazil as an insecticide 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. The substance is also essential to control greening, a disease affecting citrus orchards worldwide. May we recall that greening has been recognized by EFSA itself as a priority pest for control, according to the Commission Delegated Regulation (EU) 2019/1702. Withdrawal of the register of said substance and automatic reduction of MRLs will significantly affect the income of Brazilian farmers, especially citrus producers. The Brazilian citrus industry plays an important role in generating jobs in the countryside. 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 conclusion, firstly, Brazil would like to stress the urgency for the EU to adopt MRLs for imported products in accordance with the limits set under the Codex Alimentarius. Secondly, considering European countries still approve "emergency use" of the same substance, therefore discriminating against imported products, Brazil would reiterate its request that the EU renews the approval of the active substance, which expired on 31 October. In this sense, Brazil would appreciate receiving any update on EFSA's review of MRLs for the whole group of cypermethrins.

2.230. The representative of <u>Paraguay</u> provided the following statement. We extend our thanks to Kenya and Brazil for raising this trade concern. We request that Paraguay's support and statement from the March meeting of this Committee be put on record.

2.231. Statement from March 2023 meeting, in full.⁷² 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 the European Union to take into account, when reviewing the MRLs for this substance, information on pesticides provided by the specialized agencies recognized by the WTO, such as the Codex Alimentarius, to reconsider its approach and to base its decisions on conclusive scientific evidence and real risk weightings, in accordance with international standards and principles.

2.232. In response, the representative of the <u>European Union</u> provided the following statement. The EU thanks Members for raising this issue. In principle, the EU would like to refer to its previous statements at the TBT Committee, which we made on the issue of withdrawal of approval of this substance. Additionally, a review of the residue definitions for risk assessment of pyrethroids forming common metabolites has been conducted and published by the European Food Safety Authority (EFSA).⁷³ As regards Maximum Residue Levels (MRLs), the review of the whole group of cypermethrins (including alpha-cypermethrin) under Article 12 of Regulation (EC) No 396/2005 has been recently finalized and published by EFSA.⁷⁴ Existing Codex Maximum Residue Limits and Import Tolerances have been considered in this review, where EFSA performed a risk assessment to evaluate the safety of these levels. A first discussion on a possible draft Regulation amending MRLs for cypermethrin took place in the meeting of the Standing Committee on Plants, Animals, Food and

 $^{^{71}}$ For previous statements follow the thread under ID <u>694</u>.

⁷² G/TBT/M/89, paras. 2.488-2.489.

⁷³ EFSA, Review of the residue definitions for risk assessment of pyrethroids forming common metabolites, EFSA Journal 2023;21(5):8022,

https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.8022.

⁷⁴ EFSA, Review of the existing maximum residue levels for cypermethrins according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2023;21(3):7800, https://www.efsa.europa.eu/en/efsajournal/pub/7800.

Feed, section Phytopharmaceuticals – pesticides residues.⁷⁵ The draft Regulation will be notified to the <u>WTO/SPS</u> Committee in November 2023 allowing non-EU countries to comment on it before a final decision will be taken (expected for February 2024). If 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 [4] on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

2.1.4.23 Indonesia - Government Regulation 28 of 2021 – Implementing Regulation (for the Manufacturing/Industry Sector) to Law No. 11 of 2020 the "Job Creation Act", <u>G/TBT/N/IDN/152</u> (ID 724⁷⁶)

2.233. The representative of the European Union provided the following statement. The European Union continues to remain seriously concerned by Government Regulation No.28 of 2021 and the requirements for Indonesian National Standard (SNI) certification. This Regulation is one of the implementing regulations of the Omnibus Law on Job Creation (Law 11/2020). Government Regulation 28/2021 aims to increase the competitiveness of Indonesia's national industry and mainly outlines measures related to raw materials. It also introduces new requirements with regard to product certification bodies. The new requirements affect in principle all products subject to SNI certification, thus making export to Indonesia very complicated. Additionally, due to lack of available quidelines, the situation does not improve. Certain sectors are particularly concerned (e.g. toys, tyres and machinery). The European industry continues to report that various requirements of this measure continue to represent an unnecessary barrier to trade. The European Union would like to refer to its previous statements made during recent TBT Committee meetings and notes that the majority of the issues raised therein remains unanswered. The European Union invites Indonesia to respond to concerns we raised previously, and in particular to make sure that the conformity assessment bodies continue certification process for foreign products. The EU remains available to discuss this issue bilaterally.

2.234. The representative of the <u>United States</u> provided the following statement. The United States continues to have serious concerns with the Government of Indonesia Regulation No. 28 of 2021 (GR28/2021), which is the Implementing Regulation (for the Manufacturing/Industry Sector) to Law No. 11 of 2020 of the "Job Creation Act." We still have not received responses to many of our long-standing concerns. In its most recent statement at the June 2023 TBT Committee, Indonesia stated that it remains committed to complying with its transparency obligations under the WTO TBT Agreement. However, it failed to provide reasonable time for Members to comment on the implementing regulation, "Regulation of Minister of Industry No. 45 Year 2022 regarding Standardization of Industry" (G/TBT/N/IDN/152), which was notified in January 2023, despite being signed and entering into force in November 2022. Indonesia also has not explained what steps it took to take Members' comments into account, considering that the comment period was provided after the measure entered into force. Among other concerns raised, we continue to request a response from Indonesia providing a justification for requiring conformity assessment testing to be conducted by Indonesian civil servants residing in Indonesia, and how these requirements relate to the ability to perform conformity assessment. This, along with the other requirements of this measure, continue to raise concerns regarding Indonesia's compliance with its TBT Agreement commitments. We again refer Indonesia to our previous statements from November 2021; March, July, and November 2022; and March and June 2023. Without reiterating them, the United States requests that Indonesia provide a response that specifically addresses Members' concerns.

2.235. The representative of <u>China</u> provided the following statement. China appreciates Indonesia's response to this concern at meetings, but our manufacturers still face complicated procedures and cost burdens in obtaining SNI certification. China once again suggests that Indonesia could cancel the requirement that an auditor can only audit one factory at one time in B/1027/Indonesia BSKJI.4/IDN/assist/2021; and product certification should be conducted by Indonesian auditor in GR 28/2021. Meanwhile, it is recommended to provide the rationale for requiring the enterprise's

⁷⁵ https://food.ec.europa.eu/system/files/2023-10/sc_phyto_20230918_ppr_sum.pdf [4] 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.

 $^{^{76}}$ For previous statements follow the thread under ID $\underline{724}$.

own brand also possess an existing SNI certification, as specified in Article 34(3)C of Regulation of Minister of Industry No. 45 Year 2022 regarding Standardization of Industry.

2.236. The representative of <u>Canada</u> provided the following statement. Once again, Canada reiterates the following points from previous meetings of the Committee, specifically outlined in our statement at the July, 2022 TBT Committee in paragraphs 2.402-2.404 of <u>G/TBT/M/87</u>, and which we are again referring to today for the record. Canada thanks Indonesia for its response to Canada's comment letter dated 14 June 2023. In its response, Indonesia notes that the implementation of the conformity assessment procedure shall continue to be carried out in accordance with the previous regulations, until such regulations are amended. Can Indonesia provide a timeline of when the regulations will be amended? The response also highlights that all provisions regarding the standards and the conformity assessment scheme apply equally for both domestic and foreign manufacturers. However, the requirement that the conformity assessment body be located in Indonesia would provide a significant advantage to producers in Indonesia and be a significant barrier to trade for Canadian exporters. Can Indonesia provide its rationale for such a requirement? Canada would also like again to reiterate the following request to Indonesia: namely to provide a rationale as to why Indonesia notified Regulation No 45 in January 2023 when it entered into force in November 2022 as well as how Members and stakeholders' comments were taken into account

2.237. In response, the representative of Indonesia provided the following statement. Indonesia thanks to the European Union, the United States, China and Canada for their continued interest to Government Regulation 28 Year 2021. We would like inform that GR 28 of 2021 has been amended to GR No. 46 of 2023 that contains several changes in provision related to commodity balances, the ease of importation of Raw Materials and/or Auxiliary Materials for Industry, and Industrial Standardization. This regulation does not yet specifically regulate the SNI certification of specific products. According to Minister of Industry Regulation Number 45 of 2022 (G/TBT/N/IDN/152), Article 14-15, Indonesia is committed to fulfilling the transparency principle of the WTO TBT Agreement by notifying all relevant technical regulations regarding specific products mandatory standards certification. Indonesia emphasizes that currently there is no changes to the current regulations until specific regulations regarding certain products are issued. It means, the conformity assessment bodies can still carry out the SNI certification process normally according to the statutory provision. We suggest that if Members are facing obstacles during the SNI certification process, kindly send that information through Indonesia WTO TBT Enquiry Point to be reviewed by the relevant regulator. Prior to the enactment of GR 28 of 2021, Indonesia already had a policy for the conformity assessment bodies also operate their own testing laboratories for all products subject to SNI certification. The type 1 and type 5 scheme certification are commonly used for product certifications in accordance with international standards ISO 17067. Currently, Indonesia has 1,863 testing laboratories; 145 inspection bodies and 129 conformity assessment bodies accredited by National Accreditation Body (Komite Akreditasi Nasional) according to the ISO/IEC 17025, 17020, and 17065. This number is sufficient to carry out the mandatory SNI certification for all sectors. The appointment of conformity assessment bodies for the specific product should refer to Art. 16-17 Minister of Industry Regulation Number 45 of 2022. We accept test results from accredited foreign testing laboratories, under the framework of mutual recognition agreements and the availability of technical regulatory agreements between Indonesia and its partner countries. The mandatory application of standard and conformity assessment of product certification will be regulated through specific Minister of Industry's regulation.

2.1.4.24 European Union - Draft Commission Regulation amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products, <u>G/TBT/N/EU/908</u> (ID 763⁷⁷)

2.238. The representative of <u>Australia</u> provided the following statement. Australia reiterates our concerns about amendments to Regulation 396/2005 arising from Commission Regulation 2023/334 regarding maximum residue levels for clothianidin and thiamethoxam in or on certain products. The amendments consider environmental impacts in exporting countries when setting import MRLs and assessing requests for import tolerances. Australia recognises the right of WTO Members to regulate agricultural imports in a manner that protects animal, plant and human health and the environment. However, Members are also bound by WTO obligations, particularly in relation to undertaking science-based risk assessments and ensuring that measures are no more trade-restrictive than

⁷⁷ For previous statements follow the thread under ID $\frac{763}{100}$.

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necessary. Australia does not support using MRLs on imported products to achieve environmental outcomes outside the EU's borders. This extra-territorial approach impacts the ability of third countries to implement environmental policies consistent with their unique environmental circumstances. National authorities of third countries are best placed to ensure that pesticide application is undertaken in a responsible and sustainable manner in each country, and in accordance with their unique environment. Australia is concerned about the limitations of the 2018 European Food Safety Authority risk assessments cited by the EU in the draft regulation. These studies have been used to support a link between the lowering of MRLs to the limit of determination and pollinator health. We request the EU provides robust scientific evidence in support of this conclusion. Australia also requests the EU provide information on the health of pollinators in all trading countries where the new MRLs are likely to apply. The EU may wish to consider restricting the new MRLs to only those countries where is has robust evidence to support its policy objective. 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. This approach aligns with the principles set out in the recent statement by Cairns Group members on the contribution of the multilateral trading system to support sustainable and resilient agriculture and food systems (G/AG/GEN/222). The Statement highlights the crucial role of a resilient agriculture sector in feeding the growing population and a science-based and inclusive approach to collectively address environmental challenges. We look forward to continuing to engage with the EU on this important topic.

2.239. The representative of <u>Kenya</u> provided the following statement. Kenya reiterates her previous position on this Specific Trade Concern. 1. Kenya raised this as a Specific Trade Concern in the previous TBT Committee meetings and continues to have concerns over the same issue. 2. Kenya takes note of the EU's response given in the June 2023 TBT Committee meeting. Arising from this response, Kenya looks forward to further information that the EU may have, concerning this issue. 3. Kenya wishes to express concern on the fact that the measures have been adopted despite the concerns raised by Members.

2.240. The representative of Colombia provided the following statement. Colombia is aware of the importance of foods free from excess pesticide residues that comply with international safety recommendations. However, the ban on active substances such as mancozeb, clothianidin, thiamethoxam and chlorothalonil, and the subsequent non-renewal of the approval of these substances, are hitting our country's agricultural export sector hard. While our health authorities are going to great lengths with the productive sectors to explore alternatives to meet the requirements, the search for substances to replace those that have been banned or whose approval is being modified requires time and investment, especially when potential alternatives are also becoming scarcer owing to changes to phytosanitary regulations in the European Union. A typical example of this, but not the only one, is the limited availability of an alternative to mancozeb, on account of similar substances, such as chlorothalonil, being banned in the European market. In this context, it is vital that the non-renewal or modification of approval for active substances takes into account production processes and methods in countries that could be affected. Failing to do so would violate Article 2.2 of the TBT Agreement, which stipulates that technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective. Failing to do so also seems to violate Article 12.3 of the TBT Agreement, which states that account should be taken of the special financial and trade needs of developing countries, with a view to ensuring that regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports. In this regard, we agree with arguments presented in this Committee expressing the need for the European Union to bring maximum residue levels into line with the levels established within the framework of the Codex Alimentarius and to treat farmers in third countries no less favourably than it does European farmers. We therefore invite the European Union to seek out and support solutions that would allow our agricultural producers to continue meeting the European demand for food, to the benefit of not only developing countries but also the multilateral trading system, which has already been hit hard by this and other measures.

2.241. The representative of the <u>United States</u> provided the following statement. The United States remains concerned with the European Union's Commission Regulation 2023/334 regarding the reduction of maximum residue levels (MRLs) for clothianidin and thiamethoxam, notified to the TBT Committee as <u>G/TBT/N/EU/908</u> on 6 June 2022. The United States is concerned that this precedent-setting regulation lacks sufficient technical justification to fulfil its environmental objective, and undermines the expertise of national competent authorities and good agricultural practices worldwide. Given the critical importance of pesticides such as clothianidin and

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thiamethoxam for the production of crops that are exported to the EU from the United States and other WTO Members, we are concerned that the reduction of these MRLs to the limit of determination (LOD) poses a significant obstacle to trade. As the EU has previously recognized, global environmental challenges cannot be achieved by prescriptive, one-size-fits-all approaches that are narrowly tailored to the conditions in one country or region. The United States welcomes the EU to instead pursue a collaborative approach to protecting pollinators, using appropriate international venues to advance a shared understanding of this global challenge. The United States respectfully reminds the EU that environmental considerations are not included in the Codex Committee on Pesticide Residue (CCPR) assessment process for establishing MRLs, and are hopeful that the EU will move away from the attempt to use pesticide MRLs as an environmental safety management tool.

2.242. The United States urges the EU to refrain from using pesticide MRLs outside of their intended purpose, which is to allow regulators to monitor the lawful applications of pesticides and to ensure consumer food safety. We also remind the EU that the lack of predictability that results from the consideration of import tolerance requests on a "case-by-case" basis, as in the case of this regulation, unnecessarily increases uncertainty for farmers globally and limits farmers' ability to protect crops from pests and diseases. The United States recalls that the European Food Safety Authority's (EFSA) most recent review of clothianidin and thiamethoxam MRLs recommended MRLs that were safe for consumers. We respectfully ask the EU to share the scientific and technical information evaluated by EFSA that demonstrates how the reduction of these MRLs to the LOD for products produced outside of the EU protects pollinators, including bees. Given the lack of global consensus about the factors that negatively affect pollinator health, including the health of bees, and in the absence of scientific or technical information indicating how the reduction of MRLs to the LOD for products produced outside of the EU contributes to the objective of protection of pollinators, including bees, the United States requests that the EU refrain from additional attempts to achieve global environmental outcomes through pesticide MRLs and to restore prior MRLs for clothianidin and thiamethoxam.

2.243. The representative of Costa Rica provided the following statement. Costa Rica wishes once again to support this trade concern, which was originally raised by Kenya and relates to the EU's intention to establish maximum residue levels (MRLs) for clothianidin and thiamethoxam as mechanisms to fulfil environmental objectives. Costa Rica reiterates, as it has done at previous meetings of this Committee, that, broadly speaking, its national policy is aligned with the EU's objective of prioritizing environmental protection, the fight against climate change and sustainable economic development, as the only viable path to secure the future of our planet. However, under no circumstances must achieving these objectives come at the expense of multilateralism and the fundamental obligations that underpin this Organization. The TBT Agreement clearly sets out the objectives that technical regulations, standards and conformity assessment procedures may legitimately fulfil. From Costa Rica's perspective, it is unclear which legitimate objective might justify the revision of an MRL, which is a matter related to food security and the protection of human health and therefore falls within the scope of the SPS Agreement. In that connection, we are struggling to understand EU notification G/TBT/N/EU/908, due to the fact that, although this notification proposes reducing the MRLs for clothianidin and thiamethoxam, it was submitted to the TBT Committee and not to the SPS Committee. Costa Rica does not agree with the EU's claim that the above-mentioned notification is justified by a "global environmental concern". Among the legitimate objectives of the TBT Agreement, we cannot find global environmental concerns as justification for a measure covered by this Agreement. Addressing global environmental concerns is also a matter of the utmost importance for Costa Rica. However, it is unclear how this objective falls within the scope of the SPS and TBT Agreements. We thank the delegations that support this concern and endorse their statements. Lastly, we request and would welcome more detailed explanations from the EU regarding this concern.

2.244. The representative of <u>Indonesia</u> provided the following statement. Indonesia reiterate that the Draft Commission Regulation as regards maximum residue levels for clothianidin and thiamethoxam, notified under <u>G/TBT/N/EU/908</u> amending Regulation (EC) No. 396/2005, will have a serious impact on farmers in developing countries producing products exported to the European Union, as it will restrict farmers from using certain technologies useful for producing agricultural commodities economically, as has been raised at previous meetings. Indonesia also reminds that Maximum Residue Levels (MRLs) is an international trade standard related to food safety and consumer protection. The Imposition of MRLs for environmental protection deviates from the purpose of MRLs themselves. Every country, including Indonesia, has unique sustainable agriculture goals and challenges. In addition to climate challenges, agriculture in our country has high pest and

disease pressure due to the combination of heat, humidity, and plant-disturbing organism pressure from various pests, diseases, and plant weeds. To overcome these problems, various methods, tools, and technologies are needed so that agriculture can sustainably meet the world's growing food and feed needs. Therefore, in accordance with regulations implemented by the government, we continue to promote more sustainable and good agricultural practices and food systems by emphasizing the combination of the best methods and techniques to achieve adequate and more sustainable production. Therefore, regulatory decisions relating to pollinator protection should take into account the uniqueness of each country's ecology and agricultural landscape, and be assessed by each country's regulators based on a scientific approach.

2.245. Indonesia understands that this draft regulation does not require non-EU countries to ban the use of clothianidin and thiamethoxam in their own territories and the aim is that food and feed consumed in the EU does not contribute to the global decline of pollinators. However, lowering the MRL to the Limit of Quantification (LoQ) is an indirect measure to avoid the use of thiamethoxam and clothianidin by countries that have different agricultural practices to control pests resulting in different but safe residue levels. We believe that non-EU countries have their own regulatory frameworks that recognize the safety of these products in use. Indonesia has adopted Codex Alimentarius standards for setting MRLs through the Indonesian National Standard (SNI), and all other crops have MRLs currently set higher than 0.01 mg/kg, except for palm oil and cocoa products. However, any new levels applied will pose a risk to our export products, as even small exceedances that are perfectly safe for human consumption could lead to refusal of shipments to the EU or return and destruction. This will result in high cost for our producers and the uncertainty process will make it less attractive due to the higher risk of rejection. We would like to appreciate the data from the EU annual monitoring program for pesticide residues in 2019, all analyzed samples originating from Indonesia, had clothianidin or thiamethoxam levels lower than the LoQ, except for tea products. We highlight a very significant decrease in MRLs for tea products, from Codex Standards and EU Regulations, which are 400 times and 14 times lower for Thiamethoxam and Clothianidin, respectively. Referring to Codex, the MRLs for Thiamethoxam and Clothianidin are 20 mg/kg and 0.7 mg/kg, whereas under the EU Regulation, the MRL should be 0.05 mg/kg. This will be a significant obstacle for Indonesian tea farmers which could lead to loss of Indonesian tea exports to the EU. Indonesia hopes that the European Union can take this into consideration and refer to the MRLs in existing international standards as a reference for setting MRLs for clothianidin and thiamethoxam in or on certain products.

2.246. The representative of Paraguay provided the following statement. Paraguay reiterates its concern about the EU's claim to use the MRLs for clothianidin and thiamethoxam, not to protect European consumers, but as a means to regulate the use of neonicotinoids in production processes and methods in third countries. In the interest of time, I will limit myself to making only a few comments and repeating some of the unanswered questions. The restrictions on international trade imposed by this Regulation will make farmers in Paraguay and the region less competitive than farmers in Europe, who do not have to contend with the same pests and climatic conditions to produce food, and who can benefit from emergency authorizations to continue using these substances. In the interest of time, I shall simply provide a brief update on the main points made at the Committee's previous meeting and the unanswered questions. With respect to comments on the notification submitted in writing within the time limit by Paraguay and several other Members: Please could the EU clarify how the comments submitted by Members are taken into account? That is, how they are taken into account in this case, but also in general, as we asked with regard to STC ID 580 on international consultations. In particular, bearing in mind the short time that elapsed between the end of the comment period and the decision of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) of the EU, which approved the proposal to reduce the MRLs for these substances without amendments.

2.247. With respect to the erroneous reference to my country in the final version of Regulation 2023/334, while it required twice as much time as it took SCoPAFF to analyse the comments of a number of members, I welcome the publication of a corrigendum. To date, however, a revised version is still not available on the official EU website so when consulting the Regulation, the erroneous reference to Paraguay remains in footnote 19. With regard to emergency authorizations, we still have not received responses to the questions on how long it takes to approve an emergency authorization and what the average cost of the approval process for an emergency authorization is in order to understand how emergency authorizations are compatible with the non-discrimination obligation. The EU insists that this depends on the members that are also WTO Members in their own right, so I would like to direct the question to the Czech Republic or Romania, given that the

most recent emergency authorizations for these substances were issued by the Czech Republic; maybe they could provide this information. Likewise, with respect to the ruling of 19 January 2023 of the Court of Justice of the EU (CJEU), we have not received responses explaining how this ruling affects emergency authorizations in general and authorizations for these substances specifically, especially since we have identified at least five emergency authorizations that were valid for periods after the ruling and at least one emergency authorization for thiamethoxam that was granted after the judgement. This authorization was granted by the Czech Republic on 4 April 2023 for the period from 20 April to 16 July 2023. Although there have been no new emergency authorizations after this, this may be because of the times of year when the substances are required, and not because of the ruling itself, so the clarification is still required.

2.248. Concerning import tolerances, I would like to use the example of another substance, tricyclazole, which, despite the fact that the European Food Safety Authority (EFSA) considered that import tolerances and "the proposed MRLs (in this case for rice) are fully supported by data and safe for consumers". And yet a number of member States did not support the approval of the draft Regulation submitted by the Commission. The draft fell short of the majority required in SCoPAFF and in the Council, and is likely to be vetoed in the European Parliament, meaning that the obligation to base measures on scientific principles has not been met. If member States fail to vote in favour of import tolerances when MRLs are set with the objective of protecting human health, how can the Commission argue that requesting import tolerances is a feasible way forward for MRLs set with environmental objectives (for example, those covered by this Regulation)? With respect to the extraterritoriality of the measure, I do not think it is necessary to reiterate how this measure fails to recognize the ability of national authorities to establish regulatory frameworks based on sound science, which are applied to registration processes in order to assess the risks of pesticides and their uses, including the assessment of the risk to the environment and to pollinators. I will only ask the EU how this is consistent with its obligations under WTO rules and under its founding agreements. These and other questions were submitted to the EU as part of the corresponding trade concerns raised in the SPS Committee, in document G/SPS/GEN/2140. We look forward to receiving responses shortly.

2.249. The representative of Brazil provided the following statement. Once more, Brazil supports the STC raised by an impressive number of countries, which should speak for itself, regarding the proposition notified as G/TBT/N/EU/908, which resulted in the publication of Commission Regulation 2023/334, withdrawing approval of the active substances thiamethoxam and clothianidin and restricting the maximum residue levels in or on certain products. Reassessing the concerns expressed in June and the European Union's comments, Brazil would much appreciate further explanation on some topics that were not entirely clarified. The first topic regards extraterritorial effects. Even though the EU states "the Regulation (EC) No 2023/334 does not regulate the use of clothianidin and thiamethoxam by non-EU countries in their own territory", it also states that the new regulation "will become applicable from 7 March 2026, to provide enough time to operators in third countries, especially in least developed and developing countries, and food business operators, to prepare themselves to meet the new requirements". How does the EU explain such contradiction? The second topic regards taking into account different local circumstances. "About the risks that thiamethoxam and clothianidin may have on bees' population worldwide, Brazil understands that one could not expect to extend to all countries of the world trade-restrictive measures that do not consider the variety of local conditions, including climate and soil." The EU responded that it "acknowledges that non-EU countries may face production conditions and pest pressures different from those in Europe", but Brazil did not understand how such recognition was given regulatory effects and would appreciate further comments on this matter.

2.250. As previously stated, the Brazilian State of São Paulo is the main citrus juice producer and it is also where 84% of honey production is concentrated. In that state, there is no evidence of a decline in the number of pollinators. On the contrary, honey production in that region has increased by about 136% in 15 years (2008-2022, BR Citrus). The third topic, closely related to the previous one, refers to the lack of scientific basis. Brazil identifies the need for further discussion, under sound scientific basis and proper dialectic approach, about the risks that thiamethoxam and clothianidin may have on bees' population worldwide. To highlight how it is unclear for Brazil that the trade restrictions proposed by the EU would be justified, thiamethoxam is one important substance used in control strategies of pests such as the citrus psyllid, an insect that transmits the greening disease. The fourth and last topic refers to the lack of scientific basis. If the concept of MRL related to human health issues is well established by the Codex Alimentarius, a proper (or any) concept of MRL related to

environmental issues is not established either multilaterally or scientifically and occurs in disagreement with what is recommended in the risk analysis flowchart established in the Codex. Resuming the arguments presented in June, Brazil reiterates concern over the lack of scientific support and underlines that any unilateral extraterritorial measure is in breach of the TBT Agreement (Article 2.2). One could not expect to extend to all countries of the world trade-restrictive measures that do not consider the variety of local conditions, including climate and soil, the different needs and challenges and the different technical procedures for approving substances to use in agricultural production, which can vary deeply from country to country. In order to effectively protect the environment, a broad study would be required, followed by inclusive discussions, in the WTO and/or multilateral fora, which led to individualized diagnosis and national commitments.

2.251. The representative of Japan provided the following statement. Japan reiterates its concerns about the EU's regulation, which lowers the Maximum Residue Levels ("MRLs") of clothianidin and thiamethoxam in or on certain products, without due consideration for the concerns expressed repeatedly by Japan and other Members at previous TBT Committee meetings. Japan once again wishes to emphasize that we do not support using MRLs to achieve environmental purposes. The measures adopted by the EU, which lower the MRLs of the two active substances for purposes of protecting pollinators outside the EU, clearly deviate from current principles concerning the setting of MRLs, which aim to protect human life or health, and from efforts toward international harmonization of MRLs. Although the EU insists that the measure is not linked directly to the health of citizens, Japan believes that when taking a new approach to measures that affect third countries, such as MRLs, it should be discussed thoroughly with the relevant third countries at relevant international fora, including the SPS Committee. Japan also is concerned about the regulation's extra-territorial approach. By uniformly applying the MRLs to products from other countries based on the EU's own risk assessment concerning bees, the EU is not respecting the regulatory decisions made by each individual country, based on each country's own scientific evidence and deep understanding of its own environmental conditions and local agricultural practices.

2.252. The EU should not make judgments about the appropriateness of the use of specific pesticides, under specific conditions, in other countries, through the application of EU measures. Last, but not least, the EU has yet to respond to Japan's questions regarding the unclear requirements for setting and applying import tolerances. Paragraph 20 of the preamble to the regulation indicates that import tolerances may be set if the applicant provides scientific evidence that the use of these two active substances does not adversely impact pollinators. However, the EU has not made clear what kind of evidence will be required in the application process, or the criteria by which an unacceptable risk to pollinators will be measured, especially for outdoor uses of these substances. Given that this lack of clarity further increases the trade restrictive effect of the measure, Japan once again requests that the EU provide a clear explanation of these issues.

2.253. The representative of <u>India</u> provided the following statement. India reiterates its concerns regarding lowering of existing MRLs for clothianidin and thiamethoxam by EU. During the last meeting, in its reply, the EU acknowledges that non-EU countries may face production conditions and pest pressures different from those in Europe. However, EU has not granted exemption to those countries where the use of clothianidin and thiamethoxam cannot be avoided due to (a) different soil and other production conditions and including pest pressures and environmental conditions; and (b) non-availability of efficacious alternative pest control products. A blanket universal prohibition without taking into account the differences in the conditions prevailing in different countries is highly inappropriate. India requests EU to develop a methodology whereby difference in the conditions of the production and pest pressures are taken into account and appropriate derogations are granted.

2.254. The representative of <u>Canada</u> provided the following statement. Canada supports Members' concerns raised here today and at previous meetings. Canada reiterates its concerns that the EU has integrated their environmental objectives into their import tolerance setting process. This will have negative and unnecessary impacts on trade. This approach is unnecessarily trade restrictive and does not take into consideration unique circumstances (e.g., climate and growing conditions) and risk management measures of exporting countries. As previously shared with the EU, Canada has put in place effective mitigation measures that resulted in reduced bee mortality. We would be happy to share our data and experience with the EU to ensure MRL and import tolerance decisions are based on science and data. If a pesticide does not cause dietary risk, there is no evidence of health risks to EU consumers. To that end, if EFSA cannot conclude a risk assessment due to data gaps, the EU should maintain the MRLs or harmonize with Codex MRLs. By reducing neonicotinoid MRLs to default values when no dietary risks of concern have been identified, Canada is of the

opinion that the European Union is unjustifiably applying their domestic legislative requirements extraterritorially, and we hope this will not become a pattern that continues.

2.255. The representative of Argentina provided the following statement. Argentina reiterates its concern about the consistency of this measure with WTO rules. We consider that the measure is inappropriate and disproportionate and that the EU's decision is an extraterritorial application of law because it clearly has an impact on third party decisions and a totally negative effect on trade, as either the European market is lost for certain products that are exported or the use of these pesticides must be stopped in the territory of the exporting countries, even if their use is required on account of climate and production conditions, etc., and bees are not affected by them. We understand that if the EU did not intend to achieve an application of its measure outside the EU, it should have examined other less restrictive measures. We reiterate that the EU has established an MRL at the level of detection to protect bees, when MRLs are actually adopted to ensure food safety, not to protect the environment. The Codex Alimentarius recently adopted new MRLs for neonicotinoids, demonstrating that they are safe for consumers. Argentina considers that the measure adopted by the EU to establish limit of quantification values for these neonicotinoids is not clearly justified and constitutes a disguised restriction on international trade within the meaning of Article 2.2 of the TBT Agreement because it is disproportionate to the objective that it claims to protect and unduly restricts trade as it prevents the marketing of any product that has been treated with these neonicotinoids that may exceed the limit of quantification, even though the EU cannot demonstrate that MRLs at the level established by the Codex may affect the health of consumers, which ultimately is the intended purpose of an MRL.

2.256. The representative of <u>Chile</u> provided the following statement. The delegation of Chile echoes the views expressed by Australia, Kenya, the United States, Colombia, Costa Rica, Indonesia, Paraguay and the other delegations supporting this STC. Using MRLs for clothianidin and thiamethoxam, as a means to regulate the use of neonicotinoids in production processes and methods in third countries for environmental reasons, would constitute an unjustified restriction on trade, since MRLs are not an appropriate or effective instrument for achieving environmental outcomes. We kindly request the EU to reconsider this Regulation, as it constitutes an inappropriate measure on the EU's part to pressure other WTO Members, with the aim of imposing a one-size-fits-all approach to environmental issues, without taking into account the particular regional conditions of producer countries or the negative consequences the Regulation has on the availability of effective phytosanitary products used to tackle pests affecting agricultural crops.

2.257. The representative of Uruguay provided the following statement. Uruguay would like to thank the delegations of the United States, Indonesia, Australia, Colombia, Costa Rica, Paraguay and Kenya for keeping this specific trade concern on the agenda. Uruguay regrets the approval of Regulation 2023/334, amending the MRLs for clothianidin and thiamethoxam, despite the substantive comments and concerns submitted in all relevant bilateral and multilateral forums by many trading partners, representing different geographical and productive conditions and different levels of development. In this regard, we echo the doubts just expressed by the delegation of Paraguay on the extent to which the EU effectively takes into account the comments submitted by its trading partners in the consultation processes and in other relevant forums. Setting pesticide MRLs is a tool designed to protect consumer health from ingestion risks and, therefore, it naturally falls within the scope of the SPS Agreement. The international reference body for such issues is the Codex Alimentarius Commission, in which health-related issues are comprehensively addressed in relation to the adoption of MRLs, without currently examining, in the relevant risk analyses, aspects related to the environment. Without prejudice to other standards within the vast and complex European regulatory framework, Article 3(d) of Regulation (EC) No. 396/2005, the main and specific rule on MRLs for pesticides in food and feed, defines MRLs as: "the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers". In this legal provision, there would seem to be a convergence with the view expressed by Uruguay and an overwhelming majority of WTO Members on the nature of MRLs, which is in line with the assertion repeated by the EU itself - at least until March 2022 - that, as a matter of principle, concerns regarding the setting of MRLs for pesticides and any specific issue related to their application are matters to be discussed in the SPS Committee, and not the TBT Committee.

2.258. Uruguay still has serious doubts as to both the relevance and the legal basis, in EU regulations and WTO standards, of reducing MRLs to the level of detection on the grounds of "environmental issues of global concern" or other issues unrelated to human health. While we are

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aware of the importance of environmental aspects, we understand that these are not included in the process of establishing MRLs, as they are and must be addressed by countries individually in their territory using appropriate tools, on the basis of their own productive and regulatory systems, environmental conditions and policies. In this regard, we wish to point out that, in Uruguay, plant protection products affected by this Regulation are already regulated by the competent national authority to ensure correct, safe and recommended usage, as part of a National Environment Plan focused on good agricultural practices. Uruguay thus shares the concern about promoting the protection of pollinators, in line with environmental and biodiversity protection, and supports the establishment of regulatory environments based on scientific criteria, so as to avoid putting food security at risk or erecting barriers to trade. In this regard, Uruguay reiterates its willingness to cooperate with other Members, including the EU, to find mechanisms that can be used to achieve these objectives without unnecessarily restricting trade, while also ensuring environmental conservation and protecting human, animal and plant health. Lastly, like other delegations, we are concerned that emergency authorizations for the use of these substances continue to be granted to producers from EU member States, which would appear to contradict the EU's stated aim when it introduced this measure, as well as being discriminatory in nature. In this connection, we would like to have an update from the EU on how emergency authorizations for the use of these substances, and possibly others that might be subject to restrictions at the Community level, would be affected by the judgment of 19 January 2023 of the Court of Justice of the European Union (CJEU), which considers such authorizations to be illegal in certain cases. In this regard, we note with interest the cases referred to by the delegation of Paraguay, and we look forward to the EU's comments on the matter.

2.259. The representative of <u>Guatemala</u> provided the following statement. Guatemala reiterates its trade concern in this regard, since despite having shared its concern about this subject at several meetings, none of the concerns Guatemala presented were resolved, nor were its ideas heard. The EU is implementing this measure to regulate the use of neonicotinoids in production in third countries, which is an extraterritorial approach that fails to recognize the efforts made by countries in the area of pollination and the differences among trading partners like Guatemala, which are not on the European continent and face challenges that are typical in tropical countries. I think it is clear that there is concern regarding this measure, which I will not repeat because I associate myself with the statements made by previous Members, in particular as regards the consequent change to MRLs. Argentina clearly explained the impact of this measure on the EU's trading partners, and we support that view. I will be brief: I would like to ask the European Union to explain how it plans to resolve this concern. We need a solution other than import tolerances, which, as Paraguay stated, is not a real solution. In light of this, we would appreciate it if the EU could make clear its solution to Members' concern regarding this measure.

2.260. In response, the representative of the European Union provided the following statement. The EU would like to thank the intervening Members for raising this topic. 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 March and June 2023. The Commission Regulation (EU) 2023/334 was adopted and published⁷⁸ on 2 February 2023. It will become applicable from 7 March 2026, to provide enough time to operators in third countries, especially in least developed and developing countries, and food business operators, to prepare themselves to meet the new requirements. The EU acknowledges that non-EU countries may face production conditions and pest pressures different from those in Europe. The EU would like to reiterate that the Commission Regulation (EC) No 2023/334 does not regulate the use of clothianidin and thiamethoxam by non-EU countries in their own territory. The EU's actions related to neonicotinoids used as pesticides, such as this Regulation, are coordinated with other EU programmes and international activities such as: - The EU pollinators initiative which integrates holistic actions on pollinators across different sectorial policies, addressing the main known causes for pollinator decline and strengthening the collaboration between all the actors concerned. - The active EU collaborations with the Food and Agriculture Organization of the United Nations in its "Global Action on Pollination Services for Sustainable Agriculture" and with the International Union for Conservation of Nature in projects to address the decline of pollinators.

⁷⁸ COMMISSION REGULATION (EU) 2023/334 of 2 February 2023 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products. OJ L 47, 15.2.2023, p. 29–45.

2.261. Moreover, promoting the generation and implementation of more sustainable alternatives to chemical pesticides is a key element for a global transition towards more sustainable food systems. The EU is funding several research projects, under the Horizon Europe programme, dedicated to find alternatives to chemical pesticides and combinations of tools and technologies for integrated pest management, including several innovative low-risk products. In addition, the EU finances several programmes to assist third countries to comply with EU legislation and to build capacity and knowledge, such as the new Agrinfo programme (managed by COLEAD- the Committee Linking Entrepreneurship Agriculture and Development), further the existing Fit for Market and Plantwise Plus programmes to name only a few examples. The EU also organizes specific training courses related to plant health, integrated pest management and food safety in relation to pesticide residues. The EU would like to thank again intervening Members for their interest in the subject and is ready to continue the dialogue on the implementation of the Regulation in question.

2.262. The representative of <u>Paraguay</u> provided the following statement. Could the European Union highlight any new developments or new information presented with respect to this trade concern as the statement is identical to that of the June meeting.

2.263. The representative of the <u>European Union</u> provided the following statement. We take the comments into account and we will look at a further update for the next Committee.

2.1.4.25 European Union - Draft Commission Regulation laying down ecodesign requirements for mobile phones, cordless phones and slate tablets pursuant to Directive 2009/125/EC of the European Parliament and of the Council, <u>G/TBT/N/EU/918</u> (ID 768⁷⁹)

2.264. The representative of the <u>Republic of Korea</u> provided the following statement. The Korean government appreciates the opportunity to deliver its comments on the European Union's "Commission Regulation (EU) 2023/1670 laying down ecodesign requirements for smartphones, mobile phones other than smartphones, cordless phones and slate tablets pursuant to Directive 2009/125/EC of the European Parliament and of the Council." Korea would like to express our gratitude to the EU for reviewing Korea's comments made in the previous TBT Committee meeting in June and an official letter submitted in August. However, some industry concerns remain unresolved, and Korea requests that the EU reconsider these outstanding issues and address the industry concerns. First, for foldable devices, Korea requests that the EU allow "foldable-related spare parts" (i.e. the Hinge assembly, the Mechanical display folding mechanism and the Battery(-ies)) to be supplied as combined with the Display Assembly. If the device passes the folding-unfolding durability test of over 150,000 cycles, meets the IP47 rating, and its battery demonstrates at least 83% of the rated capacity after 500 full charge-discharge cycles, supplying related spare parts in conjunction with a higher-level assembly will better ensure the durability and reliability of the folding feature.

2.265. Second, for foldable devices, Korea requests that the dust tight rating requirement be scaled down to IP47. Due to the inevitable slits for movability, the dust tight rating achievable by current commercialized foldable devices is IP4x. Third, for functionality updates of Operating Systems (OS), it is requested that either the mandatory provision period be shortened to 3 years, or the commencing point of the mandatory period be changed to the market release date. Excessive requirements on the OS update period may delay the introduction of new innovative technologies or cause unnecessary price increases of the physical device, limiting consumers' right to choose from a wide range of the latest products and services.

2.266. The representative of <u>China</u> provided the following statement. 1. For (EU) 2023/1670 Annex II B/D 1.1 (5) (a), it requires that the process for replacement of display assembly shall, as a minimum, be able to be carried out by a generalist, while 1.1 (5) (b) requires 1 (c) the spare parts except for the battery needs to be replaced by layman, and the list of spare parts in 1 (c) contains the display assembly again. The two requirements are contradictory. We recommend that the EU further clarify the requirements and, in view of the professionalism of the replacement display assembly, we recommend following the 1.1 (5) (a) requirements. 2. For (EU) 2023/1670 Annex II B/D 1.1 (6), "accessible" is not defined in the draft, which is easy to misunderstand. Manufacturers have doubts about which form of representation can be identified as "accessible". To facilitate enterprise compliance, please further clarify. 3. Regarding (EU)2023/1670Annex II B 1.2 (6)(a) and

 $^{^{79}}$ For previous statements follow the thread under ID <u>768</u>.

G/TBT/M/91

Annex II D 1.2 (5)(a), it requires that from the date of end of placement on the market to at least 5 years after that date, manufacturers, importers or authorized representatives shall, if they provide security updates, corrective updates or functionality updates to an operating system, make such updates available at no cost. This clause poses challenges in terms of enforcement. (1) It is recommended that the EU further clarify whether the upgrade of the Android major version also satisfies the aforementioned requirements? (2) The implementation of the system update service relies on technical support from the operating system and chipset platform, so it is recommended that the EU consider constraints not only on manufacturers but also on operating systems and chip suppliers.

2.267. 4. Regarding (EU)2023/1670 Annex II/D 1.1 (1), the availability period of spare parts has been extended from 5 years (in draft regulation) to 7 years now. It is recommended that the EU could reassess the input-output benefits and consider shortening this period. Extending the availability period of spare parts to improve maintainability can be helpful, but it puts a great burden on enterprises as manufacturers need to establish production lines of spare parts or store a large number of them with continuous updates and iterations. It would also lead to electronic waste when spare parts fail. Therefore, it is recommended that the EU could evaluate the input-output benefits and consider shortening the availability period of spare parts. 5. The detachable requirements of battery in regulation (EU)2023/1670 are inconsistent with regulation (EU)2023/1542. It is recommended to clarify. (1) Article 11 of Regulation (EU)2023/1542 states that all portable batteries should be removable and detachable by the end user during their life cycle, without any exemptions. According to the definition of portable batteries, batteries of mobile phones and tablets are considered portable batteries. With regard to regulation (EU)2023/1670, it states that manufacturers, importers, or authorized representatives may provide the battery or batteries only to professional repairers if the battery endurance in cycles achieves a minimum of 1,000 full charge cycles, and the device meets IP67 rating. (2) The availability period of battery spare parts for portable products is within 5 years after the date of end of placement on the market; whereas, in regulation (EU)2023/1670, the requirement for the availability period is 7 years.

2.268. 6. For Annex II B/D 1.3, it requires plastic components shall be marked by the appropriate standard symbols or abbreviated terms set. It is recommended that the EU could provide recommended standards for symbols with reference to (EU)2019/2021, facilitating the implementation of the industry. 7. Regarding paragraph 3 of (EU)2023/1669 ANNEX IX, it is recommended that the battery endurance in cycles for compliance verification be independent of the operating system version. Due to the lengthy battery endurance in cycles and constraints in the product development timeline, batteries are typically conducted separately by testing methods referred to in Annex Iva of 2023/1669, rather than through comprehensive system-level testing based on operating systems. It is advisable to maintain consistency in market supervision verification procedures.

2.269. In response, the representative of the <u>European Union</u> provided the following statement. The EU would like to thank the Delegations of the Republic of Korea and China for their continued comments on the draft Ecodesign measures for mobile phones, cordless phones and slate tablets pursuant to Directive 2009/125/EC of the European Parliament and of the Council. The additional comments received are detailed and require technical interpretation, which could not be ensured in the context of this plenary meeting. The EU could therefore provide more information in bilateral discussion. Further, the EU would like to reassure China and Korea that a written reply to these comments is currently being finalised and will soon be sent to your TBT enquiry points. The Ecodesign Regulation on mobile phones and tablets⁸⁰ and Energy Labelling Regulation on smartphones and tablets⁸¹ were published on the Official Journal of the European Union on 31 August 2023. A dialogue with manufacturers to provide clarifications on the Regulation was set up. A first informal meeting was held with manufacturers on 11 October 2023 and Korean and Chinese companies participated as well. Any other Chinese or Korean company, which may be interested in this exchange is welcome to join this discussion.

⁸⁰ https://eur-lex.europa.eu/eli/reg/2023/1670/oj

⁸¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32023R1669

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2.1.4.26 European Union - Proposal for a Regulation on packaging and packaging waste amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC, <u>G/TBT/N/EU/953</u> (ID 786⁸²)

2.270. The representative of Mexico provided the following statement. The delegation of Mexico refers to the Proposal for a Regulation of the European Parliament and of the Council on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC, which was notified by the EU to members of this Committee in document G/TBT/N/EU/953. While the Government of Mexico agrees that promoting sustainable practices is important, it must be expected that technical regulations will affect foreign industries. In this regard, the delegation of Mexico would like to voice the following concerns and requests. Taking into consideration that bottling in Mexican territory is a necessary requirement in the production of 100% agave tequila, the Regulation could constitute a barrier to the marketing of Mexican beverages. Moreover, it is important to highlight that packaging differences are key to preventing counterfeiting. This becomes complicated when marketing aspects are disregarded and when the packaging performance criteria fail to recognize differences in design or presentation. Accordingly, we request that all products protected by geographical indications and appellations of origin, including tequila, be exempt from compliance with the packaging performance criteria set out in Annex IV to the Regulation. Lastly, the delegation of Mexico refers to the amendment related to the "additional sustainability requirements", which could lead to greater fragmentation of the European market, creating additional costs for foreign exporting producers. The delegation of Mexico thanks the delegation of the European Union for giving its consideration to this statement.

2.271. The representative of <u>China</u> provided the following statement. 1. Regarding the requirements for labelling of packaging, it is recommended to unify the current labelling system at the EU level, coordinating all existing requirements of member States. The European Union, as a single market, faces challenges arising from divergent requirements among member States, resulting in inconsistent compliance and impeding the free movement of goods while burdening operators. In light of this legislation's objective to establish harmonized regulations at the EU level, it is recommended to coordinate the current labelling system and stipulate member states' uniform adherence to Article 11. Furthermore, it is suggested that material composition information and recycled content could be displayed through digital identification such as QR codes. 2. Regarding Article 9, it is recommended to revise the assessment of packaging minimization by excluding the fillings as empty spaces and introducing an exemption clause for packaging protected by trademarks and IPR protection. The fillings are used to provide more reliable protection for the product. If they are minimized as empty space, the manufacturer will lack effective ways to ensure safe transportation of the goods, which may result in accidental damage. Meanwhile, the regulation stipulates an exemption for packaging that should display a geographical indication of origin. It is suggested to exempt packaging that is safeguarded by trademarks and IPR protection. 3. With regard to the definition of transport packaging, it is recommended to further clarify the definition of terms and provide guidance including specific examples. 4. Regarding requirements for recycled content of plastic packaging, it is suggested to simplify the calculation method of recycled content(e.g., by establishing a minimum recycling content requirement based on the average value of packaging placed in the EU market by manufacturers within a specific period). It is also advisable not to impose recycled plastic content requirements on electronic and electrical products, particularly those directly in contact with the product. The current mainstream technology does not support the design of plastic packaging that can utilize recycled materials, and the performance and appearance of recycled plastic packaging fail to meet the requirements. Additionally, electronic and electrical products often contain numerous sensitive devices. Due to the complex source, recycled plastics may introduce various ions, which can result in ion pollution of electronic components and ultimately functional failure.

2.272. 5. Article 21 stipulates that the empty space ratio for grouped packaging and transport packaging (including e-commerce packaging) should not exceed 40%. It is recommended to eliminate the aforementioned requirements on empty space ratio. The empty space ratio of transportation packaging and e-commerce packaging cannot be below 40%. In the case of purchasing multiple products at once for e-commerce or express packaging, the variety of products and the limited size of general packaging often result in a high empty space ratio. The final quantity of boxes also poses a challenge in meeting the empty space ratio, therefore it is advisable to avoid imposing mandatory demands. 6. Chapter 4, Article 26/1 specifies reusable and repeatable filling

⁸² For previous statements follow the thread under ID <u>786</u>.

targets: By 2030, reusable packaging should be used for shipping 90% of large appliances. It is not recommended to set the reusable index for the packaging of electronic and electrical products. The majority of electronic and electrical products in EU rely on imports. Considering the climate and environmental impact throughout their life cycle, it is not necessarily optimal for the environment to prioritize packaging reuse. 7. For Annex VII, it is recommended to delete the conceptual design and drawing requirements for providing components, sub-components, circuits, etc. The regulation should regulate the conformity assessment of the packaging, however, the components, circuit diagrams and other documents are generally provided for the conformity assessment of the electronic and electrical equipment.

2.273. The representative of the <u>Russian Federation</u> provided the following statement. The Russian Federation refers to its statement at previous TBT Committee meeting with regard to the EU Proposal for a Regulation on packaging and packaging waste. Over the past Committee meetings we raised certain questions in respect of the EU proposal, such as the inconsistency of the proposed requirements with international standards, the absence of approved at the international level test methods confirming the safety of the use of recycled materials, as well as the absence of scientific evidence for the proposed requirements. All these questions remain valid. In this context, the Russian Federation once again underlines that the proposed Regulation seems to be inconsistent with WTO rules and may create significant uncertainty in the EU market, as well as unnecessary obstacles to international trade. We urge the EU to revise draft Regulation on packaging and packaging waste and bring it into compliance with WTO rules.

2.274. The representative of <u>India</u> provided the following statement. India took note of EU's response in the last TBT meeting that EU will provide reply to Members' concerns on how it is planning to address the gaps in legislative framework and implementation process. While India appreciates EU's thoughts towards addressing environmental concerns, however, India also believes that any proposal in this regard should take into account the complexity of business sectors in question and appropriate packaging solutions. In this regard, India awaits EU to share the relevant international standard which has been used as a basis for the proposed regulation. India also requests EU to share its analysis on which the discretionary space of the economic operators has been taken into account.

2.275. The representative of Guatemala provided the following statement. With regard to this trade concern, there are certain elements that we believe should be analysed further and in greater detail. Guatemala would therefore be grateful if this matter could be addressed and the definitions contained in the draft Regulation carefully assessed. For example, Articles 30, 31, 32, 33 and 34 establish the guidelines for the conformity assessment of packaging. However, they do not specify which authority is competent to carry out the assessment and provide authorization. It would appear that there is uncertainty regarding the criteria for this assessment, which leaves open the possibility of having multiple criteria. In addition, Article 13.5 indicates that packaging must bear an identification number, such as a batch number. However, in the case of reusable packaging, on which the batch number is printed by laser, the previous batch number cannot be erased, which will lead to problems with new products and may cause confusion when tracing them. We therefore ask for account to be taken of these aspects and characteristics of reusable packaging on which the batch number has been printed by laser. Article 11 mentions the requirement for a label, but it is unclear to us whether it is referring to an additional label supplementing the one carried by the product, such as when a product already placed on the market has a QR code. We also ask whether the same QR code can be used to provide information on the packaging materials. We would appreciate clarification from the EU regarding our concerns, with a view to advancing trade and ensuring that it is also beneficial for trading partners. We would appreciate clarification in this regard.

2.276. In response, the representative of the <u>European Union</u> provided the following statement. The EU thanks Members for their interest in the proposal for a Regulation on packaging and packaging waste amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC. The EU notified the proposed Regulation under the TBT Agreement on 27 February 2023. The EU received comments on this proposal from several Members, including from China, Japan, the US, the UK and Canada. We thank Members for their interest and constructive comments, to which we have recently replied. We believe that these replies will provide Members with sufficient information, regarding their concerns. It is currently to early to predict the exact date of adoption of this proposal. The EU internal procedures are in motion to reach an agreement in 2024 before the end of the current legislature mandate. The final act, once adopted, will be notified to the TBT Committee.

2.1.4.27 India - Viscose Staple Fibres (Quality Control) Order, 2022, <u>G/TBT/N/IND/234</u> (ID 790⁸³)

2.277. The representative of the <u>European Union</u> provided the following statement. The policy of adopting Quality Control Orders (QCOs) across sectors continues to send worrying signals to EU industry, EU investors and EU member States, as majority of the QCOs introduced by India appear to have protectionist orientation and raise questions in relation to their compliance with the WTO's TBT Agreement obligations. The EU remains deeply concerned by the fact that QCOs usually prescribe India specific standards, where international standards already exist. Furthermore, they make mandatory conformity assessment procedures that are more stringent and restrictive than necessary to fulfil their legitimate objective. The EU welcomes detailed information provided by India in its statement at the previous TBT Committee meeting, however, significant issues faced by EU exporters remain and cause significant problems in accessing the Indian market. The EU would like to recall its request to India to explain the reasons for establishing India-specific QCO for Viscose Staple Fibres when EU exports already comply with internationally recognised standards like ISO. The Viscose Staple Fibres QCO, is based on a registration process with the Bureau of Indian Standards (BIS). Manufacturing facilities in the exporting country must be audited in person by a team of BIS officials.

2.278. The EU is deeply concerned not only about the significant cost of such registration, but also by the requirement to disclose commercially sensitive information regarding pricing and production, as well as a requirement to make a USD 10.000 bank guarantee in favour of BIS, which is held as a "quality performance guarantee". The proposed measures for Viscose Staple Fibres 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, testing and certification. The certification process is costly, burdensome and includes requirements to submit commercially sensitive information. The products covered by this Order 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. For this reason, the mandatory certification by the BIS is considered as unnecessary. The QCO in question is not in line with Article 2.2 of the TBT Agreement, which states that Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. Furthermore, as a bank guarantee is required for all imported products, the QCO appears to run against Article 2.1 of the TBT Agreement, according to which Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

2.279. It is worth recalling that EU-based producers of man-made fibres already comply with a wide range of quality, safety, and environmental protection related certifications and standards, such as ISO 9001, 14001, and 45001, EU Ecolabel and European Pharmacopoeia. The EU reiterates its request to India to re-consider the current standard and conformity assessment procedures set in this QCO and to consider aligning the BIS standards and conformity assessment procedures with international standards and approaches, as well as to accept test certificates issued outside India based on ISO standards. The EU would also like to point out that mandatory affixing of the ISI mark is redundant and results in excessive certification costs, while strict packaging requirements constrain innovation and even limit the use of more environmentally friendly materials. In addition, the EU once more requests India to clarify the scope of the product(s) under the Quality Control Orders by clearly indicating in the QCO the HS code(s) of the goods concerned. The EU regrets that the entry into force of this QCO was not deferred and entered into force on the 29 March 2023. Article 2.12 of the WTO TBT Agreement requires a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers to adapt their products or methods of production to the new requirements. The EU would also like to recall that according to the 2001 WTO Ministerial Decision on Implementation-related Issues and Concerns, Ministers agreed that the phrase "reasonable interval" shall be understood to mean normally a period of not less than six months, except when this would be ineffective in fulfilling the legitimate objectives pursued. The EU remains open to discuss this matter bilaterally at the experts' level.

2.280. The representative of <u>Indonesia</u> provided the following statement. Indonesia reiterates its concern regarding the implementation of Viscose Staple Fibres (Quality Control) Order, 2022. Since December 2022, Indonesian companies have applied to BIS for the certification process for VSF

 $^{^{83}}$ For previous statements follow the thread under ID $\underline{790}$.

product. However, as of today, BIS has not yet conducted any factory inspections to Indonesian VSF companies without any explanation and clarity regarding the verification schedule. Indonesia deeply regrets this delay in on-site inspections as it has resulted in significant losses to Indonesia's VSF industry. Moreover, since the enforcement of the VSF QCO on 29 March 2023, Indonesian companies have not been able to export to India at all because certification has not yet been carried out. This condition causes uncertainty in trade operations and harms the rights and business interests of our industry. Indonesia also questioned the different treatment of Indonesian companies. Based on information from Indonesian companies, there are already several companies from other countries that have conducted factory inspections. In addition, BIS has also conducted factory inspections of several Indonesian companies that produce other textile products besides VSF. We expect India to be able to give equal treatment to every company that will be certified. We urge India to implement the QCO system in a manner in compliance with Articles 2.1 and 2.2 of TBT Agreement. And once again, Indonesia requests India to consider the option of international recognition under the MRA/MLA framework for conformity assessment results and/or conformity assessment bodies from the country of origin. This will speed up the certification process, avoid duplication of testing and certification procedures, and may reduce the cost of conformity assessment. Indonesia sincerely hopes that India could response to the enquiry we sent on 11 August 2023 related to this issue.

2.281. In response, the representative of <u>India</u> provided the following statement. We would refer to the statement made on this issue in the previous Committee on TBT meeting where we had provided specific details on the dates for this QCO, the licences granted and the rationale for bank guarantees. It may be noted that the conformity assessment requirements (like affixing of IS mark on goods and packaging) as specified in the draft QCOs are equally applicable to domestic manufactures as well as foreign manufacturers who intend to export their products to India. We also thank EU for the ongoing bilateral engagement on this issue.

2.1.4.28 China - Interim Regulation on Radio Management of Wireless Charging (Power Transmission) Equipment, <u>G/TBT/N/CHN/1711</u> (ID 784⁸⁴)

2.282. The representative of the <u>United States</u> provided the following statement. The United States would like to express continued concerns today with China's Interim Regulations on Radio Management of Wireless Charging Equipment. As China published the final regulation in June, will additional implementing measures be forthcoming? Can China offer an anticipated timeline for any additional implementing measures or guidelines? We ask that China notify any relevant implementing measures to the TBT Committee. In June we noted that the scope of the draft regulation was non-radio equipment that radiates radio waves, including the energy transmitter connected to the power supply and the power receiver acting on the load. We thank China for its confirmation in June that the frequency only defines that of the transmitter and not the receiving device. Aside from this, the United States maintains several of our concerns, given the significant impact this measure may have on international trade. First, China's TBT notification stated that the objective and rationale for issuing this draft is for quality requirements and harmonization. However, one of the frequency ranges China adopted is not included in the relevant ITU-R standard (SM.2129). Can China please explain why it has included this additional frequency range (13553-13567kHZ) that is not in the published international standard? China has indicated that its rationale for allowing only the three specified frequency bands stems in part from a lack of compatibility analysis between those bands and others to ensure the avoidance of harmful interference but that the regulation is subject to future adjustments per advancement of industry and technology. Both ITU-R and the Wireless Power Consortium have examined interference issues as part of the development process for the SM.2129 and Qi 2.0 standards, respectively. Will China commit to reevaluating additional frequency ranges that may be included in these standards, once they are finalized?

2.283. Second, regarding electric vehicle wireless charging equipment, we note that the SAE International has developed standard J2954, and standard J2954/2. Could China explain how it considered these standards when developing its draft measure? We request that China use these two standards as a basis for its regulation. Third, has China conducted a regulatory impact assessment on the potential negative environmental and climate impacts of limiting the frequency ranges? As we understand it, chargers that operate at the frequency range of 315-400 kHZ and 1.7-1.9MHZ for portable devices, which would not comply with the proposed measure, are able to consume less overall energy due to their quick charging ability and are already in use by millions of devices in many markets. Fourth, regarding product labelling, China indicated in its June response

 $^{^{84}}$ For previous statements follow the thread under ID $\underline{784}$.

that it would allow for "special identification" on outer packaging or in the product instructions under certain conditions. This is helpful, but we urge China to consider allowing for the information to be displayed electronically and to include this in any subsequent implementing guidance. Finally, China also indicated that it will set up a reasonable transition period and will continue to allow the sale of existing products produced or imported until the end of that transition period.

2.284. The representative of Japan provided the following statement. Japan has ongoing concerns with regard to China's Interim Regulations on Radio Management of Wireless Charging (Power Transmission) Equipment. The Interim Regulations stipulate the frequencies which wireless charging (power transmission) equipment must comply with. Those are three frequency bands, namely 100-148.5 kHz, 6765-6795 kHz and 13553-13567 kHz. Japan appreciates China's comments at the last TBT Committee meeting that it had specified those frequency bands based on relevant recommendations from the International Telecommunication Union (ITU) and the development status of the industry. However, since Japan's concerns are still not resolved, Japan once again wishes to raise this STC. First, although the Qi2.0, the international standard provided by the Wireless Power Consortium (WPC), was already released in April 2023, and the Qi2.0 includes 360 kHz as a frequency for wireless charging, China's interim regulations do not include this frequency band. Also, China's regulations do not include any of the multiple frequency bands such as 315-400 kHz and 1700-1800 kHz, which the ITU has decided to include in its revised international standards. Therefore, it is hard to say that China has adequately used the relevant international standards as a basis for the Interim Regulations, and we also believe they would be inconsistent with Article 2.4 of the TBT Agreement.

2.285. Additionally, China explained that the purposes for introducing the Interim Regulations are to regulate the use of wireless charging (power transmission) equipment, to avoid harmful interference to services complying with the law, and to maintain order for radio waves. However, the Qi2.0 of the WPC and the revised ITU-R guidance as international standards are established based on the consensus of members including China to justifiably maintain order for radio waves, so by complying with the international standards, the purposes of the Interim Regulations given by China can be supposed to be achieved. Therefore, as stated above, since products complying with the international standards can achieve the purposes of the Interim Regulations, the Interim Regulations which prohibit the import, sale and use of products complying with the international standards are likely to be an unnecessarily trade-restrictive measure and may violate Article 2.2 of the TBT Agreement. Japan continues to request China to use international standards as a basis for formulating the Interim Regulations on Radio Management of Wireless Charging (Power Transmission) Equipment so as not to become more trade-restrictive than necessary.

2.286. In response, the representative of <u>China</u> provided the following statement. The regulation was officially released in May 2023 and will be formally implemented in September 2024. In the future, the Ministry of Industry and Information Technology will release additional implementing measures about the requirements for dedicated identification. With regards to the operating frequency ranges of mobile and portable wireless charging equipment, MIIT has specified three frequency bands including the 13000kHz band, based on relevant recommendations from ITU, the industry's development status, and the result of the test experiment. At present, frequency ranges outside these three bands lack sufficient compatibility and sharing study, which may cause harmful interference to incumbent services and deployed systems. MIIT has been keeping close attention to the dynamics of ITU standards, and will timely adjust the regulation's relevant contents in the future, according to the ITU's newest standard, industry development and technology evolution.

2.1.4.29 Ireland - Draft Regulations Under Section 12 of the Public Health (Alcohol) Act 2018, <u>G/TBT/N/IRL/4</u>; Related to Previously Raised STC ID 516 (ID 794⁸⁵)

2.287. The representative of <u>Mexico</u> provided the following statement. The Mexican delegation refers to Ireland's Public Health (Alcohol) (Labelling) Regulations 2022, notified to the members of this Committee in document <u>G/TBT/N/IRL/4</u>. The delegation of Mexico also refers to the communication sent by the Government of Mexico to the Government of Ireland on 3 April 2023, in which it made comments on the Regulations that focused on the following. The Government of Mexico's concern regarding the disruption to harmonized EU legislation and the fragmentation of the region's market that the Regulations could cause, thereby hampering international trade, and regarding the divergence between the Irish Regulations and Regulation (EU) No 1169/2011 in terms

 $^{^{85}}$ For previous statements follow the thread under ID $\underline{794}$.

of the requirements for declaring energy value and alcohol content. In this connection, the delegation of Mexico asks that the delegation of Ireland provide: The technical and scientific evidence forming the basis for the wording of the health warnings proposed in the Regulations; Information on any alternative measures to labelling alcoholic beverages that were considered as a means of addressing the issue in a less trade-restrictive way. Lastly, the delegation of Mexico requests the Government of Ireland provide a reply to the comments submitted during the public consultations on the Regulations. The delegation of Mexico thanks the delegation of Ireland for giving its consideration to this statement.

2.288. The representative of Colombia provided the following statement. First, like Mexico, Colombia would like to say that it agrees with the objective of making relevant health information available to consumers in order to assist them in making more sound decisions regarding alcohol consumption. Nevertheless, Colombia would like to express its trade concern regarding the Draft Regulations under Section 12 of the Public Health (Alcohol) Act 2018, notified in document G/TBT/N/IRL/4, which refer to the information that labels of alcoholic beverages must contain. While we understand that this draft has already been enacted as a Public Health Act, we would appreciate, in application of the principle of transparency, a response to the comments that Colombia submitted on 4 May through its contact point, to which we will now add the following points: Scientific and technical evidence supporting the warnings proposed in the Regulations; the discrepancy between the requirements imposed by Ireland and European Union law, in terms of how alcohol content is displayed (grams vs percentage of alcohol by volume); and the need for a mechanism to enable the use of similar labels approved in third countries, including the European Union, without changing the labelling. We would appreciate clarification on how alcohol and energy content is being dealt with, in accordance with existing European Union legislation. The Regulations, once implemented, will affect trade by requiring exporters to produce specific labels for the Irish market, generating additional costs and affecting the ability to redirect products within the European market. For this reason, Colombia would like to know how the comments made by countries during the consultation process were taken into account and, on that basis, would appreciate constructive and open dialogue to address these issues by seeking mutually beneficial solutions.

2.289. The representative of the United States provided the following statement. The United States supports Ireland's objective of combatting harmful alcohol consumption and communicating important health information to consumers to assist more informed decision-making about alcohol consumption. Even though the Ireland Public Health (Alcohol) (Labeling) Bill was finalized and signed into law in May 2023, we would like to reiterate our concerns about the potential for this legislation to cause trade disruptions. While we would like to thank Ireland for notifying its bill to the WTO on 6 February with a 90-day comment period, the United States remains deeply concerned that Ireland finalized this measure on 22 May 2023; a mere two weeks following the end of the WTO comment period. Displaying information in grams could also potentially confuse the consumer and not send a clearer health signal, as has been asserted. We would appreciate information on any assessments undertaken related to consumer understanding of labelling alcohol content in grams per container. In addition, the labels do not include information about the amount of product being measured, i.e., full container, 100 ml, or specific serving size. If energy and alcohol content is supposed to be representative of a full container, there is a question about the utility of this type of information and the potential to confuse consumers. Has Ireland considered adjusting its requirements to include clarifying information regarding the amount of product? We understand the EU is planning to revise the Food Information to Consumers (FIC) regulation. In this revision, will the EU set uniform alcohol labelling requirements to harmonize discrepancies across EU member States? We look forward to receiving Ireland's response to our comments.

2.290. The representative of <u>Australia</u> provided the following statement. Australia thanks the European Union for their engagement regarding this trade concern. Australia recognizes the importance of labelling to promote consumer awareness and public health, but remains concerned Ireland's new alcohol labelling regulations could impact trade and undermine the concept of the European single market. We note the EU advised a sticker may be affixed to the container of the alcohol product to meet Irish requirements. We suggest this remains a barrier and creates unnecessary burden for exporters. We also note the European Union advised they are going to review food labelling rules, including the labelling of alcoholic beverages. We suggest this initiative will achieve a similar objective to Ireland's alcohol labelling regulations while not undermining the European single market. Indeed, Ireland's regulations may further complicate the implementation of future European Union requirements in this area. Ensuring consistency in labelling between Ireland and other EU member States is important in reducing unnecessary barriers to trade. Australia

supports concerns raised on this issue and is willing to work with the Government of Ireland to resolve this matter.

2.291. The representative of <u>Chile</u> provided the following statement. The delegation of Chile would like to thank Mexico, Colombia and the United States for the opportunity to refer to Ireland's draft Public Health Regulations of 2022 on the labelling of alcoholic beverages, notified to this Committee in document <u>G/TBT/N/IRL/4</u>, which concern measures relating to warnings and health information that must be displayed on alcoholic beverage containers. My delegation submitted comments through the Technical Barriers to Trade contact point, which so far have not been addressed by the delegation of Ireland. In our comments on the notification, we informed Ireland of our concern regarding the health warning requirements set out in Part 2 of the Regulations. These requirements directly link the consumption of alcohol to the development of deadly neoplastic diseases such as cancer, while failing to make any distinctions as regards consumption levels or other risky behaviours associated with the consumption of alcohol. We consider that these provisions obstruct trade, as there is no conclusive evidence that moderate alcohol consumption is the direct cause of liver cancer or other deadly cancers. In light of the foregoing, the Regulations create unnecessary technical barriers to trade, particularly Article 2.2 of the Regulations. We hope that the Government of Ireland will welcome and respond to the comments we have submitted through its TBT/WTO contact point.

2.292. The representative of <u>New Zealand</u> provided the following statement. New Zealand shares the concerns of other parties surrounding the Irish Public Health (Alcohol) (Labelling) Regulations 2023. We continue to emphasise the questions that we laid out in the previous Committee, which we consider have not yet been addressed by Ireland or the EU. In particular, we note our concern that the measure requires parties to express a product's quantity of grams and energy on the labelling differently to the European Commission's Regulation 2021/2117, while achieving substantively the same outcome. We seek clarification from Ireland on whether it has considered alternatives to enable the Regulations to be less trade restrictive on imports from Ireland's trading partners. For example, has Ireland considered aligning its Regulations with EU Regulation? New Zealand also wants to highlight for Ireland's continued consideration the potential for these measures to affect stock in trade from other countries. While New Zealand understands the new measures do not come into effect until 22 May 2026, we note that wine has a very long shelf-life and there may be old, and high-value, stock already in trade (such as from older vintage stock in cellars) that does not display Ireland's required warnings and energy information. New Zealand would appreciate clarification from Ireland on how it intends to ensure these regulations do not unintentionally prohibit trade of such old stock.

2.293. The representative of <u>Argentina</u> provided the following statement. Argentina would like to thank the delegations that included this trade concern on the meeting agenda and Ireland for its notification. Argentina recognizes the importance of informing consumers about alcohol consumption. At the national level, both the National Grape-Growing and Wine Production Institute and the industry have promoted the concept of responsible consumption, with the aim of reducing the impact of alcohol consumption on non-communicable diseases, based on the premise that consumer education is the most appropriate tool for achieving this aim. Although Argentina understands that the warnings under the Irish regulations are intended to inform consumers about alcohol consumption, we believe that they may unnecessarily harm trade and that they might not take account of differences between alcoholic beverages, in terms of their alcohol content in particular, but also their composition. We therefore encourage Ireland to consider other strategies to promote moderate and responsible drinking that do not create unnecessary obstacles to trade.

2.294. The representative of <u>Guatemala</u> provided the following statement. We recognize the objectives of combating alcohol abuse and ensuring that Irish consumers are directly informed of alcohol-related health risks and receive support in making healthier choices with regard to alcohol consumption. However, as has already been pointed out by other Members, there are concerns about the Regulations because their implementation could create an unnecessary barrier to trade. We request Ireland to consider the following: We request that Ireland revise the warning statement so as to address health risks in general, providing information in an accurate and clear manner in accordance with current research. We request that products that feature similar pictographic pregnancy-related warnings be recognized without requiring a change of label. We urge Ireland to ensure that information on alcohol content and energy is provided in accordance with Regulation (EU) No. 1169/2011 on the provision of food information to consumers. In addition, we ask Ireland to clarify why the quantity of grams of alcohol needs to be provided, contrary to EU regulations. We

encourage Ireland to consider alternatives, such as QR codes or websites, to inform consumers of the risks associated with alcohol consumption.

2.295. In response, the representative of the European Union provided the following statement. The EU would like to thank the United States, Mexico, Colombia, Australia, New Zealand, Chile, Argentina and Guatemala for their comments on the Irish proposal under Section 12 of the Public Health Act of 2018. First, the EU would like to apologize once again for the delay in providing a reply. In light of the detailed and numerous questions asked, the EU's assessment has taken longer than expected. The EU hopes to finalize these replies and send them to your TBT enquiry points soon. Second, the Irish Regulations at issue aim to communicate in simple and direct terms information to the consumer on the content of the alcohol product as part of a series of public health measures. Data reported by Ireland provide a particularly alarming picture as regards, inter alia, the significant incidence of deaths and disease, including cancer which are directly related to the consumption of alcohol in Ireland, the lack of awareness among the national population of the health risks associated with alcohol consumption, as well as high proportion of drinkers reporting a hazardous level of consumption. The design of the label and related statements was informed by the available national and international evidence on the most effective messaging. More information can be found in the document "Notification and Justification" notified together with the notified draft. Furthermore, the Covid-19 crisis demonstrated that closing premises where one can consume alcoholic beverages only demonstrated a marginal impact on reducing average alcohol consumption in Ireland.

2.296. In addition, the measure was designed with the aim to minimize the impact on cross-border trade. In fact, the health warnings, symbols and information can be attached to containers by using a sticker allowing for some flexibility on how the information will be provided. The labelling does not have to be carried out during the manufacturing process and products can be imported without the information on the label. Health warnings are only mandatory when sold to consumers, not when imported into Ireland. The mandatory minimum dimensions of the health information and warnings are set small and the requirement to provide a pregnancy warning can be met by simply displaying an image without the need for accompanying text. Furthermore, there is a three-year transition period for the measure. It won't go into effect until 22 May 2026 and this three-year lead-in time is to give businesses the time to prepare for the changes. On a final note, the EU has indeed announced its intention to review its food labelling rules under the regulation on Food Information to Consumers Regulation, including the labelling of alcoholic beverages. However, we are still very early in the process. Currently the preparatory work and evidence-gathering are in progress with the preparation of an impact assessment.

2.1.4.30 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 133⁸⁶)

2.297. The representative of <u>Indonesia</u> provided the following statement. Indonesia would like to reiterate its concern on Pneumatic Tyres and Tubes for Automotive Vehicles as raised in previous TBT Committee meeting. By this time, Indonesia 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 six 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. 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 tyre products from Indonesia.

2.298. 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. We are further disappointed that India appears to have issued Automotive Vehicles Pneumatic Tyres for passenger car Vehicles as per IS 15633:2022 without first notifying it to this Committee. This regulation requires manufacturers to adapt their products to fulfill the revisions of regulation.

 $^{^{86}}$ For previous statements follow the thread under ID <u>133</u>.

Meanwhile, manufacturing needs time to adjust to these regulations and the certification application process which must be approved by BIS. We ask India to notify this revision regulation to the Committee, allow a reasonable time for stakeholder comments, and to take those comments into consideration as it implements the measure. As stated in the provisions of Articles 2.1 and 2.2 of the WTO TBT Agreement, Indonesia is of the opinion that the application of the policy to imported tire products is inconsistent with the principle of non-discrimination and has the potential to unnecessarily impede international trade. Indonesia expects that India will further clarify the situation, notify the WTO TBT Committee of any relevant regulations, and assess the application of these policies to ensure that it is in line with WTO rules.

2.299. The representative of <u>Canada</u> provided the following statement. Canada thanks Indonesia for raising this STC, and for the record, we wish to reiterate our concerns as highlighted in para. 3.285 of the minutes of the June TBT Committee meeting (<u>G/TBT/M/90</u>). At the June meeting, India noted in its response that it was reviewing the comments made by Canada. Can India provide today responses to the questions and issues raised by Canada?

2.300. In response, the representative of <u>India</u> provided the following statement. We refer to our statement made in the previous Committee meetings on this issue. We believe that we have already responded to substantive points raised today. Additionally, our capital is reviewing the issues raised in the June meeting. We also remain open to discuss this issue bilaterally.

2.1.4.31 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 428⁸⁷)

2.301. The representative of the <u>Republic of Korea</u> provided the following statement. The Republic of Korea would like to express our pleasure in continuing cooperation between the regulatory authorities of China and Korea. We also recognize China's goal and purpose of strengthening overall supervision while encouraging innovation and development in the medical device industry, which China outlined at the previous Committee meeting. Considering the purpose of China's laws and regulations, we believe that the inclusion of "internationally accredited testing laboratories" in "qualified testing laboratories" will lead to expedited supply of internationally safe and high-quality medical devices to the Chinese market as those laboratories are equipped with proper resources in accordance with relevant international standards and regulations, further contributing to innovation in the Chinese medical device industry and improvement of public health. Therefore, Korea reiterates the request to include 'internationally accredited testing laboratories' in "qualified testing laboratories" specified in Article 14 of the Regulations for the Supervision and Administration of Medical Devices (No. 739) in China.

2.302. In response, the representative of China provided the following statement. Since the release and implementation of the new Regulations on the Supervision and Administration of Medical Devices in 2021, the National Medical Products Administration (NMPA) has revised a number of supporting regulations and documents such as the Measures for the Registration and Filing of Medical Devices, the Measures for the Registration and filing of in vitro diagnostic Reagents, the Measures for the Supervision and Administration of Medical Device Production, and the Measures for the Supervision and Administration of Medical Device Management, so as to further improve the medical device supervision and regulation system. Regulations and methods scientifically set clinical evaluation requirements, simplify the review and approval process, and further encourage innovative and highquality development of the industry. After the issuance of the regulations, NMPA actively carried out publicity, provided policy interpretation through government websites and other platforms, and organized relevant training, such as training for imported medical device registrants. At the same time, the registrant system is implemented, the main responsibility of enterprises is strengthened, and the whole process of supervision is strengthened. In the next step, China will continue to pay attention to the implementation of the Regulations on the Supervision and Administration of Medical Devices, listen to the opinions and suggestions of the industry, including the registrants of imported medical devices, and improve the relevant supporting measures.

 $^{^{87}}$ For previous statements follow the thread under ID <u>428</u>.

2.1.4.32 Viet Nam - Cybersecurity Measures (ID 544⁸⁸)

2.303. The representative of <u>Japan</u> provided the following statement. Japan continues to request that the security assurance obligations for devices and systems stipulated by the Cybersecurity Law and Decree No.53/2022/ND-CP (hereinafter "Decree 53") be implemented in compliance with the TBT Agreement. At the previous meeting, Viet Nam mentioned that subsidiaries established by foreign companies need to store data and establish branches or representative offices in Viet Nam only if the services provided by the companies are used to commit acts that violate the Law on Cybersecurity and they have refused or failed to comply with an order from the Department of Cybersecurity and Counter High-Tech Crime of the Ministry of Public Security of Viet Nam. However, as of the moment, Japan is unable to confirm that the above exemption is stipulated in Article 25 of the Degree related to the Cybersecurity Law and Article 26 of Decree 53, which respectively stipulate obligations to store data and establish branches in Viet Nam. Japan kindly requests Viet Nam to provide explanation for the articles which provide the exemption. In addition, even if the exemption is stipulated in any articles, Japan understands that the Cybersecurity Law and Decree 53 impose the obligation on domestic enterprises to store data in Viet Nam. If the domestic enterprises include foreign enterprises' subsidiaries established in Viet Nam under Vietnamese laws, such subsidiaries would have the obligation to store data in Viet Nam, even though their parent enterprises are foreign enterprises. In general, foreign enterprises collect and manage data in an integrated manner outside Viet Nam. These foreign enterprises are more likely to incur burdens such as additional investment costs and to be placed in de facto unfavourable competitive conditions compared to domestic enterprises that collect and manage data in Viet Nam. As the concerns Japan has raised remain unsolved, Japan would like to request feedback from the competent authority.

2.304. In response, the representative of <u>Viet Nam</u> provided the following statement. Viet Nam appreciates the continued interest of Japan in Viet Nam's cybersecurity measures. All the comments are acknowledged however the official response has not yet been finalized. Viet Nam would like to propose Japan to allow more time for us to discuss internally and to provide further feedback in the next TBT Committee.

2.1.4.33 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>, <u>G/TBT/N/CHN/1673</u>, <u>G/TBT/N/CHN/1674</u>, <u>G/TBT/N/CHN/1682</u> (ID 576⁸⁹)

2.305. The representative of the <u>United States</u> provided the following statement. The United States maintains that it has serious concerns with CSAR and the consistency of some of its implementing measures with certain WTO obligations, including the treatment of imports; overly burdensome and disproportionate information requirements; lack of procedures to ensure the protection of confidential and proprietary information; duplicative in-country testing; and continued challenges with transparency in the development and implementation of the CSAR measures. However, China finalized several additional technical guidelines in late August. While we are in the process of reviewing these, could China please clarify the implementation timelines of these measures, in light of Announcement Number 34's intent to extend the transition period? We reiterate our request from the last two Committee meetings that China provide clarity on NMPA's Announcement Number 13 of 2023, issued in January on matters related to the notification and inspection of general cosmetics. Our understanding is that firms manufacturing in China will have the option of self-testing for general cosmetics, if they have a cosmetics production licence and they meet additional conditions. Could China please confirm? We also ask that China clarify whether importers will also be given the option to self-test. Further, if these requirements and procedures were not included in previously notified measures, would China please notify them to the WTO TBT Committee? As we have long noted, US industry faces pressing challenges in trying to comply with China's often unrealistic implementation timelines for CSAR and its conflicting technical regulations - complicated further by the lag from prior Covid-19 shutdowns over the past three years, and the testing backlog at labs in China.

 $^{^{88}}$ For previous statements follow the thread under ID $\underline{544}.$

⁸⁹ For previous statements follow the thread under ID <u>576</u>.

2.306. In prior meetings, we asked that China consider extending the national CSAR implementation deadlines for the notified measures contained in G/TBT/N/CHN/1459, G/TBT/N/CHN/1515, G/TBT/N/CHN/1526, and G/TBT/N/CHN/1525, including extending the deadlines that have already gone into effect. We appreciate that China's 27 March announcement extended the deadlines for cosmetics ingredients filings, and we urge that China provide further flexibility in extensions across the other measures, given the aftereffects of the pandemic and the requirements for in-country testing. We also ask that China consider how it can rely upon international recognition schemes for conformity assessment to reduce the timelines for companies to comply. We understand that China may be drafting some provisions regarding overseas inspections. We again ask China the same question from the June meeting: is China able to provide a timeline on when these provisions will be notified for public comment? US companies remain eager for a means to 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. Does China have any plans for this? Finally, we refer to previous US statements for other unresolved issues and unanswered questions. We ask that China discontinue its practice of responding to requests for clarification by merely reiterating CSAR's requirements and instead acknowledge and resolve the specific, tangible concerns expressed by the United States and many other WTO Members.

2.307. The representative of the <u>Republic of Korea</u> provided the following statement. The Republic of Korea would like to reiterate previous concerns regarding the "Cosmetics Supervision and Administration Regulation", "Specifications for Cosmetic Efficacy Claim Evaluation", "Specifications for Registration and Filing of New Cosmetic Ingredients", "Administrative Measures on Cosmetic Labeling", and "Specifications for Cosmetic Registration and Filing". Korea recognizes the China's policy objective to strengthen and implement cosmetics-related regulations to ensure the quality and safety of Chinese cosmetics and protect consumer health. We also understand that balancing consumer safety with market access is difficult. Nevertheless, we are still concerned about the lack of harmonization with international practices in relation to China's "Cosmetics Supervision and Administration Regulation" and implementation of measures, and infringement of corporate intellectual property rights by requesting more detailed information than necessary to carry out the purpose of cosmetics market management. Especially, China's regulation states that test reports required for cosmetic product registration must be issued by testing laboratories that have obtained the CMA (China Metrology Accreditation) certificate. This is considered a technical barrier to international trade that requires unnecessary resources such as time and effort for the distributed cosmetics whose safety and quality have already been secured. Accordingly, Korea reiterates the request that China adopts more flexible measures, such as recognition of the test reports issued by internationally accredited laboratories outside China.

2.308. The representative of Japan provided the following statement. Japan continues to express the following concerns about the "Cosmetics Supervision and Administration Regulation" and its implementing of detailed regulations in China. Japan would like to request that China continue to address not only the matters in the statements in the meetings, but also all of the matters uploaded on the eAgenda. 1. Tests conducted for cosmetics test reports required by the "Cosmetics Registration Filing Information Management Regulations" must be conducted by testing laboratories that are located in China and that have obtained CMA (China Methodology Accreditation) certificate. Japan has received responses from China stating that it does not prohibit or restrict foreign laboratories from obtaining CMA based on the "Administrative Measures for the Accreditation of Inspection and Testing Institutions". However, Article 4, Article 14, etc. of aforementioned Administrative Measures explicitly stipulate that only testing laboratories within the territory of China can be qualified for CMA. Consequently, this does not meet Japan's request to accept the test results of foreign laboratories with testing capabilities equivalent to laboratories that have obtained CMA. As Japan has repeatedly stated, the location is essentially irrelevant to testing capability, therefore Japan would like to continue to request that China treat foreign laboratories with capability equivalent to the laboratories located in China that have obtained CMA as equal and also accept test results of such foreign laboratories as being equally valid, regardless of where they are located, in a manner consistent with Article 5.1 of the Agreement on Technical Barriers to Trade (hereinafter referred to as the TBT Agreement).

2.309. 2. Regarding the efficacy claim evaluation methods required by the "Specifications for Cosmetic Efficacy Claim Evaluation", China responded at the previous meeting that "Based on the principle of equivalence, the efficacy claim evaluation test method does not limit the selection of internationally recognized foreign regulations or technical standards, such as the ISO or OECD." However, the test methods applied to the efficacy claim of special cosmetic products such as

sunscreens are limited only to the ones listed in the Safety and Technical Standards for Cosmetics. Similarly, China requires microbiological, physical, chemical and toxicological tests to be conducted in accordance with the test methods specified in the Chinese national standards and relevant regulations, and in the case of using a test method which is not specified in the national standards and the regulations, China additionally imposes the verification of equivalence with the test methods specified in the national standards and regulations, and storing the test results in preparation for inspections. Japan would like to request that China treat internationally accepted methods such as those from the ISO or OECD as equal to the methods stipulated in China's national standards or relevant regulations. If they are not regarded as equivalent test methods, Japan would like to ask for China's clarification as to why they are not treated as acceptable.

2.310. 3. Regarding the efficacy claim evaluation methods required by the "Specifications for Cosmetic Efficacy Claim Evaluation", Japan considers that the following points, in particular, are more stringent and restrictive than necessary for the purpose of guaranteeing the scientific validity and reliability of efficacy claim evaluation and protection of consumer legal interests. Japan reiterates its request for the implementation of a flexible framework considering internationally recognized practice. • "Attachment 1, Requirements of Cosmetic Efficacy Claim Evaluation Item" specifies four types of evidence. It finely stipulates which evidence can be used for each efficacy claim. According to the internationally recognized practice, the types of evidence for each efficacy claim are determined individually by cosmetics registrants and filers based on the specific wording of claims and scientifically valid testing method for each one, as the types of evidence depend on the specific wording of claims. • Applying the "Guiding Principles of Equivalent Evaluation" stipulated in the "Specifications for Cosmetic Efficacy Claim Evaluation" to skincare products, hair-care products, etc. is not allowed. Also, even in the case of makeup products, the quotation of "common efficacy claim" evaluation test data is only allowed in exceptional circumstances such as cases where only colorants differ in the formula of make-up series with multiple colors of the same registrants or filers. Therefore, in all cases, even minor changes to formulations necessary to comply with regulations, etc., require retesting. This creates heavy burdens for cosmetics registrants and filers. Japan would like to request that China consider expanding the scope of the "Guiding Principles of Equivalent Evaluation," based on international trends and stakeholder opinions. • Regarding the evaluation test for freckle-removing/whitening products, Japan would like to request that China answer with a clear reason why the "Read-Across" approach, which is commonly used and allows the evaluation test to be omitted under certain conditions, as was proposed in Article 16 (freckle-removing/whitening effect cross-reference) of the "Specifications for Cosmetic Efficacy Claim Evaluation (Draft for Comments)" announced in September of 2020, was removed in the final regulation.

2.311. 4. The "Provisions for the Supervision and Administration of Toothpaste" announced in March 2023 stipulate that the efficacy evaluation of toothpaste "conforms to laws, regulations, mandatory national standards, technical norms and relevant requirements for quality safety and efficacy evaluation regulated by the National Medical Products Administration". Particularly, human efficacy tests are required for anticavity, control of dental plaque, anti-dentin hypersensitivity and reduction of gum problems. This necessitates retesting of many products, including even ones that have been approved to be effective overseas without human efficacy tests. Also, as with cosmetics, human efficacy tests relevant to toothpaste must be conducted by testing laboratories that are located in China, and there are only a few such laboratories eligible for the qualification requirements within China, such as schools of dentistry. Given these circumstances, we are concerned that retesting will take a long time and affect many toothpaste products currently on the market. Japan would like to request a flexible framework of using results from in vitro tests using oral-derived bacteria, cells, and tissues and open literature, as international practices adopted to confirm efficacy. In relation to this, the "Announcement on Matters Relating to the Implementation of Toothpaste Regulation and Simplification of Filing Requirements for Listed Toothpastes (announcement No.124, 2023)" published in September 2023 stipulates that submission of evidence of efficacy will be required for products to be on the market from 1 December 2023, but the final version of the "Standards of Information File for Toothpaste Notification" has not been published as of October 2023. Considering the time for preparation, it is obviously impossible to comply with this requirement. To ensure that the measures are consistent with Articles 5.8 and 5.9 of the TBT Agreement, Japan would like to request that China provide an adequate grace period of at least one year after promulgation of all relevant regulations and guidelines in a consistent manner.

2.312. 5. According to the "Measures for Further Optimizing Cosmetic Ingredient Safety Information Administration (announcement No.34, 2023)", for products that have been registered (licensed) or filed by 31 December 2023, the Cosmetic Ingredients Safety Information (except for high-risk

ingredients) should be kept by the registrant/filer for inspections. However, for products to be applied for registration or filed on or after 1 January 2024, the submission of the Cosmetic Ingredients Safety Information will still be required for all ingredients. The safety assessment report for products including the safety information of the ingredients and final products is required at the time of product registration or filing, and it is a duplicate requirement to separately submit the Cosmetic Ingredients Safety Information. Therefore, Japan would like to request that the registrant/filer keep the Cosmetic Ingredients Safety Information for all ingredients for inspections, regardless of whether the risk is high or low and the timing of application for registration or filing. This approach is exactly the same for toothpaste ingredients stipulated by the "Standards of Information File for Toothpaste Notification", and Japan would like to request that the registrant/filer keep the Ingredients Safety Information for all ingredients for inspections, regardless of whether the risk is high or low and the timing of application for registration or filing. In addition, the "Guidelines for Submitting Information through the Cosmetic Ingredient Safety Information Submission Platform" announced on 4 September of 2023 and the related platform updates have made it impossible to obtain an ingredient registration code for mixed ingredients, but no official indication has been given as to how to cope with this, causing considerable confusion among cosmetic companies. Japan requests that China provide appropriate opportunities to explain the changes to relevant parties, including foreign cosmetic companies and industry associations, and secure sufficient transition time in the event of a fundamental change in its current administrative operation to be consistent with Article 5.9 of the TBT Agreement.

2.313. 6. The Technical Guidelines for Cosmetic Safety Assessment stipulates that a full version of the report must be submitted for products registered and filed on or after 1 May 2024 instead of the current simplified version of the report. In the full version of the report, historical use experience of ingredients can no longer be used as evidence for safety, which was allowed in the simplified version. Therefore, for ingredients without evaluation results from public organizations such as the CIR (Cosmetic Ingredient Review) or SCCS (Scientific Committee on Consumer Safety), it is necessary to gather safety data for ingredients and to submit some of those to the authorities. Japan considers that it is more stringent than necessary for the purpose of safety that China requires the retesting of safety data for ingredients based on the evidence for historical use experience of ingredients. Also, the full report requires reporting of product stability tests and tests of compatibility with packaging materials, but guidelines for their operation have not yet been published, making it impossible to have test results ready by 1 May 2024. Japan requests a flexible framework including the prompt announcement of the guidelines and the postponement of the enforcement date.

2.314. 7. Japan recognizes that transition periods are set in all relevant regulations, but disagrees that each transition period is long enough. Japan would like to strongly request that China provide an adequate grace period of at least one year after promulgation of all relevant regulations and guidelines in order to prevent market turmoil and in order for cosmetics registrants and filers to adapt cosmetics to new requirements. 8. Regarding the "Interim Measures on the Administration of Overseas Inspections of Cosmetics," Japan would like to request that China clarify which laws and regulations are used to assess conformity and specific purposes for conducting foreign inspections. Japan also asks that China ensure that the inspections will not be more trade restrictive than necessary to achieve the purpose of protecting human health. Moreover, information related to research and development is the most important confidential information for companies, but it is not the information that directly affects product safety assurance. Furthermore, inspections within China are limited to the production sector and this indicates that it is not necessary to conduct inspections of R&D sections. Therefore, Japan requests that China ensure that R&D sections that may possess confidential information be excluded from the subject of foreign inspections. Japan also requests that confidential information not be disclosed to persons other than those necessary for the legitimate purpose of the inspection. 9. 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 favorably than products that are produced in China, in other words, Japan requests that China abolish the obligation to acquire the sales certification for imported products. Regarding the "Administrative Measures on Cosmetic Labeling," which was promulgated on 3 June 2021, Japan would like to continue to express its following concerns.

2.315. 10. In the TBT Committee meeting in November 2022, China explained that the content of the Chinese labels regarding only product safety and efficacy must be consistent with the original labels. Japan would like to request that China clarify that the labels stipulated only by regulations of

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the country of origin do not have to be consistent with the content of the Chinese labels, including information regarding product safety and efficacy. 11. Article 7 requires the indication of "producers," "registrants or filers," and in the case of imported products, a "responsible person in China" on the product labels of cosmetics and toothpaste. The "Cosmetics Supervision and Administration Regulation" that China mentioned at the previous TBT Committee meetings, and the "Provisions for the Supervision and Administration of Toothpaste" clearly stipulates that registrants and filers are fully responsible for quality, safety and efficacy claims of products. In order to clarify responsibilities and avoid confusion among consumers, Japan would like to request that the labels of cosmetics and toothpaste should indicate only a single responsible person ("registrants or filers," and if needed, a "responsible person in China" as a contact person can be added), and that China delete content that requires the indication of producers. 12. In the previous TBT Committee meetings, China explained that ingredients of 0.1% or less can be labeled as "other trace ingredients" in no particular order. However, with respect to the rules for labeling 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 without a description. Japan would like to request that China assure that the rules for labelling follow the internationally recognized practice, including for toothpaste, so as not to be more trade restrictive than necessary for the purpose of showing consumers the safety and efficacy of products.

2.316. 13. Japan understands the purpose of the sample retention system, and Japan is not against sample retention per se. However, "Public Notice Related Matters of Provisions for the Supervision and Administration of Cosmetics Production and Distribution" (No.140, 2021), requires that, regarding products imported to China from foreign registrants or filers, domestic responsible persons retain samples of each batch of cosmetics. Essentially, registrants or filers are responsible for the cosmetics in any case. Even in the case of imported cosmetics, Japan would like to request that China accept that samples do not always have to be retained in China if the testing system can be utilized immediately when problems occur. 14. With regard to the exemption of toxicological testing documents via certification documents related to the quality management system and good manufacturing practice qualifications, Japan requests China's continued consideration for accepting certifications issued by competent international organizations or industry associations which are authorized to issue certifications by government agencies in the country or region where the cosmetic manufacturer is located.

2.317. The representative of the European Union provided the following statement. The EU welcomes that the Chinese authorities have extended the deadline for registration of cosmetics' raw materials and finished products until 1 January 2024, as well as the announced changes in terms of limited submission requirements to specific ingredients. At the same time, the EU would like to refer to its earlier statements on this topic, as the EU's concerns outlined therein remain unchanged. We continue to support the statements by the delegations of the Republic of Korea, Japan, the United States, Australia, and New Zealand. The European Union has confirmed that it supported the CSAR's objective of ensuring consumer safety. However, CSAR and its various implementing regulations remain more stringent than necessary to ensure the safety and quality of imported cosmetics. In particular, this pertains to consumer safety and traceability of the ingredients used in cosmetics. CSAR's provisions diverge from international practice, as such an extensive level of information is not required elsewhere in the world for notification and registration purposes. The obligation to transmit confidential information on new products and their ingredients to Chinese authorities continues to remain one of EU's most important concerns. According to the EU, the mandatory disclosure of commercially sensitive information required in the notification and registration process, touching on intellectual property rights (IPR) of companies involved, goes far beyond what is required in line with internationally recognised practices.

2.318. Chinese measures therefore pose significant risks to companies' intellectual property and commercially sensitive information and are not proportionate to the objectives sought. The EU would like to recall that Chinese requirements go far beyond the EU's Cosmetics Regulation – considered to be most stringent in the world. As regards efficacy testing, the multiple China-specific requirements will require significant re-testing of products for which the efficacy was already established in a third country. This also affects thousands of products that have already been placed on the market in China and for which the claim substantiation still needs to be completed. The EU is looking forward to a constructive dialogue with the Chinese authorities to find a satisfactory solution to ensure cosmetics safety without unnecessarily overburdening importers.

2.319. The representative of <u>Australia</u> provided the following statement. Australia remains concerned that measures under China's Cosmetics Supervision and Administration Regulation (CSAR) and various implementing regulations, which entered into force on 1 May 2021, are more stringent and trade restrictive than necessary for low-risk cosmetics. These concerns relate to testing and registration requirements, government certification requirements and requirements to provide detailed information on production processes and other aspects of their intellectual property. Additionally, Australia remains concerned that China has maintained its requirement for mandatory animal testing of children's cosmetics products, regardless of the level of risk presented by individual products. The Australian Government looks forward to working with China on CSAR implementation.

2.320. The representative of <u>New Zealand</u> provided the following statement. New Zealand would like to reiterate our well-documented concerns from previous meetings in relation to China's regulatory system for cosmetics. We continue to urge China to consider additional measures to allow for: The exemption of animal testing requirements through non-government regulatory authority-issued GMP certification or other trade facilitative mechanisms for providing product assurances; Providing flexibility in respect of product testing requirements. In particular, we encourage China to accept test reports from accredited laboratories situated outside of China; and Further limitations on product disclosure requirements, particularly in relation to sensitive information – i.e. limited to that which is required to assure product safety in China's domestic market, so as not to compromise intellectual property. New Zealand looks forward to engaging further with China on its Cosmetics Supervision and Administration Regulations (CSAR) to address these issues.

2.321. In response, the representative of <u>China</u> provided the following statement. Firstly, regarding the inspection required for cosmetics registration and notification, requiring the inspection for cosmetics registration and notification to be carried out by professional institutions aims to protect consumers' rights and ensure the accuracy of the inspection results. Inspection institutions shall obtain the certification of inspection and testing qualification (CMA) in the field of cosmetics. However, China does not prohibit foreign inspection institutions from getting the certification, and China's Administrative Measures for the Accreditation of Inspection and Testing Institutions do not restrict foreign inspection institutions. The formulation of the specification for the Evaluation of Cosmetic Efficacy Claims is to further ensure the scientificity, accuracy and reliability of the evaluation of cosmetic efficacy claims, and safeguard the rights and interests of consumers. Based on the principle of equivalence, the efficacy claim evaluation test method does not limit the selection of internationally recognized foreign regulations or technical standards, such as OECD or ISO.

2.322. Thirdly, regarding the cosmetics labeling-related issues. The information of cosmetics manufacturers includes the relevant information of the manufacturers and their locations, and etc, which is an important measure to protect consumers' rights. When marking enterprise information, the corresponding guide language should be used for marking, and there is no situation that will confuse consumers. It stipulates that ingredients with weight percentage not exceeding 0.1% (w/w) should be labelled with "other trace ingredients" as indicating words. The measure does not require a descending order of ingredient content or any other specific order. Lastly, regarding the protection of trade secrets and intellectual property rights, the procedures and data requirements for the registration and notification of cosmetics and new raw materials are detailed and clear in relevant regulation papers. Reguiring registrants to submit safety-related materials is also a common practice aiming for the safety review of health-related products in various countries. It is exactly for the purpose of protecting the intellectual property rights and trade secrets of enterprises that in the process of formulating relevant technical documents, the evaluation data required of cosmetic efficacy claims only include the summary of the supporting material of the efficacy claims rather than the full text. The required technical materials of new raw materials only cover the basic aspects, such as the names, registration number, source, composition, physical and chemical properties, purpose of use, scope of use, safe amount of use, precautions, storage conditions and best before period, rather than the complete information. The authorities and administrative staff will strictly protect trade secrets in handling cosmetics registration, as prescribed by all relevant laws and regulations.

2.1.4.34 Qatar - Ministry of Public Health Circular regarding shelf life for cheese (ID 602^{90})

2.323. The representative of the European Union 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 ultra-heat treatment (UHT) milk and white cheese that entered into force already in 2019 and followed later by additional Circulars issued by Qatar on this issue. These trade restrictive measures are still kept in place to date. One of the main EU concerns as regards these import conditions is the short shelf-life period imposed for several dairy products, including milk, cheese and butter, which do not seem to be based on science nor on international standards. In practice, it is impossible for EU exporters to continue shipping certain dairy products to Qatar under these conditions. At the same time, local dairy producers in Qatar are favoured as they are not affected by the long transport time that foreign exporters need for shipping their dairy products to the country, and thus can comply with shorter shelf-life periods. The European Union would like to refer to constructive mutual exchanges on this important concern, however, despite the continued positive dialogue, the import measures are still in place. During our dialogue on this matter, Qatar signalled to be working on a solution to be offered in near future. The EU is looking forward to Qatar solving this issue at short term and we stand ready to continue working constructively with Qatar.

2.324. The representative of <u>New Zealand</u> provided the following statement. New Zealand continues to support the EU's interventions and requests the science evidence behind the assessment that resulted in such restrictive shelf-life requirements. New Zealand remains strongly of the view that Qatar's shelf-life requirements for imported cheese and other dairy commodities are trade restrictive, not based on science, and not in line with Codex standards. New Zealand continues to request that Qatar use internationally recognized standards such as Codex for the setting of shelf-life requirements.

2.325. In response, the representative of <u>Qatar</u> provided the following statement. Qatar has taken note once again of the continued concern of the European Union, New Zealand, and the United States regarding Qatar's Ministry of Public health circular on quality standards for certain dairy products and more specifically shelf-life periods for several dairy products, including milk, cheese and butter, and thanks them for their interest in this matter. As it has already been said, the relevant measures apply equally to domestic and imported products and are therefore non-discriminatory in nature. These measures do not have a significant effect on trade, and product-specific requirements applied in the State of Qatar do not prevent the importation and sale of any products that meet quality standards. That said, Qatar has held very constructive discussions on this matter with the European Union and is ready to explore constructive discussion with the interested Members to provide additional explanation where necessary.

2.1.4.35 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 598⁹¹)

2.326. The representative of <u>China</u> provided the following statement. China appreciates India's previous response. However, a significant backlog of factory inspections that cannot be completed in time and the need to ship samples back to India for testing make our industry difficult to obtain BIS certification. China would like to indicate that the COVID-19 prevention and control measures have been adjusted. We once again urge India to improve the efficiency of factory inspections and carry out inspections on Chinese manufacturers as soon as possible. China suggests that India could enhance the transparency of information on factory inspection and timely release information such as factory inspection schedule, facilitating enterprises' arrangements of production.

2.327. In response, the representative of <u>India</u> provided the following statement. We have already provided responses to all the questions raised by China in the previous Committee meeting. Since no new questions have been raised, we request the delegation of China to refer to our past responses. We remain open to discuss this issue bilaterally.

 $^{^{90}}$ For previous statements follow the thread under ID <u>602</u>.

 $^{^{91}}$ For previous statements follow the thread under ID <u>598</u>.

2.1.4.36 China - Draft Administrative Measures for Registration of Overseas Producers of Imported Foods, <u>G/TBT/N/CHN/1522</u> (ID 611⁹²)

2.328. 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 the difficulties experienced by China in the implementation of CIFER as part of its roll out of Regulation on Registration and Administration of Overseas Manufacturers of Imported Food (Decree 248). Australia appreciates the continued cooperation of officials from the General Administration of Customs China (GACC) to work through the many system issues experienced in the CIFER system. We remain willing to engage with China to minimise trade disruptions but are still concerned at the resource and-labour-intensive costs borne by exporters and exporting country competent authorities to comply with the CIFER registration process. This burden is exacerbated by the number of technical issues, delays and lack of clarity experienced within the CIFER system. Australia encourages China to improve engagement with trading partners on CIFER through the provision of: regularly updated and detailed guidance material; a pathway to recognition of trading partner systems; guarantee of continuity of trade to registered establishments when IT system issues in the CIFER system are not resolved. Australia reminds China that its regulations must not discriminate against imported goods. Delays in processing registration renewals, lifting suspensions and approving new applications from overseas food producers, only lead to imported foods being treated less favourably than China's domestic product.

2.329. The representative of the <u>United States</u> provided the following statement. The United States remains deeply concerned with this measure, published as Decree 248 in April 2021, and implemented in January 2022. We are taking the floor for the 12th and likely final time in this Committee to share our concerns with this measure and the companion measure, Decree 249. We are extremely disappointed that China finalized and implemented this measure as proposed, despite extensive efforts at constructive engagement by the United States and the international community, including in TBT, SPS, and CTG meetings, in bilateral engagements, and through joint letters from nine WTO Members. China did not meet the requests of trading partners to meaningfully engage in the explanation of the new requirements, provide a scientific or technical justification, or publish changes that reduce unnecessary trade burdens for the billions of dollars' worth of safe food exported to China under these requirements. Despite being in effect for nearly two years, Decree 248 continues to create new challenges for global food producers and competent authorities as China regularly alters the scope of the measure without notification of the changes, implements new requirements without advance notice, and applies inconsistent criteria for review of applications for registration. We ask once more that China meet its international and bilateral obligations, and we maintain our commitment to seek solutions to these outstanding concerns and welcome meaningful dialogue with China to reduce barriers to trade in safe food products. We acknowledge that the discussion in this Committee has led China to implement this measure in a manner that is less restrictive than the measure itself appears to require, including by appearing to informally waive certain documentation requirements that would have imposed an immense burden on the US competent authority. We maintain our commitment to support and collaborate with WTO Members who are also requested changes and are harmed by this measure We will continue to work together to monitor implementation.

2.330. The representative of <u>Japan</u> provided the following statement. Japan, like other Members, would like to raise its concerns again regarding the implementation of Decree 248 by China concerning administrative measures for registration of overseas manufacturers of imported food. Japan appreciates China's flexibility to address the difficulties Japanese manufacturers faced in renewal of registrations. Having said so, Japan is still concerned that the procedures lack predictability and transparency and are more trade-restrictive than necessary. Japan requests China to improve the operation of the CIFER system, and to ensure that the procedures related to the Decree 248 are undertaken and completed without undue delay and in a transparent manner. Japan would also like to ask China the following: To establish a standard processing period for applications made through the CIFER system (i.e., a standard timeline to be followed from application through registration), and make that processing period known to the Members and foreign manufacturers. To give sufficient explanation for the reasons when application is rejected through the CIFER system, and ensure its consistency. To notify the Members promptly of any changes in the operation of the regulations or the CIFER system, including changes to product codes (HS CIQ) used in the system,

 $^{^{92}}$ For previous statements follow the thread under ID <u>611</u>.

which will or might affect exports. Should any changes occur, we also ask that the GACC provide a reasonable transitional period. To correct any defects in the CIFER system as soon as possible, including: (a) the current, considerable delays in the registration process; (b) its inability to accept letters of proxy; and (c) the fact that some of the product codes (HS CIQ) are missing from the list shown on the system. To proceed in a timely manner with review of additional information submitted by registered manufacturers. Even now there are manufacturers who have not received any response from the GACC, that is 145 out of 899 manufacturers for products designated in Article 7 of Decree 248. To respond to unanswered questions within a reasonable time, Japan would like to communicate closely with China to address our concerns in a cooperative manner.

2.331. The representative of The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu provided the following statement. As we have already expressed in previous meetings, we remain deeply concerned about these measures, as uncertainties and a lack of transparency persist even after they have been implemented for more than one and a half years. First, a lack of sufficient information remains a major obstacle, particularly for those facilities that must register directly with the General Administration of Customs of China (GACC). While China has indicated that technical guidance, regulatory interpretations, and supporting documentation have already been provided, we would urge that these materials be regularly updated and placed on a publicly available website so that they can be accessed by overseas facilities. Second, the standard or anticipated processing time for the review and approval procedures has yet to be disclosed, little is known about the individual stages of the application process, and our facilities have reported that their applications have been rejected by the GACC without explanation. We would therefore once again urge the GACC to comply with its obligations under Articles 5.2.2 and 5.2.8 of the TBT Agreement so as to ensure that its review and approval procedures are efficient and transparent. Ever since China notified the WTO of its intent to pass these measures in 2020, we have repeatedly expressed concern and sought clarification regarding their implementation through bilateral channels as well as the TBT Committee, yet these concerns have yet to be adequately addressed. We look forward to China's response.

2.332. The representative of the <u>Philippines</u> provided the following statement. The Philippines acknowledges China's strong support in addressing the issues raised by concerned Members. We appreciate the enhancements implemented in the CIFER system facilitating better registration processes within the GACC. Nevertheless, we align with the concerns expressed by Australia, the United States, Japan, Chinese Taipei, and Korea. The core of the issue lies in the registration of traders and consolidators with the GACC which remains problematic. This is because Decree 248 mandates the registration of food manufacturers, processors, and storage facilities but fails to include traders and consolidators. Furthermore, the Philippines notes that the GACC has not established a clear timeline for the CIFER system applications processing.

2.333. The representative of the <u>Republic of Korea</u> provided the following statement. The Republic of Korea echoes the concerns raised by Australia, the United States, Japan, and Chinese Taipei under this STC. Korea respects China's efforts to ensure the safety of its consumers from risks caused by food products, and appreciates its continued cooperation through bilateral channels such as Korea and China Food Safety Cooperation Commission. Unfortunately, Korea notes that the registration process still requires up to two months to reach completion despite applicants conforming to the GACC requirements when applying for product category registration. Moreover, the lack of an explanation when registration is rejected poses challenges for the exporting manufacturers. Therefore, we would like to ask China to provide a clear explanation of the reasons behind registration rejections. Furthermore, we acknowledge that the practice of registration subjecting product categories imposes a trade burden by repeatedly demanding information from already validated manufacturing facilities. Regarding this, we would like to ask China to reconsider the subject of registration, changing the focus towards manufacturing facilities, thereby facilitating the process. As the new measures would significantly affect bilateral trade, Korea would like to ask China to respond to our statement.

2.334. The representative of <u>Canada</u> provided the following statement. Canada appreciates the efforts made by Chinese authorities to facilitate the registration and renewal process of establishments in the CIFER system. However, greater consistency in the registration and renewal process as well as efforts to reduce administrative burden would ensure the CIFER system does not cause delays. Canada also reiterates its request that China appropriately consider the relative risk of different products. China could reduce the administrative burden of the registration process by expanding the scope of "low risk" products for which foreign establishments may submit applications directly in the CIFER system without requiring approval by foreign competent authorities.

2.335. The representative of the <u>European Union</u> provided the following statement. The EU would like to support concerns raised about the implementation of Decree 248 of the General Administration of Customs of the People's Republic of China (GACC). Almost two years after its entry into force, the EU considers that the whole implementation process of Decree 248 is still burdensome, both for authorities and operators, including issues with the registration process, notably the electronic submission of documents through the CIFER system, which is cumbersome and time consuming, be it to apply for new registrations, or to amend or correct existing ones. The EU requests that China guarantees continuity of trade while Decree 248 is being implemented. In this context, new requirements should not be implemented without advance notice and China should regularly publish updated guidance on Decree 248 implementation.

2.336. In response, the representative of <u>China</u> provided the following statement. In order to effectively implement the Food Safety Law and its implementation Regulations, the GACC has revised the Administrative Measures for Registration of Overseas Manufacturers of Imported Foods (Decree 248), which came into force on 1 January 2022. We have notified the measure to the WTO and adopted reasonable comments. The transitional period is in line with the requirements of the TBT/SPS Agreement. With the strong cooperation of the food safety authorities of all members, more than 80,000 overseas manufacturers from 165 economies have been registered in China. Among them, there are 6,434 US companies registered in China, 6,030 from Japan, 2,999 from South Korea, 2,193 from Australia, 1,162 from Canada and 502 from the Philippines. In 2022, in the first year of the implementation of CIFER system, China imported RMB 1.39 trillion Yuan of food, an increase of 10.4%. It also proves the effectiveness of import registration in ensuring the safety of imported food and promoting food trade to China. To support the implementation of the regulations, the GACC had successively issued the interpretation of the regulations, the guidelines, and supporting documents and forms for registration application, and launched the registration information system for overseas enterprises.

2.337. In order to better understand the regulation by the competent authorities and enterprises of members, the GACC has held regulatory briefings and training with more than 100 Members. In addition, GACC published a video demonstration of the CIFER system operation on their official website. We need to emphasize that the establishment of the CIFER system aims to facilitate overall management, optimize services, simplify trade procedures, and promote the healthy development of trade. China organized an information session on the margin of the 91st TBT Committee in June 2023. At the information session, China shared the implementation information about GACC Decree 248, made an introduction to the operation and optimization of the registration system, and gave an explanation of the common questions on the registration system, they are welcome to raise questions at any time, and GACC will respond in a timely manner and provide technical support.

2.1.4.37 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>, <u>G/TBT/N/COL/246</u> (ID 609⁹³)

2.338. The representative of <u>Costa Rica</u> provided the following statement. Costa Rica wishes to reiterate its trade concern in support of a systemic defence of the principles of the TBT Agreement relating to the adoption of measures based on scientific evidence and the harmonization of rules through the use of regulations issued by international reference organizations such as the Codex Alimentarius. The Codex Alimentarius has no standards that may act as a basis for setting percentages for maximum sodium, fat or sugar content (as is the case with the list of foods prioritized by Colombia and the maximum sodium percentages). As a result, there are different regulatory systems for international trade in processed foods, which makes sectors less competitive and restricts trade more than necessary. As with other trade concerns raised at this meeting, Costa Rica remains open to receiving further information on the international reference organization standards used by the Colombian authorities to prepare this regulation.

2.339. The representative of <u>Paraguay</u> provided the following statement. Paraguay recognizes and supports the right of Colombia to protect the health of its population by limiting the sodium content of some foods as part of efforts to protect against chronic non-communicable diseases. However, Paraguay is concerned that the procedure is more restrictive than is necessary to achieve the legitimate objective pursued by Colombia with this measure. We therefore request that Paraguay's

 $^{^{93}}$ For previous statements follow the thread under ID <u>609</u>.

support for this concern be put on record and that its statement from the March meeting be recorded in the minutes in its entirety.

2.340. Statement from March 2023 meeting, in full.⁹⁴ We thank Costa Rica for the inclusion of this trade concern on the agenda and we request that Paraguay's support be recorded. Paraguay recognizes and supports the right of Colombia to protect the health of its population by limiting the sodium content of some foods as part of efforts to protect against chronic non-communicable diseases. However, Paraguay is concerned that the procedure is more restrictive than necessary to achieve the legitimate objective pursued by Colombia with this measure. In particular, it is concerned that the first party declaration may no longer be used, given the accreditation of an entity to certify compliance and the expiry of the period for using this type of certification (two years from the accreditation of the certifying entity).

2.341. The representative of <u>Guatemala</u> provided the following statement. Guatemala wishes to thank Costa Rica for including this item on the agenda. We recognize the Colombian Government's legitimate objective of safeguarding the population's health, and the efforts made to lower total sodium intake in Colombia in order to reduce hypertension and other related diseases. We are aware that Colombia's Ministry of Health carried out a simple regulatory impact analysis for the revision of Resolution No. 2013 of 2020, which establishes the Technical Regulation defining the maximum sodium content for the food prioritized in the framework of the National Strategy for the Reduction of Sodium Consumption. We look forward to the outcomes of the public consultation and would be grateful to the Government of Colombia if consideration were given to the comments made, and hope that updated information can be provided.

2.342. In response, the representative of <u>Colombia</u> provided the following statement. First, I would like to express our gratitude for the comments made on previous occasions and at this meeting. Second, I would like to highlight the importance of our work with various countries to address certain aspects of the measure, such as permitted certification schemes and the acceptance of first-party declarations, among other matters. As a result, our Ministry of Health and Social Protection has determined that it is possible to amend Resolution No. 2013 of 2020, and is doing so in two respects: Revising sodium levels for some products; Streamlining the conformity assessment procedure for manufacturers, which will allow for the submission of first-party declarations. To conclude, we reiterate our willingness to continue technical discussions to facilitate enforcement of the measure and put an end to this trade concern.

2.1.4.38 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 608⁹⁵)

2.343. The representative of <u>Costa Rica</u> provided the following statement. Costa Rica would like to reiterate this concern and emphasize the importance of harmonizing food labelling schemes, in particular front-of-pack nutritional labelling, on the basis of Codex Alimentarius standards (Guidelines on Nutrition Labelling CXG 2-1985, Annex 2, adopted in 2021). In this regard, we invite Mexico to use the Codex guidance on the subject as a reference to ensure that regulations are consistent with the international consensus and do not create unnecessary restrictions on trade. Costa Rica, as it has done for similar concerns raised at previous meetings of the Committee, wishes to remind other Members present of the importance of the work undertaken within the framework of the Codex Alimentarius and of the need for any food labelling measures adopted to be based on scientific evidence and on Codex Standards, in accordance with the provisions of the TBT Agreement.

2.344. In response, the representative of <u>Mexico</u> provided the following statement. The Government of Mexico recognizes the importance of using international standards as a starting point for developing technical regulations. However, at the time NOM-051 (and the amendment thereto) on the labelling of pre-packed food and non-alcoholic beverages was being drafted, there were no applicable international standards or guidelines to guide the implementation of front-of-pack labelling. Similarly, the Mexican delegation would like to state that the adoption, amendment or annulment of technical regulations in Mexico is governed by the standardization process established under the Law on Quality Infrastructure and is in compliance with the procedures stipulated in that Law, which are consistent with Mexico's international commitments. However, to date, NOM-051 has

⁹⁴ <u>G/TBT/M/89</u>, para. 2.106-2.107.

 $^{^{95}}$ For previous statements follow the thread under ID $\underline{608}.$

not been included in the National Quality Infrastructure Programme for 2024; therefore, no amendments are expected in the short term. The Mexican Government reiterates its commitment to fulfilling the international commitments under the TBT Agreement and the free trade agreements to which it is party, and reiterates that NOM-051 fulfils the legitimate objectives of priority concern of protecting public health and the right to commercial and health information on food and non-alcoholic beverages, by providing for consumers to make an informed purchase.

2.1.4.39 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 651⁹⁶)

2.345. 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 and reiterate some of its concerns with regard to this measure voiced at previous TBT Committee meetings. The additional costs that the issuance of these certificates carries for exporters are very high, particularly as there is a need for a certificate for each container in each consignment of fresh fruit and vegetables exported to India. This is even more important taking into consideration that the cost is entirely unnecessary since no fruits or vegetables in the EU can be genetically modified under EU legislation. India still did not provide justification on why it considers 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 would like to ask India to waive the requirement to attach the certificate for food items or alternatively to consider a less burdensome approach to meeting the Order's stated objectives.

2.346. The representative of the United States provided the following statement. This is the tenth TBT Committee meeting in which the United States has raised concerns regarding India's Order mandating "non-GM (genetically modified) origin and GM free certificates" for certain agricultural imports into India, notified on 2 September 2020, as G/TBT/N/IND/168. The United States once again acknowledges India's right to regulate "GM" foods, as laid out in their Environment Protection Act (1986) and Rules 1989. However, the United States continues to insist that India provide the rationale for requiring a non-GM certificate on a per-consignment basis for each of the 24 crops named in the Order. In response to India's request that Members cite specific trade issues in connection with the Order, the United States resubmits for the record that US apples experienced immediate and significant trade disruption upon the entry into force of the Order in March 2021, which was only resolved by a US State issuing a non-GM certificate. Additional US products have been affected by the Order, and the United continues to face further market access issues with genetically engineered products, in particular. Despite continuing to engage with India on this Order, we have been unable to make substantive progress to resolve these concerns. The United States requests that India immediately revoke this trade restrictive Order and engage in further dialogue with the United States to find mutually agreeable alternatives that do not unnecessarily impact trade.

2.347. The representative of <u>Japan</u> provided the following statement. Japan, like other Members, reiterates that the measure which requires 24 agricultural products imported by India to be accompanied by a certificate stating that they are not of genetically modified origin and do not contain genetic modification, is not based on scientific principles or proper risk assessment, and is a measure which is more trade-restrictive than necessary and could create unnecessary obstacles to agricultural trade between India and WTO members. In Japan, under domestic laws, the import, distribution, cultivation, and other general uses of genetically modified agricultural products for human consumption are subject to safety evaluations, and agricultural products that are not approved by the evaluation process could not be imported nor distributed domestically. If certain items are already under appropriate control in the origin country, India's objectives can be addressed in a less trade-restrictive manner. Japan requests India to withdraw the requirement to the attachment of certificates for foods that are properly controlled in the origin country.

2.348. The representative of <u>Canada</u> provided the following statement. Once again, Canada wishes to reiterate its concern regarding India's August 2020 Order, which mandates that a non-genetically modified or GM free certificate accompany imported consignments of 24 imported food products. Our concerns are detailed in comments submitted through India's TBT Enquiry Point in October 2020. We continue to wait for India's response. Canada views that India's Order unnecessarily restricts international trade, and disproportionately impacts the ability of GM-food producing countries to export to India, and could jeopardize India's need for healthy and nutritious food

 $^{^{96}}$ For previous statements follow the thread under ID $\underline{651}$.

products. While we understand India's commitment to ensuring the health and safety of its population, it still remains unclear to Canada how India's non-GM certification requirement will fulfil its intended objective given the lack of available scientific information and/or justification to support its implementation. We would like to emphasize again that foods derived from GM sources have a long history of safety and nutrition as compared to non-GM foods, and undergo rigorous risk assessment processes under robust regulatory frameworks managed by many different competent authorities worldwide.

2.349. We continue to call on India to share the scientific and technical information on which it has based its approach to support a transparent, predictable, risk- and science-based trading environment – in line with India's WTO commitments. Canada once again reiterates its request that India immediately suspend the implementation of this measure and allow trade to continue without a GM-free certificate requirement. We urge India to consider alternate, less trade-restrictive approaches that would meet India's objectives. Canada remains available and would welcome the opportunity to share its extensive experience regulating GM food safety while encouraging food innovation, and to pursue further discussions on this issue in a bilateral setting. Finally, Canada continues to reiterate its request for India to notify the non-GM Order to the SPS Committee given the Order's stated objective is "to ensure the safety and wholesomeness of articles of food imported into India."

2.350. The representative of <u>Argentina</u> provided the following statement. We would like to thank the United States and the European Union for once again including this specific trade concern on the Committee's agenda and request that Argentina's support be put on record. With respect to India's measure, Argentina regrets having to once again reiterate its concern and again stresses that the measure has no scientific explanation to support it. India has not responded to the concerns raised in a timely manner by Argentina, so our concern regarding this measure remains valid. We refer to statements made at previous meetings of this Committee.

2.351. The representative of <u>Paraguay</u> provided the following statement. We extend our thanks to the United States and the European Union for raising this trade concern. We are especially concerned that this measure may create an unjustified assumption that GM food products evaluated and authorized on the basis of sound regulatory processes are less safe than non-GM food products. GM products have undergone rigorous scientific safety assessments in accordance with international standards, guidelines and recommendations to ensure that they are considered as safe as their conventional counterparts. We request India to notify the Order to the SPS Committee, considering the objective being pursued, namely ensuring the safety and wholesomeness of imported foods, and to reconsider this policy, as it is not consistent with its WTO obligations.

2.352. The representative of Uruguay provided the following statement. Uruguay wishes to thank the delegations of the United States and the EU for, once again, including this concern on the agenda. Uruguay recognizes India's right to take measures to guarantee food safety and the health of its population. However, there should be a logical connection between the proposed measure and the objective pursued, and in this case, beyond the answers provided by India to date, there appears to be no technical justification for the implementation of the proposed certification measure, taking into account the cited legitimate objective of ensuring the safety and wholesomeness of imported foods. In the light of this objective, we wish to reiterate that, in our opinion, this measure should be notified to the SPS Committee. We consider it opportune to recall, once again, the existing international consensus that genetically modified products, approved by exporting countries on the basis of Codex recommendations relating to risk assessment methodologies, are equivalent to their conventional counterparts. Furthermore, Uruguay would like to stress how important it is for Members to establish measures based on scientific principles, and, in particular, for these measures to be implemented with the objective of minimizing negative trade effects, in line with the SPS and TBT Agreements. Lastly, we wish to reiterate the questions posed by Uruguay following the March and April 2023 meetings of the SPS and TBT Committees and the Goods Council, on the relationship between the measure referred to in this specific trade concern and the measure notified by India to the TBT and SPS Committees on 5 January 2023 (as documents G/TBT/N/IND/240 and

<u>G/SPS/N/IND/290</u>, respectively), regarding the Draft Food Safety and Standards (Genetically Modified Foods) Regulations, 2022.⁹⁷

2.353. In response, the representative of India provided the following statement. India thanks Member Countries interest in India's Non-GM cum GM free certificate requirement. The import of GM foods are not allowed in India (as per Environment Protection Act, 1986 and FSSAI Act, 2006). Therefore, to ensure that only Non-GM food crops are imported into India, FSSAI has notified the requirement of Non-GM certificate to be accompanied with imported food consignment, which is an assurance provided by the Competent Authority of exporting country that the food crops which are not approved by GEAC (Genetic Engineering Approval Committee) are not imported in India and importer has to provide the certificate as per the format notified by FSSAI. On similar lines, India has been issuing such certificates for its exports to other countries. Noting the restriction of GM foods in India, the tolerance limit for adventitious presence of GMOs at 1% is permissible in imported food crops and the same was notified vide FSSAI order dated 8 February 2021. Accordingly, import is permissible if the adventitious presence of GM content is less than notified tolerance limit. Further, 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 on date, our several trade partners are already providing requisite certificate and trade is going on smoothly. FSSAI is open to interact with trading partners for discussing the said matter in order to facilitate trade. However, with respect to specific query raised by the countries, India would like to state that: The TBT Agreement recognizes the right of a Party to adopt international standards as per the appropriateness or effectiveness for the Party. The precautionary measures have been taken by FSSAI since GM food is not allowed in India. Further, on similar lines, India also issues more than 7,000 GM free certificates yearly as per the requirement of the exporting countries.

2.1.4.40 Argentina - Decree Implementing Law No. 27.642 on the Promotion of Healthy Eating, <u>G/TBT/N/ARG/435;</u> <u>G/TBT/N/ARG/435/Add.1</u> (ID 772⁹⁸)

2.354. The representative of <u>Costa Rica</u> provided the following statement. Costa Rica wishes once again to express its concern regarding the Argentine regulation on the promotion of healthy eating, doing so in support of a systemic defence of the principles of the TBT Agreement relating to the adoption of measures based on scientific evidence and the harmonization of rules through the use of regulations issued by international reference organizations such as the Codex Alimentarius. Costa Rica is concerned by the lack of harmonization among the various food labelling standards and regulations, which has led to the proliferation of schemes with different content percentages requiring a warning, thereby creating unnecessary barriers to trade. Costa Rica wishes once again to stress the importance of harmonizing food labelling schemes, on the basis provided by the Codex Alimentarius, and encourages other Members to actively participate in the discussions on front-of-pack labelling within this international reference organization. Costa Rica undertakes to maintain an open dialogue between both countries' delegations to the WTO, with the aim of exchanging communications and information relating to the Argentine regulation.

2.355. In response, the representative of <u>Argentina</u> provided the following statement. For the record, our full response is available on eAgenda and is in line with our statements from previous sessions. We appreciate Costa Rica's interest in Law No. 27.642 on the promotion of healthy eating

⁹⁷ "In this connection, we would like to recall that the Order of 21 August 2020, establishing the certification requirement for the importation of consignments of any of the 24 crops specified in its Annex, indicates in point 2 that this requirement is adopted to ensure that only non-GM food crops are imported into India while regulations relating to products subject to genetic engineering or modification are developed in accordance with Section 22 of the Food Safety and Standards Act of 2006. The draft standard notified on 5 January 2023 refers in its recitals, *inter alia*, to Section 22 of the Food Safety and Standards Act 2006, which is the same as that referred to in the Order of 21 August 2020. In this regard, in line with the bilateral discussions on the margins of this meeting, we would like to request India to clarify the relationship between the two measures, if there is one, including whether or not the recently notified draft corresponds to the standard referred to in the Order of 21 August 2020. If so, does this mean that the certification requirement under the said Order will cease to apply once the draft standard notified on 5 January 2023, as it stands or modified, enters into force? If not, could India inform this Committee of the status of development of regulations concerning products subject to genetic engineering or modification as provided for in Section 22 of the Food Safety and Standards Act of 2006?"

 $^{^{98}}$ For previous statements follow the thread under ID <u>772</u>.

and we reiterate that it is consistent with the rules contained in the TBT Agreement. At previous meetings of this Committee, Argentina has provided detailed explanations of the development and implementation process for this Law. In recent years, essential population studies were published in Argentina that allow for a closer characterization of the epidemiological situation relating to nutrition and food. This is characterized by ever-increasing consumption of ultra-processed products and an increase in malnutrition rates, especially through excess, in all social groups. The excess consumption of critical nutrients regulated by labelling is associated with increased cardiovascular and cerebrovascular diseases, obesity, diabetes, cancer and hypertension, among others, which are the cause of most deaths each year in Argentina. Furthermore, studies carried out in 10 countries, including Argentina, also concluded that the consumption of products containing excess critical nutrients according to the Pan American Health Organization/WHO definition (which has been adopted by the Law and its implementing regulations in Argentina) is associated with significant non-compliance with WHO recommendations on the intake of these nutrients. Lastly, we reiterate our readiness to continue engaging bilaterally with the delegation of Costa Rica.

2.1.4.41 India - Footwear (Quality Control Order), 2020, G/TBT/N/IND/172 (ID 79799)

2.356. The representative of the United Kingdom provided the following statement. The United Kingdom thanks India for our bilateral engagement on their Quality Control Orders for Footwear which sets out quality control requirements for footwear made from leather and other materials. Like India, the United Kingdom acknowledges the importance of implementing high standards for footwear to ensure consumer protection. However, we believe that the applicable international standards provide an adequate means of ensuring product quality and safety. The Quality Control Orders in their current iteration seem to require manufacturers to manufacture to two different standards. The measures are being particularly burdensome to smaller manufacturers who may be unable to absorb the additional, unjustified costs. We believe that there are other, less trade restrictive options to ensure footwear is of a high quality and urge India to reconsider this measure. We again encourage India to continue their participation in the ISO/TC 216 Footwear and ISO/TC 94 Foot Protection Committees and to recognize that conformity with ISO relevant standards would fulfil Indian quality control requirements. Whilst the United Kingdom thanks India for extending the implementation of some of these standards until 31 December 2023, there continues to considerable uncertainty around how manufacturers can meet the new requirements, including those implemented in July. We request that India provide clearly accessible, written, step-by-step guidance on all requirements initially notified under symbol G/TBT/N/IND/172, to enable manufacturers to meet the requirements. Until there is clarity and appropriate guidance issued on the processes required to meet India's Quality Control Orders for Footwear, including the costs associated with certification, we request that India further delays the implementation of these standards. We would encourage India to allow for a period of at least six months in order to enable businesses to comply with the new requirements. The United Kingdom looks forward to continuing conversations towards resolution with India on this matter.

2.357. The representative of the <u>United States</u> provided the following statement. The United States would like to support the statement provided by the United Kingdom. We understand that India notified its Footwear Quality Control Orders in <u>G/TBT/N/IND/172</u> in 2020. Subsequently, in June 2022, India rescinded both 2020 Footwear QCOs and published the "Footwear Made from Leather and Other Materials (Quality Control) Order, 2022" and the "Footwear Made from all-Rubber and all Polymeric Material and its Components (Quality Control) Order, 2022," which have been in force since 1 July 2023. We would appreciate if India would notify an addendum to reflect the final measure entering into force, along with any additional changes or amendments contained in the 2022 Footwear QCOs to the WTO TBT Committee. We recognize the importance of ensuring consumer protection and addressing counterfeit goods. However, we are concerned that given the lengthy process in place to secure inspections as required by the QCOs, such requirements pose significant, time consuming, and costly burdens on manufacturers. It strikes us that there are less trade restrictive options available to address India's concerns, and we continue to encourage India to consider such alternatives.

2.358. The representative of the <u>European Union</u> provided the following statement. The European Union (EU) would like to support the United Kingdom and the United States. The EU recognizes the importance of high standards for footwear regarding product and chemical safety. However, standards must not become restrictive on companies that already apply high safety standards. The

 $^{^{99}}$ For previous statements follow the thread under ID <u>797</u>.

EU remains deeply concerned by the increasing number of Quality Control Orders (QCOs) issued by India across many sectors. The EU would like to recall that the majority of QCOs introduced by India appear to have a protectionist orientation and consequently raise questions regarding their compliance with the WTO's TBT Agreement obligations. The EU is particularly concerned by the fact that QCOs usually prescribe India-specific standards where international standards already exist. In fact, while dealing with QCOs, the procedures involved pose a greater hurdle than complying with the technical standards. The EU would like to remind India that Article 2.4 of the WTO TBT Agreement requires Members to use international standards, where they exist, as basis for their technical regulations, except, when such international standards or relevant parts would be ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems. India's notification <u>G/TBT/N/IND/172</u> sets out quality control requirements for footwear made from leather and other materials. Although, the notified standard applies to all footwear entering the Indian market, both India-made and imported, puts exporters in a disadvantaged position as the QCO restricts the imports.

2.359. As the QCO officially came into effect on the 1 July 2023, the utmost priority of footwear exporters lies in ensuring full compliance with the new legal framework. It is important to note that certain uncertainties persist to date, despite the multiple postponements of the entry into force date. The EU would therefore like to request the Indian authorities to consider granting targeted temporary exemptions for the following specific cases: Products already available on the market, particularly those for which the standards have been revised; The compulsory use of the standard mark on notified products, as specified in the QCO issued in order to cover the new standards; Professional sports footwear, for which the revised standard has not been released yet. The EU would also like to request India to provide a comprehensive list of HS codes of products covered by this QCO. The EU would like to recall that international standards should be used to facilitate trade and to limit the costs incurred by footwear manufacturers. Additionally, footwear imported to India should be allowed to be tested in laboratories outside of India. Testing only in India causes delays and additional costs. The EU would like to suggest to India to allow those brands, which meet the EU standards in footwear production to export to India, based on self-certification.

2.360. In response, the representative of <u>India</u> provided the following statement. India has taken various initiatives to improve the quality of footwear and QCOs are an important component in this regard. However, level playing field has been ensured for foreign and domestic manufacturers. India has its own quality standards developed by BIS and import of footwear and leather items to India has to follow these standards. Being one of the largest consumer markets, India has to protect the consumer's rights. As per the BIS Act, 2016, Leather and Footwear QCOs comes under scheme-I (ISI Mark Scheme) for which self-testing is not allowed to prevent the risk to human life and safety. All concerns of foreign manufacturers are being appropriately addressed by having meeting with them at various levels. We thank the UK and EU for the ongoing engagement on a bilateral basis on this STC.

2.1.4.42 European Union - Chlorothalonil (pesticide active substance), <u>G/TBT/N/EU/625</u>, <u>G/SPS/N/EU/394</u> (ID 579¹⁰⁰)

2.361. The representative of <u>Colombia</u> provided the following statement. Colombia is aware of the importance of foods free from excess pesticide residues that comply with international safety recommendations. However, the ban on active substances such as mancozeb, clothianidin, thiamethoxam and chlorothalonil, and the subsequent non-renewal of the approval of these substances, are hitting our country's agricultural export sector hard. While our health authorities are going to great lengths with the productive sectors to explore alternatives to meet the requirements, the search for substances to replace those that have been banned or whose approval is being modified requires time and investment, especially when potential alternatives are also becoming scarcer owing to changes to phytosanitary regulations in the European Union. A typical example of this, but not the only one, is the limited availability of an alternative to mancozeb, on account of similar substances, such as chlorothalonil, being banned in the European market. In this context, it is vital that the non-renewal or modification of approval for active substances takes into account production processes and methods in countries that could be affected. Failing to do so would violate Article 2.2 of the TBT Agreement, which stipulates that technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective. Failing to do so also seems to violate

 $^{^{100}}$ For previous statements follow the thread under ID $\underline{579}$.

Article 12.3 of the TBT Agreement, which states that account should be taken of the special financial and trade needs of developing countries, with a view to ensuring that regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports. In this regard, we agree with arguments presented in this Committee expressing the need for the European Union to bring maximum residue levels into line with the levels established within the framework of the Codex Alimentarius and to treat farmers in third countries no less favourably than it does European farmers. We therefore invite the European Union to seek out and support solutions that would allow our agricultural producers to continue meeting the European demand for food, to the benefit of not only developing countries but also the multilateral trading system, which has already been hit hard by this and other measures.

2.362. The representative of <u>Costa Rica</u> provided the following statement. Costa Rica wishes to reiterate this concern and refers to previous statements expressing its concern about the measure notified by the EU in document <u>G/TBT/N/EU/625</u>, which relates to the non-renewal of the approval of the active substance chlorothalonil. Costa Rica thanks the EU for its willingness to discuss agrochemicals policy, taking into consideration international foreign trade-related obligations and the agricultural and environmental policy objectives of the member countries of the international community. Costa Rica also reiterates its request and its commitment to leaving nobody behind in the implementation of its Green Deal policy.

2.363. The representative of Brazil provided the following statement. Brazil reiterates its support to STC 579, which has been brought to the attention of the TBT, in the form of STC, since March 2019. As much as Brazil thanks for the thorough attempts to explain such measures, it still constitutes a clear breach of the TBT Agreement and of other more general WTO principles and mandatory guidelines, for the reasons stated below: It lacks an adequate risk analysis; It is not in compliance with long-standing scientific principles; The use of chlorothalonil is currently authorized in more than 100 countries; Codex states that it could reach up to 70 mg/kg. 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 and watermelon, among other products. In this sense, Brazil would appreciate a brief explanation about the reasons for such discrepancy between Codex and the UE estimates. Which risks where identified regarding chlorothalonil residues? Were there concrete circumstances in which consumers were harmed? Furthermore, Brazil would appreciate being informed about how many import tolerance authorizations have been issued in the last five years. While thanking for the link provided in G/SPS/GEN/2139, it could not be accessed. Brazil would also kindly request that the EU informs objectively, transparently and inclusively what kind of information is considered appropriate for "import tolerance" or "emergency use" authorizations to be issued. If other countries are being benefited by any type of special waiver in this matter, the European Union will not only be imposing unnecessary technical barriers to trade, but also incurring in discrimination.

2.364. 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. We therefore refer to previous statements and request that the statement we made at the previous meeting of this Committee be included in the minutes of this meeting. Thank you very much.

2.365. *Statement from June 2023 meeting, in full.*¹⁰¹ 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. We once again request that the European Union take into consideration information on pesticides provided by the specialized agencies recognized by the WTO, such as the Codex Alimentarius. We also ask it to 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.

2.366. In response, the representative of the <u>European Union</u> provided the following statement. The EU thanks WTO Members for raising this issue once again. As explained in detail at several previous meetings, on 29 April 2019, the European Commission adopted the Implementing

¹⁰¹ <u>G/TBT/M/90</u>, para. 3.413.

Regulation (EU) 2019/677¹⁰² on the non-renewal of approval of the active substance Chlorothalonil, which was previously notified to the TBT Committee. This was based on a peer-reviewed risk assessment carried out by an EU member State (the so-called "rapporteur" member State) and the European Food Safety Authority (EFSA). Several serious concerns were raised by EFSA, so that the approval conditions for the substance were not fulfilled. As regards consumer safety, EFSA identified a genotoxicity concern for residues to which consumers would be exposed. Following the non-renewal of the approval decision and based on the fact that consumer health concerns were identified by EFSA, the EU prepared a draft Regulation lowering the Maximum Residue Limits (MRLs) for Chlorothalonil to the relevant limits of quantification. The draft Regulation was notified to the WTO/SPS Committee (G/SPS/N/EU/394) and published after its adoption as Commission Regulation (EU) 2021/155¹⁰³ of 9 February 2021. The EU wishes to emphasise that, although the substance chlorothalonil also meets the cut off criteria, decisions on MRLs in the EU are always based on a risk assessment and that this approach has also been followed for chlorothalonil. The new MRL values apply to all food products since 2 September 2021. Since then, there has been no further developments in the EU on this substance as no new data to support import tolerances were received. Import tolerance requests, which need to be supported by substantial new data addressing the concerns, remain possible and will be assessed on a case-by-case basis by the "rapporteur" EU member State and EFSA.

2.1.4.43 Australia - Maturation requirements for imported alcohol (ID 636¹⁰⁴)

2.367. The representative of <u>Brazil</u> provided the following statement. In advance I would like to thank the Australian delegation for our bilateral. It was a very important and constructive conversation and I believe the cooperation of Australia is very positive. The regulation "Australian Customs Notice No. 2007/19", which requires that some alcoholic beverages must be matured in wood for a minimum of two years, continues to impose a barrier to the trade of cachaça with less than two years of aging. Brazil and Australia both agree that there is no plausible technical reason to require maturation of sugarcane derivatives. In this sense, after four years since first bringing this matter up for discussion, it is high time the Australian government provides a concrete solution. As much as Brazil appreciates the current measures to promote legislative reform, a clear violation to the TBT Agreement cannot persist for that long for bureaucratic reasons. In that sense, the Brazilian government requests that immediate provisional concrete measures be taken to remove this ban, while a more permanent solution is unavailable.

2.368. In response, the representative of <u>Australia</u> provided the following statement. Australia acknowledges Brazil's interest in Australia's maturation requirements for certain imported alcohol products and its concern with how these requirements impact cachaca. As the Committee is aware, Australia established a whole-of-government working group in 2022 to consider trading partners' concerns regarding the maturation requirements for the importation of certain alcohol products into Australia. This working group continues to meet, most recently in August 2023. This is a complex issue which requires resourcing from multiple government portfolios. Any legislative changes to section 105A of the Customs Act 1901 and any other possible changes to requirements contained in other legislation need to be made in accordance with Australia's domestic regulatory reform processes. Australia takes seriously these concerns and has ensured Government Ministers remain updated on the status of this issue. We appreciate the patience shown while we work through the complexities of a resolution. The Australian Government will notify the TBT Committee of any proposed changes to address the issue when we are able, in accordance with Australia's obligations under the TBT Agreement. We remain committed to our productive bilateral engagement on this matter.

¹⁰² Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 concerning the non-renewal of the approval of the active substance chlorothalonil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending Commission Implementing Regulation (EU) No 540/2011. OJ L 114, 30.04.2019, p. 15.

¹⁰³ Commission Regulation (EU) 2021/155 of 9 February 2021 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products. OJ L 46, 10.2.2021, p. 5.

¹⁰⁴ For previous statements follow the thread under ID 636.

2.1.4.44 Colombia – Good manufacturing practices of overseas production establishments, <u>G/TBT/N/COL/242</u> (ID 697¹⁰⁵)

2.369. The representative of the <u>European Union</u> provided the following statement. The European Union would like to thank Colombia for its engagement in the WTO-TBT Committee and for the extensive bilateral discussions. The EU understands that Colombia is currently in the process of amending the relevant Decree to remove the GMP certification requirement and welcomes this development. We also understood that an impact assessment on the modification of the decree was carried out and concluded on 15 August this year. In this respect, the EU would be thankful for any further information on this process, notably on the envisaged timeline and confirmation of the final content of the modification. We are looking forward to a rapid conclusion to avoid any legal uncertainty and/or disruption of trade flows. The EU would like to thank again Colombia for their cooperation in this matter.

2.370. In response, the representative of <u>Colombia</u> provided the following statement. First, I would like to highlight the work that has been carried out by the health authorities of Colombia and the countries concerned, with a view to clarifying the concerns raised regarding this measure. Second, a regulatory impact analysis was indeed carried out, and the comments received were assessed during the national public consultation held last August. As a result, our Ministry of Health has stated that it is possible to amend and update Decree No. 162 of 2021, which it is in the process of doing. With this update, Free Sales Certificates may once more be used to indicate the quality of alcoholic beverages, thus addressing concerns raised by some trading partners and streamlining procedures for importers and certificate validation. Third and final point, we reiterate our willingness to continue discussions to facilitate enforcement of the measure and put an end to this trade concern.

2.1.4.45 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>, <u>G/TBT/N/EGY/313/Add.2</u>, <u>G/TBT/N/EGY/313/Add.6</u> (ID 718¹⁰⁶)

2.371. The representative of the <u>European Union</u> provided the following statement. The European Union would like to express 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 the negative impact of this measure on food and beverages imports to Egypt. The EU has noted that the waiver for dairy products was then extended several times, most recently until 31 December of 2023, by the latest Addendum 6, as introduced on 8 August. We would like to appreciate this considerable level of flexibility of Egypt's authorities, which is very helpful to economic operators. Nevertheless, economic operators still miss several important and practical information, as mentioned in EU comments from January 2022, such as deadlines for issuance of certificates by IS EG Halal, details on audits, etc. EU comment regarding the monopolistic position of the IS EG Halal, does not seem to have been considered either. There have been unverified reports that a second certifier has been appointed and rumours that rules are being drafted to open up the possibilities to other companies to apply to become certifiers.

2.372. In this context 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. The requirement to re-certify, by IS EG Halal, products already certified by other certification bodies, is an unnecessary duplication and leads to delays and ultimately to higher costs for consumers in Egypt adding to inflationary pressures. The EU would like to ask Egypt to consider keeping the Halal certification and labelling voluntary for dairy products, 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. 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 a detailed description of the certification procedure, its duration, costs, and required documents, as well as the process for registration of

 $^{^{105}}$ For previous statements follow the thread under ID <u>697</u>.

 $^{^{106}}$ For previous statements follow the thread under ID $\underline{718}.$

suppliers. 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.

2.373. The representative of <u>Australia</u> provided the following statement. Australia thanks Egypt for ongoing bilateral communication on the implementation of new Halal certification requirements for food and beverage products of animal origin. Australia reiterates the importance of open and transparent communication on these requirements for trading partners and so Egypt can meet its policy goals while ensuring measures are not more trade restrictive than necessary. Australia continues to seek written feedback to comments on TBT notification <u>G/TBT/N/EGY/313</u> provided in January 2022 and would welcome a response from Egypt. Australia also invites Egypt to separately notify the TBT Committee of the revised Egyptian standard 4249 "General Requirements on Halal Food according to Islamic Sharia" before finalization and publication. Australia welcomes ongoing discussion on the implementation of Egypt's Halal certification measures.

2.374. The representative of New Zealand provided the following statement. New Zealand thanks the Egyptian Organization for Standards and Quality (EOS) for publication of the final halal standard, ES4249. We note the scope of the new Standard's application is meat products, and animal fats and lipids, and only those general food products which contain specific non-dairy animal product additives. New Zealand understands that Egypt will provide further clarification on the implementation of the ES4249 standard. We request that this set out clearly: (1) the responsibility of the respective Egyptian government agencies for the different steps of the halal certification process, and their relevant contact points; and (2) the specific steps that domestic and foreign suppliers of halal products must follow to comply with the Standard, including publication of issues such as timeframes, registration/audit requirements, fee schedules and labelling requirements. Once it has been notified to the WTO and has been consulted on as a final set of requirements for Halal imports into Egypt, New Zealand requests that a reasonable transition period, of at least 6-12 months is provided. This transitional period will allow exporters time to understand and comply with any new requirements. We invite Egypt to further consider the approval of multiple halal certification bodies for certification of halal food products into the Egyptian market, in accordance with international best practice. Allowing multiple, well-established, certification bodies to certify products as halal will make Egypt's halal regulations less trade restrictive, reduce the impact of duplication and other unnecessary costs on consumers, help resolve supply chain issues, and promote Egypt's overall food security.

2.375. The representative of Canada provided the following statement. Canada continues to be concerned by Egypt's new halal certification requirements for all imported food and beverage products. While Canada understands Egypt's objective to ensure that Egyptian consumers are confident that they are buying and consuming Halal-certified products, we believe that such measures should not create unnecessary barriers to international trade or be more trade-restrictive than necessary to fulfil that objective. Canada welcomes Egypt's delayed implementation of the halal certification for dairy products to 31 December 2023. However, Canadian exporters require additional information to adapt to these new measures. The current lack of clarity surrounding procedures, fee structures, audit details, documentation requirements, and the specific implementation process is causing ongoing ambiguity and uncertainty. In light of these concerns, Canada refers to our previous statements made at this committee and urges Equpt to reconsider the implementation of this measure. The absence of a clear implementation protocol, coupled with unnecessary added cost and administrative burden further highlights the need for Egypt to reconsider this measure. Canada strongly encourages Egypt to engage in open and transparent discussions with trading partners to share information, provide further clarification on the requirements associated with this new measure and to consider the impact it may have on trade. Canada also recommends that Egypt explore the establishment of halal certification offices overseas or partner with existing certification bodies in other member countries, including Canada. Until these concerns are addressed, Canada respectfully requests that Egypt suspend the implementation of this measure. This would allow for the necessary dialogue and collaboration between both nations, fostering a conducive environment for trade and ensuring the smooth transition for Canadian exporters.

2.376. The representative of <u>India</u> provided the following statement. India would like to reiterate its previous concern as we await Egypt's response to the previous statement. India joins other WTO Members in raising concerns with Egypt's new halal certification requirements for all imported food and beverage products. In the context of the Egyptian Standard ES 4249/2014 on General Requirements for Halal Food according to Islamic Sharia, India seeks detailed information concerning

implementation of the same. Further, India seeks Egypt's reconsideration on the decision to grant the right to certify the compliance with halal requirements to a single entity, and requests Egypt to provide a system that would allow other certification entities to certify as well. In light of the currently prevailing challenges with the measure, India requests Egypt to delay the implementation until the challenges are resolved.

2.377. The representative of <u>Switzerland</u> provided the following statement. We share the concerns expressed by other Members regarding the requirements for halal certification and refer to previous statements in this Committee. We appreciate that the Egyptian authorities have extended the period during which imports of milk and dairy products without a halal certificate are allowed until the end of 2023. To prevent ambiguities and uncertainties, Switzerland asks for a further extension of the exemption for milk and dairy products until at least six months after the publication and TBT notification of a clearly defined and final scope as well as clear guidelines and procedures for the implementation of halal requirements for milk and dairy products. We also reiterate the importance of recognizing – in accordance with the international best practices – foreign halal certification bodies and to clarify the criteria for the acceptance of foreign halal certificates.

2.378. The representative of the <u>United States</u> provided the following statement. The United States continues to have concerns with the lack of clarity provided by Egypt in its implementation of changes to its halal certification requirements. The continuing lack of clarity has resulted in growing uncertainty for U.S. exporters who seek to comply with this measure. While the United States appreciates Egypt delaying implementation of this measure until 1 January 2024, what is most needed is clear information that will allow exporters to understand and comply with the new requirements. The United States renews its request that Egypt publish a technical regulation that describes the implementing procedures for all products that require halal certification as a condition of import, including dairy products. While Egypt has deferred previous questions about implementation to the designated certifier, details about fee structures, documentation requirements, production process requirements, test methods, etc., are the responsibility of the regulatory authority. We encourage the Government of Egypt to publish these details to ensure uniform implementation of this measure and to maintain halal integrity.

2.379. The United States also requests that Egypt include in the technical regulation a clear scope of products that require halal certification, which will consolidate or resolve discrepancies in previous notifications. Finally, the United States renews its request that Egypt allow overseas certification bodies to again provide halal certification services for products exported to Egypt. Having multiple halal certification companies increases halal assurance while lowering certification costs. With recent approval of a new halal certifying body in Egypt, we also request that Egypt communicate the criteria and process that it uses to determine which certification bodies are approved or not approved? Does Egypt have a timeline for when it plans to approve additional certification bodies, including those based in the United States? The United States thanks Egypt for its continued willingness to work with the United States and other trading partners to ensure that exporters have adequate information to understand and comply with its new halal requirements. The United States looks forward to Egypt's response and toward continuing to provide quality halal products to Egyptian consumers.

2.380. The representative of <u>Paraguay</u> provided the following statement. Paraguay reiterates its concern and requests that its statement from the March 2023 meeting be put on record.

2.381. Statement from March 2023 meeting, in full.¹⁰⁷ We thank the delegations of the United States of America, the European Union, India, Kenya and Canada for including this item on the Committee's agenda and we request that the support of Paraguay be recorded. While Paraguay shares Egypt's interest in providing its consumers with certainty regarding the purchase and consumption of halal-certified products, the lack of clear information and details on application procedures prevents operators from being able to adapt to comply with them. Paraguay again requests Egypt to suspend the implementation of new halal certification requirements until Members have all the requested information and business operators have sufficient time to adapt in order to comply.

2.382. In response, the representative of <u>Egypt</u> provided the following statement. Egypt thanks the United States, the European Union, India, Canada, New Zealand, Switzerland, Australia, Paraguay

¹⁰⁷ <u>G/TBT/M/89</u>, para. 2.275.

for their interest in this issue and their continued engagement on the matter, while recognizing Egypt's right to adopt the halal certification requirements, which we deem necessary and appropriate to achieve our legitimate policy objective yet remain consistent with our obligations under the TBT Agreement. Recognizing the comments that our trading partners raised in the last Committee meetings and in the bilateral meetings we had with them, Egypt would like to point out that since the introduction of the requirement with respect to milk and dairy products by General Organization For Veterinary Services (GOVS), Egypt has introduced a number of facilitating measures extending the timeline to abide by the requirement for more than a year now. This has provided the business operators an appropriate period of time to adapt to the set of requirements. It is also important to note that since its initial notification, Egypt has been clear that the certification body currently recognized by the required authority is ISEG Halal. In fact, a lot of exporters have indeed approached ISEG Halal and issued the Halal certification successfully.

2.383. It is also important to clarify that the Egyptian standard ES4249 does not and shall not provide for any supervision requirements for a specific certification body. As per notification G/TBT/N/EGY/313/Add.6, the extension of the time period during which imports of milk and dairy products that are not accompanied by a Halal certificate were allowed to enter into Egypt until the end of this year, as a trade-facilitating measure and in response to the requests made in this respect. It is also worth noting that during the period April 2023 until now, no imports of milk and dairy products have been denied entry if not accompanied by a Halal certificate. Moreover, the relevant authority is currently preparing the necessary technical regulation with respect to Halal requirements for dairy products that comprise: the product coverage which will be confined to dairy products as stipulated in ES4249/2023; the role of the relevant entities involved including the Halal certification bodies, to be approved by the relevant authority; also there will be a transitional period between issuance of the regulation and its entry into force to allow producers in exporting countries to duly adapt. Furthermore, the competent authorities would also publish the criteria for approving Halal certification bodies, including the requirement for registration at the relevant authority. It will be duly notified once issued. Finally, I would like to stress that Egypt is committed to continue its bilateral exchanges on the matter with all interested trading partners and to take into account their concerns as appropriate and stress our commitment to the transparency requirements under the TBT Agreement.

2.1.4.46 India - Order related to requirement of Health certificate accompanied with imported food consignment of Milk and Milk Products, Pork and Pork Products & Fish and Fish Products, <u>G/TBT/N/IND/233</u> (ID 780¹⁰⁸)

2.384. The representative of the <u>European Union</u> provided the following statement. The EU would like to thank India for postponing, until 1 January 2024, the entry into force of the certificate for the import milk and milk products, and for putting on hold, until further notice, the two certificates for the imports of pork and pork products and fish and fish products. The EU would also like to thank India for the bilateral exchange that helped clarify a number for open issues. In relation to the animal health and food safety (integrated) certificate for import of milk and milk products, the EU would like to ask India to remove from the certificate all the requirements that are not covered by the Codex Alimentarius, such as those related to pesticides, several antibiotics and other drugs, or to provide a scientific justification to maintain those requirements. In relation to the integrated certificates for import into India of pork and pork products and fish and fish and fish products, the EU would like to ask India to: - Clarify the state of play of the two integrated certificates; - Confirm that the food safety certificates are the only certificates required; - Confirm that the food safety certificates were withdrawn.

2.385. In relation to the certificates used to import the three types of products (milk, pork, fish, and their respective products), the EU would like to ask India to: - Remove from all certificates the non-animal health and non-food safety elements and requirements, such as invoice numbers, limitation of certain milk coagulating enzymes, etc.; - Clarify the modalities related to audits to the exporting countries, inspections of facilities, questionnaires, regionalization, border checks and listing of establishments associated to all the certificates, if and when these requirements will be made obligatory by any of the authorities of India; - Notify to both the WTO TBT and SPS Committees the above-mentioned modalities and all future certificates – including integrated certificates – well in advance of the date of their entering into force, to ensure full transparency and timely follow-up by all the competent authorities, producers and exporters; - Take into consideration the comments

 $^{^{108}}$ For previous statements follow the thread under ID $\underline{780}$.

that the EU has sent or may still send to India in relation to the certificates and provide in writing the scientific justifications for not taking those comments into account; and - In the future, avoid the duplication of sanitary measures in and associated to the different certificates, which are required by different competent authorities of India; Finally, the EU reiterates its availability to cooperate with the competent authorities of India, to enhance mutual understanding and avoid unnecessary and unjustified disruptions to trade.

2.386. The representative of Australia provided the following statement. Australia supports the concerns of the European Union, New Zealand, Japan, Switzerland and Canada. Australia respects India's commitment to protect the safety standards for food products imported into India. Australia thanks India for providing clarification on the requirements of the certification order, including that a single certificate incorporating both FSSAI's and DAHD's requirements is acceptable. Australia also thanks India for extending the deadline for dairy certificate negotiations until 31 December 2023 and providing a formal response to Australia's proposed dairy health certificate. Australia maintains a well-established, robust export system and is a source of reliable, wholesome, and safe agricultural exports. Australia's export system is underpinned by a strong regulatory framework enforced through compliance with Australia's export control legislation. This legislation provides trading partners with assurance that exported food products are free from harmful contaminants, are suitable for human consumption, and that importing country requirements are met. Australia is committed to working with India to negotiate mutually agreeable health certification for imports of Australian milk and milk products into India before the proposed 31 December 2023 deadline. Australia encourages India to minimize requirements that duplicate commercial information provided and consider recognising equivalent food safety outcomes in certification. As noted in previous statements Australia would appreciate India's assurance that existing health certification for milk and milk products, previously bilaterally agreed with DAHD, will continue to be accepted until certification negotiations are concluded, should negotiations extend beyond 31 December 2023.

2.387. The representative of <u>New Zealand</u> provided the following statement. New Zealand thanks FSSAI for the interactive process that was undertaken to gain approval for the New Zealand certificates and supports FSSAI's goal in ensuring India has robust food safety requirements. We would like to ask that for any future changes to India's certification requirements, FSSAI allows longer implementation periods, factoring in time to consider submissions by Member countries on the relevant WTO notification, and time for countries to do any required assessment and implement changes to requirements accordingly. A minimum of six months, but preferably twelve months, would likely provide countries sufficient time for adequate implementation. The certificate approval process by both FSSAI and DAHD is lengthy and New Zealand requests that consideration is given to simplifying this process for government-to-government negotiated certificates that don't exactly line up with the proposed template i.e. provision of equivalent assurances as per CAC/GL 38-2001 Codex Guidelines for Design, Production, Issuance and Use of Generic Official Certificates. New Zealand recommends that DAHD and FSSAI's internal processes be coordinated prior to issuing any new food safety certification requirements, to avoid unnecessary duplication particularly when there is no added food safety benefit.

2.388. The representative of Japan provided the following statement. Japan reiterates again its concerns regarding India's Order related to requirement of health certificate accompanied with imported food consignment of milk, pork, fish and related products. India has announced the extension of the date of implementation, and a specific date of implementation has not been announced yet. Although Japan appreciates India's decision to extend the date of implementation, we still think that India should set sufficient transition period before the implementation of the Order in order to allow time for exporting Members to adapt their system to the new health certificate forms. Japan notes that one of the objectives of India's Order is to ensure the safety of imported food products into India. If that is the case, Japan considers that India should notify the Order under the SPS Agreement as well.

2.389. The representative of <u>Switzerland</u> provided the following statement. Switzerland shares the concerns expressed by other Members with regard to India's requirement of a health certificate in particular for milk and milk products. Switzerland thanks India for the bilateral discussions on the health certificate to date and remains committed to work with the Indian authorities to find solutions for an amended Swiss health certificate in order to avoid unnecessary obstacles to trade. We ask India to postpone the introduction of new health certification requirements until there is more clarity with regard to the content as well as to the coordination of the competent authorities' procedures in order to avoid duplication.

2.390. The representative of <u>Canada</u> provided the following statement. Canada welcomes India's decision to delay the implementation of FSSAI's new certification requirements until further notice, giving sufficient time for competent authorities to develop a joint certificate. Canada reiterates its concerns with a number of new FSSAI certification requirements, which reference Indian regulations, requirements and product standards, and encourages India to streamline certification requirements, and base its requirements on international standards. Canada again requests India to notify these requirements to the SPS Committee given that India's proposed regulation covers food safety measures aimed at protecting human health and safety.

2.391. In response, the representative of India provided the following statement. Considering the representations received from various stakeholders including member nations, FSSAI and Department of Animal Husbandry and Dairying agreed on an integrated veterinary health certificate (VHC) for milk and milk products, which covers both food safety as well as sanitary related provisions, required by both the departments (FSSAI and DAHD) to facilitate trade. Accordingly, order related to the integrated veterinary health certificate for milk and milk products was issued vide DAHD O.M. no. L-11/1/2019- Trade (E-11542) dated 31 March 2023. For further facilitation of trade, transition time for implementation of the requirement of integrated Veterinary Health Certificate for milk and milk products has been extended till 31 December 2023 vide DAHD O.M. dated 17 July 2023. Therefore, the imported consignments of milk and milk products having bill of lading/ date of issuance of VHC from exporting countries after 31 December 2023 will only be considered for post- import clearance, based upon integrated veterinary health certificate for import of milk and milk product into India. FSSAI has received proposed integrated veterinary health certificates from various countries for negotiation regarding language and requirements given in the integrated veterinary health certificate by India. The received draft health certificates have been examined for General Information and Food Safety related conditions. The deficiencies observed in the draft certificates have been communicated to the respective countries. Majority of countries have agreed with the Integrated Health Certificate. However, few countries have raised minor concerns with respect to modification in the language, which have been addressed. Specifically, bilateral engagements with Australia and New Zealand are ongoing on this issue. We also acknowledge constructive bilateral dialogue with the EU on this STC.

2.1.4.47 Morocco - Conformity assessment, <u>G/TBT/N/MAR/28</u> (ID 779¹⁰⁹)

2.392. The representative of the European Union provided the following statement. On 18 December 2019 Morocco notified to the WTO TBT Committee the verification of conformity of certain imported industrial goods under reference G/TBT/N/MAR/28. The EU sent comments in January 2020 and also followed up with bilateral discussions and two letters. Despite these discussions concerns remain on the EU side. As regards the conformity control system for industrial products, Morocco informed us that the legislative framework does not make a distinction on the basis of whether the product is imported or manufactured locally. However, the arrangements for checking compliance vary depending on whether imported or local products are concerned. Since the introduction of the new system in February 2020, checks on imported industrial products have been outsourced for a lot of products and require the systematic obtaining of a certificate of conformity issued by one of the five approved bodies, which is very burdensome and costly. On the other hand, checks on local products are carried out based on a national market surveillance plan, and risk-based according to the products in question, so not on a systematic basis. This difference in treatment seems problematic to us. The TBT Agreement (Article 5.1) provides that conformity assessment procedures should be prepared, adopted and applied so as to grant access to suppliers of like products originating in other Members under conditions no less favourable than those accorded to suppliers of like products of national origin, in a comparable situation.

2.393. We have furthermore been informed by our industry that of the five conformity assessment bodies that can perform these checks, two are currently suspended. This makes it even more difficult for the EU industry to access the Moroccan market. The Moroccan conformity assessment procedure for the respective products create an unnecessary obstacle to international trade as the procedures seem stricter than necessary to give Morocco adequate confidence that products conform with the requirements set out in technical regulations. In this respect some aspects of the procedures need to be clarified, such as whether there is any possibility for importers to avoid repeating the conformity assessment procedure for any shipment to Morocco, which seems to be unnecessarily burdensome in particular for less risky products. Moreover, as to Morocco's technical regulations

 $^{^{109}}$ For previous statements follow the thread under ID $\underline{779}$.

that impose the use of Moroccan standards corresponding to international and EU standards, Morocco should accept EU certificates that are based on the same international and EU standards and done by ILAC laboratories like a lot of countries are doing world-wide. Another important problem that we face is that some Moroccan regulations depart from international standards without providing an adequate justification. The standardization process and the subsequent transformation of the national standards into compulsory technical regulations also raise questions of transparency. We would be grateful if Morocco could take these concerns into account and work on the review of their conformity assessment system. We are ready to engage in bilateral discussions in order to clarify the issue further.

2.394. The representative of <u>Morocco</u> did not provide a response to the concerns raised.

2.1.4.48 India - Safety requirements with respect to the Rechargeable Electrical Energy Storage System (REESS) for electric power train vehicles, of AIS-038 and AIS-156 (ID 774¹¹⁰)

2.395. The representative of the Republic of Korea provided the following statement. Korea would like to express our gratitude to India for the sincere response provided at the March WTO TBT Committee and bilateral meetings in response to Korea's review request regarding the "Standards for Safety Requirements for Rechargeable Energy Storage Systems (REESS) for Electric Powertrain Vehicles". In September, Korea submitted some follow-up comments on the REESS requirements via the TBT Enguiry Point but is yet to receive India's reply. Korea is reaching out once again through this STC to enquire and address concerns raised by pertinent industries. In accordance with India's responding statements to the STC, it is expected that reviews, analysis and stakeholder consultations are in progress or will take place for Amendment 3 of AIS-038 (Rev.2) and Amendment 3 AIS-156. However, Korean companies exporting automotive batteries/cells to India are currently in confusion regarding the implementation schedules of the aforementioned standards, given that phased implementation dates for the amended testing standards published on the MoRTH (Ministry of Road Transport and Highways)'s website last 27 September were specified as 1 December 2022, and 31 March 2023. Therefore, Korea would like to make an inquiry about the current implementation status of the Amendments to AIS-038 (Rev.2) and AIS-156. If they are not yet in effect, we would like to request information about their tentative schedules or upcoming timelines.

2.396. In addition, according to the "Testing Parameters to Enhance Human Safety of Incentivised Electric Vehicles" (hereinafter, the 'Guidelines for Battery Safety Test') disclosed by the Ministry of Heavy Industries (MHI) of India on 2 November 2022, it is our understanding that starting from 1 October 2023, UL 1642 will be mandatorily applied for electric vehicle battery cells, and either UL 2271 or UL 2580, along with IEC 62133-2, will be mandatorily applied for battery packs, to verify that the battery products for electric vehicles meet Advanced Chemistry Cell (ACC) criteria, which in turn determines eligibility for incentives. However, the UL 1642 standard covers lithium battery cells that are user-replaceable and used in portable devices. Since automotive battery cells have a higher lithium content than portable device battery cells and cannot be replaced by the user (i.e. the driver), we would like to request for your clarification on the reasons for adopting UL 1642 as the ACC verification standard for automotive cells. Finally, the Guidelines for Battery Safety Test do not provide clear test procedures and criteria for the Battery Management System (BMS), making it difficult for the related industries to comply with the MHI regulation. Therefore, it is also requested that more specific information for the BMS tests be provided.

2.397. In response, the representative of <u>India</u> provided the following statement. India would like to reiterate the detailed reply given in the previous meeting. As informed earlier, the concerns raised by stakeholders including industry from Germany and Korea were internally reviewed by the panel of experts. After examining the proposed modifications in the standards and the intended purpose of the clause of the standard, certain suggestions were considered for acceptance. The standards are based on Indian conditions.

 $^{^{110}}$ For previous statements follow the thread under ID $\underline{774}$.

2.1.4.49 Malaysia - Revision of the Regulations on Alcoholic Beverages in Food Regulations 1985, <u>G/TBT/N/MYS/114</u> (ID 793¹¹¹)

2.398. The representative of the European Union provided the following statement. The European Union would like to thank Malaysia for the notification G/TBT/N/MYS/114 of 27 October 2022 on amendment to Regulations 361 to 368A and 387 and insertion of a new Regulation 384A to Food Regulations 1985. We would like to provide appreciation for very constructive exchanges, which we had with Malaysia between December 2022 and June 2023, on the subject covered by the said notification. At the same time, we are looking forward to further exchanges, until this STC is positively resolved. We have also been informed that Malaysian authorities started a supplementary review of the legislation in question and there seem to be some positive signals, as regards considering comments from international partners. The EU very much appreciates this latest development and is waiting for further official information from our Malaysian colleagues, particularly as regards the planned timeline and the estimated adoption of the adjusted version of the abovementioned legislation. By that time, the EU would also highly appreciate a flexible approach from the Malaysian authorities as regards the implementation of the said Regulations in their current version, in order to prevent any further trade disruptions. At the moment, e.g. aperitifs (<15% abv) and ready-to-drink products are banned from the market and we understand from Ministry of Health that it will take several years (5) to insert new product categories in the Food Regulations.

2.399. The representative of Japan provided the following statement. We welcome Malaysia's comments in the previous Committee on Technical Barriers to Trade in June that "It is of Malaysia's utmost interest to ensure smooth flow of trade with trading partners and we remain ready to facilitate the importation of goods into Malaysia, in line with Article 2 of the TBT Agreement." We highly appreciate the flexibility that Malaysia has shown in the amendment regulations for alcoholic beverages with respect to lowering minimum alcohol content of Liqueur from 17% to 15% by considering Japan's requests partially. However, even if Malaysia lowers minimum alcohol content of liqueur to 15%, it is still not possible to import liqueur products with less than 15% alcohol content such as prepared cocktails, because there is no such category in Malaysia at the moment. We recognize that Malaysia's measure to have no applicable category of liqueur products with less than 15% alcohol content is more trade restrictive than necessary to achieve a legitimate objective. Thus, this measure may conflict with the Article 2.2 of the TBT Agreement. We would appreciate if Malaysia could explain the valid reason why there is no category under which liqueur products with less than 15% alcohol content, while there are some categories for other types of alcohol beverages with less than 15% alcohol content in Malaysia. Although we understand that the process of revising the Food Regulations 1985 is currently in its final stage, we appreciate if Malaysia could consider the definition of liqueur again, particularly about deleting or lowering the minimum alcohol content of liqueur. Though the Food Regulations 1985 is revised once every five years, we also highly hope that Malaysia will remove the barrier on trade on liqueur products with less than 15% alcohol content without waiting for the timing of the next revision. Lastly, we are very much grateful that we were able to have a bilateral meeting in October to exchange opinions frankly with each other. We also would like to continue to follow up on this issue while exchanging opinions with Malaysia.

2.400. In response, the representative of Malaysia provided the following statement. Malaysia thanks the European Union and Japan for their continued interest in our proposed amendments related to the alcoholic beverages. On behalf of my Capital, Malaysia truly appreciates the constructive engagements and we are glad for the opportunity to give better clarity on this matter. The requirements for standard and labelling compliance for alcoholic beverages under the Malaysian Food Regulations 1985 are existing regulations that have been enforced since their gazettement. They are not new regulations, including the categories of alcoholic beverages and their specified minimum percentage of alcohol content. As we have explained in the previous TBT Committee Meeting, the TBT notification involves proposed amendments to the Food Regulations 1985 related to alcoholic beverages regulations, as part of the national five-years review. The proposed amendments involve specific requirements of alcoholic beverages regarding the alcohol content, the addition of other ingredients, the use of food additives and labelling requirements. Following the end of the commenting period, Malaysia has positively taken into account the international partners' comments in the final draft. Among others, these include amendments related to the alcohol content of wine, wine cocktail, shochu, rice wine, and liqueur, as well as definition of liqueur, rum and vodka. Turning to the European Union's statement, we wish to highlight that currently, the proposed amendments are in the final stage which is under the review of the Attorney General's Chambers of

 $^{^{111}}$ For previous statements follow the thread under ID $\underline{793}$.

Malaysia, before final approval by the Minister of Health Malaysia. We will update the interested international partners on the date of entering into force, once the amendments are gazetted and published. Normally, a minimum interval of 6 months will be provided between the publication of the new amendments and their entry into force. Until the new amendments are gazetted and enforced, the existing regulations under the Malaysia Food Regulations 1985 shall be complied for food products that are imported or sold in Malaysia. We appreciate the European Union's understanding on this matter.

2.401. With regard to the statement by Japan, Malaysia would like to reiterate that we prioritize the Codex standard as the main reference in the development of food standards requirements under the Malaysian Food Regulations 1985. For alcoholic beverages, it is important to note that there is no specific Codex commodity standard prescribed in the Codex standards. The food category in the Codex General Standard for Food Additives (GSFA) only states the definition of food categories and requirements of food additives for alcoholic beverages. According to the notes on food category system in the GSFA, the Codex food category descriptors are not to be legal product designations nor intended for labelling purpose. As we understand on the nature of the Codex standards that Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply. In this case, its applicability to Malaysia is depending on the provisions in the Malaysian Food Regulations 1985. Acknowledging the on-going technical bilateral efforts with Japan, we welcome the opportunity for our authority and technical experts to continue discussing on this issue. In conclusion, thank you again to the EU and Japan for highlighting their views and concerns, and we are ready to engage further with both parties, as well as other Members.

2.1.4.50 European Union - Amendment of the authorisation for the active substance sulfoxaflor, <u>G/TBT/N/EU/853</u> (ID 792¹¹²)

2.402. The representative of <u>Brazil</u> provided the following statement. Brazil would like to refer to the European Union's notification <u>G/TBT/N/EU/853</u> and to the Commission Implementing Regulation (EU) 2022/686, restricting the use of sulfoxaflor to indoor uses only, in order to protect bees. Sulfoxaflor is a priority crop protection tool used by Brazilian growers of orange. It is used to control pests such as the citrus psyllid, an insect that transmits the greening disease, recognized by the European Food Safety Agency (EFSA) as a priority pest for control in EFSA's List of Priority Pests of October 2019. Greening is a major cause of losses in orange production not only in Brazil, but worldwide. Considering the relevance and potential impacts of such measure, Brazil would like to reiterate that a solid risk analysis, consistent with the Codex Alimentarius' recommendations, will be important to ensure transparency and predictability in the regulatory process. Regulators should consider the variety of local conditions, including climate, soil and the different needs and challenges posed by agricultural production in each country. In Brazil, the use of sulfoxaflor has been approved by relevant authorities after rigid technical procedures, including an assessment by the Brazilian Institute for the Environment that considered the effects of the substance in bees.

2.403. The Brazilian State of São Paulo is the main citrus juice producer and it is also where 84% of honey production is concentrated. In that state, there is no evidence of a decline in the number of pollinators. On the contrary, honey production in that region has increased by about 136% in Brazil reiterates, 15 years (2008-2022, BR Citrus). moreover, concern over the extraterritoriality effects of the intended measure. It is out of the scope of the TBT Agreement to support unilateral policies aimed at supposedly protecting the environment in third countries (Article 2.2). Furthermore, Brazil respectfully asks the EU whether the EFSA study considered data from other regions, whether this would be the least trade-restrictive measure, in addition to seeking to clarify whether the objective of the measure is to protect pollinators outside EU territory. Once more, Brazil would highly appreciate if the EU could provide further clarifications on the proposed measure and take these comments into consideration in the regulatory process.

2.404. In response, the representative of the <u>European Union</u> provided the following statement. The EU notified the draft Commission Implementing Regulation amending the conditions of approval of the active substance sulfoxaflor on 17 November 2021 (<u>G/TBT/N/EU/853</u>), based on the evaluation of confirmatory data, as required in Regulation (EU) 2015/1295 approving its use in the EU. On 28 April 2022, the European Commission adopted the Commission Implementing Regulation (EU) 2022/686 restricting the use of sulfoxaflor to indoor uses only. The conclusion is based on a

 $^{^{112}}$ For previous statements follow the thread under ID $\underline{792}$.

risk assessment (peer-reviewed at EU level under the lead of the European Food Safety Authority -EFSA). EFSA concluded risk to bees is low when plant protection products containing sulfoxaflor are used in permanent greenhouses. The measure therefore aims at restricting the conditions of approval of the active substance sulfoxaflor to uses only inside permanent greenhouses in order to protect bees. In line with Article 3 of the Regulation 2022/686, the EU member States had to withdraw, where necessary, or amend, by 19 November 2022 at the latest, authorisations for plant protection products containing sulfoxaflor as an active substance. Furthermore, according to Article 4 any grace period granted by the EU member States (in accordance with Article 46 of Regulation (EC) No 1107/2009 for marketing and use of existing stocks) expired by 19 May 2023. The EU would like to re-assure that the measure does not lead to any immediate disruptions of trade in agricultural goods, as it does not amend MRLs. Separate action will likely be taken on MRLs, following the expiry of all grace periods for stocks, and a separate notification will be submitted to the SPS Committee.

2.1.4.51 Angola - Executive Decree No. 64/2023: Implementation of high security tax stamps on alcoholic beverages and liquids, tobacco and its substitutes (ID 803¹¹³)

2.405. The representative of the European Union provided the following statement. On March 10, 2022, Angola published the Executive Decree n°149/22 introducing the obligation to affix High Security Tax Stamps on certain products including beverages (beer, wine, spirits, soft drinks) and tobacco in order to fight smuggling. On 8 April 2022, the Angolan authorities published the Executive Decree nº186/22, which suspended the mandatory affixing of high-security tax stamps on all alcoholic beverages. On 12 May 2023 Angola published a new decree 64/2023 that entered into force on 11 July 2023 even though there were many calls for a longer transition period. Angola has not notified the draft measure to the TBT Committee, and we request Angola to notify as soon as possible, so that all Members can provide their comments on the draft measure well ahead of the adoption and entry into force. A small but important concession was made in this new draft: operators will have the ability to affix tax stamps in Angola, even if they are not AEO accredited in Angola, for stocks placed in Angola before 11 July and for products for which the import process started before 11 July. A number of important concerns remain that we want to see addressed rapidly: A stock exhaustion clause for products already placed on the market. The decree foresees a 180 days period for unstamped products currently on the market to be retrieved by the operator to affix tax stamps - this is not realistic. If products have been sold to third parties, it becomes practically impossible to retrieve them for the purpose of affixing tax stamps.

2.406. The period of validity of tax stamps after purchase is too short. The decree states that tax stamps are valid for 180 days from the date of receipt. However, with the problems and delays in shipping, imported products bearing tax stamps may arrive in Angola more than six months after the receipt of tax stamps, and it is not clear what will happen to these products. More flexibilities is needed in terms of where tax stamps could be affixed: there should not be a requirement for operators to be AEO-accredited in Angola to authorize them to affix tax stamps in bonded warehouses. In addition, getting the flexibility to affix tax stamps in bonded warehouses in third countries logistics hubs would also help. Current provisions mean that the vast majority of EU operators will be forced to affix tax stamps in the country of production – which will place them at a disadvantage compared with local operators. We recall that it is very important to notify the new decree to the WTO TBT Committee. We would like to stress that as a result of the new decree, some brands have already decided to stop exporting to Angola. It is therefore essential that the elements mentioned are taken up by Angola as a matter of urgency.

2.407. The representative of <u>Mexico</u> provided the following statement. The Mexican delegation refers to Angolan Executive Decree No. 64/2023 on the implementation of high security tax stamps on alcoholic beverages and liquids, tobacco and its substitutes. This Decree entered into force on its date of publication of 12 May 2023 and was not notified to WTO Members. In this connection, the delegation of Mexico would like to voice the following concerns and requests. Failure to notify the Decree and its entry into force contravenes the provisions of Articles 2.9.2, 2.9.4 and 2.12 of the TBT Agreement. The Government of Angola is therefore kindly requested to suspend implementation of the Decree, and to notify the TBT Committee, thus giving its trading partners an opportunity to submit comments. In addition, it is a matter of concern that the Decree establishes that tax stamps will become mandatory from 12 July 2023, that is, 60 days after the publication of the Decree. This time frame is insufficient for producers exporting foreign spirits to register and obtain the tax stamps required, in contravention of Article 2.12 of the TBT Agreement. Accordingly, we ask the Government

 $^{^{113}}$ For previous statements follow the thread under ID $\underline{803}.$

of Angola to grant an extension to the transitional period provided under Article 18 of the proposal, of at least six months.

2.408. On the other hand, the Decree lays down provisions imposing burdensome and costly requirements that impede international trade, contrary to the principle of proportionality provided for in Article 2.2 of the TBT Agreement. Of particular concern is the requirement that operators must recover products currently on the market without a stamp within 180 days, in order to affix a tax stamp to these products. This measure is too burdensome and complicated for producers. In this connection, the Government of Mexico suggests that an exhaustion clause be included for products already on the market, with the aim of maintaining trade flows. Furthermore, the Decree establishes that, 30 days after its publication, operators must declare to the General Tax Administration the quantity of goods, produced domestically and imported, in stock. In practice, this is a complicated process and producers need to be granted enough time to carry out these operations. Lastly, the measure establishes that imported products must be stamped at the place of origin, so operators will have to affix the stamps in the country of production, putting them at a disadvantage compared to local operators. The Government of Mexico therefore suggests that greater flexibility be granted as regards the physical location at which tax stamps may be affixed. The delegation of Mexico thanks the delegation of Angola for giving its consideration to this statement.

2.409. In response, the representative of Angola provided the following statement. Angola would like to thank European Union and Mexico for their continued interested in this matter. The Executive Decree no. 64/23 of May 12, currently in force, establishes the procedures applicable to the tax stamp process, sales prices for seals, requisition and affixing rules, conditions of use, periods of use and validity, and the definition of dimensions by type of packaging, quantities, weight, number of minimum and maximum units of said packaging. It also clarifies the treatment to be given to beverages that are already in national territory and the time for applicability. The moratorium was lifted, and we had extensive discussions with manufacturers and the beverage industry association, so the Executive Decree 64/23 clarifies the conditions for affixing the stamps and the treatment to be given to drinks that are already in national territory on the date the decree comes into force, particularly article 11, 12 and 18. Moreover, the Agreement on Technical Barriers to Trade aims to avoid unnecessary obstacles to international trade and to recognize the possibility for all WTO members to protect legitimate interests according to their own regulatory autonomy, while promoting the use of international standards. The list of legitimate interests that can justify a restriction on trade is not exhaustive and includes the protection of environment, human and animal health and safety. Article 2 of the TBT Agreement obliges states to notify each other of proposed technical barriers to trade. With regard to Angola's notification on the matter under discussion, we would like to clarify that we have had administrative setbacks due to changes in government, however the process should be sent to the WTO Secretariat in the next few days, via Angola's permanent representation in Geneva. We thank you for your patience and reiterate our commitment to the TBT agreement, but above all to guaranteeing the safety and public health of Angolans.

2.1.4.52 India - Battery Waste Management Rules, 2022 (ID 800¹¹⁴)

2.410. The representative of the <u>Republic of Korea</u> provided the following statement. Korea respects India's efforts to protect the environment, and the Korean industry is making efforts to comply with the "Battery Waste Management Rules" (hereinafter, Rules) that came into force on 24 August 2022. However, despite Korea's consecutive submission of official letters of comments through the Enguiry Points (on 23 February, 10 May, 3 July and 6 September) and an STC raised at the June TBT Committee meeting, Korea has not yet received a substantive response from India to date and thus would like to reiterate the pertinent industry's concerns and requests. First, Korea requests an exemption from applying the waste battery collection requirement to batteries produced outside India. The Rules mandate the collection of 100% of waste batteries relative to the total weight of the battery placed in the market during each specified compliance cycle (7, 10 and 14 years) as determined by the type of battery. The Rules also set the minimum annual collection target rate. Indeed, the mandatory 100% waste battery collection target for each compliance cycle is an unparalleled requirement that has not been implemented in other countries. This has posed significant challenges for the industries involved, making compliance a daunting task. Second, Korea requests an exemption from applying the requirement of minimum use of domestically recycled materials (in item 4.(14) of the Rules) to new batteries produced outside India. The companies producing batteries in countries other than India will have to produce batteries exclusively for the

 $^{^{114}}$ For previous statements follow the thread under ID $\underline{800}$.

Indian market in order to fulfill this requirement. Enforcing such rules would present a nearly insurmountable challenge for those companies.

2.411. In response, the representative of India provided the following statement. India thanks Korea's interest in India's "Battery Waste Management Rules". The Extended Producer Responsibility target for recycling or refurbishment of waste batteries has been obligated on producers of battery manufacturers including importers of batteries. Compliance of EPR target is required to be achieved by producers as per the targets provided during the compliance cycle, as applicable. There are two compliance cycles. First compliance cycle has EPR target every year. Second compliance cycle is periodic. However, 60% of the average quantity of batteries placed in the market per year during the applicable second compliance cycle can be carry forwarded to the next compliance cycle. The Extended Producer Responsibility target shall include the collection targets mentioned in the tables of Schedule II of Battery Waste Management Rules, 2022 and 100% recycling and/or refurbishment target of Extended Producer Responsibility collection target of the respective year. Producer will meet their Extended Producer Responsibility obligation through the Extended Producer Responsibility certificate made available by recycler or refurbisher. In case of non-availability of Extended Producer Responsibility certificates with recyclers or refurbishes, the Producer shall have the responsibility of collection as well. Rule 4(14) specifies the following: "In case of imported Battery, the Producer shall have to meet the obligation of the minimum use by way of getting such quantity of recycled materials utilised by other businesses or by way of exporting such quantity of recycled materials." The producer includes importer here. The said rule promotes domestic recycling by mandating importers as well to obtain minimum recycled content and get it utilized by other businesses or by way of exporting such quantity of recycled materials.

2.1.4.53 Oman - Water heaters-energy performance requirements; Electrical Clothes Washing Machines Energy and Water performance requirements and Refrigerators, Refrigerator-Freezers and Freezers-Energy Performance, Testing and Labeling Requirements (ID 673¹¹⁵)

2.412. The representative of the <u>Republic of Korea</u> provided the following statement. Korea government appreciates the response provided by the Omani government on 5 September regarding the Energy Performance Requirements for washing machines and refrigerators. However, there are still concerns within the Korean industry related to the regulations that we would like to convey. In Oman's previous response, it was mentioned that the standards were adopted in 2022, and are set to be implemented in 2023, allowing manufacturers more than a year to prepare and adapt. However, with regard to these standards, there is currently no testing laboratory designated by the Omani government. Also, there is a lack of implementation guidelines detailing the testing procedures. This situation leaves manufacturers incapable of complying with the regulation. It is our understanding that at least 12 months are required for the Korean exporters to comply with the applicable standards, including 5 months for new product development, 3 months for testing, 2 months for product registration, and 2 months for shipping and transportation. Korea requests a one-year postponement of the implementation from the point when sufficient number of testing laboratories are designated, and final versions of the guidelines and related documents on conducting tests have been published, allowing manufacturers adequate time to comply.

2.413. Second, in the previous letter, Korea communicated concerns regarding some ambiguous testing standards that it anticipated would pose difficulties in conducting tests. Regarding this matter, the Omani government has replied that they will provide clear instructions. However, as of present, we have yet to receive this information, so we would like to enquire once again. Specifically, regarding the testing voltage for washing machines, while the Scope of OS 1651/2022 stipulates that the Energy Performance Test Standard shall apply to washing machines operating at 240V, Annex B of OS 1651/2022 stipulates that the washing machines must be tested at 230V, meaning that the values are different even within the same standard. In addition, Annex B of OS 1653/2022, the Energy Performance Test Standard for refrigerating appliances, does not specify the temperature and humidity requirements necessary for calculating the energy consumption of anti-condensation heaters, making calculation impossible. Therefore, it is requested that these two aforementioned test criteria be clarified and appropriate amendments be provided in this regard. Lastly, Korea has not yet received any information regarding the seminar for stakeholders and relevant parties which

 $^{^{115}}$ For previous statements follow the thread under ID <u>673</u>.

was mentioned in Oman's previous response. We kindly request details such as the date, location, and any additional information pertaining to this seminar.

2.414. In response, the representative of <u>Oman</u> provided the following statement. Implementation Timeline: We acknowledge the concerns regarding the implementation Timeline. However, it is essential to clarify that the standards were adapted in 2022, and only the timeline for implementation was announced in June 2023. This means that there has been more than a 12-month transition period from date of adoption of the standards, providing manufacturers with ample time to adapt. The requirements being implemented align with standards already in place under other recognized schemes, and we believe that manufacturers familiar with these globally recognized testing methodologies will find transition smoother. Registration Information: For the issuance of Energy Efficiency (EE) Label for these products, the registration will be carried out through the Omani EE Platform (Energy Efficiency Rating Labels for the Sultanate of Oman (gso.org.sa)). We have ensured that all procedures related the EE label is harmonized across various product categories, providing a consistent and streamlined experience for manufacturers and exporters. This harmonization is part of our commitment to simplify and standardize the process, making it easier for all stakeholders. 3-Test Criteria Clarity: a-Voltage Discrepancy is OS 1651:2022: it is common for International standards to allow a range or specific conditions for testing at different voltages. We will provide clear instructions on the applicable voltage for testing. b-Temperature and Humidity Requirements in OS 1653:2022: precise temperature and humidity requirements are vital for accurate and consistent consumption calculations. We will review the existing guidelines and benchmarks, and ensure that clear and well-defined criteria are set, aligning with internationally recognized methods for energy performance testing of refrigerating appliances. c-Engagement with Stakeholders: We have plan for seminar to the relevant parties. In conclusion, we appreciate the active engagement and feedback from the Republic of Korea. Such collaboration is vital in refining our standards to ensure they are both rigorous and globally aligned. Please do not hesitate to reach out for further questions or clarifications.

2.2 Exchange of Experiences

2.2.1 Transparency

2.2.1.1 Statements of Implementation under Article 15.2

2.415. The <u>Chairperson</u> shifted the discussion to Item 2B(i) on Transparency, specifically addressing Statements of Implementation under Article 15.2. She reminded the Committee that Article 15.2 obliges Members to inform about measures enacted to implement the Agreement and to notify any alterations over time. It was pointed out that there were no new notifications under this Article at the moment. She noted, however that 19 Members had not yet submitted their statement of implementation as required by Article 15.2. Despite the Committee's generally robust record on transparency, the Chairperson acknowledged existing shortcomings in this area. She also mentioned the ongoing efforts of the Transparency Working Group, which is acting on a recommendation from the Ninth Triennial Review to create a template for Article 15.2 notifications to be submitted through ePing. The Chairperson expressed optimism that the forthcoming online form and accompanying instructions would simplify the process of submitting initial or subsequent Article 15.2 notifications.

2.2.1.2 Report on Transparency Working Group Meeting

2.416. The <u>Chairperson</u> reported that the Transparency Working Group, established in March 2022, convened its fifth meeting on 3 October 2023. An annotated agenda to guide the discussions was circulated in advance as document <u>JOB/TBT/513</u>. She proceeded to provide a concise report on the meeting's agenda items:

- a. Materials from the special meeting on transparency in June 2023, including her own report, were made accessible on a dedicated webpage. Given that this special meeting is biennial or triennial, she continued to invite feedback from delegations for planning future meetings.
- b. The Secretariat had updated the <u>dedicated webpage</u> to track transparency-related materials and events relevant to the working group's activities. This webpage now features a comprehensive <u>list of the 19 transparency-related recommendations</u> from the Ninth Triennial Review, noting any follow-up actions undertaken by the Secretariat and/or Members, as documented in a "live" document that delegations could utilize to monitor progress and as a reference for the upcoming Tenth Triennial Review.
- c. Canada's suggested amendments to the notification guidelines, outlined in document <u>JOB/TBT/485/Rev.1</u>, and Colombia's comments on this proposal, as recorded in document <u>JOB/TBT/496</u>, were topics of discussion. Canada had indicated ongoing discussions with Colombia to address their feedback. Additionally, the United States had made some drafting suggestions concerning item 6 of the guidelines. It was agreed to revisit a revised version of Canada's proposal in the Committee's November session. Meanwhile, Canada had submitted an updated proposal in <u>JOB/TBT/485/Rev.2</u>, which the Committee would address shortly.
- d. An update on the initiative to facilitate Article 15.2 notifications through ePing was provided by the Secretariat. This project was based on preliminary inputs from the United States¹¹⁶ and Australia as well as deliberations within the working group. The plan involved sharing a mock-up for the ePing structure to gather Member comments, although this was postponed due to resource limitations. The working group agreed to address this matter in its subsequent meeting, while the Secretariat was asked to disseminate an outline of the draft structure.
- e. A new symbol series for Article 15.2 notifications was being introduced by the Secretariat to clearly identify these notifications by Member, designated as "G/TBT/15.2/N/ISO country code of Member". This symbolization would be applied to future Article 15.2 notifications.

¹¹⁶ JOB/TBT/495

f. The Chairperson conveyed that the working group received an update on the collaborative effort by seven volunteer Enquiry Points to draft a guide on preparing comments on notifications. Speaking on behalf of the group, Australia announced their intent to present an initial draft to the working group by the end of the year, integrate feedback, and share a second draft for comments in the new year. The objective was to complete the guide by the June 2024 Committee meeting. They also called for Members to contribute examples of effective outcomes from the commenting process to be featured as case studies in the guide.

2.417. In conclusion, the Chairperson invited Members to provide comments or questions on the discussed topics. She then moved to address the revision of the notification guidelines, referencing Canada's revised proposal in <u>JOB/TBT/485/Rev.2</u>, and invited Canada to introduce this document.

2.418. The representative of <u>Canada</u> acknowledged Colombia, Singapore, and the United States for their engagement and suggested edits to Canada's proposal. After collaborating with these Members following the October Transparency Working Group meeting, Canada had updated their proposal, as circulated by the Secretariat on 25 October in <u>JOB/TBT/485/Rev.2</u>. This version, Canada noted, had no further comments and contained changes that were self-explanatory. Canada recommended integrating these revised guidelines into the compendium of notification format and guidelines in <u>JOB/TBT/507</u>. They also thanked Members and the Secretariat for their support in completing this activity from the Ninth Triennial Review.

2.419. The representative of the <u>United Kingdom</u> voiced strong support for the proposal that enhanced transparency, a fundamental issue for the Committee.

2.420. The representative of <u>Australia</u> thanked Canada for their work on the proposal and highlighted how the updated notification guidelines could aid those unfamiliar with the process and improve efficiency and publication quality. Australia mentioned their use of ePing's functionalities, such as providing drafting rights to other users, which the new guidelines would further support.

2.421. The <u>Chairperson</u>, noting the general consensus, moved to adopt the revised guidelines. It was so <u>decided</u>.¹¹⁷ She thanked Canada and all Members for their cooperative efforts, which addressed a specific recommendation from the Ninth Triennial Review. She instructed the Secretariat to incorporate the revised guidelines into the compilation in <u>JOB/TBT/507</u>¹¹⁸ and also in ePing's online submission section.. She announced that she would coordinate with the Secretariat to schedule the next transparency working group meeting.

2.2.1.3 Update by the Secretariat on ePing

2.422. The <u>Secretariat</u> reminded the Committee that the Secretariat had been tasked during the June meeting to clarify different user access levels on ePing. In response, the Secretariat had circulated <u>G/TBT/GEN/363</u>, which included a table delineating user functions and access rights within the platform. The Secretariat welcomed feedback on the document and alsothanked delegations for participating in the ePing walk-in session held earlier in the week. These sessions were very valuablefor receiving feedback and further improving the platform.

2.423. The representative of <u>Canada</u> thanked the Secretariat for the document, originally suggested by Canada within the Transparency Working Group. Canada viewed the chart as a beneficial tool for understanding the various privileges of different ePing accounts and for helping users maximize the platform's functions.

2.2.2 Conformity Assessment Procedures (Guidelines)

2.424. The <u>Chairperson</u> proceeded to discuss the development of the Guidelines for conformity assessment procedures, providing an update on the progress. She reminded the Committee that the guidelines were initiated during the Eighth Triennial Review of the TBT Agreement to aid regulators in selecting and crafting conformity assessment procedures and that their finalization was agreed upon in the Ninth Triennial Review. Since the regular meeting in June, the Chairperson conducted

¹¹⁷ The revised guidelines were subsequently issued in G/TBT/52 on 15 November 2023.

¹¹⁸ The updated compilation was subsequently issued in JOB/TBT/507/Rev.1 on 23 November 2023.

consultations on July 7, September 21, and October 19, which were open to all Members. She expressed gratitude for the positive involvement from delegations and noted good progress in reviewing and refining the draft text. Additionally, she indicated her plan to start smaller group discussions to tackle some of the more challenging issues, with the first of these consultations occurring alongside the last month's informal meeting. The Chairperson also mentioned a dedicated webpage providing further details and the latest version of the working text for the guidelines. She acknowledged the ongoing work and considered that significant advancements were being made, encouraging all Members interested in the consultations to participate.

2.2.3 Thematic sessions

2.2.3.1 Reports by moderators

2.425. The <u>Chairperson</u> noted that the Committee had held two thematic sessions on Tuesday, 7 November: one session focused on the "<u>Use of Digital Technologies and Tools in Good Regulatory</u> <u>Practices</u>" and the second session on "<u>Conformity Assessment and E-Commerce</u>".

- a. The <u>Moderator¹¹⁹</u> for the Thematic session on the Use of Digital Technologies and Tools in Good Regulatory Practices, provided his report. The full report is contained in <u>G/TBT/GEN/367</u>.
- b. The <u>Moderator¹²⁰</u> for the Thematic session on Conformity Assessment and E-Commerce, provided her report. The full report is contained in <u>G/TBT/GEN/366</u>.

2.426. The <u>Committee took note</u> of the moderators' reports. The <u>Chairperson</u> thanked both moderators for their contributions. For more information on these sessions, the Chairperson referred delegations to the <u>TBT Gateway</u> where the full agenda and the presentations as well as the video-recordings were collected.

2.2.3.2 Planning of next sessions

2.427. The <u>Chairperson</u> noted that the Committee had completed 12 of 14 thematic sessions which were mandated by the Ninth Triennial Review. The remaining two were: i) conformity assessment (the key role of the NQI in Members' regulatory systems) and ii) standards (how Members incorporate international standards in their regulatory processes, inclusive of conformity assessment). She noted that in2024, following past practice during triennial review years, the regular sessions would normally be proceeded by informal meetings focused on the Tenth Triennial Review. Still, there could be an opportunity, for example in March, to conduct one or two thematic sessions, especially if there were only a limited number of proposals under the Triennial Review.

2.428. The representative of the <u>United States</u> indicated that the possibility of such discussions would largely depend on the number of proposals expected for March. If there were many robust proposals, time might not permit a thematic discussion. However, with fewer proposals, there might be an opportunity. Given the unpredictability, the representative of the United States suggested it would be prudent to allow flexibility in the agenda to accommodate discussions rather than risk insufficient time for proposal consideration.

2.429. The <u>Chairperson</u> found this to be a sensible approach. With no objections, she decided to keep the planning open for the time being and also announced her intention to call an informal committee meeting early in the year to reassess the situation.

2.3 Other Matters

2.3.1 10th Triennial Review

2.430. The <u>Chairperson</u> shifted the discussion to the Triennial Review process. She reminded the Committee that the Ninth Triennial Review was concluded in November 2021, as documented in <u>G/TBT/46</u>, and noted that, in accordance with Article 15.4 of the TBT Agreement, the Tenth Triennial

¹¹⁹ Mr. Diego Franco (Paraguay).

¹²⁰ Ms. Dora Trofor (United Kingdom).

Review is due to be concluded by November 2024. Following established procedures, the first step in the Review was for the Committee to establish a timeline, which was agreed upon during the last TBT Committee meeting and detailed in <u>G/TBT/W/775</u>. With one year remaining to complete this process, she emphasized that the Review will be propelled by substantive proposals from Members that pertain to specific areas of the Committee's work. The Chairperson encouraged Members to submit their contributions as early as possible. Additionally, she announced the launch of a <u>dedicated</u> <u>10th Triennial Review page</u> on the TBT Committee webpage, which includes the timeline and information on all previous Triennial Reviews as well as the current one, promising that this resource will continue to be updated.

2.3.2 Better Functioning of the CTG and its Subsidiary Bodies

2.431. The <u>Chairperson</u> referred back to the June meeting, where the Committee, guided by a Secretariat Note (JOB/TBT/510), agreed to three specific actions to enhance the TBT Committee's functioning: 1) extending eAgenda to all agenda items on a trial basis, 2) regular briefings by the Secretariat, and 3) annotated agendas for informal meetings also on a trial basis. Following this, the Secretariat expanded eAgenda to cover all agenda items starting with the November meeting. There were Secretariat briefing sessions held on September 19 and earlier in the week, concentrating on the Triennial Review Process. The first annotated agenda was shared prior to the informal meeting on 3 October 2023. The Chairperson noted that no further comments or inputs were provided by delegations at that informal meeting.

2.432. The Chairperson also reminded that all CTG subsidiary bodies had been asked to report to the CTG before the first week of November on discussions held and improvements made since the conclusion of MC12. She disseminated a report under her own responsibility as Chair, initially shared with delegations as a draft on 10 October in <u>JOB/TBT/515</u>, inviting comments by 24 October 2023. No comments were received, and the report was forwarded to the CTG in document <u>G/L/1504</u> – <u>G/TBT/51</u>.

2.433. The representative of <u>Paraguay</u> thanked the Secretariat for the report and mentioned other good practices being incorporated into committee practices, particularly praising the introduction of the new e-delegate system that would facilitate processes in countries like Paraguay, where workload and time constraints are significant. This system is expected to enhance control over delegation activities and streamline their work.

2.434. The representative of <u>Australia</u> expressed gratitude for the Secretariat's follow-up on the decisions from June, highlighting the usefulness of the annotated agendas for informal meetings. Regarding the expansion of eAgenda, Australia saw it as a positive step and encouraged members to utilize its functionalities fully. However, Australia raised a question about the content of the "previous meeting" tab in eAgenda, suggesting it could revert to including all statements from past meetings.

2.435. The <u>Secretariat</u> acknowledged the query about eAgenda, mentioning that changes were made to align with the SPS approach and agreed to look into Australia's suggestion to potentially restore the "previous meeting" tab.

2.436. The <u>European Union</u> acknowledged and thanked the Chair for her report to the Chairperson of the Council for Trade in Goods.

2.437. The <u>Chairperson</u> noted that the United States had submitted a cross-Committee communication on the integration of developing countries into the SPS and TBT agreements (<u>G/TBT/GEN/362</u>) and invited the United States to speak on this communication.

2.438. The representative of the <u>United States</u> elaborated on the thematic work initiated in the Committee on Trade and Development (CTD) Special Session, which is part of a broader dialogue. This dialogue aims to better operationalize existing flexibilities in key WTO agreements, such as the SPS and TBT, TRIPS, TRIMS, and ASCM. The focus is on areas, particularly in SPS and TBT, where these flexibilities are not fully utilized and to encourage the development of best practices led by developing countries.

2.439. In early November, the United States, in collaboration with the SPS and TBT Committees, disseminated a paper entitled "Highlights of Activities on Better Integration of Developing Countries in the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade." This paper discusses several key points: (i) the challenges and opportunities associated with using digital tools like the ePing SPS&TBT platform; (ii) the role of a global network of national SPS and TBT Enquiry Point offices in facilitating comments on notifications and providing responses to Member inquiries; and (iii) the strides developing countries are making towards implementing and operating competent Enquiry Points that are responsive to stakeholders, showcasing their progress in becoming leaders in TBT and SPS activities within their respective Committees.

2.440. The United States affirmed its commitment to working with WTO Members to introduce diverse and insightful perspectives into the WTO's work. The representative of the United States expressed openness to further develop the initiatives begun at the CTD Special Session and invited everyone to review their paper. She looked forward to engaging with Members on ideas that build on their submission, aiming to foster productive discussions.

2.441. The <u>Chairperson</u> thanked all delegations for their input and the Secretariat for promptly implementing the agreed actions. She encouraged delegations to propose further improvements to the Committee's work, mentioning that the Tenth Triennial Review would be a suitable platform for such discussions.

2.3.3 Any Other Matters Related to Implementation and Administration of the Agreement

2.442. The representative of the <u>Russian Federation</u>, addressing the Chair, referred to the current sub-agenda item. This item allows delegations to raise any matters related to the implementation and administration of the agreement. The representative sought clarification from the Chair on whether this was the appropriate place for Members to present reports about relevant activities in the field of technical regulation.

2.443. The <u>Chairperson</u> responded to the Russian Federation, stating that the decision to make such a report rests with each member. She invited the Russian Federation to proceed if they wished to make a report.

2.444. The representative of the <u>Russian Federation</u> clarified that he did not intend to present a report but raised the question for the benefit of the membership and to avoid ambiguity in future meetings about where a WTO member can make such a report.

2.445. The <u>Chairperson</u> said that it was up to each Member to decide when to make a report and sought confirmation that the Russian Federation was *not* planning to make a report under this agenda item and expressed her gratitude for the confirmation.

3 TECHNICAL COOPERATION ACTIVITIES

3.1 Information from Members

3.1. The representative of the <u>United States</u> informed Members that the Standards Alliance had been renewed for additional funding. The report was subsequently circulated in document <u>G/TBT/GEN/365</u>.

3.2 Information from Secretariat

3.2. The <u>Secretariat</u> provided a report regarding its technical assistance activities. In the current year (2023), ten in-person TBT national activities had been organized, four of which were joint TBT-SPS events. These events took place in the Dominican Republic, Cambodia, Peru, India, Nigeria, El Salvador, Morocco, Colombia, Kenya, and Bahrain. Additionally, one virtual national activity, a joint TBT-SPS, was conducted in Chile. The Secretariat also mentioned that they would conduct a final national in-person activity in Guyana towards the end of November. Furthermore, there would be a Regional workshop (TBT) for Asian countries in Manila, the Philippines. Looking ahead to 2024, the Secretariat shared plans to organize a national in-person activity (joint TBT-SPS) in Namibia and a national virtual activity (ePing) for Ecuador. They also indicated preliminary plans for a possible

regional TBT event for Latin America. The Secretariat would provide an update on the planned TBT activities for the next year in the first meeting of March 2024.

3.3. Regarding the upcoming Manila workshop, the Secretariat briefed the Committee on the upcoming Manila workshop. This event, scheduled for the following week, was highlighted as an example of their activities: a regional workshop for Asian members of the WTO from developing countries. The workshop, it was noted, is set to include around 14 countries, including Bhutan, Cambodia, China, India, Indonesia, Malaysia, Maldives, Mongolia, Myanmar, Nepal, Sri Lanka, Chinese Taipei, Thailand, and Vietnam. It would span two and a half days. On the first day, the agenda involves setting the scene regarding current issues, technical regulations, standards, and similar topics. The second day focuses on more specific issues, such as transparency and the work of the committee. The workshop will have a thematic focus on environmental issues, examining environment-related topics that have been discussed in the TBT Committee. For the final part of the workshop, external speakers will contribute, particularly focusing on standards and steel as an example of areas where TBT, regulations, and standards play a significant role. This Manila workshop exemplifies the type of event organized by the Secretariat and showcases the content and structure typical of such gatherings.

3.4. The Secretariat recalled that a detailed update on the objectives and outcomes of the pilot Transparency Champions initiative had been presented during the Committee's previous meeting held in June. As the pilot programme employed a notably different approach and pedagogy compared to the Secretariat's other technical assistance activities. the ITTC's Monitoring and Evaluation unit had undertaken a comprehensive evaluation of the pilot initiative. The evaluation report found that the programme achieved significant positive results and did so in an efficient manner. The report also offered recommendations for enhancing the programme and suggested expanding it to other beneficiaries. The Secretariat mentioned that they are currently contemplating the possible continuation of this programme. They also invited feedback and suggestions from Members to aid in this consideration.

3.5. The representative of the <u>United States</u> asked if there could be a document generated that summarized the Secretariat reports on technical assistance so that information could be passed to US embassies – it would help them understand the TBT Secretariat's training.

3.6. The <u>Secretariat</u> responded positively.

3.7. The representative of <u>Namibia</u> thanked the Secretariat for their work on the Transparency Champion Programme and supported the continuation of this programme in support of other Members.

4 OBSERVERS

4.1 Updates from Observers

4.1. The representative of the <u>African Organization for Standardization</u> (ARSO) thanked the Chairperson and mentioned that a full update was available online. ARSO, which was admitted as an observer to the WTO-TBT Committee in November 2015, is an intergovernmental organization founded under the auspices of the Organization of African Unity, now the African Union (AU), and the United Nations Economic Commission for Africa in 1977. Its mission is to facilitate the harmonization of standards and conformity assessments across Africa. ARSO, with 43 member states, continues to perform its mandate through activities including:

- a. The harmonization of standards, with over 1,600 African standards harmonized across key priority areas, involving international standards harmonization with the input of African experts across 15 sectors, such as agriculture, pharmaceuticals, automotive, textiles, and leather industries, supported by 85 technical committees.
- b. In conformity assessment activities, they have harmonization and mutual recognition arrangements in place with six countries: Ghana, Kenya, Nigeria, Rwanda, South Africa, and Zimbabwe. They also manage transparency and notification activities through the ARSO Documentation Information System.

c. ARSO conducts capacity-building and awareness-raising in standardization activities, which includes organizing training workshops for African experts and Small and Mediumsized Enterprises (SMEs), the ARSO Webinar series with 39 sessions since 2020, annual continental essay competitions since 2013, now in its 11th edition, and the promotion of standardization and trade policy instruments. This encompasses the African Quality Policy adopted by the AU in February 2023 and the African Continental Technical Regulatory Framework, which is under consideration for the harmonization of technical regulations by the AU, along with the Gender Mainstreaming in Standardisation and Policy Document.

4.2. ARSO maintains cooperation with various international organizations, including ISO, IEC, WTO, ITC, and UNIDO, and appreciates the mutual cooperation with the WTO. This cooperation is instrumental in raising awareness in Africa about the challenges of Technical Barriers to Trade (TBTs) and the need for enhancing quality infrastructure. This includes collaboration in the Transparency Champions Initiative, aiming to improve transparency in standards harmonization processes within the framework of the African Continental Free Trade Area (AfCFTA) according to the WTO TBT Agreement and the AfCFTA Agreement, specifically TBT Annex 6, Article 11 on transparency. The ARSO update was subsequently circulated in document <u>G/TBT/GEN/368</u>.

4.3. The representative of <u>United Nations Economic Commission for Europe</u> (UNECE) informed the Chairperson that UNECE had submitted an online report detailing their activities relevant to TBT members, which includes several links to pertinent information and is accessible to the committee members. The representative mentioned UNECE's recent collaborations with various WTO groups, expressing gratitude for the partnership, especially with the Informal Working Group on Trade and Gender and the Standards for Trade Development Facilities. They noted UNECE's support in launching Gender Action Plans. The representative announced that UNECE would soon launch a new publication entitled "The Basics of Quality Infrastructure for Trade", which was expected to be online before the end of the year. Furthermore, UNECE was revising Recommendation K on metrology assurance for conformity assessment and testing, as well as Recommendation M, which focuses on the role of market surveillance in combating counterfeit products and conducting further studies on regulatory and procedural barriers to trade, notably for Turkmenistan.

4.4. The representative also reported that the UNECE Working Party on Regulatory Cooperation and Standardization Policies (WP6) would hold its 33^{rd} annual session from 23 to 24 November, including a conference on targeting continuous compliance. Flyers about the event had been distributed, and information was made available at the entrance. The TBT Chairperson was thanked for agreeing to provide a keynote speech to inaugurate the conference. The event aimed to address the conformity of products with embedded artificial intelligence and other technologies, not only at the point of market entry but throughout their lifecycle, including after remote updates from outside the country. The representative invited Member States working on this topic to participate in the event and noted that while it was planned to be in-person, it would also be publicly accessible for streaming. Instructions for accessing the stream would be sent out by UNECE colleagues. The UNECE update was subsequently circulated in document <u>G/TBT/GEN/369</u>.

4.5. The representative of the <u>International Organization of Legal Metrology</u> (OIML) referenced a brief written report provided to the Secretariat, which contains detailed information and links to various documents available on their website. The representative highlighted two items in particular: the welcoming of Montenegro as a new member state in September and increasing OIML's total membership to 64 member states and 64 corresponding members. Additionally, the 58th meeting of the OIML International Committee of Legal Metrology was held in Chiang Mai, Thailand, emphasizing the importance of maintaining in-person contact, with 37 of the 64 member states present or represented. The representative also thanked Ukraine for sending two delegates to the committee meeting despite travel challenges and noted Ukraine's increasing engagement in OIML's technical work. Furthermore, during the meeting in Thailand, a proposal was put forward by the Kingdom of Thailand focusing on the development of OIML's work in countries with emerging metrology systems, guided by four principles. More details were available in the written report. The OIML update was subsequently circulated in document <u>G/TBT/GEN/370</u>.

4.6. The representative of the <u>World Health Organization</u> (WHO) recalled their statement from the June 2023 TBT Committee meeting regarding labelling measures for alcoholic beverages in WHO instruments. The representative then underscored two points concerning the relationship between alcohol consumption and health risks, particularly cancer. Firstly, alcohol is classified as a Group 1 carcinogen and is a risk factor for over 200 diseases. In 2019, alcohol consumption was attributable

to 2.6 million deaths and, in 2020, to more than 740,000 cancer cases. Secondly, the representative pointed out that despite the substantial health, social, and economic consequences of alcohol consumption, there is often an inaccurate public perception of its risks. They argued that labelling measures, such as health warning labels on alcoholic beverages, are recognized as effective in increasing consumer understanding and influencing behaviour, citing evidence of their effectiveness, especially during pregnancy, and public support for health warnings on alcoholic beverages in the European Union. The representative concluded by emphasizing the importance of health warning labels and the need for coherence across the international system. The WHO update was subsequently circulated in document G/TBT/GEN/371.

4.7. The representative of the International Organization for Standardization (ISO) reported on ISO's Annual Meeting 2023, which took place in Brisbane in September. The five-day event served as a platform to unite efforts to meet global needs, enhance collaboration, utilize technology, and prioritize sustainability. The event highlighted how international standards play a crucial role in building trust, facilitating trade, and accelerating progress toward an inclusive, sustainable, and digital future. Dedicated sessions were held on topics such as trade and standards, global trade, the importance of accountability claims, and the future of hydrogen. The representative noted that Mr. Erik Wijkström, the Head of the WTO TBT Section, participated in the 57th ISO Committee on Developing Country Matters (DEVCO) during that week and delivered a keynote speech.

4.8. The representative of ISO also drew delegations' attention to a new publication entitled "Standards and Public Policy, a Toolkit for National Standards Bodies," developed under the ISO Standards and Public Policy Program. The intended to work with the WTO TBT team to provide capacity-building support to national standards bodies and the WTO TBT National Inquiry Points. ISO, she said, is also participating in discussions to develop an internationally legally binding instrument on plastic pollution and in the WTO Dialogue on Plastic Pollution. They mentioned a policy paper published by ISO to inform discussions on the role that international cooperation on standards can play in efforts to end plastic pollution. ISO's Committee on Conformity Assessment (CASCO) is actively working on applying the CASCO toolbox to the environmental, social, and governance (ESG) space.

4.9. The ISO representative also highlighted the creation of a competency framework for standards development professionals, a collaboration with the United Nations Development Programme (UNDP) on initiatives to enhance international standards for sustainability, and a research project entitled "Standards and Regulations" to guide policymakers on referencing international standards in national laws. Over the next year, ISO plans to conduct a pilot research project examining the societal impacts of standards in developing countries. Finally, the representative mentioned ISO's presence at COP28 in Dubai, emphasizing the role of international standards in accelerating credible climate action and supporting climate policy implementation. The ISO update was subsequently circulated in document <u>G/TBT/GEN/372</u>.

4.10. Further update had been provided by BIPM in <u>G/TBT/GEN/373</u>.

4.2 Pending requests

4.11. The <u>Chairperson</u> drew Members' attention to an updated list of observers, including pending requests for observer status, contained in document <u>G/TBT/GEN/2/Rev.17</u>. In addition, 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. Regarding pending requests, the Chairperson had no new information that would lead her to believe that the situation had changed from where the Committee stood at the last meeting.

5 ANNUAL REPORT (2023) TO THE COUNCIL FOR TRADE IN GOODS

5.1. The <u>Chairperson</u> noted that a draft of its Annual Report to the Council for Trade in Goods contained in <u>JOB/TBT/516</u> had been circulated on 10 October 2023. The report was <u>adopted</u> and subsequently circulated in <u>G/L/1518</u>.

6 OTHER BUSINESS

6.1 China on MC13 Declaration

6.1. The representative of <u>China</u> thanked the Chairperson and provided an update on the outreach efforts regarding the TBT Ministerial Declaration. Since the introduction of the Declaration at the June meeting, China had contacted over 60 WTO members through their Geneva-based delegates, including discussions at the Senior Officials Meeting the previous month. The feedback received was predominantly positive, with a common understanding of the importance of strengthening regulatory cooperation among Members. Many of the delegations had forwarded China's proposal to their capitals for further consideration, which China greatly appreciated. The representative took the opportunity to thank all interested members for their positive feedback and questions, with special thanks to those who have confirmed co-sponsorship or are actively considering it. This support and engagement are crucial for advancing the initiative.

6.2. During outreach, several common themes emerged in discussions. Some members had questioned the relationship between the TBT Ministerial Declaration and the existing work of the TBT Committee, particularly concerning the potential additional workload. The representative from China emphasized that the proposed declaration would not create new work streams for the TBT Committee but is intended to raise awareness among high-level policymakers about the importance of the Committee's work and available tools for regulatory cooperation within the TBT context. The substance of the work would remain the responsibility of the TBT Committee members, who already have well-functioning procedures. The aim is to elevate political awareness without interfering with the Committee's work.

6.3. Additionally, there were inquiries about the added value and relevance of a TBT Ministerial Declaration, with some thinking there is no need for TBT work to be raised to the ministerial level. China argued that much of the work discussed in the Committee and thematic sessions is highly relevant to global challenges faced by all, including climate change, environmental protection, and sustainable development. The TBT Agreement is deemed relevant to these challenges, with effective implementation helping to address them even after nearly three decades. A ministerial declaration could reaffirm the Agreement's continued relevance, making policymakers more aware of the TBT Committee's crucial role in bridging regulatory and standardization gaps.

6.4. China believes a ministerial declaration could broaden awareness and participation in TBT activities, especially for members lacking the capacity to follow TBT Committee meetings, such as the Triennial Review. They stressed that the emerging challenges are common to all and the TBT Committee process has been inclusive. The goal is to build on the positive trends observed in recent years, such as increasing engagement on notifications.

6.5. Regarding the process leading to MC13, the representative stated that China views the process as bottom-up and is committed to communicating with all members to build consensus for launching the initiative on a multilateral basis. They reiterated the unique opportunity MC13 presents for a TBT Ministerial Declaration, which could boost stakeholder confidence in the WTO and motivate more member engagement in the Tenth Triennial Review of the TBT Agreement.

6.6. In conclusion, China continued to urge members to consider the relationship between emerging challenges and the TBT Agreement, seeking a forward-looking approach. With MC13 approaching, they encouraged members to reflect on the initiative and invited interested members to join as co-sponsors.

6.7. The representative of <u>Singapore</u> thanked China for its report and the clarifications made. Given the short runway to MC13, Singapore encouraged China to continue its outreach efforts in an intensive manner. Singapore remained supportive and continued to see value in the initiative. Singapore congratulated China on the positive progress and was committed to continue working with China with a constructive spirit.

6.8. The representative of the <u>United Kingdom</u> thanked China for the update and expressed support for a TBT outcome at MC13 through a high-level TBT Declaration. The UK believes such a declaration could enhance the visibility of the Committee's significant work in fostering international collaboration and tackling trade barriers. Despite the proximity of the MC13 conference, the UK

welcomed the chance to collaborate with China and other interested Members towards a constructive result.

6.9. The representative of the <u>European Union</u> thanked China for the update on the draft ministerial declaration aimed at strengthening regulatory cooperation to mitigate technical barriers to trade. The EU expressed its intention to collaborate with China and any other interested Member on refining the draft ministerial declaration introduced by China in June. The EU emphasized the importance of allowing the TBT Committee to discuss the draft declaration to consider all Members' perspectives.

6.10. The representative of the <u>United States</u> thanked China for its efforts towards an MC13 ministerial declaration. The US echoed sentiments from Singapore, the UK, and the EU regarding collaboration with Members to produce a successful document that could be endorsed by all.

6.11. The representative of <u>Japan</u> appreciated China's update and initiative on the proposal, stating that practical proposals like this should be discussed among TBT Committee experts before being presented at a higher level. Japan sought to understand China's and other Members' views on the best way to discuss and advance this proposal.

6.12. The representative of <u>Australia</u> thanked China for their update on the proposal and acknowledged their efforts in advancing this work. Australia remained open to constructive dialogue about the proposal and welcomed any chance to emphasize the significance of the TBT Committee's work on new and emerging trade issues, such as sustainability and digital trade, to the wider WTO community. Australia recognized concerns about the declaration's purpose and its relation to the 10th Triennial Review process, agreeing that the proposal should remain principles-based and avoid imposing additional workloads on the Committee.

6.13. The representative of <u>Canada</u> also appreciated China's update and further clarifications on feedback received regarding the proposed MC13 TBT Declaration. Canada remained willing to engage with China and other interested Members on the subsequent steps.

6.14. The representative of <u>New Zealand</u> thanked China for the update and the context provided about the declaration's intent, expressing willingness to engage constructively in progressing the matter. New Zealand echoed the positive views of other Members on the value of the process.

6.15. The representative of <u>Brazil</u> thanked China for the update. Brazil had discussed the issue informally with China on a few occasions and hoped to continue these discussions to move forward with the initiative.

6.16. The representative of the <u>United States</u> sought clarification on the process moving forward, asking if there would be an update or if China planned to organize consultations on the next steps.

6.17. The representative of <u>China</u> expressed appreciation for the support from Members and their willingness to discuss the matter in the future, indicating that China is open to further dialogue. On the question from the US and Japan, given the proximity of MC13, the priority for China was to gather co-sponsors and communicate with the Secretariat and the Chairperson to find a suitable way of moving the matter forward.

6.2 Standards-related work of the WTO Secretariat for the upcoming UN climate conference, COP28

6.18. <u>The Secretariat</u>, represented by Deputy Director-General Jean-Marie Paugam, updated the Committee on standards-related work of the WTO Secretariat for the upcoming UN climate conference, COP28. DDG Paugam's statement is contained in document <u>G/TBT/GEN/364</u>.

6.19. The representative of the <u>United Kingdom</u> highlighted collaboration with Germany as co-leads of the Steel Breakthrough, aiming to support a coalition of leading international organizations in the development of the Steel Standards Principles, which will be launched at COP28. The UK anticipates that these principles will be a significant step in mobilizing stakeholders throughout the steel industry value chain to hasten the harmonization and interoperability of standards for near-zero emission steel. They looked forward to further dialogue across governments and the industry on such key cross-cutting issues.

6.20. The representative of <u>Australia</u> reiterated their commitment to addressing the climate crisis and striving to keep 1.5 degrees of warming within reach. Australia is dedicated to international climate leadership and taking significant action on climate both domestically and internationally. Enhancing collaboration with other countries toward rapid global decarbonization and climate adaptation is a key goal of Australia's engagement in the COP28 Action Agenda. Within the context of the Committee, Australia recognizes the pivotal role international standards can play in facilitating international collaboration on important areas, promoting harmonized and interoperable approaches that facilitate trade.

6.21. The representative of <u>China</u> thanked the Deputy Director-General for sharing information on the Steel Standards Principles set to be introduced at COP28. China viewed the launch of these principles as inspiring for the TBT Committee's work and expressed a desire to closely monitor progress and maintain communication with members interested in this matter.

6.22. The representative of the <u>United States</u> voiced concerns regarding the timing and nature of the briefings on joint statements between COP28 and the WTO on decarbonization principles for the iron and steel industry. The US questioned the inclusiveness of the process and whether the TBT Committee was merely an afterthought, as they felt not sufficiently consulted but merely informed. The US stressed the importance of equal footing with other WTO Committees and requested that WTO TBT Secretariat inform the Committee of climate change-related activities relevant to standards and technical regulations in a timely and regular manner, ensuring member-driven decision-making. They also requested that any WTO endorsements of principles should be clear that it is WTO Secretariat work and is endorsed by Secretariat staff rather than on behalf of the Members.

6.23. The representative of the United States requested that the WTO TBT Secretariat inform the Committee of WTO climate change-related activities that are relevant to standards, conformity assessment, and technical regulations in a timely and regular manner. This should include intersessional communication to the committee on any WTO-wide proposals, allowing for member input when comments can be effectively considered. The United States emphasized that the TBT Committee, as a regular and standing Committee of the WTO with established rules of procedure, deserves to have the same status as other WTO Committees and ad hoc groups, especially on issues directly pertinent to its work.

6.24. The United States called for any WTO briefings on climate change activities that involve the WTO TBT Agreement to be scheduled on the Committee's agenda in a timely manner, and not at the last minute to address in "other matters."

6.25. While supporting the decarbonization of steel and iron as a legitimate climate change goal, the representative questioned the WTO's approach on these joint principles as we understand the WTO will endorse them as an organization, along with private organizations. The United States highlighted that WTO Members have not agreed to this statement of principles. This is a departure from a member-driven decision or outcome, and our stakeholders will be confused by it, who might wrongly assume that the United States endorses a document it has not, given the WTO's nature as a consensus-based organization representing governments, not the private sector.

6.26. The representative also pointed out that when the WTO directly engages with private sector stakeholders from the United States, it disrupts the internal consultation process with the US trade advisory committee and government agencies, which is fundamental for creating consensus-based positions for the WTO TBT Committee. This practice was described as crucial for internal coordination and as a model of good regulatory practice.

6.27. The United States advocated for greater transparency, which they believe will lead to more substantial input and smoother acceptance of climate change outcomes. They insisted that if WTO Secretariat staff wished to endorse a set of principles independently, it must be clear that such endorsements were personal opinions of the staff and did not reflect the consensus position of the Members. The United States requested that appropriate disclaimers be included in COP documents to clarify that these are not consensus positions of the Members.

6.28. The representative of the <u>European Union</u> thanked the Chair and Deputy Director-General Paugam for the update. The EU expressed support for initiatives aimed at accelerating the

decarbonization of sectors such as steel and welcomed collaboration on the definition of international standards within established international forums.

6.29. The representative of <u>Paraguay</u> hadn't planned to speak since the topic was listed under "other business" and there hadn't been time to consult with their capital for a more informed statement. However, seizing the moment, they concurred with the United States on the point that the WTO is a member-driven organization. They highlighted a recent instance where they learned through the press about a Task Force on carbon pricing officially launched in the WTO, which reportedly took place in a private setting in London. As members of the WTO, they wanted to underscore this aspect.

6.30. The representative of <u>Guatemala</u> thanked the Deputy Director-General for the information provided about COP28 and aligned with the United States' position. They emphasized the necessity of including a disclaimer clarifying that the documents and positions outlined do not originate from the WTO Members but require a consensus among members for adoption.

6.31. The representative of <u>India</u> thanked Deputy Director-General Paugam for his update. Sharing some of the concerns raised in the meeting, they requested that the WTO ensure that any standards, guidelines, or documents reflect that they do not represent Members' national positions, but are initiatives undertaken by the WTO Secretariat on its own responsibility.

6.32. The <u>Secretariat</u>, represented by Deputy Director-General Paugam, acknowledged the comments made by the Members. He clarified in response to the United States that the document in question does not represent a joint declaration with the UNFCCC or COP; it was merely presented at COP, which is not an institutional partner in the matter. He also noted the observations regarding the consultation process and stated they would consider the feedback. He committed to communicating the text of the principle as an annex to his written report for the committee. Furthermore, he indicated that there would be more interaction with Members about the Secretariat's engagement at COP in the next Committee on Trade and Environment (CTE) meeting.

6.33. The representative of the <u>United States</u> expressed support for the concept of principles but was concerned about the timing of the process, mentioning that it seemed rushed and that documents bearing the WTO logo alongside private sector logos had been seen by the US private sector before the government. This presented a procedural issue, as they would have preferred to be aware of the document or to have approved by the Committee, which had not happened. The US emphasized the importance of transparency and involvement of the Committee in the initiative.

6.34. The <u>Secretariat</u>, represented by Deputy Director-General Paugam, took note of the questions raised. He pointed out that if private sector organizations were to endorse the document, it would, by definition, not be a WTO document reflecting the membership's consensus.

6.35. The representative of the <u>United States</u> appreciated DDG Paugam's responsiveness.

6.3 Communication From Brazil - Enhancing Food Security through the Reform in Agriculture and the use of current flexibilities (<u>JOB/TBT/517</u>)

6.36. The representative of <u>Brazil</u> present a document entitled "Enhancing Food Security Through the Reform in Agriculture and the Use of Current Flexibilities," which had been circulated in the TBT committee as <u>JOB/TBT/517</u>. This paper was also submitted to various WTO bodies to draw the attention of TBT delegates. Brazil clarified that the document was not intended as a modality or a substantive proposal but rather as a conceptual contribution to the discussions and negotiations in agriculture leading up to MC13. With the pressing challenges of food security, Brazil's stance is that agri-food production systems are heavily distorted due to subsidies and trade barriers, including technical barriers to trade, rather than being inherently broken. The document emphasized that reform in the agricultural sector, particularly regarding market access, is crucial.

6.37. Brazil pointed out that the food security landscape would improve without the extensive tradedistorting domestic support and increasing barriers currently in place. The representative brought attention to discussions in the committee concerning measures like maximum residue levels (MRLs), which are more trade-restrictive than necessary, often not in line with international standards or scientific evidence, and negatively impact agricultural production, especially in developing countries. 6.38. Brazil said that its approach to combating food insecurity relies on enhancing productivity and creating favorable conditions for small, medium-sized, and family farmers to engage in global markets. The document aims to contribute to the MC13 discussions by seeking improvements in the functioning of agricultural markets and mitigating the adverse effects of misguided agricultural policies. Brazil expressed the belief that reform, including the elimination of unnecessary technical barriers to trade in agriculture, is vital for better global food distribution. The representative concluded by expressing hope that the paper would positively influence discussions towards MC13.

6.39. The representative of <u>Paraguay</u> thanked the Brazilian delegation for introducing the document entitled "Enhancing Food Security Through the Reform in Agriculture and the Use of Current Flexibilities," noting its importance in the context of agricultural negotiations and related work within the WTO. They highlighted that out of the new issues addressed in the Committee's meeting, five were related to food security and market access, which are often hindered by technical barriers to trade. Paraguay appreciated Brazil's role in bringing attention to specific trade concerns that impact the trade of food products.

6.40. The representative of <u>Australia</u> thanked Brazil for the presentation of its submission, which emphasizes the complex and interconnected nature of food security issues across various WTO committees. Australia echoed the points made by Brazil, which are in line with the views of the Cairns Group members and Australia's long-standing position that food security can be achieved without heavy reliance on subsidies or other production and trade-distorting policies, including those within the scope of the TBT Agreement. The representative also mentioned the statement from Cairns Group members on the contribution of the multilateral trade system to sustainable and resilient agriculture and food systems (<u>G/AG/GEN/222</u>), which aligns with Brazil's submission in highlighting concerns about the emergence of increasingly onerous, unilaterally-imposed import requirements affecting trade in agri-food products ostensibly on environmental sustainability grounds. It highlights the importance of Members upholding WTO commitments by ensuring all trade measures are transparent and consistent with international standards where they exist, and/or are risk-, science- and evidence-based. With MC13 approaching, Australia highlighted the potential for these discussions to contribute towards a more food-secure and sustainable future, urging members to engage with both documents.

6.41. The representative of the <u>United States</u> thanked Brazil for the submission and indicated they would review it.

6.42. The representative of <u>Uruguay</u> thanked Brazil for presenting it in the TBT Committee, and in other committees. They agreed with the statements made by Paraguay and Australia, especially on the significance of addressing regulatory practices on agricultural and food products to enhance global food security.

6.43. The representative of <u>Chile</u> expressed gratitude towards Brazil for the document.

6.44. The representative of <u>Brazil</u> appreciated the supportive comments and interventions regarding their document and expressed the hope to continue working with other Members leading up to MC13 and negotiations in agriculture to achieve a positive outcome, including on food security. For Brazil, agriculture is inseparable from food security, and they believe agriculture can contribute to the success of MC13. They looked forward to collaborative efforts with other members to achieve this goal.

7 DATE OF NEXT MEETING

7.1. The next regular meeting of the Committee will take place on 13-15 March 2024. It will be preceded by informal meetings on 12 March. The dates for all meetings in 2024 are contained in document <u>JOB/TBT/500/Rev.1</u>, issued on 22 March 2023.