



Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 13-15 JULY 2022

CHAIRPERSON: MR. ANWAR HUSSAIN SHAIK

Note by the Secretariat¹

1	ADOPTION OF THE AGENDA	1
2	IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT	4
2.1	Specific Trade Concerns	4
2.1.1	Reported progress on STCs	4
2.1.2	New Specific Trade Concerns.....	4
2.1.3	Previously raised concerns	15
2.2	Exchange of Experiences	120
2.2.1	Transparency	120
2.2.2	Conformity Assessment Procedures.....	123
2.2.3	Regulatory Cooperation between Members (MSMEs)	125
2.2.4	Covid-19	125
2.2.5	Other Matters.....	126
3	TECHNICAL COOPERATION ACTIVITIES	127
4	OBSERVERS.....	127
4.1	Updates from Observers	127
4.2	Pending requests.....	127
5	OTHER BUSINESS.....	128
6	DATE OF NEXT MEETING.....	128

1 ADOPTION OF THE AGENDA

1.1. The Committee adopted the agenda contained in [WTO/AIR/TBT/23](#).

1.2. The representative of Ukraine expressed his delegation's gratitude for Members' assistance to Ukraine, for their leadership and unwavering support in the hardest possible time. According to the Preamble of the WTO Marrakesh Agreement, Members needed to work together to improve the welfare of people around the world, raise living standards, create jobs and improve people's lives by "entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international trade relations"; and, also – to "develop an integrated, more viable and durable

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.

multilateral trading system". These noble goals and principles of work at the WTO had been – and were currently – horrendously destroyed by the Russian aggression.

1.3. Once more, Ukraine emphasized that Russia's invasion of Ukraine undermined the established work of the multilateral trading system, hindered the development of and people's welfare in developing and least developed countries (LDCs), as well as impaired the proper functioning of international organizations, the WTO in particular. The war launched by the Russian Federation on Ukraine had caused immense suffering and destruction and the national system for the development of technical regulation had been seriously affected by the war. Many employees had been forced to work under extremely harsh circumstances. Experts from the competent bodies of Ukraine in the sphere of technical regulation had been redeployed to perform their official duties in other regions of the country.

1.4. 81 conformity assessment bodies were designated in Ukraine to ensure conformity assessment procedures with the requirements of technical regulations as a third party prior to Russia's full-scale invasion of Ukraine. After the introduction of martial law in Ukraine these bodies had inquired about their ability to conduct procedures for assessment of conformity to technical regulations during the martial law regime in Ukraine. As of 12 July 2022, only 44 of the 81 designated bodies, located in different regions of Ukraine, had informed the national authority in the TBT sphere and confirmed the capability to continue to fully conduct conformity assessment procedures within their permanent locations. No information had been received from the remaining 37 bodies located in regions, part of whose territory was currently under occupation and constant shelling. Against this backdrop, the national competent bodies continued to diligently fulfil their professional obligations to ensure that technical regulations, standards and conformity assessment procedures did not create unnecessary obstacles to trade.

1.5. Regarding exports of Ukrainian products, the representative of Ukraine was grateful to its partners for the measures taken to resume Ukraine's ability to produce and export of goods. Ukraine recalled that the WTO, as well as other international institutions, had been created to promote peaceful cooperation between governments on a variety of issues. The Russian Federation by its act of aggression against the sovereignty of Ukraine and its sovereignty had ruined this underlying purpose. In this regard, the representative of Ukraine informed Members that Ukraine had requested ISO, the International Bureau of Weights and Measures (BIPM), International Electrotechnical Commission (IEC), International Organization of Legal Metrology (OIML), European Telecommunications Standards Institute (ETSI) to unequivocally condemn the aggressive actions of the Russian Federation, noting that they represented a clear violation of Ukraine's sovereignty and territorial integrity, and that these actions ran contrary to the principles enshrined in these organizations.

1.6. The representative of Canada strongly condemned Russia's unjustifiable and unprovoked invasion of Ukraine. The attacks were causing widespread humanitarian consequences. This was not just an attack on Ukraine, this was an attack on international law including UN Charter as well as democracy, freedom and human rights.

1.7. The representative of Australia condemned in the strongest possible terms Russia's unprovoked and unjustified attack on its neighbour, Ukraine. The invasion was a gross violation of international law and the UN Charter. Australia called on Russia to withdraw its forces from Ukrainian territory. Australia deeply regretted the already high number of casualties, in particular the Ukrainian civilians, killed so far in the conflict.

1.8. The representative of the United States thanked the delegate from Ukraine for his statement and reiterated her country's strong support for Ukraine. The United States condemned Russia's premeditated and unprovoked attack on Ukraine, as well as the actions of the Belarus regime which was complicit. The United States called upon Russia to immediately cease the use of force against Ukraine and refrain from any further use of force against any UN member State. The actions of Russia were incompatible with the rules-based system that the international community as a whole had built; Russia's aggression undermined the rights of Ukraine in the WTO and was fundamentally incompatible with the values and principles of this organization.

1.9. The representative of the European Union stressed, like others in the room, that the Russian Federation's invasion of Ukraine was a flagrant violation of international law and the rules-based

international order and had effects that spread well beyond Ukraine's borders. The European Union urged Russia to stop its indiscriminate attacks against civilians and civilian infrastructures and to immediately and unconditionally withdraw its troops and military equipment from the entire territory of Ukraine within its internationally recognized borders. As reflected in the EU and Partners March Joint Statement to the General Council, and in the recent G7 Leaders' Communiqué, the EU and its partners continued to fully support Ukraine's sovereignty and territorial integrity. The EU and its Partners restated their unity in respect of sanctions against Russia and on providing short- and long-term reconstruction assistance to Ukraine. The EU stood by Ukraine.

1.10. The representative of the United Kingdom condemned Russia's recent aggression against Ukraine. Since February, Russia had continued its unprovoked and illegal aggression against a democratic State and a fellow Member of this Organization. Russia must urgently de-escalate and withdraw its troops and cease its violations of international law. The UK would continue to work with our partners across the multilateral system to condemn Russia's actions and isolate it on the international stage.

1.11. The representative of New Zealand unequivocally condemned the unprovoked and unjustified attack by Russia on Ukraine. The actions of President Putin were a great breach of international rules; the use of force to change borders was strictly prohibited under international law, as was the targeting of civilians. New Zealand was appalled by reports of the devastating and indiscriminate attacks on Ukraine's population by Russian troops, including evidence of crimes against humanity and war crimes, as well as the destruction of civilian infrastructure including hospitals, schools, and homes. New Zealand supported and would spare no effort in holding those responsible for this aggression to account. New Zealand remained united with the international community to maintain pressure on Russia and hold those responsible for violations of humanitarian and international law to account. New Zealand had repeatedly called for President Putin to act consistently with international obligations, cease Russia's invasion of Ukraine, withdraw troops and return to diplomatic negotiations as a pathway to resolve the conflict. New Zealand's thoughts were with the people of Ukraine and with the Ukrainian Community, particularly in light of the distressing reports of atrocities against civilians.

1.12. The representative of Japan said that Russia's aggression against Ukraine was an infringement of the sovereignty and territory of Ukraine which constituted a clear violation of international law; it challenged the foundation of international order. Japan had no tolerance towards this. Russia's action was an outrageous act that disrupted supply chains and caused concerns on food security. Japan condemned Russia's aggression in the strongest possible terms and urged Russia to cease its military operations in Ukraine and to withdraw its forces immediately. Japan continued to stand in solidarity with Ukraine and its people and to cooperate with the Members of the international community to improve the situation.

1.13. The representative of the Republic of Korea expressed concern about Ukraine's inability to fully participate in the WTO TBT Committee and the related fields and joined others in strongly condemning Russia's invasion of Ukraine as a violation of principles of the UN Charter and international law. The use of force that caused innocent casualties could not be justified under any circumstances. Ukraine's territorial sovereignty and political independence had to be respected.

1.14. The representative of Switzerland condemned the Russian military aggression on Ukraine in the strongest possible terms. It was a violation of international law; it violated the prohibition of the use of force and the territorial integrity and sovereignty of Ukraine. Switzerland called on Russia to respect its international obligations and to reverse its actions as well to withdraw its troops and to contribute to the de-escalation. Switzerland called on all actors to respect international law including international humanitarian law.

1.15. The representative of Costa Rica expressed solidarity with the people of Ukraine for the unjustified attack by Russia. The human tragedy that millions of families were suffering was unthinkable for a country like Costa Rica with a democratic and peaceful tradition. The impact on world trade was obvious and this was an issue that had to be addressed at the WTO. The impact of the war was generating consequences in both the short and long term; there was contamination of the soil, and human lives were being affected – and this was when many people were already suffering from the food crisis. Costa Rica would continue to be a strong defender of multilateralism and international architecture that served peace, security, sustainable development and protection of human rights. Costa Rica called for dialogue and respect for the rule of law.

1.16. The representative of the [Russian Federation](#) repeated his delegation's view that the consideration of matters of global or regional security concerns, the humanitarian situation, the UN Charter, enforcement or compliance, did not fall under the mandate of the TBT Committee – more the WTO itself. Russia was ready to consider the situation in Ukraine in relevant UN Agencies and Bodies. The unilateral trade restrictions measures introduced by Members that had intervened in the Ukrainian issue fell under the Mandate of the WTO, these measures represented a violation of WTO rules, and undermined the multilateral trading system and the rules-based order. Also, with due respect, the representative of Russia recalled that according to Rule 17 on the Rules of Procedure for meetings of the General Council, contained in document [WT/L/161](#), whenever the debate between Members steered away from the adopted agenda, it was the responsibility of the Chairperson of the meeting to call a speaker to order if the remarks of the speaker were not relevant. From our point of view, the remarks of delegations were not relevant, not just for this Committee but for the WTO itself.

2 IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

2.1 Specific Trade Concerns

2.1.1 Reported progress on STCs

2.1. The delegation of the [European Union](#) thanked the Kingdom of Saudi Arabia for the good cooperation on ceramics.² The STC had not been raised during the current meeting as a TPR investigation was also underway. The EU noted that a lot of progress had been made due to Saudi's engagement, including many bilateral meetings. Despite certain things still needing to be implemented, positive developments were observed and the EU hoped that it would not need to raise the concern in the future.

2.2. The delegation of [Australia](#) thanked the United Kingdom for its constructive engagement on the issue of STC 663 to date.³ In light of the UK's cooperative work in addressing their concerns regarding wine labelling requirements, Australia had decided to cease raising this STC for the time being and that they were working towards a permanent resolution. Australia looked forward to continued engagement with the UK to ensure permanent resolution in implementing in a timely manner.

2.1.2 New Specific Trade Concerns

2.1.2.1 China - Key Points and Judgment Principles of GMP Inspection for Cosmetics; Safety and Technical Standards for Cosmetics (2022); Technical Guidelines for Children's Cosmetics, [G/TBT/N/CHN/1673](#), [G/TBT/N/CHN/1674](#) (ID 749⁴)

2.3. The delegation of the [United States](#) provided the following statement. The United States appreciates that China notified the TBT Committee of two new draft implementing measures for the Cosmetics Supervision and Administration Regulation (CSAR): the Key Points and Judgement Principles of Good Manufacturing Practice (GMP) Inspection for Cosmetics ([G/TBT/N/CHN/1673](#)), and the Safety and Technical Standards for Cosmetics ([G/TBT/N/CHN/1674](#)). We submitted comments to China in response to your notifications on 24 June 2022. However, we question China's commitment to giving meaningful consideration to stakeholder input given the timelines provided for implementation and the lack of an explanation as to why China deems relevant international standards, guides, or recommendations inappropriate to meet its regulatory objectives. First, we are concerned that while China provided a 60-day comment period for the GMP Inspection Points ([G/TBT/N/CHN/1673](#)), US industry has informed us that the measure went into force on 1 July 2022, only six days after the WTO comment period closed and just three months after a draft of the measure was first notified in China. The GMP Inspection Points are complex and add many new requirements for cosmetics companies that were not included in the related measure, Good Manufacturing Practices for Cosmetics ([G/TBT/N/CHN/1626](#)). We ask that China delay its timeline

² Kingdom Of Saudi Arabia - Technical Regulation For Building Materials – Part 4: Bricks, Tiles, Ceramics, Sanitary Appliances, And Related Products (Published On The Official Gazette On 22/03/2019) ([ID 698](#))

³ United Kingdom - Wine labelling requirements at the end of Brexit period ([ID 663](#)).

⁴ For previous statements follow the thread under [ID 749](#).

for adoption and implementation of this new measure to allow sufficient time to consider stakeholder comments, and to re-notify the measure if there are substantive updates.

2.4. Second, we ask that China clarify how the GMP Inspection Points will be used and if there will be flexibilities in how China assesses companies' conformity. For example, Attachment 2 of the draft measure includes several inspection items for the entrusted production enterprise that in many companies are instead overseen within corporate headquarters or via contracts with third parties. Third, we are concerned that China informed the United States it will not notify the Technical Guidelines for Children's Cosmetics to the Committee. However, the Technical Guidelines do appear to introduce new requirements for cosmetic product use and ingredient restrictions that were not included in the Provisions for the Supervision and Administration of Children's Cosmetics ([G/TBT/N/CHN/1615](#)). Due to the mandatory nature of these two Technical Guidelines, we request that China notifies this measure to the TBT Committee. We also ask that once the measure has been notified with a reasonable period for comment and consideration of input, China provides a minimum of two years for companies to adapt their products or methods of production and an additional year to sell through products already in the market.

2.5. Fourth, we ask that China clarify its timeline for public consultation, finalization, and implementation of updates to the Safety and Technical Standards for Cosmetics ([G/TBT/N/CHN/1674](#)). Although these standards update an existing measure, China has made substantive changes, including by its own count, amendment of 15 testing methods. Fifth, we ask that whenever China proposes an update to a standard, technical regulation or guideline related to CSAR, that China first considers whether the update is based on relevant international standards, guides, or recommendations, and if not, that China provide an explanation for why those standards, guides, or recommendations are inappropriate to meet China's regulatory objectives. We thank China for its consideration and look forward to responses to our questions.

2.6. In response, the delegation of China provided the following statement. As this is the first time a Member raises this concern in this Committee, China is listening to have an idea of what your concerns are and then we will contact the relevant authorities and give you the reply.

2.1.2.2 European Union - Proposal for a Directive of the European Parliament and of the Council amending Directive 2014/53/EU on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment (COM/2021/547 final), [G/TBT/N/EU/859](#) (ID 750⁵)

2.7. The delegation of the United States provided the following statement. We thank the EU for notifying its proposed amendment to the Radio Equipment Directive to the WTO TBT Committee. We provided comments to your notifications on 15 March 2022. While we greatly appreciate your response to our comments on 5 May 2022, we have remaining concerns about the proposal as written and reported provisional agreement. We oppose the EU's decision to prescribe the USB Type-C receptacle within the regulation rather than allowing greater flexibility for mobile phone producers to use other receptacle interfaces that meet existing voluntary international standards. We also remain concerned about how a prescribed standard for mobile phone chargers will impact innovation. We have heard concerns from our industry stakeholders that future innovation for chargers, especially as it relates to energy efficiency, will be disincentivized under this proposal. While the EU has provided reassurances that the notified draft provides a mechanism to allow for swift adoption of new or updated relevant technical specifications, we encourage the EU to recognize other international standards that support future innovation for chargers and provide up-to-date and safe solutions without the additional hurdle of prescriptive approval processes to adopt new technical specifications.

2.8. We again encourage the EU to specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics. We also understand that there have been amendments to the original proposal included in the provisional agreement which expand the scope of the proposal, including to devices that were not contemplated under the impact assessment. We understand this has taken many stakeholders by surprise and leaves uncertainty as to the impact of this proposal on the marketplace and barriers to trade. Finally, we ask the EU to

⁵ For previous statements follow the thread under [ID 750](#).

provide any updates it might have on the expected timeline for finalizing and implementing this proposal.

2.9. In response, the delegation of the European Union provided the following statement. Concerning United States' opposition to prescribe the integration of the USB Type-C receptacle for certain categories or classes of radio equipment, the EU would like to emphasize that, for more than ten years, the European Commission has supported a voluntary approach. Though, it allowed to reduce the number of solutions from more than 30 to currently three, it has been ineffective in solving the lack of interoperability between radio equipment and chargers still causing inconvenience for consumers. The harmonized charging receptacle (USB-C) is a technology that has been and is developed by a consortium that includes major ICT manufacturers. Their specifications are open and translated into international (and European) standards. As regards the impact on innovation, the EU would like to highlight that the text includes provisions to act swiftly to update the technical requirements. Additionally, the proposed measures do not impede manufacturers to continue developing their own solutions, provided that they do not hamper the well-functioning of the harmonized charging solution (receptacle and communication protocol). Furthermore, the biggest upcoming developments in charging technologies are expected for wireless charging. For this purpose, the current text does not impose a harmonized solution but sets ground to introduce an efficient solution that will appear on the market.

2.10. Regarding the specifying of technical requirements in terms of design characteristics, this is the only possible way to achieve full interoperability between radio equipment and chargers (consumer convenience) and reduce the proliferation of un-necessary chargers (environmental benefits). Combining a harmonized charging solution with the unbundling of the external power supply will deliver results only if each category of products covered is equipped with the same receptacle. As for the amendments to the scope of the proposal, indeed, e-readers, earbuds, keyboards, mice, portable navigation systems, and laptops were added to enhance the benefits of the proposal in terms of consumer convenience and environmental benefits. Impacts from the inclusion of earbuds and e-readers were assessed in the 2021 study. While the inclusion of other additional categories was not subject to an impact assessment, technical analysis revealed that there were no technical obstacles for their introduction in the scope of the measure. In addition, market developments confirm that USB-C receptacle is adapted and technically sound for application to these categories of products. As far as laptops are concerned, a longer transition period (40 months compared to 24 months for the other categories) is foreseen in order to give manufacturers sufficient time to adapt to this inclusion. The formal adoption process by the European Parliament and the Council will take place after the summer. The text will enter into force following its publication in the Official Journal of the European Union.

2.1.2.3 China - Measures for the Administration of Data Security in the Field of Industrial and Information Technology Sectors (For Trial Implementation) (ID 751⁶)

2.11. The delegation of Japan provided the following statement. Japan has concerns about the "Measures for the Administration of Data Security in the Field of Industrial and Information Technology Sectors," especially referring to the unclear relationships between many articles of the measures and the related provisions of the Cybersecurity Act. The Japanese government has already submitted comments including this point on the second public consultation in February 2022. Moreover, the definitions of "general data", "important data", and "core data" do not provide objective and specific criteria for classification. In addition, although Article 7 of the measures stipulates that the Ministry of Industry and Information Technology (MIIT) is to formulate a detailed inventory of "important data" and "core data", depending on the specifics of the detailed inventory and related regulations, it may have a significant impact on the businesses involved in the industrial information field. Therefore, Japan would like to request that China utilize transparent procedures in formulating the detailed inventory, so that the opinions of stakeholders including foreign companies can be widely heard and reflected, and ensure that undue burden is not placed on business operators.

2.12. In response, the delegation of China provided the following statement. In order to further promote the implementation of "Data Security Law", China has crafted the "Measures for Data Security Management in the Fields of Industry and ICT (For Trial Implementation)". Based on the characters of industry and ICT, the measures has refined relevant requirements and provided more

⁶ For previous statements follow the thread under [ID 751](#).

operational guidance for data processors of industry and ICT to fulfil their data security protection obligation.

2.1.2.4 European Union - Draft Commission delegated regulation amending regulation (EU) 2019/2144 of the European Parliament and of the Council to take into account technical progress and regulatory developments concerning amendments to vehicle regulations adopted in the context of the United Nations Economic Commission for Europe, [G/TBT/N/EU/882](#) (ID 752⁷)

2.13. The delegation of [China](#) provided the following statement. *a.* In this draft notification, some of the UN regulations adopted by the EU were issued less than 15 months before implementation. For new models that are already under development, there is not enough time to make technical adjustments before 6 July 2022, and additional configuration is required, which will lead to longer model development time and increased costs. For the certified models (in production), there is no time to upgrade the new version certificate before 6 July 2022, which will block sales on those original certified vehicles after 6 July 2022. China proposes the EU to specify whether the upgraded regulation in the Annex, point (1) can apply to the buffer period of the transitional provisions of the individual UN regulations, or modify the implementation date in Annex, point (2) to leave enterprises more buffer time.

2.14. *b.* For vehicles with existing approval and new types of vehicles, the implementation time of some Annex II individual technical regulations in [G/TBT/N/EU/882](#) is earlier than the implementation time of UN regulations, and the transition period or exemption clause adopted are not explained accordingly, which has caused great trouble for enterprises to apply for EU type approval. This part of the regulations mainly influences the vehicles with existing approval (in production). Automobile export enterprises in China has developed an upgrading plan according to UN single regulation requirements. If (EU) 2019/2144 was implemented on 6 July 2022, most certified vehicles exported to the EU would not meet the upgrading requirements, causing risks of violation and affecting the sales market severely. China proposes the EU to further explain the difference between the implementation time of (EU) 2019/2144 Annex II and the transition period of the upgraded UN regulations adopted in Annex I, and China hopes the EU to comply with UN WP.29 - The 1958 Agreements. For example, UN R141-01 series, although the implementation time for UN Regulation on certified models (in production) is also on 6 July 2022, Article 12.6 of the regulation provides that parties shall continue to accept 00series type approval if the vehicle or vehicle system is not affected by 01 series. Under this condition, will the 00 series certificate of the certified models not be affected by the 01 series and remain valid after 6 July 2022?

2.15. *c.* Annex, point (2), (j) Item D4 on "Protection of the vehicle against cyber attacks" applies to STU (Separate Technical Unit) and component. The European Commission adopts UN Regulation No 155 as the implementation regulation of this requirement, and plans to implement on Class M, Class N models, and STU from 6 July 2022. However, UN Regulation No 155 only applies to vehicle type approval, and STU cannot obtain type approval under this regulation. China proposes that Annex, point (2), (j) ItemD4 not apply to STU. *d.* Annex, point(2), (n) Item E4 on "Driver availability monitoring system", (o) E6 on "Systems to replace driver's control", E7 on "Systems to provide the vehicle with information on the state of the vehicle and surrounding area" will adopt UN Regulation No 157 as the type approval regulation for these projects. UN Regulation No 157 is a type approval regulation for ALKS systems, but it is unclear which parts of UN R157 Item E4/E6/E7 should comply with, leading to misunderstanding. China proposes the EU to further clarify which sections of UN Regulation No 157 should be implemented. Meanwhile, if multiple Items adopt the same type of approval regulations, please further explain the conformity assessment procedures of separate type approval certificates for these items.

2.16. In response, the delegation of the [European Union](#) provided the following statement. The European Union would like to thank the People's Republic of China for the comments on notification [G/TBT/N/EU/882](#), sent on 13 May 2022. The EU regrets that China did not make its statement on this trade concern available in time, and therefore cannot answer the concerns contained therein. However, the EU may provide some elements to answer China's concerns as presented in official TBT comments. The EU will respect its obligations in accordance of UN Regulations and will not mandate the latest amendments of UN regulations before the agreed transitional provisions set out

⁷ For previous statements follow the thread under [ID 752](#).

in these amendments. The table in Annex II to Regulation 2144/2019 only lists which UN Regulations shall apply for a specific topic without mandating a specific version of the concerned regulations.

2.17. Annex I to Regulation 2144/2019 lists the UN Regulations that apply on a compulsory basis and refers to the latest versions of UN Regulations published in the EU official journal. This is without prejudice to the transitional provisions included in the UN regulations. As a standard, the EU applies on a mandatory basis the transitional provisions set out in the amendments to UN regulations, unless the topic in Regulation 2144/2019 applies from a later date. This is reflected in the notes inserted after the table in Annex I. As an example, the highest requirements for advanced emergency braking systems (AEBS) for pedestrians and cyclists will apply from 1 May 2024 for new vehicle types of vehicles in UN Regulation 152, but AEBS for pedestrians and cyclists will be required in the EU for new vehicle types only from 1 July 2024 (i.e. at later date). The EU currently finalizes the analysis of China's comments and will shortly provide an official reply through the Enquiry Point.

2.1.2.5 Canada - Proposed Prohibition of Certain Toxic Substances Regulations, 2022, G/TBT/N/CAN/673 (ID 753⁸)

2.18. The delegation of Japan provided the following statement. Japan shares the following concerns regarding the proposed DBDPE restrictions in the Proposed Prohibition of Certain Toxic Substances Regulations, 2022. DBDPE is widely used in electrical and electronic equipment, automobiles, aircraft, medical equipment, industrial equipment, social infrastructure equipment, agricultural machinery, industrial machinery, construction machinery and industrial vehicles. DBDPE is an alternative to decaBDE, a globally banned brominated flame retardant, and is not restricted by international conventions or other jurisdictions. In addition, since there is no equivalent flame retardant for many applications that can be used as a substitute for DBDPE currently, we are concerned that there will likely be significant and serious impacts on the trade and distribution of the above equipment in case that the use of DBDPE is prohibited. In particular, medical equipment, industrial equipment, social infrastructure equipment, agricultural machinery, industrial machinery, construction machinery and industrial vehicles are important instruments that support those industries and the citizens' lives in Canada. We understand that the Canadian government seems to be considering the introduction of the regulations carefully. However, Canada should be particularly cautious about considering alternatives to DBDPE including safety assessments and establishing a grace period for implementation, with additional hearings from stakeholders. It should also be noted that the risk of exposure to humans and the environment is limited because these devices are collected under strict control after use and properly recycled or disposed of.

2.19. Canada cited the protection of endangered whales and belugas as the main reason for regulating DBDPE. Although we understand the objectives of policy, Japanese industry reports that DBDPE contained in articles poses a very low risk of adverse effects on humans and the environment, including these endangered species. Therefore, in order to ensure that the proposed DBDPE restriction is not more trade restrictive than necessary to achieve its legitimate objectives, Japan would like to request that more thorough risk assessment regarding humans and the environment should be conducted on the effects of DBDPE contained in articles, while taking into account the consistency with results of risk assessment from other countries and regions, and that a realistic feasibility study should be conducted on the alternatives.

2.20. In response, the delegation of Canada provided the following statement. Canada notified the Proposed Prohibition of Certain Toxic Substances Regulations, 2022 ([G/TBT/N/CAN/673](#)) to the WTO TBT Committee on 18 May 2022, providing Members the opportunity to review the measure and share comments by 28 July 2022. While we note Japan's intervention, and the fact that this is the first opportunity we have to hear Japan's concern with the proposed rule, Canada would encourage Japan to share its comments in writing via Canada's Enquiry Point before the 28 July deadline. Canada is also open to engage bilaterally with Japan to discuss its views and concerns over the measure.

⁸ For previous statements follow the thread under [ID 753](#).

2.1.2.6 South Africa - Regulations Relating to the Labelling of Alcoholic Beverages - revision, [G/TBT/N/ZAF/48/Rev.2/Add.1 \(ID 754⁹\)](#)

2.21. The delegation of the European Union provided the following statement. The EU thanks South Africa for notifying their proposed revisions to their alcohol beverage composition, production, and labelling regulations on 12 December 2021. The EU sent written comments on 16 February 2022. Our key concerns relate to the following South African categories: spirit aperitif, gin, description of pot still brandy and vintage brandy. The category of "spirit aperitif" with its minimum and maximum alcoholic strength together with the existing minimum alcohol limits set for other "defined classes in South Africa (example whiskey) could result in a number of EU spirit drinks no longer having the right to be marketed in South Africa. We suggested that South Africa creates a new category "spirit drink" for products that do not fall under South Africa categories due to their alcohol content. Without the flexibility that a "spirits drink" category could offer, many EU products will no longer be exportable to South Africa, due to the proposed changes. We would be grateful if South Africa could take these concerns into account. We would also welcome a precise indication of the likely timelines for adoption of the revision.

2.22. The delegation of the United States provided the following statement. The United States would again like to encourage South Africa to consider our concerns regarding classification of flavoured spirit products. It is our understanding that South Africa's spirit aperitif category includes a 30% maximum alcohol by volume (abv) requirement. Further, South Africa's specific category for flavoured whiskey includes a 43% minimum abv requirement. In the United States, some whiskeys are produced with an abv greater than 30% but less than 43%. The United States is concerned that this measure may unnecessarily restrict imports of US flavoured spirits that fall between the alcohol content requirements of the spirit aperitif category and other specific categories. Can South Africa please confirm what the appropriate classification would be for such products? In its response to the U.S. Government's comments, South Africa indicated that the 43% minimum abv requirement for whiskey was a long-standing requirement. Would South Africa consider raising the maximum abv requirement for the spirit aperitif category instead to account for flavoured spirit products containing greater than 30% abv, but less than 43% abv? We thank South Africa for considering our comments and concerns and look forward to continued engagement with South Africa to address these concerns and ensure trade of US flavoured spirits is not unnecessarily disrupted.

2.23. The delegation of Mexico provided the following statement. With regard to this specific trade concern, we are of the understanding that it is a concern about the same measure that was included in the previous meeting of the Committee and that now also features as Specific Trade Concern No. 80. Despite this duplication, in order to ensure the traceability of concerns, we will be making statements under both items to keep them separate. The delegation of Mexico refers to its statement made at the previous meeting of this Committee in March 2022 on the Regulations relating to the composition, production and labelling of wine and spirits intended for sale in the Republic of South Africa, notified to the Members of the Committee on 20 December 2021 in document [G/TBT/N/ZAF/48/Rev.2/Add.1](#). Firstly, we thank the Government of South Africa for responding to the comments sent during the public consultation period, in which both the Mexican industry and Government participated to share observations on what we consider could have an impact on Mexican exporters of tequila and mezcal, as well as on potential exporters of raicilla and bacanora. However, the delegation of Mexico wishes to point out that these concerns remain, since South Africa's response to the comments sent by the Government of Mexico do not address each of the remarks made in Official Circular No. 500/RVL/044/2022 of 11 February 2022.

2.24. In this regard, we appeal to the good offices of the delegation of South Africa to address the following comments relating to concerns stemming from the lack of inclusion in the Regulations of clear definitions for beverages of Mexican origin: We ask that, separate from the "100% agave" class, there be a clear specific class for tequila that complies with the applicable Mexican regulations, taking into account that tequila has been registered as a certification mark in South Africa since 2004. In order to avoid potential confusion among consumers, we ask that no reference be made in the "100% agave" class to tequila or its classes or categories, even in Spanish. We also highlight the request for uniform definitions for Mexico's emblematic beverages, such as mezcal, bacanora and raicilla, which have their own origin, physico-chemical specifications and identity characteristics, as established in the respective Mexican Official Standards. In addition, and with the aim of following up on our concerns in a timely manner, we would be grateful if the delegation of South Africa would

⁹ For previous statements follow the thread under [ID 754](#).

provide us with a contact point through which we could regularly follow up on the development of the Regulations. The delegation of Mexico thanks the delegation of South Africa for giving its consideration to this statement.

2.25. In response, the delegation of South Africa provided the following statement. We thank the EU and the US for the interest they have shown in the notification submitted by South Africa and the comments that Mexico has previously submitted on the regulations relating to the labelling of alcoholic beverages in document [G/TBT/N/ZAF/48/Rev.2/Add.1](#). We acknowledge that there has been communication between the EU and South Africa and between the US and South Africa. This communication has not resolved the issues but new questions posed and more issues to be clarified. We have provided a detailed response to this. We believe that addressing the issues in a consultation with relevant Members with a view to resolving them instead of statements presented to the TBT Committee will provide much needed clarification and specific responses to questions raised. We are ready to engage constructively to resolve all the concerns and all comments that the EU, the US and Mexico have raised. Our South African Permanent Mission in Geneva could be contacted to facilitate such engagement and we hope that we can report in the next meeting that the STC has been resolved amicably.

2.1.2.7 United States - Energy conservation program: energy conservation standards for room air conditioners, [G/TBT/N/USA/305/Rev.1](#) (ID 755¹⁰)

2.26. The delegation of China provided the following statement. The calculation method of energy efficiency testing in this regulation is different from international standards. *a)* There are two CEER test methods for RAC products, for fixed frequency air conditioners and frequency conversion air conditioners. It is unreasonable for two calculation methods targeted to one index (CEER), nor can these methods reflect the real gap between fixed frequency and frequency conversion products. Therefore China suggests that the US unify the testing methods of unified fixed frequency and frequency conversion products when upgrading the energy efficiency. *b)* Seasonal energy efficiency can evaluate products' comprehensive performance. The EU and other Members such as Japan, South Korea, and Australia all adopt seasonal energy efficiency. At present, many Members have changed to use seasonal energy efficiency evaluation when upgrading their energy standards. However, the RAC product energy efficiency proposal in the US still uses a single point of energy efficiency index CEER for product evaluation, which is different from the international standards.

2.27. Therefore, China suggests the US use the energy efficiency test method consistent with the international standard ISO 16358. The CEER index value in this proposal increases, compared with the current DOE energy consumption regulations and the Energy Star index, and the CEER energy-saving index of room air conditioning greatly increases. The excessive increase of the index will result in a significant increase in the cost of design, manufacturing and logistics for export enterprises. China proposes the US gradually increase the index based on the average increase of index in the previous energy efficiency standards to ensure the healthy development of the industry.

2.28. In response, the delegation of the United States provided the following statement. The United States appreciates the comments submitted by China on 2 June 2022. The United States will take into consideration all comments received during the open comment period and respond to each substantive comment in the next published rulemaking procedure on standards for room air conditioners.

2.1.2.8 France - Order specifying the substances contained in mineral oils the use of which is prohibited in packaging and in printed matter distributed to the public, [G/TBT/N/FRA/216](#) (ID 756¹¹)

2.29. The delegation of the Republic of Korea provided the following statement. The Korean government appreciates this opportunity to provide its comments on the final text of the "Order Specifying Substances Contained in Mineral Oils Prohibited for Use on Packaging and Printing Materials Distributed to the Public", which was published on 3 May 2022. Korea fully respects and strongly supports France's efforts to introduce a regulation banning the use of mineral oils on the packaging and printed matter with the aim to improve the recycling of waste and protect public health. However, because we have not yet received any replies from the relevant competent

¹⁰ For previous statements follow the thread under [ID 755](#).

¹¹ For previous statements follow the thread under [ID 756](#).

authorities of France regarding our comments submitted through the French Enquiry Point on 29 March and 6 May 2022 twice, Korea would like to deliver the following concerns.

2.30. First, we would like to request that France clarify the application scope of the regulation. It is difficult to identify the regulated substances with only the reference of MOAH (1 to 7 aromatic rings) and MOSH (C16 to C35 carbon atoms) in Article 2 of the published Order. Therefore, more specific substance information, such as CAS Numbers., etc, needs to be provided. In addition, we would like to request that France confirm whether the target of the ban is the content of mineral oil in ink or the residual amount of mineral oil in printed materials. If the regulation targets the residual amount in printed and packaging materials, rather than in ink, banned substances may be detected unintentionally during the conformity assessment process, so we seek a clear confirmation in this regard. Also, we request that France confirm whether the sticker labels attached to products or packaging fall under the scope of regulation. Second, we request information regarding the type of conformity assessment (whether it is Certificate of Conformity or Declaration of Conformity), the detailed test methods and the list of laboratories to use for conformity assessment.

2.31. If the regulation requires DoC (Declaration of Conformity), could France confirm the entity responsible for issuing the declaration and provide a verification guideline that finished product manufacturers may use? France is the only country that restricts MOAH and MOSH in packaging materials for non-food products. Therefore, in the event of ink manufacturers in other countries not issuing a declaration, finished product companies will need guidance to perform verification. Lastly, in the final text of the Order, it is stated that the regulation will be enforced from 1 January 2023, and a regulated item's compliance deadline depends on its date of manufacture or import. We request that France clarify which date the suppliers should reference for compliance in case of a discrepancy between the date of manufacture and the date of import. In addition, we request a confirmation whether France will allow the distribution in commerce for products with the existing packaging materials until 31 December 2023, which is the deadline for the disposal of the remaining stocks.

2.32. The delegation of the United States provided the following statement. The United States appreciates France's 3 February 2022, notification of this Order to the WTO and thanks France for acknowledging receipt of our corresponding comments on 6 April 2022. While we support France's objective of combating waste and limiting the use of non-recyclable materials, we have questions regarding the specifics of the draft regulation. We are concerned about the proliferation of divergent packaging, labelling, and recycling laws within the EU and its member States. We encourage France to ensure that such regulations do not have the effect of creating unnecessary obstacles to international trade. We are concerned that this Order will create an undue burden for companies selling products in France. As outlined in our comments sent to France's Enquiry Point, we continue to seek clarity on the scope, timeline, and objectives of this Order. Could France please provide an update on when we can expect to receive responses to our 6 April comments? We have heard concerns from some manufacturers and exporters of packaging and printed matter, including that made from recycled materials, that they will not be able to adapt their products or methods of production to comply with the order before the implementation date of 1 January 2023. We request that France take into account stakeholder comments regarding their ability to meet the proposed timeline and adjust implementation dates to ensure a reasonable transition period as required under the WTO TBT Agreement.

2.33. In response, the delegation of the European Union provided the following statement. Thank you to the delegations of Korea and the United States for their interest in the "Order specifying the substances contained in mineral oils the use of which is prohibited in packaging and in printed matter distributed to the public", notified by France to the WTO under reference [G/TBT/N/FRA/216](#). France received Korea's comments on this TBT notification. A reply is currently under preparation and it will be sent to Korea via the European Union TBT Enquiry Point. As regards the clarification of the scope of the regulation and the identification of substances of concern, the Order reflects the French Agency for Food, Environmental and Occupational Health and Safety opinion (ANSES) which does not allow a simple designation by CAS Numbers or such identification. As regards the target of the ban, Article 1 of the Order clearly states that it is the content of mineral oil in ink that has to be considered. Nevertheless, in order to give some flexibility to demonstrate compliance, the assessment might be possible after printing (in particular due to the volatility of certain substances).

2.34. Further to this, the French Order does not prescribe specific test methods to demonstrate conformity. According to article R.543-49 of the Environmental Code, the demonstration should be

based on the production of written or technical documents. A working group will be set up in order to identify, with stakeholders, solutions available, difficulties and needs by the 2025 deadline. Appropriate solutions to demonstrate compliance could be discussed as well. Regarding the Declaration of Conformity, the entity in charge of controlling the conformity is the department in charge of consumer affairs, competition and the repression of fraud (DGCCRF). So far no guidelines on performing verification have been set up. We would like to clarify that the date that has to be considered for a packaged imported product to be placed on the market in France is the date of import, not the date of manufacturing. Therefore, if the packaging was manufactured before 1 January 2023 – the entry into force of the Order - but the product itself or its packaging is imported to France after that date, the ban will apply.

2.1.2.9 India - Alert Regarding Implementation of QR Code for Refrigerators (ID 757¹²)

2.35. The delegation of the Republic of Korea provided the following statement. Korea respects the efforts of the Indian government to protect the consumers. Furthermore, Korean companies are endeavouring to comply with the regulation of India. However, Korea would like to deliver Korean companies' concerns as there are difficulties in the industry regarding the "Implementation of QR Code for Refrigerators" announced on 31 March 2022 without any notification according to the WTO TBT Agreement. First of all, according to the document published on 31 March 2022 by BEE (Bureau of Energy Efficiency) of India, the requirement to affix a QR Code below the BEE Star Label on each unit of refrigerator will be enforced mandatory from 1 January 2023. However, this measure is against Article 2.9.2 of the WTO TBT Agreement to "notify other Members through the Secretariat of the products to be covered by the proposed technical regulation", and Article 2.9.4 of the Agreement to "allow reasonable time for other Members to make comments in writing". Therefore, Korea requests that India provide Members with time to make comments in accordance with the TBT Agreement.

2.36. As the regulation is scheduled to be enforced without any WTO notification process and period for comments from Members, it would be difficult for manufacturers to meet the regulatory requirements by the proposed date of enforcement. Korean companies claim that they need at least 12 months in order to comply with the new regulation. Therefore, Korea requests that India carry out the due notification and comment processes, and then provide a transition period of 12 months from the publication date of the final text of the regulation, so that companies can adapt their production facilities for QR Code labelling. Additionally, unlike other countries such as the EU, United Kingdom, Türkiye, China, and Saudi Arabia, which require QR Codes assigned to each model name, India runs a different system that requires QR Codes assigned to each serial number of the product. As such, the regulation is excessive that the Korean companies have difficulties complying. Therefore, Korea requests that India improve the regulation in a way that the QR Code labels are to be generated by the model name rather than by the serial number of the refrigerator.

2.37. In response, the delegation of India provided the following statement. The energy performance benchmarks (star rating levels) under Standards & Labelling (S&L) programme are implemented by Bureau of Energy Efficiency (BEE) in accordance with Section 14 of the Energy Conservation Act, passed by the Parliament of India. The regulatory mechanism of the S&L programme encompasses a provision of Monitoring and Verification, under which, BEE has proposed to implement the secure QR code along with star label on the appliance/equipment in order to enable authenticate/validate the star rating specifications of the label by the consumer himself. The discussion for implementation of QR Code on refrigerators was initiated during the year 2019. In this regard the first meeting of stakeholders including manufacturers of product from various countries including Korea was held on 5 November 2019 wherein, workflow and the effective timelines for 1 March 2020 was announced and circulated to the stakeholders including the Korean manufacturers registered with BEE under S&L programme. However, the implementation timeline of the QR code got delayed due to the COVID-19 pandemic situation. Further, during the year 2021, the new timelines of 1 January 2023 was communicated to all the stakeholders through virtual meetings. Various comments and inputs received from the manufacturers on the workflow of QR code were addressed by BEE from time to time.

2.38. Subsequently, BEE had issued a formal alert during March 2022 on the mandatory timeline for Implementation of QR code with effect from January 2023. This alert was issued based on the request received from manufacturers to issue a formal announcement before eight to nine months

¹² For previous statements follow the thread under [ID 757](#).

from the date of issue of the Gazette notification. The energy performance benchmarks (star rating levels) under Standards & Labeling (S&L) programme are implemented by Bureau of Energy Efficiency (BEE) in accordance with Section 14 of the Energy Conservation Act, which is passed by the Parliament of India. As such, no formal notification through other platform is required for implementation of the QR code under S&L program. Further, it may please be noted that, few manufacturers have successfully completed the pilot run in the month of May 2022. The objective of implementation of QR code is to authenticate / validate the star rating specifications of the label to protect the interest of consumers. It may be noted that, generation of QR code by model name rather than by serial number of each unit of refrigerator may defeat BEE's purpose of validating the credibility of star label affixed on each unit / product of refrigerator being purchased by the consumer.

2.1.2.10 France - Decree on the minimum proportion of re-used packaging to be placed on the market annually, [G/TBT/N/FRA/223](#) (ID 758¹³)

2.39. The delegation of the United States provided the following statement. The United States appreciates France's 3 March 2022, notification of this Decree to the WTO and thanks France for acknowledging receipt of our corresponding comments on 28 April 2022. While we support France's objective of increasing the availability of reusable packaging and reducing the amount of pollution caused by packaging waste in the environment, we continue to have questions about the proposed path outlined in the draft regulation. Regarding this particular measure, we note that France provided a 60-day comment period with an adoption date of 31 days after the notification's distribution. How did France take all stakeholder comments received within the comment period into account if the adoption date occurred before the end of the comment period? Can France confirm that the Decree was adopted on 3 April 2022, as was stated in the notification? Can France provide an update on the proposed date of implementation? We ask that France continue to work with its trading partners to fully assess impacts to trade resulting from the implementation of this measure. We encourage France to respond to our questions submitted to France's TBT Enquiry Point and ensure the views of WTO Members are fully considered before implementing the measure.

2.40. The delegation of Argentina provided the following statement. We note that the measure was notified in document [G/TBT/N/FRA/223](#) in March this year. The Decree establishes the obligation to recycle a certain percentage of containers and packaging, increasing over time, in order to reduce waste and move towards a circular economy. Accordingly, it establishes deadlines and procedures for those within the supply chain to organize themselves to comply with this obligation. The definition of producer includes importers, which is why, although this is not specified, the Decree could affect wines exported to France. Argentina is therefore concerned about this measure and wishes to consult France on the scope of this Decree in relation to imported products, how it intends to apply it to imported products and whether this does not amount to an extraterritorial application of a provision that aims to reduce waste and recycle in order to protect the environment.

2.41. In response, the delegation of the European Union provided the following statement. The EU would like to thank the delegation of the United States for its interest in the "Decree on the minimum proportion of re-used packaging to be placed on the market annually", notified by France to the WTO under reference [G/TBT/N/FRA/223](#). The EU can confirm that this decree was published in the French Journal official in April 2022. The draft decree was amended during its examination by the Council of State, especially to take into account some difficulties raised by the representatives of the United States or raised by Producers Responsibility Organisation, to facilitate their compliance with the provisions of the decree. Increasing the re-use of packaging is crucial to achieve the phasing out of all single-use plastic packaging by 2040, as prescribed by the French anti-waste law of February 2020. Therefore, a dedicated structure, the Re-use Observatory, hosted by the Ecological Transition Agency, has been set up to ensure the collection and dissemination of information and studies related to the re-use. The Observatory might conduct any study necessary to assess the relevance of re-use and recycling solutions from an environmental and economic perspective. It might support, in conjunction with Producers Responsibility Organisation, the implementation of experiments and will ensure the coordination of the stakeholders concerned by re-use.

¹³ For previous statements follow the thread under [ID 758](#).

2.1.2.11 Viet Nam - Draft national technical regulation on 5G user equipment - radio access; draft national technical regulation on non-standalone 5G user equipment - radio access, [G/TBT/N/VNM/188](#), [G/TBT/N/VNM/202](#) (ID 759¹⁴)

2.42. The delegation of [China](#) provided the following statement. Viet Nam Regulations QCVN 127:2021/BTTTT and QCVN 129:2021/BTTTT require that starting from 1 July 2022, all certificates obtained in accordance with the old 5G regulations must be updated in accordance with the new technical regulations to ensure a smooth import process. Viet Nam has released a list of laboratories for the new 5G Regulations, and as it is clearly shown that these laboratories are all located in Members that have signed bilateral accreditation agreements with Viet Nam. Since China and Viet Nam are signatories to a multilateral recognition agreement for ILAC testing agencies, China proposes Viet Nam accept the CE/FCC 5G report from relevant Chinese laboratories and clarify the certification operation mode on 5G products that are certified but do not meet the technical requirements of the new 5G Regulations.

2.43. In response, the delegation of [Viet Nam](#) provided the following statement. Viet Nam thanks China for the interest in the drafts of national technical regulations on 5G user equipment and non-standalone 5G equipment- radio access. These drafts of national technical regulations were notified to WTO Members in notifications [G/TBT/N/VNM/188](#) and [G/TBT/N/VNM/202](#) in 2021 with a comment period of 60 days from the date of notification. During the comment period, Viet Nam received comments from WTO Members, including China, these comments have been reviewed and taken into consideration in the final measures as QCVN 127:2021/BTTTT and QCVN 129:2021/BTTTT. On 17 June 2022, Viet Nam issued Document No. 2361/BTTTT-KHCN guiding the application and facilitation of testing under QCVN 127:2021/BTTTT and QCVN 129:2021/BTTTT, which accepted test results of foreign testing laboratories accredited to ISO/IEC 17025, or of the manufacturers, according to international standards equivalent to 3GPP/ETSI to certify 5G equipment. The respective Chinese laboratories can apply the guideline document 2361/BTTTT-KHCN and accept the test results. From 1 July 2022, all 5G devices imported into Viet Nam must be tested according to QCVNs or equivalent international standards as mentioned in the guiding document and submit a dossier to the Certification bodies appointed by the Ministry of Information and Communications to be granted a certificate of conformity.

2.1.2.12 India - Amendment to notification on mandatory testing and certification of telecommunication systems (MTCTE) – Phase III & IV, [G/TBT/N/IND/229](#) (ID 760¹⁵)

2.44. The delegation of [China](#) provided the following statement. Article 5 "Only test results/reports issued by labs accredited by ILAC signatories from none-border sharing countries will be accepted" does not conform with Articles 2.1, 2.2, 5.1.2, and 6.1.1 of the WTO/TBT Agreement. China proposes India amend article 5 of "Amendment to Notification on Mandatory Testing and Certification of Telecommunication Systems (MTCTE) - Phase III&IV" to accept test results from all laboratories approved by the International Organization for Laboratory Accreditation Cooperation (ILAC) signatories.

2.45. In response, the delegation of [India](#) provided the following statement. Testing and Certification requirements under Mandatory Testing and Certification of Telecommunication Systems (MTCTE) scheme were notified through Indian Telegraph (Amendment) Rules, 2017 (WTO TBT Notification [G/TBT/N/IND/66](#)). MTCTE Scheme is being launched in a phased manner and telecom products are gradually being brought under MTCTE regime. This is an amendment to the notification issued for MTCTE Phase III & IV published vide [G/TBT/N/IND/218](#) on 15 November 2021 and amendment vide [G/TBT/N/IND/229](#) dated 17 March 2022.

2.1.2.13 China - Recommended National Standard (GB/T) for Office Devices (Information security technology – Security specification for office devices) (ID 761¹⁶)

2.46. The delegation of [Japan](#) provided the following statement. Japan has concerns with regard to the amendment of the Chinese Recommended National Standard (GB/T) for office devices like multifunction peripherals and printers. Japan is currently in contact with the information that draft amendment to the Chinese Recommended National Standard (GB/T) for office devices such as

¹⁴ For previous statements follow the thread under [ID 759](#).

¹⁵ For previous statements follow the thread under [ID 760](#).

¹⁶ For previous statements follow the thread under [ID 761](#).

multifunction peripherals and printers is being considered in China. Japan has heard that, regarding to office devices including multifunction peripherals and printers procured by the Critical information infrastructure operators etc., the draft amendment of the national standard requires as follows: (i) Office devices such as multifunction peripherals and printers including their components are required to be developed, designed and produced in China; (ii) the information to prove that office devices and/or their components are developed, designed and produced in China is required to be disclosed.

2.47. If the national standard including such requirements is introduced, considering that the application of this national standard is recommended by a government, this national standard is highly likely to be generally adopted. There is a concern that the national standard will be practically enforced as mandatory. In such case, imports of finished products such as multifunction peripherals and printers will not be permitted. Also, the use of imported components will not be permitted, and the use of the components made in China will be forced. Thus, it will be inevitable that foreign products including Japanese imports will be treated discriminatorily against domestic products. This would be inconsistent with Article 2.1 and Article 2.2 of the TBT Agreement and Article 3.4 of the GATT. By the actual operation of the national standard, for example, Japan concerns that this national standard will effectively force technology transfer when foreign producers have no choice but to provide their technology to China for production in China. This would be inconsistent with Article 7.3 of the WTO protocol on the accession of China. Just in case Japan notes that, although certain obligations do not apply to standards for government-procured products under Article 1.4 of the TBT Agreement and Article 3.8 (a) of the GATT, Japan has heard that the description of the scope of the amendment to the national standard is not limited to government-procured products therefore Japan recognizes that it cannot be justified by the government-procured exceptions under the TBT Agreement and the GATT. Japan strongly hopes that the amendment of this national standard, and any systems and/or guidelines related to this national standard, which include content that discriminates foreign products or producers against domestic ones and forces technology transfer, will not be realized. Japan also recalls that China is obliged to notify the proposed measures, which would be effectively mandatory, to the WTO in advance in accordance with the obligations of Article 2.9.2 of the TBT Agreement.

2.48. The delegation of the European Union provided the following statement. The EU would like to support this STC, also noting that we do not agree with localization requirements in standards, and requests that China provide information on this measure, preferably in English, and notify to the WTO, where applicable.

2.49. In response, the delegation of China provided the following statement. This is a new concern and this is the first time the concern has been added. China takes note of your concerns and will provide a reply at a later date.

2.1.3 Previously raised concerns

2.1.3.1 China - Requirements for information security products, including, inter alia, the Office of State Commercial Cryptography Administration (OSCCA) 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS) (ID 294¹⁷)

2.50. The delegation of the European Union provided the following statement. Regarding the Multi-Level Protection Scheme (MLPS), the EU would like to refer to its comments raised at previous TBT Committee meetings, namely concerns around (i) the lack of clarity in certain definitions, and (ii) the unwarranted and significant market entry restrictions, including by demanding that all networks above Level 3 be subject to the legal obligations that were originally destined for Critical Information Infrastructure (CII). The EU calls for enhanced proportionality and transparency in the implementation of the Cyber-MLPS.

2.51. The delegation of Japan provided the following statement. Japan continues to have concerns regarding China's Regulation on Commercial Encryption Products and Cybersecurity Multi-Level Protection Scheme. Japan would like to refer to the previous statement we made at the last TBT Committee in March 2022. Japan would like to continue to request that China provide relevant information regarding the current revision process of the Regulation on Commercial Encryption

¹⁷ For previous statements follow the thread under [ID 294](#).

Products that was subject to public consultation up to 19 September 2020, and the current drafting process of the Cybersecurity Multi-Level Protection Scheme that China described at the last TBT committee, and that those regulations are to be implemented transparently.

2.52. In response, the delegation of China provided the following statement. With regard to the management of commercial encryption products, China has, from 1 January 2020, cancelled the approval of varieties and models of commercial encryption products in accordance with the law, and established a unified national certification scheme for commercial cryptography. The management of commercial encryption products fully reflects the principles of non-discrimination and fair competition. It treats domestic and foreign products and companies equally. China implements mandatory testing and certification on commercial encryption products that involve national security, national economy, people's livelihood, and public interest, and implements voluntary testing and certification on other commercial encryption products. Regarding the MLPS, with technology development, in response to more complicated cybersecurity circumstances, an information security multi-level protection scheme needs to be improved. Based on experience in past years and responding to new development, Cyber-security Law stipulates that China will carry out the cyber-security MLPS, which is based on information security MLPS. To fulfill the requirements in Cyber-security Law, regulations on cyber-security MLPS are under drafting, which was published for comments in June 2018 and will replace the former administrative measures on information security MLPS.

[2.1.3.2 European Union - Draft Implementing Regulations amending Regulation \(EC\) No. 607/2009 laying down detailed rules for the application of Council Regulation \(EC\) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products, G/TBT/N/EEC/264, G/TBT/N/EEC/264/Add.1, G/TBT/N/EU/44, G/TBT/N/EU/570, G/TBT/N/EU/571 \(ID 345¹⁸\)](#)

2.53. The delegation of the United States provided the following statement. This is the longest continuously-raised STC in the history of the TBT Committee. The United States has raised concerns on lack of transparency and market access for wine for well over a decade. Despite asking for updates on the US applications for the use of traditional terms for wine exports to the EU both in this forum and bilaterally, our exporters have no expectations that their pending applications will ever be processed as our requests do not result in substantive responses. The EU's traditional terms for wine regime restricts exporters' use of the following terms unless specifically granted the right to use those terms by the EU: chateau, classic, clos, cream, crusted/crusting, fine, late bottled vintage, noble, ruby, superior, sur lie, tawny, vintage, and vintage character. While we do not agree that the EU should claim exclusive use of these common terms, our exporters nonetheless sought to comply with the regime. To date, the EU has only approved two (classic and cream) of the 13 applications we submitted in June 2010, and has yet to act on our applications for the 11 remaining terms.

2.54. It is incredibly disappointing that this issue has not been resolved with one of our major trading partners. The persistent lack of meaningful dialogue towards a resolution leaves us to believe that the EU never intended to act on the pending applications in good faith. It is clear that raising this issue in this forum has not been successful. Thus, this is the last time that the United States intends to raise this issue at the TBT Committee. Understanding the EU's process and timeline for review of our industry's pending applications for use of traditional wine terms remains a priority for the United States. We will continue to engage the EU outside of the TBT Committee on these concerns.

2.55. The delegation of New Zealand provided the following statement. We refer the European Union to New Zealand's statement on this trade concern made at the March 2022 TBT Committee and those preceding it. New Zealand recognizes that Members have the right to protect their consumers from deceptive practices in line with their obligations under the World Trade Organization. New Zealand asks that the European Union takes into consideration concerns raised by Members relating to the scope and application of the system of traditional terms, as well as transparency, process and timelines relating to applications by third countries who wish to use traditional terms in the European Union.

¹⁸ For previous statements follow the thread under [ID 345](#).

2.56. The delegation of [Argentina](#) provided the following statement. We thank the United States for including this specific trade concern (STC) on the Committee's agenda. Argentina reiterates concerns expressed at previous meetings of this Committee regarding the discrimination suffered by national wines, which are prevented from using the traditional terms "Reserva" and "Gran Reserva" on their labels, even though our country completed the substantive procedure to approve such terms in March 2012 under EU Law. We once again urge the EU to activate all applications for the registration of traditional terms submitted by third countries such as Argentina, which have come to a standstill without any legal justification, thereby constituting a technical barrier to trade.

2.57. In response, the delegation of the [European Union](#) provided the following statement. The EU understands the continued interest of the United States and other Members in this issue. The EU believes that its internal legislation offers a meaningful and transparent system of protection to traditional terms used on wine products from the EU, as well as on products from third countries. The EU has demonstrated its ability to address specific Members' concerns in this area either via its internal legislation or via bilateral agreements. The EU treats applications to protect traditional terms from both member States and third countries as is foreseen under Regulation 1308/2013¹⁹ establishing a common organization of the markets in agricultural products (the "CMO Regulation"). Such applications for traditional terms are rather limited. The CMO Regulation does not set a deadline for approval or rejection. As to the specific questions by Members in previous TBT Committees, the EU refers to Commission Delegated Regulation (EU) 2019/33²⁰ on the applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, and, in particular, to Article 50 in conjunction with Annex IV part B, which contains the list of wine grape varieties and their synonyms that may appear on the labelling of wines, also for imported wines. A definition of "generic" can be found in Article 27(3) of Commission Delegated Regulation 2019/33. On the barrel-aged indication, the EU refers to Annex V of this Regulation.

2.1.3.3 Indonesia - Halal Product Assurance Law No. 33 of 2014 and its implementing regulations, [G/TBT/N/IDN/123](#), [G/TBT/N/IDN/131](#), [G/TBT/N/IDN/131/Add.1](#), [G/TBT/N/IDN/134](#), [G/TBT/N/IDN/139](#), [G/TBT/N/IDN/140](#) (ID 502²¹)

2.58. The delegation of the [European Union](#) provided the following statement. The European Union reiterates its serious concerns on the Indonesian Halal Product Guarantee Law No 33 of September 2014 and its implementing provisions, which require mandatory halal certification and labelling for a very wide range of products to be placed on the Indonesian market, resulting in significant obstacles to EU trade with Indonesia. The EU regrets that, contrary to Article 2.9 of the WTO TBT Agreement, Indonesia failed to notify to the TBT Committee the Halal Product Guarantee Law. As regards recent implementing provisions, the EU regrets that, on 6 January 2022, Indonesia adopted Regulation N° 2/2022 on International Cooperation on Halal product assurance ([G/TBT/N/IDN/139](#)), which entered into force that same day, before the expiration of the 60-day commenting period at the TBT Committee. In a similar way, Indonesia adopted Decree 1360/2021 on materials excluded from the halal certification obligation ([G/TBT/N/IDN/140](#)) on 27 December 2021, even before notification to the TBT Committee on 6 January 2022, without respecting the period for comments.

2.59. Indonesia is required to notify any relevant technical measures when still in draft form and to leave sufficient time for comments, as provided in Article 2.9.4 the WTO TBT Agreement. In addition, Indonesia is required, in accordance to Article 2.12 of the TBT Agreement, to allow a reasonable interval of no less than six months between the publication of the measure and its entry into force. The EU acknowledges the recent notifications by Indonesia of the final texts of the Regulation on International Cooperation and the Decree on materials excluded from Halal certification, via Addendum, respectively, on 27 April 2022 and 14 June 2022. The EU kindly invites Indonesia to provide a written reply to its comments of 12 May 2020 on Regulation 31/2018 on Processed Food Labelling ([G/TBT/N/IDN/124](#)). The EU thanks Indonesia for the consolidated general written reply of

¹⁹ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007, OJ L 347, 20.12.2013, p. 671.

²⁰ Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation, OJ L 9, 11.1.2019, p. 2.

²¹ For previous statements follow the thread under [ID 502](#).

7 March 2022, at the informative session of 7 March 2022, covering several Members' comments on several implementing halal measures.²² Nevertheless, we invite Indonesia to reply in written to the EU specific comments for each of these measures.

2.60. The EU stresses the excessive restrictive impact on trade of the adopted Halal Law and implementing provisions and invites Indonesia to consider less restrictive alternatives to the current, wide-ranging mandatory halal certification and labelling, in order to pursue the legitimate objective of ensuring reliable information for consumers without unduly hindering trade flows. Among the main issues of concern for the EU in the Halal Law and implementing measures are the "non-halal" information requested for non-halal products or the extension of halal requirements to products other than food and beverages. Furthermore, in order to ensure the workability of the system for foreign operators, there is a need for more clarity and a pragmatic approach as regards the requirements for recognition by Indonesia of foreign halal certificates. In particular, the pre-condition of a specific government-to-government mutual recognition arrangement for recognition by Indonesia of foreign halal certification bodies and certificates would appear unduly complex, represent an excessive burden for economic operators and not allow for smooth trade relations. The EU looks forward to exploring more feasible and agile options with Indonesia.

2.61. The EU encourages Indonesia to recognise the EU-Partnership and Cooperation Agreement (EU-Indonesia PCA) as the umbrella or framework agreement to meet the requirements for a Government-to-Government Agreement with the EU and its member States, in recognition of the EU as a single market of its 27 member States. Similarly, the EU encourages Indonesia to continue to allow halal certification bodies (FHCBS) in a given EU member State to certify products in other EU Member States, as this is in line with the functioning of the EU single market. Clarification on transitional provisions for existing certificates would also be welcomed. Meanwhile, the exclusion of end-products from the coverage of foreign certification and the additional registration requirement for halal certifications of certain products by foreign halal certification bodies also appears to be unduly unjustified, costly and duplicative. In addition, the EU is concerned about the possibility for Indonesia to impose much higher halal certification fees for goods and services from foreign businesses. The EU would also appreciate further clarifications on the criteria used for the list of materials excluded from the halal certification obligation and the procedure to review the list.

2.62. The EU stresses the importance of ensuring the continued possibility to place non-halal products on the Indonesian market and urges Indonesia to review the halal measures with a view at adopting a more trade-friendly approach that does not create unnecessary obstacles. Notably, the EU firmly calls upon Indonesia to: limit halal requirements to food and beverages; avoid the excessively burdensome requirement for mandatory "non-halal" information as regards non-halal products; clarify its approach to international cooperation on halal and provide for a flexible and pragmatic process for the recognition of foreign halal certification bodies and acceptance of foreign certificates, building on existing bilateral cooperation and working arrangements on halal certification; and provide information on the timeline for adoption and publication of the remaining measures to fully implement the Halal Law. 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.

2.63. The delegation of the United States provided the following statement. The United States acknowledges Indonesia's goal to provide reliable, relevant information regarding the halal integrity of certain products to consumers and we have sought to work with Indonesia, bilaterally and in multilateral settings, since 2015 to ensure that objective is achieved in a way that is consistent with Indonesia's WTO obligations. We urge Indonesia to continue bilateral engagement with WTO members and industry stakeholders. Unfortunately, many of our long-standing concerns remain unanswered. We refer Indonesia to our previous statement from March's TBT Committee, as well as outstanding questions submitted as [G/TBT/W/761](#). We ask that Indonesia respond to all the questions and concerns laid out in this document, as well as by all Members on the floor. As such, we will not repeat all of our outstanding concerns here.

²² (i) Draft Government Regulation (RPP) 39/2021 on Halal Product Assurance implementing the Omnibus Bill on Job Creation ([G/TBT/N/IDN/131](#)); (ii) draft Decree regarding types of products and consumer goods to be Halal-certified ([G/TBT/N/IDN/134](#)); (iii) Regulation on Halal fees ([G/TBT/N/IDN/138](#)); (iv) draft Regulation on international cooperation on Halal product assurance ([G/TBT/N/IDN/139](#)) and, (v) draft Decree on the materials excluded from the Halal certification obligation ([G/TBT/N/IDN/140](#)).

2.64. We remind Indonesia of the obligation to notify draft measures to the Committee before they take effect, allow a reasonable time for stakeholder comments, and take such comments into account before draft measures are adopted and implemented. Can Indonesia confirm whether there are further implementing regulations for the Halal Law forthcoming, and if so, what is the expected timeline for notifying those regulations? To allow US industry time to adjust to these new requirements, and to allow Indonesia time to adequately clarify and answer WTO Members' outstanding questions and concerns, we request that Indonesia postpone commencement of the Halal Law phase-in until Indonesia finalizes all of the relevant implementing regulations related to the Halal Law. We remain committed to working bilaterally with Indonesia to address the aforementioned concerns, and those raised by other Members in this Committee, and to ensure that Indonesia's halal measures do not create unnecessary obstacles to international trade.

2.65. The delegation of [Australia](#) provided the following statement. Australia welcomes ongoing discussions on the Indonesian Halal Product Assurance Law no.33 of 2014 (Halal Law) and continues to seek for the law to be implemented transparently and in close communication with businesses and trading partners. We encourage Indonesia to continue to facilitate an open dialogue with trading partners to allow foreign businesses and their valued Indonesian importers to remain adequately informed of Halal Law implementation regulations. Australia is eager to ensure that our existing halal assurance processes will continue to be recognized when the grace period for Law 33/2014 ends in 2024 and welcomes Indonesia's clarification of this. Australia thanks Indonesia for the informative Halal Assurance System Regulations information session held by the Indonesian Halal Product Assurance Agency (BPJPH) on 7 March 2022. We appreciated the opportunity to receive further clarification on previous TBT Committee notifications submitted by Indonesia concerning implementation of the Halal Law.

2.66. We welcome Indonesia's list of natural products that are exempt from the halal certification requirement, including fresh fruits, vegetables, grains, and some dairy products. Australia would appreciate further clarity on specific products that would be included and excluded from halal certification under the Halal Law, as it was not clear why some processed food products – such as honey – were included and others – such as milk – were excluded. Australia thanks Indonesia for their recent verbal advice that the Indonesia-Australia Comprehensive Economic Partnership Agreement will be utilised as an overarching government-to-government bilateral agreement for halal certification, and looks forward to receiving written advice to confirm this approach. We look forward to further dialogue on the Halal Law to ensure its implementation is no more trade restrictive than necessary.

2.67. The delegation of [Switzerland](#) provided the following statement. Switzerland is following this matter with interest and shares the concerns expressed by other Members regarding the Indonesian Halal Product Guarantee Law No 33 of 2014 and its implementing provisions, which require mandatory halal certification and labelling for a large range of products. While Switzerland recognizes Indonesia's legitimate objective to ensure reliable information for consumers related to the halal integrity of certain products, we expect Indonesia to fully meet its WTO obligations. We believe that the halal implementing provisions should not be more trade restrictive than necessary to ensure that the legitimate objectives are met and the products fulfill the halal requirements, as prescribed by the Islamic Law. Switzerland is concerned about the requested "non-halal" information for non-halal products or the extension of halal requirements to products other than food and beverages. We encourage Indonesia to reconsider the respective provisions of its recently adopted regulations.

2.68. Furthermore, Switzerland asks Indonesia to consider a more trade-facilitating approach related to the recognition of foreign halal certificates. The pre-condition of a government-to-government mutual recognition arrangement for recognition by Indonesia of foreign halal certification bodies and certificates seems to represent a significantly trade-restrictive policy approach. The additional registration requirement for halal certifications of certain products by foreign bodies also appears to be more trade restrictive than necessary. In this respect, we encourage Indonesia to provide flexibility for the recognition of foreign halal certification bodies and the acceptance of foreign halal certificates. Finally, Switzerland encourages Indonesia to notify any relevant technical measures when still in draft form and to provide sufficient time for comments, in accordance to the WTO TBT Agreement.

2.69. The delegation of [Canada](#) provided the following statement. Canada appreciates Indonesia's positive engagement bilaterally to move forward with the accreditation of Canadian halal certification

bodies. Canada hopes that further progress can be made so exports of certified halal food products can resume in the near term. While Canada appreciates this progress, a number of concerns remain and Canada would appreciate that Indonesia provide written responses to its comment letters on [G/TBT/N/IDN/139](#) and [G/TBT/IDN/140](#). Without full and complete information, it will be difficult for Canadian producers to ensure their production processes fully comply with Indonesia's halal regime. While Indonesia has taken steps to clarify the scope of products that will require halal certification, confusion remains. The only way to be clear about what products require certification is to provide specific HS codes for each product that requires halal certification. There are also issues of consistency. For example, while we are pleased to see that frozen fish appears to be exempted from the halal requirement, other frozen seafood products are not listed. Canada would appreciate confirmation, in writing, that frozen fish and seafood that is not otherwise processed will be exempt from halal certification requirements.

2.70. Further, there is confusion around whether genetically modified plant products require halal certification. Canada would appreciate if Indonesia could clarify whether genetically modified products that are not otherwise processed require certification and if so, why. Canada appreciates Indonesia's efforts in notifying these measures, however, we would like to remind Indonesia of its WTO transparency obligations to provide trading partners with adequate time and information to comment on a given measure and to ensure that these comments are taken into consideration prior to that measure being finalized.

2.71. The delegation of [The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu](#) provided the following statement. We would like to support the delegations of the United States, European Union, Australia, Switzerland and Canada. We are aware that on 2 February 2021 the Indonesian Government issued regulation No. 39 of the Halal Product Assurance Law for implementation. It stipulates that only products with halal or non-halal labelled information can be imported and distributed in the Indonesian market. Since this law and its draft implementing regulation affect the trade of numerous products and Indonesia's halal certification bureau (BPJPH) has to date not yet completed mutual recognition with any foreign halal institutions, we urge Indonesia to provide clear and explicit information on mutual recognition certification between the BPJPH and foreign halal institutions.

2.72. The delegation of [New Zealand](#) provided the following statement. New Zealand thanks Indonesia for its ongoing engagement on the implementation of the Halal Assurance Law and associated implementation regulations to date. New Zealand respects Indonesia's desire to increase the robustness of the halal assurances associated with products moving into commerce in Indonesia. However, we are also very interested in working with Indonesia to ensure the halal certification controls and systems operating in New Zealand are recognized without the application of restrictive additional inspection, control or approval processes and associated costs. We ask for some clarity on the status of Overseas Halal Certification Bodies who were previously listed with MUI, and the timelines for their registration with BPJPH. Is there a deadline for their registration and will this registration need to be periodically renewed? With regard to the recently-released Ministry of Religious Affairs regulations 748/2021, can Indonesia please clarify both the criteria and process, including WTO notification and consultation, by which items are added to the appendix listing the type of product that is obliged to be halal certified? The regulation reads that the head of BPJPH is obliged to include a product on the list if a business actor has applied for halal certification for a non-listed product. Will there be a WTO-consistent notification and consultation process and an appropriate grace period after products are added to the list that will allow other business actors enough time to apply for halal certification? Can Indonesia clarify the mechanism by which the updated list will be notified publicly?

2.73. In response, the delegation of [Indonesia](#) provided the following statement. Indonesia would like to refer to its statement on the previous TBT meeting on March 2022. Moreover, Indonesia has provided clarification to all questions raised by the Members in the informative session on 7 March 2022. Therefore, we would like to ask Members to refer to the document that was sent to all participants from the Members. Indonesia once again would like to reiterate its openness and transparency to international cooperation on Halal Assurance System based on the principle of mutual cooperation, mutual recognition, and mutual acceptance in accordance with international regulations and practices.

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

2.74. The delegation of the European Union provided the following statement. The EU has raised the Security Review of Network Products and Services, among many aspects of the Cybersecurity Review Measures, in this Committee on several occasions, stressing our concerns related to these measures, which entered into force on 1 June 2020 and were subsequently amended in January 2022, and entered into force on 15 February 2022. We remain concerned that the measures are quite general and very broad discretionary powers are left to the authorities in charge of the security review, raising concerns for foreign ICT operators. The Amended Measures contain few explanations of the issues we raised before and new issues have arisen since. The EU regrets that the Measures were adopted without a longer grace period, of at least 12 months, so that companies would have sufficient time to prepare for compliance with the Amended Measures. The Amended Measures have significantly increased the scope of application and many operators need time to understand and cope with their compliance obligations and the related business impact.

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

2.76. The EU seeks clarification on the following points: The continued use of "listing in a foreign country". Does this indicate the regulatory intention to exclude operators listed in Hong Kong from the obligation of applying for a mandatory Cybersecurity review? Based on the previous draft, entities subject to Cybersecurity reviews have changed from "data processors" to "online platform operators". The final Measures do not define "online platform operators", but the Draft Regulations define it as "data processors who provide Internet platform services such as information publishing, social networking, transaction, payment or audio-visual services". The EU urges China to clarify if the scope of "online platform operators" is narrower than "data processors", which was used previously and excludes self-operated e-commerce services of fast-moving consumer goods companies that do not provide online platform services. The vagueness of "online platform operators" leaves room for interpretation by regulators. Neither "core data" nor "important data" are clearly defined. The Measures include important telecommunication products as one kind of "network products and services". However, the Measures still do not provide a specific scope of "network products and services". This leads to the definition of "important communication product" to be even more unclear. The EU urges China to clarify these terms as soon as possible. The EU urges China to ensure clarity, transparency and objectiveness in the security review so that the Measures do not become a market access barrier.

2.77. The delegation of Japan provided the following statement. Japan continues to have interest in and concerns regarding the Cybersecurity Review and would like to refer to the previous statement we made at the last TBT Committee in March 2022. China enforced the amendment of the Measures for Cybersecurity Review in February 2022. It is unclear whether the definition and scope of "Critical Information Infrastructure Operator" refers to the definition of "Critical Information Infrastructure" provided under the Regulations on the Security Protection of Critical Information Infrastructure, and there is no definition for "Network Platform Operator". Therefore, it is uncertain what kind of businesses could be subject to the Measures for Cybersecurity Review. Japan would like to request that China operate the regulations transparently for predictability without hindering business.

2.78. In response, the delegation of China provided the following statement. In recent years, with the development of network information technology and further opening-up of networks in China, more and more network products and services have been determined as critical information infrastructure, while some people take advantage of providing products and services to illegally

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

obtain users' important data, control and interfere with critical information infrastructure operation, stop the supply of its technologies, products, and services for non-technical or commercial reasons, which poses serious risks and challenges to national cybersecurity of China, especially the supply chain security of critical information infrastructure. Drawing on common international practices, China formulated the Draft implementing measures for the Cybersecurity Review of Network Products and Services in 2017. In June 2020, the Measures for Cybersecurity Review came into effect, while the Draft implementing measures for Cybersecurity Review of Network Products and Services (Trial) was abolished at the same time. On 15 February 2022, the revised Cyber Security Review Measures came into force.

2.79. The establishment of the network security review system aims to detect and avoid risks and hazards brought to critical information infrastructure by purchased products and services, ensure the supply chain security of critical information infrastructure and safeguard national security through network security review. The Chinese authority administers the internet in accordance with laws and regulations and strengthens cybersecurity and data security management. This is not only necessary to safeguard personal information security and national security, but also the common practices of other WTO Members. Taking this opportunity, I would like to reiterate that, unlike some Members, the security review of China does not discriminate against foreign technologies and products or restrict the entry of foreign products into the Chinese market. China will, as always, welcome foreign products and services to enter the Chinese market as long as they comply with the laws and regulations.

2.1.3.5 European Union - Transitional periods for MRLs and international consultations (ID 580²⁴)

2.80. The delegation of [Colombia](#) provided the following statement. Colombia reiterates its concern regarding the international consultation processes adopted by the European Union (EU) and the transition periods granted prior to the entry into force of provisions under which the EU no longer approves the marketing of certain plant protection substances and amends maximum residue limits (MRLs). These concerns are being reiterated because the EU has so far not responded to any of the requests concerning the granting of longer transition periods and has failed to take into consideration the comments made during international consultation periods. Regulatory changes on the use of plant protection substances, coupled with such short periods of transition, create difficulties and uncertainty for fruit and vegetable producing countries. They also create additional burdens for agricultural producers, who need to make decisions on the use of crop protection products a year or more before the final product arrives on the European market. This is particularly complex for products with long production and harvest cycles, as well as for processed and frozen foods, as, despite complying with European standards at the time of sowing, they may face regulatory changes that prevent exports at the time of harvest and distribution. Furthermore, Colombia maintains that notification to the WTO of non-renewal, the MRLs to be applied and transition periods should not be made by the EU as a simple formality within the regulatory process. As provided in Articles 2.9.2 and 2.9.4, the notification must be submitted within a time frame that allows the Members concerned to submit substantive observations and comments for genuine consideration by whoever is developing the technical regulation, in this case the Commission.

2.81. Moreover, within the framework of this Committee, it cannot be acceptable for the European Union to state that, as soon as the European Food Safety Authority (EFSA) recommendation and the Standing Committee on Plants, Animals, Food and Feed (PAFF) opinion are known, countries should be able to "make the relevant adjustments", given that this information must first be notified to the WTO and the public consultation period held. In that connection, we would like to ask the EU how it has taken into account the comments submitted by Members at different stages of the consultation process. Are there cases in which regulatory changes or adjustments have been effectively introduced using the information submitted by stakeholders during the consultation process? How have comments been used to determine the transition periods for the implementation of standards? In addition to these questions, which we have raised previously and to which we have still not received clear answers, there are the questions that we have raised in other settings about the use of emergency authorizations, which benefit producers in the EU and in selected non-EU countries, but which are not accessible on equal terms to all WTO Members. We invite the EU to follow the recommendations on good regulatory practices, under which standards must be based on clear and objective information, and which promote open dialogue with stakeholders, transparency and the

²⁴ For previous statements follow the thread under [ID 580](#).

minimizing of market distortions. Colombia once again welcomes the opportunity to express its concerns on this issue.

2.82. The delegation of the United States provided the following statement. We continue to raise our concern about the European Union's (EU) practices in regard to the enforcement and reduction of pesticide maximum residue levels (MRLs). We recall longstanding concerns that while trading partners do not know with certainty what the impact of the EU's active substance non-approval or restricted approval decisions will be on future MRLs, we notice that EU MRLs and import tolerances have often been reduced or withdrawn following a non-approval or restricted approval decision. Such actions may be more trade restrictive than necessary to meet the EU's legitimate objectives. To prevent food waste and to forestall food insecurity, we request the EU to extend transitional periods for MRLs where the EU has not identified risk to consumers based on dietary exposure and to allow adequate time for US and third country producers to move lawfully produced food products through the channels of trade, including shelf-stable products that have long shelf lives. In addition, we reiterate our concern about the EU's consideration of import tolerance applications. Our past experience indicates that the review of additional data is often only considered after the EU notifies its intention to not approve a renewal or to approve a renewal on a restricted basis.

2.83. Once again, the United States reiterates its request that the EU retain existing MRL levels while import tolerances are under consideration, and that the EU fully complete science-based risk assessments, taking all available evidence into account, prior to reducing MRLs. The EU's policy of enforcing MRLs at the time of importation for imported goods instead of at the time of production as applies for domestic goods, is an inconsistency that causes disruptions in trade for products destined for the EU market. Trading partners have found themselves racing to move shipments through customs to prevent rejections or turning back orders because a product that complies with an existing EU MRL standard at the time of production could face rejection at EU borders. EU growers do not face the same timelines under the current regulatory provisions. We therefore again request that imported products' MRLs be considered on the EU market at the time of production, the same as for European products.

2.84. The delegation of Costa Rica provided the following statement. We reiterate our support for this trade concern. As it has done in previous meetings, Costa Rica reiterates its request for an extension of the transition periods for compliance with the new tolerances established for various substances, in view of the impact they have on agricultural production in our countries.

2.85. The delegation of Paraguay provided the following statement. As with other similar concerns and previous meetings of this Committee, the SPS Committee and the Council for Trade in Goods, we are concerned that the European Union's approach to limiting the use of substances is more trade-restrictive than it needs to be for it to achieve its legitimate objectives under the TBT Agreement. Likewise, the reduction of MRLs, on the basis of the argument that it is impossible to determine whether the use of many substances is safe and the lack of conclusive scientific evidence, even in cases where the Codex Alimentarius has identified certain substances as being safe, is not in line with Members' obligations under the SPS Agreement. With regard to the EU's customary refusal to discuss MRLs in the framework of this Committee, its recent TBT notification concerning the reduction of MRLs for certain substances is striking. Perhaps this means that the EU will finally be in a position to answer concrete questions and address this concern that has repeatedly been raised in this and other committees, only to receive unsatisfactory answers and no follow-up at all.

2.86. The pursuance of such policies will cause significant trade damage to the economies of developing countries and jeopardize their ability to achieve the Sustainable Development Goals, including those related to food security. We urge the EU to: reassess its approach; base its decisions on conclusive scientific evidence and real risk weightings, in accordance with the relevant international principles and standards; ensure import tolerances; and, where necessary, provide adequate transitional periods that take into account the realities of the production processes and geographical locations, including distances, of its trading partners.

2.87. The delegation of Brazil provided the following statement. Brazil supports the concerns raised under STC 580 and would like to refer to our previous statements on this agenda item. We respectfully bring to the attention of the EU its obligations under Article 2.12 of the TBT Agreement, which relate to the establishment of a reasonable interval between the publication of technical regulations and their entry into force, except in cases of urgent problems of safety, health, environmental protection or national security. It is of utmost importance that the EU provides

adequate transitional periods, especially for those cases in which the scientific opinions of the EFSA on the toxicity of substances are "inconclusive" or only indicate a "suspected risk". Transitional periods should also be compatible with the production processes, so as to allow producers – and especially small farmers – to adapt to the new regulations.

2.88. The delegation of Canada provided the following statement. Canada would like to reiterate its concern with the EU's approach to transition periods for maximum residue limits. Canada considers the sudden deletion of MRLs to be disproportionate to the level of risk to human health and more trade restrictive than necessary. While Canada appreciates the EU's clarification during the recent WTO SPS Committee, Canada is of the view that the EU's approach has yet to acknowledge the reality of agricultural supply chains such as the time required to ship product, multi-year inventory and extensive shelf life, including in foreign countries. Sufficient transition periods will allow trade to continue uninterrupted, while providing adequate time for producers and exporters to adapt to the new EU requirements. At a time when ensuring food security is of high concern, Canada urges the EU to extend transition periods for MRLs to third countries, taking into account the need for exporters to adapt to new requirements, as it has done so for its domestic producers.

2.89. The delegation of Peru provided the following statement. Peru shares the concerns raised by other Members, including Colombia and the United States, and supported by Costa Rica, Paraguay, Brazil, Canada, Uruguay, Ecuador, Guatemala and Panama. These measures create additional burdens for agricultural producers, who must make decisions regarding the use of phytosanitary products a year before the final product reaches the European market. This is particularly complex for products with long production and harvest cycles, as well as for processed and frozen foods. It is very important for the European Union to provide adequate transitional periods in which to raise awareness in the food production sector and to ensure that effective substitutes for the active ingredients for whose MRLs a reduction is sought are available on the market.

2.90. The delegation of Uruguay provided the following statement. In view of harvesting periods, the stages at which plant protection products are applied, and the time required to develop and register alternative substances in practice, the transitional periods granted by the European Union in the provisions amending MRLs for active substances do not provide enough time to make the necessary adjustments to production and ensure that agricultural products, especially processed or frozen products, comply with the new, lower MRLs. Like other Members, Uruguay does not consider six months to be a sufficient period in this regard. In our view, any changes should be gradual, and a reasonable period of time, of at least two years or two harvests, should be granted to raise awareness in the production sector and among technical advisers, and to ensure that effective substitutes for the active ingredients for whose MRLs a reduction is sought are available on the market. It is inappropriate to change the rules drastically in the middle of a harvest season, given the impact this may have on international and domestic marketing. My delegation reiterates its call on Members to adopt regulatory decisions based on internationally accepted standards or to provide conclusive scientific evidence when it is strictly necessary to depart from these standards in order to meet their legitimate objectives, as provided for in the relevant WTO Agreements. Even in cases where the European Union decides, based on a full risk assessment, that it is necessary to reduce the MRLs for active substances used in the agricultural production of other Members, we encourage it to take into consideration the need to grant transitional periods that are adequately and sufficiently long to make the relevant adjustments.

2.91. The delegation of Ecuador provided the following statement. My country wishes to reiterate its concern regarding the "transition periods" granted by the European Union (EU) for implementing its measures relating to the non-renewal of the use of substances and the reduction of tolerances. Farmers, especially in developing countries, need more time to adapt to MRL requirements, as it takes 36 months on average to develop or register a new phytosanitary pest-control product. Therefore, it is necessary to establish reasonable transition periods that take into account harvesting periods and the times when agrochemicals are applied. Ecuador is aware that the EU allows its farmers to request emergency authorizations so that, in certain particular situations, they can use active substances that have already been banned in the European market. Ecuador wishes to reiterate its request to the EU 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. We kindly ask it to respond to these concerns.

2.92. The delegation of Guatemala provided the following statement. Following the lowering of maximum residue levels (MRLs) notified by the European Union, Guatemala wishes to reiterate the importance of establishing transitional periods that closely follow the stages of crop production, in particular for crops grown in tropical countries. The productive sectors require more time to adapt and, in particular, to find alternative substances, which in some cases means having to wait for suitable production cycles to commence application and testing. We reiterate our concern that our ideas for discussions focused on finding solutions have not been listened to and accepted. The trade concern regarding this issue focuses on safeguarding agricultural producers and exporters sending their goods to the European Union, who will be affected by this market's change in conditions. We would be highly grateful if the European Union would consider the following: launching genuine dialogue to discuss the importance of establishing transitional periods that closely follow the stages of crop production, following the lowering of MRLs for active substances that are commonly used for the phytosanitary treatment of these crops; extending the transitional period, with a view to preventing the obstruction of trade, and giving time for developing countries with tropical climates to adapt; providing clarification on why our comments on this process in the WTO are not taken into account within the regulations.

2.93. The delegation of Panama provided the following statement. In the interest of time, we refer to our previous comments on this matter. Panama remains deeply concerned over the transitional periods for compliance with the new MRLs. We urge the EU to follow good regulatory practices and to respect its obligations under Article 2.12 of the TBT Agreement.

2.94. The delegation of Argentina provided the following statement. The EU policy of removing import tolerances for substances that are no longer used in the EU 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 hasty and does not take into account the needs and adaptive capacities of third parties. The transition period clearly needs to be longer, and Argentina therefore calls for a review of the transition periods.

2.95. In response, the delegation of the European Union provided the following statement. The EU has provided detailed information on transitional periods for Maximum Residue Levels (MRLs) at previous TBT Committees, in particular, at the TBT Committee meeting in May 2020. The EU considers that measures lowering maximum residue levels due to concerns for human health, fall under the remit of the SPS Committee and should be discussed in that context. On the contrary, all measures concerning non-approval or restriction of active substances used in plant protection products in the EU are notified to the TBT Committee. These measures do not have direct consequences on SPS-related matters. The EU considers furthermore that, a limited number of very specific measures lowering MRLs due to environmental issues of global concern (e.g. clothianidin and thiamethoxam), should be notified to the TBT Committee.

2.96. In the interest of transparency and, further to requests by some Members, when notifying these measures under the WTO/TBT notification system, the EU additionally informs the SPS Committee of the submission of those notifications. 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 European Union would like to point out in this context that the commenting deadlines are always respected and that the comments received within those deadlines are duly taken into account in the EU's decision-making process.

2.97. 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.

2.1.3.6 Qatar - Ministry of Public Health Circular regarding shelf life for cheese (ID 602²⁵)

2.98. The delegation 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 UHT milk and white cheese that entered into force already in 2019. The scope of these measures was further expanded with Qatar's Council of Ministers instructions issued in August 2021. Regrettably, these measures affected several dairy products exported from the EU to Qatar and the European Union would like to recall the importance of addressing these concerns. During the previous TBT Committee meeting in March, Qatar informed that the Circular had been suspended, while awaiting for an internal review process. On 28 April 2022, Qatar approved a new Circular which removed some of the proposed restrictions on the shelf life of dairy products. However, these were re-introduced a few days later, on 1 May 2022, by a new Circular. The EU is concerned about the lack of predictability on the rules that operators need to follow, as well as lack of sufficient time to adapt to any regulatory changes. Could Qatar clarify if there are any currently applicable exceptions for the exports of dairy products to Qatar? We would like to urge Qatar to adopt a permanent solution which will avoid trade disruptions. In this respect, the European Union would like to insist on the need to notify any proposed measure at a draft stage to this Committee. The European Union is grateful that we had further constructive exchanges with Qatar on this matter, where Qatar signalled to be working on a solution to be offered in a near future. We stand ready to continue to work constructively with Qatar to resolve this important issue in due course.

2.99. The delegation of [New Zealand](#) provided the following statement. New Zealand joins the EU in expressing concern about Qatar Ministry of Public Health's Circular of 30 May 2019 establishing new import requirements for UHT milk and white cheese, and the subsequent expansions in the scope of the circular's application. These stringent restrictions on shelf life severely disadvantage imported products in Qatar's market, in relation to local products. Compliance with many of these requirements is not feasible for a range of New Zealand's dairy products. The measures appear to be more trade restrictive than necessary to fulfil the legitimate objective of public health protection. New Zealand recommends consideration is given to applying internationally recognised standards such as Codex Alimentarius if scientific justification for these measures is unable to be provided.

2.100. In response, the delegation of [Qatar](#) did not make a statement during the meeting. A technical statement was circulated following the meeting.²⁶

2.1.3.7 Bangladesh - Hazardous Waste (E-waste) Management Rules, 2019, G/TBT/N/BGD/3, G/TBT/N/BGD/3/Add.1 (ID 620²⁷)

2.101. The delegation of the [United States](#) provided the following statement. As noted at the last meeting, we remain interested in the status of Bangladesh's updated draft of its Hazardous Waste (E-Waste) Management Regulation, 2021 (E-waste Rules), published in June 2021. We again ask that Bangladesh notify this updated draft. We would also appreciate knowing Bangladesh's timeline for considering public comments before finalizing the E-waste Rules and for implementing the measure. As previously noted, we continue to lack clarity regarding how Bangladesh plans to implement the E-waste Rules. We therefore remain interested in receiving the information requested in our previous statements on this STC. We also encourage Bangladesh to make this information available to the public, so that industry can engage regulators and comply with the E-waste Rules. We look forward to an update from Bangladesh.

2.102. In response, the delegation of [Bangladesh](#) provided the following statement. Bangladesh circulated a draft regulation on Hazardous Waste Management (E-Waste) Management Rules 2019 on 20 February 2020 through [G/TBT/N/BGD/3](#) and requested for comments. Later by another notification, [G/TBT/N/BGD/3/Add.1](#), dated 26 May 2020, Bangladesh extended till 30 June 2020. Several Members including the US and their private sectors made comments on the draft regulation. The Government of Bangladesh updated the regulation based the recommendations by Members and based on international standards after several virtual consultations with the interested Members and their private sectors. On 10 June 2021 Bangladesh Government published the revised regulation named as "Hazardous Waste (E-Waste) Management Rule, 2021". Government of Bangladesh revised threshold limits for certain hazardous wastes under Schedule 3 of the said rules considering

²⁵ For previous statements follow the thread under [ID 602](#).

²⁶ [G/TBT/W/773](#).

²⁷ For previous statements follow the thread under [ID 620](#).

the suggestion of the US and other countries. The US industries shared their concerns in September 2021. Bangladesh also notified the name of the notification authority and the enquiry points in the revised rule.

2.103. The Rule 14(2) of Hazardous Waste (E-Waste) Management Rules, 2021 has given flexibility on the "threshold limits for certain hazardous wastes" which states: "The use of hazardous substances in the production of electrical and electronic products shall be reduced within 5 (five) years from the date of enforcement of the Rules to bring them in line with the above standards." However, it is also stated that the Government may extend this period, if necessary. Any legitimate concern raised by Members during this period will also be considered positively. Bangladesh likes to refer to Schedule 2 of Hazardous Waste (E-Waste) Management Rules, 2021, where we have given targets for e-waste collection and its management. No deadline for registration is mentioned in the rules. Department of Environment has started the registration process. After COVID-19 and changing circumstances, things have been becoming normal and Bangladesh Government has started sensitization of stakeholders through workshops and seminars. The rule is available on-line from the DoE website²⁸ and the following officials can be contacted.²⁹

2.104. The Government of Bangladesh has been working with a detailed explanatory guidelines for the implementation of the Regulation. The Regulation will be effective from 2026 and by this time the guidelines will be published. Article 2.12 of the WTO TBT Agreement suggested to provide a "reasonable interval" before enforcement of TBT regulations. As per paragraph 15 of the Decision, [G/TBT/M/26](#), 6 May 2002, and para. 5.2 of the Doha declaration number [WT/MIN\(01\)/17](#), 20 November 2001, the reasonable period suggested is not less than 6 (six) months. The Government of Bangladesh has kept a five-year time period for industries to use Hazardous Substances in the Production of Electrical and Electronic Products as stated in Rule 14 of Hazardous Waste (E-Waste) Management Rules, 2021. We believe the time period is quite comfortable for the industries and it is compliant with the WTO TBT Agreement and relevant decisions. Over the last two-three years the Government of Bangladesh has been accommodating the concerns of different WTO Members and their private sectors. The Government has revised the regulation as per the "Threshold limits for use of certain hazardous substances" based on the EU standards. Bangladesh is on the opinion that it has adopted widely accepted global standards for e-Wastes and hence all the concerns raised by Member countries have been resolved. Bangladesh is looking forward to work with the US to further clarify any issues. Bangladesh believes all the legitimate concerns of the US and other Members have been accommodated and we request Members to consider the STCs are resolved.

[2.1.3.8 Panama - Onions and Potatoes Harvest Life and Sprouting Requirements, G/TBT/N/PAN/86, G/TBT/N/PAN/102, G/TBT/N/PAN/102/Add.1 \(ID 662³⁰\)](#)

2.105. The delegation of [Canada](#) provided the following statement. Canada would like to raise this specific trade concern regarding Panama's quality requirements for fresh potatoes established by the Ministry of Industry and Commerce on 20 February 2020. As a long-standing supplier of fresh potatoes to Panama with year-round exports, Canada continues to be concerned that implementing these new quality requirements could have a direct impact on our ability to export potatoes to Panama. Canada recognizes that Panama delayed the implementation of these measures to allow for further consultations with trading partners and is appreciative of Panama's participation in a bilateral technical meeting which was held in September 2021, to address elements of concern on this issue. However, despite this positive engagement, Canada notes that our concerns were not taken into account by Panama its final measure. Canada has signalled our concern to Panama's Ministry of Commerce (MICI) with the restrictive time limits for storage and marketing, as well as the zero tolerance for sprouting. Canada respectfully requests that Panama pause the enforcement of these requirements to allow for additional technical dialogue to occur and ensure that Panama's quality standards do not create unintended barriers to our mutually beneficial bilateral trade in agriculture.

²⁸ www.doe.gov.bd

²⁹ Mr. Md. Mohammad Abdul Wadud Chowdhury, Deputy Secretary, MoEFCC, E-mail: env2moefcc@gmail.com; Mr. Mirza Shawkat Ali, Director, DoE, E-mail: mirzasa1@yahoo.com; dircc@doe.gov.bd.

³⁰ For previous statements follow the thread under [ID 662](#).

2.106. The delegation of the United States provided the following statement. We would like to support the comments made by Canada and we refer to our previous statements on this issue.

2.107. In response, the delegation of Panama provided the following statement. We take note of these concerns, which will we convey to Panama City. As noted by the Canadian delegation in its statement, we are pleased to report that our delegations have maintained a very open bilateral dialogue. Panama has proven its receptiveness to the comments and concerns of its trading partners, as evidenced earlier this year when it postponed the entry into force of the amendment for potatoes by six additional months. We reiterate our willingness to work with our trading partners to seek mutually satisfactory solutions.

2.1.3.9 India - Indian standards and import restrictions in the automotive sector (Quality Control Orders): wheel rims, safety glass, helmets, [G/TBT/N/IND/118](#), [G/TBT/N/IND/147](#), [G/TBT/N/IND/167](#) (ID 649³¹)

2.108. The delegation of the European Union provided the following statement. India continues to define and introduce specific standards and certification requirements for a number of products – under the umbrella of the Quality Control Orders (QCOs). The QCOs require physical audit at manufacturers' premises by an auditor of the Bureau of Indian Standards (BIS) in order for products manufactured in third countries to receive the approval for exports to India. In view of the still existing post-pandemic challenges this process is still slow and often results in delays. The EU deeply regrets that India repeatedly refused to consider meaningful alternative options to foreign audits – such as virtual audits or audits conducted by internationally recognized third agencies/entities. The EU welcomes the fact that applications for inspections are processed gradually. However, the EU would like to stress the benefits that virtual audits and recognition of laboratories outside India would have for India and its partners. The EU would therefore like to take this opportunity to request Indian authorities to consider preparing rules for international recognition of laboratories by the BIS, as foreseen by legislation in place. This would speed up audits, and lower the cost of mandatory testing for foreign manufacturers.

2.109. Delays in foreign audits mean that EU companies, despite doing all that is necessary to meet the Indian requirements, are not able to obtain the required Indian certification or marking. At the same time, Indian auditors are conducting domestic audits that allow domestic companies to receive certification/marketing and place their products on the market, thus according an unfair first mover advantage to these domestic companies. The delays in physical audits out of India perpetuates the current difficult situation of EU importers, prolonging the discrimination between local and foreign companies. The EU hopes that the backlog resulting from delayed audits can and will be cleared in a transparent and non-discriminatory manner. The EU would like to reiterate its stance that the QCOs in question have a protectionist orientation. The increasing number of QCOs across sectors is sending worrying signals to EU industry, EU investors, and EU member States. Once these QCOs come into force, they will cause extra burden and economic cost to the EU industry that will have to undergo cumbersome procedures to obtain necessary permissions and/or licences for products already certified under established international standards. Furthermore, the foreign manufacturers have to make necessary modifications in their tooling systems for the ISI mark, which could cause temporary shutdown of some production lines. In this context, the QCOs add little value for Indian consumers, making the reason of their introduction not evident.

2.110. The EU understands that physical audits have limited validity of two years only, after which the procedure for renewal of authorization is not clear. The current procedure is already unduly cumbersome and costly. Requiring a renewal every two years adds to the difficulty of doing business. At a time when businesses across the world have been heavily impacted by the SARS COV-2 pandemic, it would be important to facilitate trade. India should consider giving longer validity period beyond two years and renewals should be given for a longer period beyond five years. In this context the EU welcomes India's decision to further postpone the QCO on wheel rims, to 22 June 2023. The EU welcomes this decision which will ensure the continuity of imports of wheel rims into India. The EU would also like to thank India for the earlier postponement of the QCO on safety glass until 1 April 2023. The EU would like to reiterate that safety glass and wheel rims manufactured in the EU are subject to a rigorous certification process, in line with established international standards, which are not much different from the Indian ones, introduced by relevant QCOs. The EU would, therefore, like to repeat its suggestion to keep the BIS marking as optional for components, which are already in

³¹ For previous statements follow the thread under [ID 649](#).

compliance with the UN marking requirements. The EU would like to ask India, if it would be ready to accept provisionally UN certificates and markings. In light of this, the EU would like to request India to reconsider the introduction of the QCOs on automotive safety glass and wheel rims. Furthermore, the EU recalls its suggestion to keep the BIS marking as optional for components, which are already in compliance with the current marking requirements.

2.111. In response, the delegation of India provided the following statement. As acknowledged by the EU, India has already postponed entry into force of subjected QCOs. The products under mandatory certification are notified by the concerned Line Ministries (Regulator) of the Government of India through the issuance of Quality Control Orders (QCOs). As per the provisions of the QCO, the products specified therein shall bear a Standard Mark under a valid licence from BIS as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. Under this Scheme, factory inspection is a mandatory requirement for the grant of licence. Licence to use the Standard Mark on a product is granted after assessing the manufacturing and testing capabilities through factory inspection of the manufacturing premises. During this visit, conformity of the product to the requirements of the relevant Indian Standard is also established through in-house factory testing or testing at a third-party testing laboratory or a combination of both. At present, there is no provision in BIS (Conformity Assessment) Regulations, 2018, to undertake virtual audits for conformity assessment activities as an alternative.

2.112. Foreign inspections were on hold due to the prevalent restrictions on international travel imposed. As the COVID-19 restrictions have eased out, BIS has started carrying out inspection where confirmation for travelling of fully vaccinated BIS officers has been received. BIS has nominated officers and applicants are asked to remit the inspection charges for carrying out inspection. On receipt of inspection charges, inspections are being planned. Preliminary inspection for more than 100 applications has already been carried out. However, in some cases inspection are being delayed due to difficulty in issuance of VISA.

2.1.3.10 China - Commercial Cryptography Administrative Regulations (ID 644³²)

2.113. The delegation of the European Union provided the following statement. The EU is concerned about this implementation measure of the Cryptography Law, and sent comments to the State Cryptography Administration of the People's Republic of China (SCA) in September 2020. Specifically, concerns relate to (i) the scope of the law; (ii) the lack of clarity of concepts and precision of procedures; (iii) the protection of intellectual property; (iv) the imposition of pre-market & export controls; (v) the vague requirements around testing and certification and the turning of voluntary certification requirements into de facto market access prerequisites; (vi) the imposition of additional "national security reviews"; and (vii) the use of domestic standards, along with the lack of meaningful access to pertinent Chinese standards development organizations. The EU urges the SCA to address these concerns in the further development of the draft regulations in order to ensure that legal and regulatory requirements are applied on a non-discriminatory basis, do not favour specific technologies, do not limit market access and do not lead to forced transfer of intellectual property. Additionally, the EU encourages the SCA to open up, in practice, the Working Group 3 on Cryptographic Technology of the National Information Security Standardisation Technical Committee (TC260) and the "Cryptography Industry Standardisation Technical Committee" (CISTC) to foreign-invested industry based in China. The EU would appreciate its comments being taken into consideration and invites China to notify the draft regulations to the WTO.

2.114. In response, the delegation of China provided the following statement. The Revised Regulations on the Administration of Commercial Cryptography are listed in the Legislative Work Plan of the State Council for 2021. The revision of the Regulations will follow law-based, democratic, and scientific principles. And the process of the revision will be open, transparent, and ensure that all the stakeholders participate in the revision through legal channels.

³² For previous statements follow the thread under [ID 644](#).

2.1.3.11 Mexico - Conformity Assessment Procedure under Mexican Official Standard NOM-223-SCFI/SAGARPA- 2018, "Cheese Names, Specifications, Commercial Information, and Test Methods," published on 31 January 2019, [G/TBT/N/MEX/465](#), [G/TBT/N/MEX/465/Rev.1](#) (ID 678³³)

2.115. The delegation of the United States provided the following statement. The United States remains highly concerned with the revised measure and submitted comments to Mexico's Enquiry Point on 3 May 2022. We encourage Mexico to revisit and address discriminatory practices towards imports, such as lot-by-lot and increased testing for imported products. Could Mexico please provide an update on the status of this measure? The United States requests 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. Additionally, there are no relevant Codex or other international standards available for this type of analysis. 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 standard, with the NOM-223 cheese CAP versions developed through 2020–2021, and an expected 2022 update to the NOM-223 cheese standard? Once finalized, will implementation of the measure move forward based on Mexico's Quality Infrastructure Law or the law it replaced, the Federal Law on Metrology and Standardization?

2.116. Could Mexico provide clarification on the different roles that each Ministry will play in the monitoring, compliance, and verification activities listed in the draft measure? If Mexico proceeds with implementation of the current measure, the United States (Government and industry) would need at least one year to launch compliance systems. The United States urges Mexico to indefinitely delay implementation of the measure and consider less trade-restrictive alternatives as previously proposed by the US Government, other WTO members, and industry stakeholders.

2.117. The delegation of Australia provided the following statement. Australia would like to thank Mexico for providing Members with the opportunity to comment on [G/TBT/N/MEX/465/Rev.1](#). We look forward to receiving Mexico's reply to our comments on its notification. Australia would like to reiterate its concerns that Mexico's measure notified as [G/TBT/N/MEX/465](#) appears discriminatory and more trade restrictive than necessary and have made further comments on the revised notification. Australia recognizes the original objectives of the proposed measures and welcomes the review of the procedure in light of Mexico's international commitments. We kindly request an update for the release date of the new version of the procedure for public consultation.

2.118. The delegation of New Zealand provided the following statement. New Zealand welcomes the opportunity to 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 for cheese under NOM 223 are more trade restrictive than necessary, with some aspects of the procedure likely to cause difficulties for New Zealand exporters and creating unnecessary obstacles to international trade. We thank Mexico for its notification of these measures and look forward to receiving a response from Mexico on our comments.

2.119. The delegation of the European Union provided the following statement. The European Union would like to join this trade concern and refer to the written comments on the revised text notified on 8 February that were sent to Mexico on 22 April 2022. According to information from EU industry, some aspects of the conformity assessment procedure (CAP) for the Mexican Official Standard NOM-223-SCFI/SAGARPA-2018 on cheese may cause difficulties for EU exporters. The EU would appreciate a reply to the written comments and would like to ask about the state of play of the ongoing revision of the measure.

2.120. In response, the delegation of Mexico provided the following statement. As mentioned in the meeting of the Committee on Technical Barriers to Trade on 10 March, Mexico notified a new version of its Conformity Assessment Procedure on 8 February, in document [G/TBT/N/MEX/465/Rev.1](#), with a deadline for submitting comments of 9 April. The delegations of the European Union and the United States nevertheless requested an extension of the deadline to submit their comments to 30 April and 9 May, respectively. This extension was granted.

³³ For previous statements follow the thread under [ID 678](#).

2.121. The comments received during the additional public consultation period are currently being evaluated by the competent standardizing authorities. Mexico reaffirms its commitment to transparency. Any updates will be duly shared and notified in a timely manner.

2.1.3.12 European Union - Draft EU Batteries Regulation (implementation of the European Green Deal), [G/TBT/N/EU/775](#) (ID 685³⁴)

2.122. The delegation of [China](#) provided the following statement. First I would like to thank the EU for their feedback on our concerns at the last Committee meeting. Unfortunately, we think the replies given by the EU neither solved our concerns nor responded to our specific suggestions on the draft EU batteries regulation. Hence, I would like to refer to our suggestions raised at the last meeting and wish the EU can give a concrete response to our suggestions. In addition to the suggestions we made at the previous meeting, I would like to add three additional suggestions as follows. 1. Regarding Article 8 of recycled content, it is suggested that the subsidiary of recycled content could be notified to WTO Members with a comment period of at least 60 days. Meanwhile, the data access requirements related to the proportion of recycled contents shall be notified to the WTO. 2. Regarding Article 13 and Annex, it is recommended that the time of label replacement for products that are placed on the market could be set in a flexible way, for example, the labels could be replaced batch by batch. The label replacement of products that are placed on the market may involve recall and disassembly, so it is recommended to set a more flexible way for label replacement of products. 3. With regard to the registration and extended responsibility of manufacturers in articles 46 and 47, it is suggested to allow producers to submit an application for registration in only one Member state rather than in each Member state. We would encourage the EU to consider establishing a regulatory system where producers could have extended producer responsibility one time and select the specific market where the batteries are available.

2.123. The delegation of the [Republic of Korea](#) provided the following statement. Korea appreciates this opportunity to make comments on the recently published "Proposal for a Regulation of the European Parliament and of the Council concerning batteries and waste batteries" of the European Union. First of all, The Korean government fully respects and supports the efforts of the European Parliament and the Council to provide information to consumers and protect the environment. Furthermore, Korean companies are making efforts to faithfully comply with the regulation of the EU. However, in relation to the battery replacement requirements specified in Article 11 of the amendment published in March 2022, the Korean industry has difficulties regarding who and how to replace batteries, and the availability of batteries as spare parts. So we would like to deliver the following requests.

2.124. First, the amendment stipulates that batteries shall be removable and replaceable by the end-user. However, if inexperienced end-users replace batteries of some electronic products that require professional knowledge or skills about disassembly and reassembly when replacing internal parts, it will be difficult to ensure user safety and fulfill product specifications, leading to product liability issues. Therefore, we request that the EU add "independent operators" to the relevant provision and specify the person to replace batteries as the end-user or independent operators. Second, we request that the EU allow the use of commercially available tools (including thermal energy, solvents, and specialized tools) when replacing batteries. The amendment practically prevents the use of thermal energy, solvents, and specialized tools. However, since the use of adhesives is essential to guarantee the product's waterproofness, durability, and ease of assembly, battery replacement using commercially available tools, including thermal energy, must be allowed to guarantee the Rights to Repair. Third, Korea requests that the EU improve the amendment by deleting the ten-year mandatory supply period of battery components. Retaining batteries as spare parts for ten years would reduce resource efficiency and increase waste generation due to unused and oversupplied battery parts, making the requirement conflict with the ecodesign regulatory objectives. Lastly, we request that the EU make an exception for equipment which is made compactly for portability from the requirement to ensure battery replaceability. For some products that are small or waterproof, the battery cannot be replaced due to their sealing structures. Keeping the battery replaceability obligation can compromise the manufacturer's opportunity in developing designs or types for products such as wireless earphones, ring-shaped wearables, etc.

2.125. The delegation of the [Russian Federation](#) provided the following statement. The Russian Federation reiterates the statements made during the previous meetings of the TBT Committee with

³⁴ For previous statements follow the thread under [ID 685](#).

regard to the proposal for a regulation of the European Parliament and of the Council concerning batteries and waste batteries. We appreciate efforts of the EU in the fields of fighting climate change and protection of environment, however we are concerned with the lack of scientific data and international standards as a basis for proposed conditions for access to the European Union market as well as material recovery targets for waste batteries. The policy currently carried out by the European Union as a whole cannot but lead to the global imbalance in trade in basic raw materials including non-ferrous metals. This policy causes soaring prices along the entire supply chain provoking crisis and inflation while hampering the already unsustainable global trade architecture. We urge the EU to conduct its trade-related climate policy in compliance with the WTO rules and relevant climate agreements without creating obstacles to trade and preserve a sufficient level of competition between imports and domestic manufactures.

2.126. In response, the delegation of the European Union provided the following statement. The EU would like to recall that the Batteries Regulation proposal was presented on 10 December 2020 and notified to the WTO on 26 January 2021 with a commenting period of 90 days. During the commenting period, the EU received written comments from China, Japan and Canada to which the EU replied on 18 October 2021. The EU would like to remind that batteries are an important source of energy and one of the key enablers for sustainable development, green mobility, clean energy and climate neutrality. In order for the EU's product policies to contribute to these objectives, it needs to be ensured that batteries marketed and sold in the EU are sourced and manufactured in a sustainable manner. The EU has taken good note of the points raised by delegations.

2.127. The EU would like to reassure that there will be sufficient time to consider the feedback received on the notified draft prior to adoption. Implementing and delegated acts that will be developed under the notified draft will involve consultation of stakeholders, though the exact way in which this will be done is to be determined in each case. Drafts of those implementing measures and delegated acts will be notified to the WTO in accordance with the TBT Agreement. The application dates for some of the provisions in the notified draft are relatively soon. This is because significant developments in the battery sector are taking place in the near future. However, the EU would like to clarify that the indicated application dates are provisional, because it will depend on the time needed for the regulatory process to adopt the notified draft. In fact, it is clear that at least some of the application dates need to be reassessed, because the regulatory process is still ongoing. The European Parliament and the Council have concluded their respective positions in March this year. The issues raised by the delegation of the Republic of Korea concern amendments by the European Parliament. These amendments are being considered in the negotiations between the European Parliament and the Council to decide on the final Regulation. The aim is to conclude this process in the second half of this year. The EU has taken good note of the comments from the Republic of Korea.

2.128. In conclusion, the EU stresses that the notified draft seeks to fulfil multiple, interlinked objectives including the protection of the environment and human health and safety, all of which are legitimate policy objectives under Article 2.2 of the TBT Agreement. For the reasons specified above, the EU considers that the notified draft is not more trade restrictive than necessary to fulfil these legitimate policy objectives, taking into account the risks that non-fulfilment would create. Regarding Article 2.1 of the TBT Agreement, the EU does not consider that the notified measure gives rise to a risk of discrimination within the meaning of that provision. The notified draft therefore fully complies with the provisions of the TBT Agreement.

2.1.3.13 European Union - Chemical strategy for sustainability (implementation of the European Green Deal) (ID 690³⁵)

2.129. The delegation of the Russian Federation provided the following statement. Russian Federation reiterates the statements made during the previous meeting of the WTO working bodies and expresses the concern on the chemical strategy developed by the European Union as an element of implementation of the European Green Deal. The document implies potential restriction and even prohibition of materials that classified as hazardous regardless of whether sufficient scientific basis for this has been provided or not. We note that the core legal act for classification of chemicals and substances of the EU is the CLP Regulation. Currently, this regulation allows to make strict classification decisions without sufficient scientific data in accordance with the precautionary principle. One recent example of this practice is cobalt classification under the 14th ATP to the EU

³⁵ For previous statements follow the thread under [ID 690](#).

CLP Regulation. Such an approach can lead to unjustifiable prohibition of essential materials. We urge the EU to implement the strategy in full compliance with the WTO rules and principles.

2.1.3.14 Egypt – Halal Certification Measure, based on Egyptian Standard ES 4249/2014 General Requirements for Halal Food According to Islamic Sharia, [G/TBT/N/EGY/313](#), [G/TBT/N/EGY/313/Add.1](#), [G/TBT/N/EGY/313/Add.2](#) (ID 718³⁶)

2.130. The delegation of [Canada](#) provided the following statement. Canada joins the United States, the European Union and other intervening Members to raise its continued concerns with Egypt's new halal certification requirements for all imported food and beverage products. Canada understands Egypt's objective to ensure that Egyptian consumers are confident that they are buying and consuming halal-certified products in agreement with Islamic Sharia. However, we also believe that such measures should not create unnecessary barriers to international trade or be more trade-restrictive than necessary to fulfil that objective. While Canada appreciates Egypt notifying this measure to the WTO TBT Committee in December 2021, it failed to do so prior to the implementation date of 1 October 2021. As set out in Article 2.9 of the TBT Agreement, Members have an obligation to provide trading partners with adequate time to comment on a given measure (at least 60 days) and have those comments taken into consideration prior to that measure being finalized.

2.131. In addition, as per WTO obligations, a six-month period between the notification of the final measure and its entry into force is considered a reasonable amount of time to provide industry time to adapt to the new requirements. This was clearly not the case with this measure. Although Canada appreciates Egypt's delayed implementation of the halal certification for dairy products to October 2022, Canada still remains concerned with the lack of details, documentation and specificity on how these requirements will be implemented and how specific products will be impacted. For example, the proposed new regime only specifies one Egyptian certification body that will have the authority to certify halal products for the Egyptian market. It is our understanding that this has already significantly raised the halal certification fee which will have to be borne by exporters of halal product to Egypt. The new measure could result in a certification process that is overly burdensome, costly and more trade restrictive than necessary to achieve Egypt's stated objective. Canada strongly encourages Egypt to have open and transparent discussions with trading partners to share information, further clarify the requirements under this new measure and consider the impact it may have on trade. Until then, we respectfully request that Egypt suspend the implementation of the measure. Canada also notes Egypt did not provide a written response to Members at previous TBT Committee meetings and kindly asks Egypt to provide one to Members for this meeting.

2.132. The delegation of the [European Union](#) 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 regrets that Egypt notified to the TBT Committee the requirements for the importation of meat, poultry and their products, milk and dairy products only on 1 December 2021, after their entry into force for milk and dairy products on 1 October 2021, and that the notification did not include the text of the measure. The EU recalls that, according to Article 2.9.4 of the WTO TBT Agreement, Members shall allow a reasonable time (at least 60 days) for other Members to submit written comments on their draft measures, so that comments can be taken into account. In any case, the EU submitted written comments on 26 January 2022 and would welcome a reply by the Egyptian authorities. The EU understands that the rules on halal certification are in drafting process and invites Egypt to notify them to the TBT Committee, when still in draft form, so that comments can be provided. We would welcome any updated information as regards the scope and the implementation method of these rules.

2.133. We welcome some of the steps envisaged to mitigate the negative impact of the measures, such as the grace period until 15 December 2021 during which, certification by "IS EG Halal" was voluntary and for free or the acceptance of imports of milk and dairy products without a halal certificate until 28 February 2022 and the exclusion of crude milk from a halal certificate, both notified in Addendum 1 of 7 January 2022. We welcome as well the more recent facilitating measures notified to the TBT Committee on 4 April 2022 extending, until 30 September 2022, the period in which imports of milk and dairy products are accepted in Egypt without a halal certificate. Nevertheless, some of those facilitation measures are only temporary and affected companies need sufficient time to adapt to the new certification and labelling requirements. Therefore, the EU would

³⁶ For previous statements follow the thread under [ID 718](#).

urge Egypt to postpone the implementation of this measure and to provide for a reasonable adaptation period of at least one year between the publication of the measures - updated rules on halal certification and labelling requirements - and their entry into force, in accordance with Article 2.12 of the TBT Agreement. The EU would like to invite Egypt to reconsider the decision to grant the right to certify the compliance with halal requirements to a single company, IS EG Halal, and to provide for a halal certification system that would allow multiple, well-established certification entities, in accordance with the international best practices. Re-certification by IS EG Halal of products from establishments already certified by other companies would lead to longer time to market and higher costs for consumers, while Egypt is suffering food security problems, aggravated by the coronavirus pandemic. The EU would welcome clarification on whether multiple halal certification entities, including from third countries, would continue to be allowed for imports, as it is understood from point 6 of the original TBT notification form.

2.134. The EU would like to ask Egypt to consider keeping the halal certification and labelling voluntary, in order to pursue the legitimate objective of ensuring reliable information without unduly hindering trade flows. Consumers should be able to decide whether to buy halal-certified food or not, based on clear labelling. The EU would appreciate if Egypt would consider further trade facilitating measures, such as requiring halal certification for the product and not per container, as well as proportional costs of halal certification that take into account the international practice and correspond to the service rendered. The EU understands that the new requirements on halal certification will certify the compliance with Egyptian standard ES 4249/2014 on General requirements for "halal" food products in accordance with the provisions of Islamic Sharia. According to the available information in the TBT notification form [G/TBT/N/EGY/313](#), this standard is under revision and will be notified to the WTO TBT Committee. The EU would like to thank Egypt for the updated version of standard ES 4249/2014 shared in February 2022, ask about the status of the revision and invite Egypt to notify it to the TBT Committee. The EU provided comments on the draft updated halal standards via the EU delegation in Cairo and would appreciate they are taken into consideration. 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 suppliers, and the product coverage (with HS codes). The EU would also like to know whether halal certificates will be required for products that are not 100% milk, but which contain milk or milk ingredients amongst others. The EU is ready to work with Egypt on solutions that would prevent the negative impact this measure would have on food and beverages imports to Egypt.

2.135. The delegation of the United States provided the following statement. The United States continues to recognize Egypt's right to provide its consumers assurance with regard to the halal status of certain products. However, the manner in which Egypt has implemented and notified new requirements may be more trade restrictive than necessary. From the original notification ([G/TBT/N/EGY/313](#)) through the latest ([G/TBT/N/EGY/313/Add.2](#)), Egypt has failed to provide a clear, consistent explanation of the changes to its halal certification import requirements. While Egypt appears to be implementing changes to the import requirements for halal-certified products, these changes have not been notified and published in a transparent manner. This lack of consistent, predictable, and transparent requirements has substantially impacted US exports, especially in the dairy sector. While Egypt announced a delay in implementation until 30 September 2022, US exporters will still be unable to comply with Egyptian import regulations without duly notified technical standards or implementing regulations.

2.136. The United States notes that this notification should clearly delineate the scope of affected products, contain technical halal standards for any new product that will be required to be certified halal as a condition of import, and contain other implementing regulations that address fee schedules, audit procedures, labelling requirements, and export registration requirements. The United States also requests that Egypt explain its current process for approving overseas halal certification bodies. The United States notes that Egypt is changing its requirements around which certification bodies are approved to provide halal certification. These changes should also be notified in written implementing measures, with clear requirements for approving or disapproving overseas certification bodies. The United States reiterates its request for Egypt to delay implementation and enforcement of new halal requirements until Egypt notifies all draft implementing measures of any new halal requirements, and after interested parties have had an opportunity to submit written comments through the WTO TBT Enquiry Point, discuss these comments upon request, and have these comments taken into account in drafting final measures.

2.137. The delegation of [Australia](#) provided the following statement. Australia thanks Egypt for ongoing bilateral communication and engagement on the implementation of new halal certification requirements for IS EG Halal. We welcome Egypt's notification of details around these new requirements to the TBT Committee on 1 December 2021 via [G/TBT/N/EGY/313](#), to which Australia provided comments. We would appreciate Egypt's consideration of and response to these comments. We further welcome the advice received bilaterally that Egypt intends to notify further changes to product scope for IS EG Halal certification requirements, and that implementation will only occur after Members have been provided an opportunity to comment and for those comments to be considered. Australia welcomes ongoing discussion on the implementation of Egypt's new halal certification measures to ensure they meet Egypt's policy objectives while also ensuring measures are not more trade restrictive than necessary.

2.138. The delegation of [Paraguay](#) provided the following statement. Paraguay thanks the delegations of Canada, the European Union and the United States for including this item on the Committee's agenda. We find it regrettable to have to continue to support this concern in this and other forums, most recently at the meeting of the Council for Trade in Goods. However, despite repeated submissions, we still do not have the information that we requested. While Paraguay shares Egypt's concern that consumers be provided with certainty regarding the purchase and consumption of halal certified products, not having precise information on the scope of the measure or details of its implementation prevents operators from being able to adapt to comply with it. Paraguay again requests that Egypt suspend the implementation of the new halal certification requirements until Members have all the information requested and trade operators have had enough time to adapt in order to ensure their compliance.

2.139. The delegation of [Switzerland](#) provided the following statement. Switzerland is following this matter with interest and supports the concerns expressed by other Members with regard to the requirements on halal certification based on the Egyptian halal standard 4249/2014. We are concerned over the potential negative impact of these measures on bilateral trade. While Switzerland recognizes Egypt's legitimate objective of providing consumers with reliable information on the halal integrity of certain products, we expect Egypt to fully comply with its WTO obligations. We believe that such measures should not be more trade restrictive than necessary to ensure legitimate objectives are met. In this respect, we call on Egypt to provide flexibility for the continued recognition of foreign halal certification bodies and the acceptance of foreign halal certificates. Furthermore, we stress the importance of providing a reasonable period of time to allow industry to adapt to the new certification and labelling requirements. Switzerland encourages Egypt to consider less trade restrictive alternatives and additional trade facilitating measures. Switzerland invites Egypt to comply with the notification obligations under the TBT Agreement and provide detailed information about the implementation of the new measure, including detailed description of the certification procedure, its duration and cost, as well as the product coverage.

2.140. The delegation of [New Zealand](#) provided the following statement. New Zealand welcomes the opportunity to speak in support of this trade concern raised by the United States, Canada and the EU. New Zealand refers to earlier statements made on the parallel issue at the Council on Trade in Goods. We understand that Egypt is has implemented changes under Prime Ministerial Decree (No. 35/2020) to require that certification of relevant halal standard(s) shall only be undertaken by IS EG Halal, and that certification from other halal certification bodies is no longer accepted for halal food products imported into Egypt. New Zealand also understands that the measures may apply to dairy products imported into Egypt, irrespective of whether halal labelling is applied to those goods, and irrespective of whether these goods have previously been treated as halal. New Zealand still has serious concerns with these measures. New Zealand would like to better understand what consideration Egypt has accorded to less trade restrictive alternatives. We are also interested in what factors led Egypt to introduce a measure that requires halal certification of products, which have commonly been treated and accepted as intrinsically halal. We also understand that the certification process is straying into sanitary matters; both during audits or inspections and in respect of additional sanitary information being required for registration with IS EG Halal. Sanitary matters should remain out of scope for IS EG's Halal certification and be addressed by Competent Authorities responsible for sanitary matters in line with existing agreements.

2.141. New Zealand would like to thank Egypt for the WTO notification [G/TBT/N/EGY/313](#) dated 1 December 2021. We understand that Egypt is currently developing a new halal standard which will clarify which products are subject to halal certification and the standard applied. We look forward to this Halal Standard being provided and notified to the TBT Committee in accordance with

Article 5.6.2 of the TBT Agreement. New Zealand would like to thank Egypt for its ongoing bilateral engagement on this issue. We request Egypt provide clarification on the points made above and continue to request that any new measures be suspended until all WTO obligations, including those requiring consultation with other WTO Members, have been met.

2.142. The delegation of [Chile](#) provided the following statement. The delegation of Chile reiterates its previously stated concern, which was recently raised in this Committee. Chilean certification centres continue to work on this issue in order to facilitate the trade with Egypt of products with halal certification requirements.

2.143. The delegation of [Argentina](#) provided the following statement. Argentina reiterates its concern about this measure and the lack of detailed and complete information on it. The recent postponement of the entry into force of the new regime does not allay concerns and worries about it. These concerns relate mainly to the lack of transparency and predictability, as there is no information on the certification procedures or other regulatory details. In this regard, we request Egypt to provide the necessary information and that the measure not be implemented until this detailed information is available.

2.144. In response, the delegation of [Egypt](#) provided the following statement. Egypt thanks Canada, the European Union, the United States, Australia, New Zealand, Paraguay, Switzerland, Argentina, Chile for raising this issue and their continued engagement on this matter recognizing Egypt's right to determine appropriate halal certification requirements. Recognizing the comments that have been raised by our trading partners during the bilateral meetings and at the multilateral level, Egypt has taken a number of steps to take into account the concerns raised with respect to transparency and allowing for an appropriate period for implementation. In documents [G/TBT/N/EGY/313](#) and [G/TBT/N/EGY/313/Add.1](#), the product coverage and the timeline for entry into force have been clarified. Egypt has taken a number of facilitating measures including allowing imports of milk and dairy products that are not accompanied by a halal certificate to enter into Egypt until 28 February 2022, as acknowledged by our trading partners and this grace period has been extended until 30 September 2022.

2.145. Through its TBT Enquiry Point, Egypt has replied to the questions sent by the WTO Members and is currently preparing a new set of replies related to the follow-up and new questions that have been received. I would also like to refer to the statement made by Egypt during the last TBT Committee meeting as published in the minutes of the meeting. I would also like to note that ES 4249 for 2014 is currently under review and will be duly notified to the WTO TBT Committee. 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 commitments under the TBT Agreement.

2.1.3.15 United States - Protecting Against National Security Threats to the Communications Supply Chain through the Equipment Authorization Program and the Competitive Bidding Program, [G/TBT/N/USA/1771](#) (ID 714³⁷)

2.146. The delegation of [China](#) provided the following statement. First I would like to thank the US for their feedback on our concerns at the last Committee meeting. Unfortunately, the replies given by US did not respond to our specific suggestions. Taking this opportunity, China would like to refer to our suggestions and wish US can give a concrete response to our suggestions as early as possible.

1. For the new provision 47 CFR 2.903, it is recommended to revoke. The reasons are as follows: The added provision 47 CFR 2.903 prohibits the authorization of certain telecommunications equipment and services under provision 47 CFR 1.50002, but 47 CFR 1.50002 lists only five companies belonging to China, which violates WTO/ TBT non-discriminatory principles. In accordance with Article 2.1 of the TBT Agreement, 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, it is recommended to revoke this provision.

2.147. 2. For Section III. A of the draft regulations, it is recommended to provide technical standards that judge the national security threats, and that the FCC shall authorize the products that comply with the safety technical standards. The reasons are as follows: The draft regulations

³⁷ For previous statements follow the thread under [ID 714](#).

prohibit the authorization of certain telecommunications equipment and services under provision 47 CFR 1.50002, on account of national security threats. Without a public technical standard and measurement index, the fact that the United States deems products of Chinese enterprises to have security threats is violating the WTO/TBT transparency principles. It is recommended to provide technical standards and measurement index and notify WTO members, moreover, to provide opportunities to other WTO Members to make comments. 3. For section III.A.3 of the draft regulations, it seeks comments on whether to revoke any of the authorizations that have been previously granted for "covered" equipment on the Covered List(47 CFR 1.50002). it is proposed not to revoke the authorizations. The reasons are as follows: Currently, the equipment authorizations that have been previously granted are obtained strictly in accordance with the then-effective regulations, TCB-certified by the FCC, or SDOC process prescribed by the FCC. There is no violation of the situations mentioned in provision 2.939 of section III.A.3.

2.148. In response, the delegation of the United States provided the following statement. The United States notified the proposed rules, "Protecting Against National Security Threats to the Communications Supply Chain Through the Equipment Authorization Program and the Competitive Bidding Program," to the WTO on 3 September 2021. This action is a Notice of Proposed Rulemaking (NPRM) (ET Docket No. 21-232) by the United States Federal Communications Commission (FCC), adopted on 17 June 2021, in which the FCC proposes to revise rules related to its equipment authorization processes to prohibit authorization of any "covered" equipment on the recently established Covered List, included in PUBLIC LAW 116-124 Secure and Trusted Communications Networks Act of 2019, enacted by U.S. Congress 12 March 2020. The FCC accepted formal comments on the Equipment Authorization Notice of Proposed Rulemaking until 18 October 2021, and China's comments were submitted on 18 September 2021. In total, the FCC has received nearly 250 comments, including from China. All of the comments are available to the public and can be found on the FCC's website. United States appreciates China for its comments. The final rule will include information on all substantive comments received, and how the comments were taken into account. Information on any rule changes will be notified to the WTO as an addendum to the original notification. The final rule has not yet been issued so when we issue the final rule in the Federal Register we publicly address all substantive comments received, publicly, so that is how we would submit to China any concerns and we are happy to send the website when the measure is final.

2.1.3.16 Belgium - Draft law introducing additional security measures for the provision of mobile 5G services, [G/TBT/N/BEL/44](#), [G/TBT/N/BEL/45](#) (ID 713³⁸)

2.149. The delegation of China provided the following statement. China would like to thank the EU for the response given at the last Committee meeting. Regrettably, however, replies given have done little to resolve our concerns. So China would like to refer to our suggestions made last meeting and we would like to see more reasonable and practical settlement to the issue. China recognizes that WTO Members are legitimately entitled to protect the security of their 5G network. China hopes that our concerns shall be well addressed by the EU and Belgium. China welcomes any further responses and clarifications from the EU and Belgium and urges Belgium to promptly notify the revised royal decree. For the [G/TBT/N/BEL/44](#), we would like to raise concerns that: 1. With regard to point 1. A, "It is recommended to use objective and product-based technical standards for risk assessment". China has two core concerns on this issue: the first one is that the risk assessment criteria shall be objective, i.e. the non-objective risk assessment criteria based on the characteristics of vendors in the notified law, are inconsistent with the TBT Agreement, which provides that a technical regulation shall be an objectively definable standard based on the product characteristics; the second one is that relevant international standards and good practices shall be used as the basis for the risk assessment criteria, specifically, Belgium shall comply with Article 2.4 of the TBT Agreement by using, in the notified law, internationally recognised technical standards that can objectively assess the product security or certification methods that are based on international standards as the sole or fundamental assessment criteria for product security.

2.150. A. The risk assessment criteria shall be objective. With respect to China's first concern, the EU replied that the risk profile is assessed on the basis of the factors listed in the new Article 105, §5 subparagraph 4 of the adopted law and these factors come from the EU 5G Cybersecurity Toolbox. Because the EU 5G Cybersecurity Toolbox does not suffice to look at the quality of network elements and does include non-technical vulnerabilities, the notified law has taken into account the non-technical assessment criteria to guarantee the supply of network elements. The EU's reply did not

³⁸ For previous statements follow the thread under [ID 713](#).

address China's core concern on this point. As a technical regulation notified under the TBT Agreement, the notified law should be consistent with the requirement under the TBT Agreement that a technical regulation or standard shall be objectively definable, and whether it complies with the EU 5G Cybersecurity toolbox is irrelevant. The risk assessment criteria in the notified law does not contain any technical details. China reiterates that the non-objective risk assessment criteria based on the characteristics of vendors in the notified law are inconsistent with requirements of the TBT Agreement for technical regulations and standards.

2.151. B. Relevant international standards and good practices shall be used as the basis for the risk assessment criteria. With respect to China's second concern, the EU replied that, in practice, the BIPT "will refer to the most appropriate existing best practices and/or international standards in accordance the Article 2.4 of the TBT Agreement in its opinion to the ministers concerning risk assessment"; and the reason that relevant international standards or best practices are not listed in the notified law is because not all aspects of 5G technology are covered by international standards or best practices, and that these instruments are changing. The EU further mentioned that, as no relevant international standards or best practices currently exist as regards the non-technical assessment criteria, solely referring to existing international standards or best practice to evaluate the performance of the product would not be possible to effectively and appropriately fulfill the legitimate objective pursued by the notified law. The EU's reply still has yet to provide a reasonable explanation for not adopting relevant international standards or good practices in the notified law.

2.152. First, non-technical risk assessment criteria do not conform with the TBT Agreement as regards the definitions of technical regulations or standards, and a lack of existing international standards or best practices for such criteria cannot justify Belgium's non-fulfillment of its obligation under the TBT Agreement to use relevant international standards as the basis for the technical regulations or standards. China has pointed out that the TBT Agreement requires that technical regulations and standards should be objectively definable based on product characteristics. As recommended by China, there do exist international recognised technical standards or good practices that comply with the TBT Agreement and can objectively evaluate the product security. Accordingly, the EU's explanation cannot effectively address China's core concern for Belgium's not using objectively definable international standards or good practices in the notified law. Second, since the notified law and relevant provisions are notified as technical regulation, Belgium is obliged under Article 2.4 of the TBT Agreement to use international standards based on technical criteria as a basis for such technical regulations. China would like to point out that there are international standards based on technical criteria in the industry (e.g the Network Equipment Security Assurance Scheme (NESAS) and Security Assurance Specifications (SCAS) published by Global System for Mobile Communications Association (GSMA), the 3rd Generation Partnership Project (3GPP), the Common Criteria for Information Technology Security Evaluation, and the cybersecurity certification standards set out in EU's 5G cybersecurity certification scheme specified in Regulation (EU) 2019/881). Therefore, China urges that Belgium comply with Article 2.4 of the TBT Agreement by using, in the notified law, internationally recognised technical standards that can objectively assess the product security or certification methods that are based on international standards as the sole or fundamental assessment criteria for product security.

2.153. 2. With regard to point 1.C, "For Article 105, §4, al.1, it is recommended to specify the extent of prohibiting and restricting the HRVs and the procedures to revoke the identification of HRV". China's core concern regarding this issue is that the notified law does not specify the scope and method through which the HRVs are prohibited or restricted, nor does it illustrate the legal basis and the detailed procedures to seek removal of the HRV designation. The EU's replied that the Royal Decree notified by Notification [G/TBT/N/BEL/45](#) (the "notified royal decree") has already specified to what extent HRVs are prohibited or restricted; if HRVs want to challenge the HRV designation, they can appeal against the final decision of the Ministers before the Council of State. The EU's reply on this issue still did not address China's core concern. With respect to the extent HRVs are prohibited or restricted, the notified royal decree generally prohibits the use of any active elements produced by "high-risk equipment manufacturer" in specific types of networks, and does not specify how such 5G equipment or its parts are classified for their different security levels based on their different product security and actual risks. With respect to the removal of the HRV designation, the notified royal decree and related regulations only allows 5G MNOs to defend against the preliminary results of the risk assessment and to request a hearing, and do not provide legal remedies directly to those identified as "high-risk equipment manufacturers". In this regard, the so called "high-risk equipment manufacturers" are hindered from effectively seeking remedies provided to them under other Belgium laws and regulations when they are not fully informed of the reasons for the designation

nor have any change to present facts or arguments in support of their positions before the competent authorities making such designation. Moreover, the notified royal decree does not illustrate the legal basis and the detailed procedures to prohibit or restrict the high-risk equipment manufacturer or to seek removal of the "high-risk equipment manufacturer" designation. As mentioned before, it appears to be inconsistent with the requirement for the competent authority to administrate trade-related laws and regulations in a uniform, fair and reasonable manner and may constitute de facto discrimination against specific 5G equipment vendors.

2.154. China reiterates that the notified law shall adopt an objectively definable security standard based on the product characteristics, rather than the non-objective risk assessment criteria based on the characteristics of vendors, and the relevant laws and regulations or technical standards shall be prepared, adopted or applied in a manner commensurate to the intended legitimate objectives, and not with a view or with the effect of creating unnecessary obstacles to international trade. China recommends that Belgium further clarify in the notified law the specific scope, legal basis and procedures for prohibiting and restricting the HRVs from supplying 5G equipment or services, apply requirements of proportionality and necessity to products of different security levels, and specify the path for so-called HRVs to seek removal of its HRV designation with detailed procedural guidance. 3. With regard to point 1.D, "For Article 105, §4, al.4, it is recommended to adopt fact-based, objective and fair risk assessment criteria". China's core concern on this issue is that the risk assessment criteria are discriminatory and vague, lacking objectivity and impartiality. The EU replied that, the notified risk assessment criteria, especially the factor of "the likelihood of the supplier being subjected to interference from a non-EU country" are justified and explained in the explanatory memorandum to the adopted notified law. The EU's reply has still yet to address China's core concern. China recognises that WTO Members protect the security of their 5G network on the basis of objective facts and evidence, and in a manner consistent with the principles of fairness, non-discrimination and transparency. However, the criterion in the notified draft as regards the extent of interference to the vendor by a non-EU country constitutes a de jure and de facto discrimination based upon the origin of vendors and discriminates the vendors from non-EU countries. Moreover, the explanation in the explanatory memorandum further indicates that the risk assessment criteria set out in Article 105, §4, al. 4 of the notified law are discriminatory and vague, lacking objectivity and impartiality. For instance, the explanatory memorandum mentions that the term "interference" should be read in the widest possible meaning and not merely in the sense of intelligence and security services.

2.155. China reiterates that laws, regulations and technical standards with regards to cybersecurity shall by no means constitute unjustifiable discrimination or disguised restrictions on international trade; the 5G equipment security shall be assessed based on facts and industry-recognised objective security standards instead of a non-objective risk assessment of the vendors. China urges that Belgium comply with Article 2.1 and 2.2 of the TBT Agreement and other WTO requirements by developing objective, fair and non-discriminatory 5G equipment security standards and measures, taking full consideration of the characteristics and usage of 5G technology and adopting existing industrial good practices. 4. With regard to point 2, "For Article 105, §5, it is recommended to provide so-called HRVs with rationales of the assessment and with reasonable remedies ". China's core concern regarding this issue is that the notified law only allows 5G MNOs to defend against the preliminary results of the risk assessment and to request a hearing. However, the vendors of 5G equipment or services identified as the so-called HRV are not provided with any legal remedies. In response, the EU referred to its previous reply that remedies for HRV identification are provided in Article 105, §5 of the notified law, and further replied that HRVs are able to initiate appeals against the final decision of the Ministers in accordance with the first sentence of Article 19 of coordinated Acts on the Council of State.

2.156. The EU's reply did indicate that HRVs are entitled to appeal against the relevant Ministers' decision of refusing to lift the HRV designation. However, the EU did not specify whether HRVs have the right to defend against the preliminary results of the risk assessment and to request a hearing as provided for 5G MNOs in the notified royal decree and relevant provisions. Given that it is the vendors of 5G equipment or services that are subject to the risk assessment, China proposes that Belgium specify the administrative or judicial remedies for the vendors of 5G equipment or services in the notified law, require the competent authority to provide so-called HRVs with rationales and evidence of its decision, and grant vendors the right to defend themselves against unfavourable risk assessment decisions. For the BEL/45, we would like to raise concerns that: 1. China urges Belgium to promptly notify the revised royal decree in accordance with the requirements of Article 2.9.2 and other provisions of the Agreement on Technical Barriers to Trade. 2. The royal decree as well as

relevant laws, regulations and technical standards shall be provided and applied on the basis of objective facts and evidence, in a manner consistent with the principles of fairness, non-discrimination and transparency and shall by no means constitute unjustifiable discrimination or disguised restrictions on international trade. Taking Chapter 2 of the notified royal decree as an example, such Chapter prohibits or restricts the 5G mobile network operators from using active elements produced by "high-risk equipment manufacturer" without specific standards or criteria. China would like to point out that there are international standards based on technical criteria in the industry (e.g. the Network Equipment Security Assurance Scheme (NESAS) and Security Assurance Specifications (SCAS) published by Global System for Mobile Communications Association (GSMA) and the 3rd Generation Partnership Project (3GPP), the Common Criteria for Information Technology Security Evaluation, and the cybersecurity certification standards set out in EU's 5G cybersecurity certification scheme specified in Regulation (EU) 2019/881). Therefore, China suggests the adoption of internationally recognised technical standards that can objectively assess the product security or certification methods that are based on international standards as the sole or fundamental assessment criteria for product security, rather than the non-objective risk assessment criteria based on the characteristics of vendors.

2.157. 3. Any party affected by relevant laws, regulations and technical standards shall be entitled to sufficient remedies. The notified royal decree and the relevant law only allow 5G mobile network operators to defend themselves against the preliminary results of the risk assessment and to request a hearing. However, it does not directly provide any legal remedies for 5G equipment manufacturers identified as so-called "high-risk equipment manufacturers". In this regard, the so called "high-risk equipment manufacturers" are hindered from effectively seeking remedies provided to them under other Belgium laws and regulations when they are not fully informed of the reasons for the designation nor have any chance to present facts or arguments in support of their positions before the competent authorities making such designation. Moreover, the notified royal decree does not illustrate the legal basis and procedure to lift the HRV designation. China proposes that Belgium specify the administrative or judicial remedies for 5G equipment manufacturers in the notified royal decree, require the competent authority to provide rationales and evidence of its decision, and grant the 5G equipment manufacturers the right to defend themselves against unfavourable risk assessment decisions and provide for detailed procedures to remove a high-risk designation, ensuring that the 5G equipment manufacturer identified as so-called HRVs is entitled to apply for removal of the designation.

2.158. 4. The royal decree and relevant laws, regulations or technical standards shall be prepared, adopted or applied in a manner commensurate to the intended legitimate objectives, and not with a view or with the effect of creating unnecessary obstacles to international trade. Furthermore, they shall not be more trade-restrictive than necessary to fulfill their legitimate objectives. The notified royal decree generally prohibits the use of any active elements produced by "high-risk equipment manufacturer" in specific types of networks, and does not specify how such 5G equipment or its parts are classified for their different security levels based on their different product security and actual risks. China considers that different security levels can be applied on the basis of product characteristics and objectively definable product security assessment standards in order to achieve the aforementioned requirements of proportionality and necessity.

2.159. In response, the delegation of the European Union provided the following statement. The European Union (EU) would like to thank the Chinese authorities for their additional comments on (i) the draft "Law introducing additional security measures for the provision of mobile 5G Services" and (ii) the draft "Royal Decree for the secured rollout of 5G", notified by Belgium to the WTO respectively under references [G/TBT/N/BEL/44](#) and [G/TBT/N/BEL/45](#). The EU regrets that China did not make its statement on this trade concern available on e-Agenda ahead of this meeting. The EU will address nevertheless the main concerns expressed therein. The EU would like to clarify that the notified draft (hereinafter "the adopted law") under [G/TBT/N/BEL/44](#) was adopted on 10 February 2022 and that no revision of the adopted law is foreseen in the near future. Moreover, the notified draft under [G/TBT/N/BEL/45](#) has been substantially revised and will be translated into two new Royal Decrees. Both drafts were notified in early June under Directive (EU) 2015/1535 and are currently following the mandatory standstill procedure prescribed therein. As previously indicated, these two new Royal Decrees related to the law notified under reference [G/TBT/N/BEL/44](#) will then be notified in due course under the WTO TBT Agreement with a new commenting period in line with the TBT Committee recommendations. Taking this into consideration, the EU would like to provide the following general reply to the additional comments submitted by China under [G/TBT/N/BEL/44](#).

2.160. With regard to point 1.A, "It is recommended to use objective and product-based technical standards for risk assessment". First, all the criteria on the basis of which a supplier's risk profile is assessed originate from the NIS Cooperation Group's 5G toolbox³⁹, except for the following "subfactor", please see the new Article 105, § 4, 1°, (e) of the adopted law: "e) the country the supplier originates from conducts or is involved in an offensive cyber policy". The 5G toolbox includes non-technical vulnerabilities as the broader context in which the network elements are manufactured and delivered should also be considered. It does indeed not suffice to look at the quality of network elements. That is why the adopted law focuses not only on the product's terms of performance but also takes account of whether the supply of those elements can be guaranteed. Currently, no relevant best practices and/or international standards exist as regards this criteria. Therefore, solely referring to existing international standards to evaluate the performance of the product would be an ineffective and inappropriate means to fulfil the legitimate objective pursued. Furthermore, no provision in the TBT Agreement states that a technical rule must necessarily and solely focus on the purely technical aspects of the product in order to be seen as objectively definable. The objective aspect of a technical rule is rather defined by its intended purpose and its proportionality to that purpose as Article 2.2 of the TBT Agreement states: "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create."

2.161. Second, the EU would like to clarify that the adopted law provides that nearly all elements of a 5G network are subject to a safety analysis as per the new Article 105, § 1. In this regard, the risk profile of the supplier of those elements plays an important role in the safety analysis. Finally, the risk profile is assessed on the basis of the factors listed in the new Article 105, § 4, subparagraph 4 of the adopted law. Finally, in its opinion to the ministers concerned regarding the quality level, the Belgian telecom watchdog (BIPT) will refer to the most appropriate existing best practices and/or international standards in accordance with Article 2.4 of the TBT Agreement. As not all aspects of 5G are covered by best practices or international standards and as in the course of time those instruments will be revised and replaced or completed by newer versions, it is not possible nor opportune to give an exhaustive list of all those instruments in the adopted law. All technical details were included in one of the two new Royal Decrees (namely the one on ministerial authorization), as laws should be kept as simple as possible, consisting only of essential elements which are then further elaborated in a Royal Decree. It contains several referrals to ETSI-standards. ETSI is a recognized European standardization organization producing globally applicable standards for ICT-enabled systems, applications and services. ETSI has over 900 members worldwide, from 65 countries and 5 continents. ETSI-standards are well internationally recognized standards. The instruments to which China refers will be taken into account if and when the BIPT deems it appropriate.

2.162. With regard to point 1.C, "For Article 105, §4, al.1, it is recommended to specify the extent of prohibiting and restricting the HRVs and the procedures to revoke the identification of HRV". China comments that the adopted law does not specify to what degree and in what way high risk vendors ("HRV") are forbidden or restricted, nor whether and how the HRV designation can be revoked. The notified draft under [G/TBT/N/BEL/45](#) does specify to what degree and in what way HRVs are forbidden or restricted.⁴⁰ Those restrictions are differentiated according to the various parts of a 5G network, hereby taking into account the different security levels of these parts of the 5G network and of the products to be supplied. The use of active high-risk elements (so, elements for which the supplier is considered to be a high risk), for instance, is forbidden in certain parts, only restricted in other parts as far as non-sensitive areas are concerned. If a HRV wants to challenge their high-risk designation they must do so by way of written observations and/or during a hearing (which may be requested by the party applying for a ministerial authorisation and who may bring all legal and technical assistance he deems necessary, also including the so-called HRVs), and which would follow a refusal. A HRV may also appeal against this administrative legal act before the Council of State (see also the EU's response to the final question). The adopted law and the notified draft under

³⁹ Please see CG Publication 01/2020, NIS Cooperation Group: "Cybersecurity of 5G networks EU Toolbox of risk mitigating measures", an online version in English is available at: <https://digital-strategy.ec.europa.eu/en/library/cybersecurity-5g-networks-eu-toolbox-risk-mitigating-measures>

⁴⁰ Please see Articles 2-5 of the notified draft under [G/TBT/N/BEL/45](#). Please, however, note our explanations above that the notified draft under [G/TBT/N/BEL/45](#) has been substantially revised and will be notified in accordance with the TBT Agreement as a revision with a new commenting period in due course.

[G/TBT/N/BEL/45](#) do not provide for any list of HRVs. Being designated in that capacity in one case does not automatically imply that the supplier will be considered high risk in another case and vice versa. The suppliers' risk profile is assessed for each separate case.

2.163. With regard to point 1.D, "For Article 105, §4, al.4, it is recommended to adopt fact-based, objective and fair risk assessment criteria". Regarding the determination of the supplier's risk profile, all criteria are objectively and reasonably justified and explained in the explanatory memorandum to the adopted law. The EU refers to its response regarding point 1.A above. With regard to point 2, "For Article 105, §5, it is recommended to provide so-called HRVs with rationales of the assessment and with reasonable remedies". As indicated in our previous reply, the criteria for identifying HRVs are provided in Article 105, § 4 of the adopted law and provide the basis of any assessment. As to remedies, a party requesting a ministerial authorisation will receive a draft decision and may make written observations and request a hearing for which he can bring all the legal and technical assistance he deems necessary (also including the so-called HRVs), as foreseen in Article 105, § 5, subparagraph 2 of the adopted law. An appeal against the final decision of the Ministers can be lodged with the Council of State.⁴¹ The HRV is able to do initiate this appeal, since Article 19, first sentence of the coordinated Acts on the Council of State⁴² provides this can be done by any party who gives evidence of prejudice or of an interest. The possibility to go to the Council of State is a general possibility against all administrative legal acts in Belgium and should thus not again be specifically mentioned in the law nor in the Royal Decree(s). The EU would like to thank the Chinese authorities once again for providing comments. We are confident that the responses conveyed today sufficiently clarify the issues raised and will allow to a positive outcome.

2.1.3.17 China - National Standard of the P.R.C., Lithium Ion Cells and Batteries Used in Portable Electronic Equipments - Safety Technical Specification, [G/TBT/N/CHN/1576 \(ID 706⁴³\)](#)

2.164. The delegation of the [Republic of Korea](#) provided the following statement. Korea recognizes the importance for China to amend the "National Standard of the P.R.C., Lithium Ion Cells and Batteries Used in Portable Electronic Equipments - Safety Technical Specification (GB 31241)" in order to protect consumers, and Korean companies are making efforts to faithfully comply with the standard. However, the Korean industry has voiced difficulties in regulatory compliance, so we would like to deliver Korean companies' concerns. On 7 May 2022, China issued on its MIIT (Ministry of Industry and Information Technology of the People's Republic of China) website the Draft for Approval of GB 31241. The Draft contains marking requirements in clause 5.3.1 that are not harmonized with the IEC 61960-3. Regarding cell body marking requirements, we request China not to diverge from the international standard and maintain the exceptions provision as it stands in China's current regulation (GB 31241-2014, clause 5.3.1) so that unnecessary obstacles to trade can be avoided. If the Draft is approved and implemented without modification, replacement of production facilities and rework of existing products will be required solely for cells to be exported to China, which will be quite costly and time-consuming, laying an excessive burden on the relevant industry.

2.165. In response to Korea's past comments and requests for reconsideration of the regulation, China answered that "with regard to the safe use of cells and batteries, cells cannot be traced and identified effectively without necessary marking information", and we appreciate China's earnest replies. However, if cell body marking is for product tracking and identification purposes, we believe that in the same way as the requirement for cells with a maximum surface area of below 4cm² (in Draft's clause 5.3.1), China's objectives can be sufficiently achieved by marking on the cell body the minimum necessary information, which is the polarity and a Manufacturer's Code, while the Code contains all the rest of the required information, such as rated capacity, date of manufacture, batch number, etc. In other words, we request that China consider revising the standard to require marking only the two following elements: the polarity mark and a Manufacturer's Code (such as a QR code, etc.), on the cell body. Additionally, in case the amended technical regulation on cell marking

⁴¹ Please see 'Lois coordonnées du 12 janvier 1973 sur le Conseil d'Etat'. An online version in French is available at:

http://www.ejustice.just.fgov.be/cgi_loi/change_lg_2.pl?language=fr&nm=1973011250&la=F

⁴² Please see previous footnote for the reference to the concerned law.

⁴³ For previous statements follow the thread under [ID 706](#).

requirement is to be implemented, we request that a sufficient grace period of more than one year be given in consideration of the time required for the industry to adapt to the new regulation.

2.166. In response, the delegation of [China](#) provided the following statement. Marking for identification is highly important for the safe use of cells and batteries. As a matter of fact, cells are an important component of batteries, and without necessary identification information, cells cannot be traced or identified effectively. In recent years, cells without identification have caused much confusion in market regulation. Therefore, through extensive investigation and consultation during the formulation of the standard we have introduced GB 31241-20XX which proposed relevant requirements for cell body identification.

2.1.3.18 European Union - Proposal for a regulation of the European Parliament and the Council laying down harmonised rules on artificial intelligence (Artificial intelligence act) and amending certain union legislative acts (ID 736⁴⁴)

2.167. The delegation of [China](#) provided the following statement. We support the EU's governance on artificial intelligence, however, from not creating unnecessary trade barriers, China would like to raise concerns as follows: 1. It is suggested to narrow the definition of "artificial intelligence system" by eliminating Annex I (b) and (c) or further specifying the technologies mentioned in Annex I (b) and (c). Firstly, the scope of the definition of "artificial intelligence system" in article 3 (1) and Annex I of the act is too broad. The wording of the definition indicates a large number of software applications, it is unreasonable to classify all of them as artificial intelligence. For example, the logic-based approach in (b) is commonly used to check the form filling, and the "statistical methods", "Bayesian estimation" and "search and optimization methods" referred to in (c) are widely used in technologies of receiver for all digital communication systems, which is irrelevant with artificial intelligence. Secondly, the expansion of the scope of the definition of AI would also expand the scope of high-risk AI, which would result in the enterprises of the AI systems act covered in the supervision would be much higher than the 10% expected by the European Commission, exacerbating the burden of enterprises and regulation, which is inconsistent with the legislative purpose of the EU.

2.168. 2. It is recommended to clarify the specific scope of the safety components in Article 3 (14), for example, to make a list. The safety component is related to the defined risk level for artificial intelligence systems, but the definition of the safety component in the draft is not clear. In the existing NLF harmonization regulations, the Directive 2006/42/EC has an unequivocal definition of "safety components" with an updated indicative list annex V. It is suggested to refer to Directive 2006/42/EC to clarify the specific contents of "safety components" by making a list so that the providers can accurately judge whether their artificial intelligence system belongs to high-risk level or not. 3. It is suggested to make public classification guidance of prohibited artificial intelligence referred to in article 5 (1) as soon as possible. The wording now used to define prohibited artificial intelligence is unclear and subjective which makes it difficult for compliance. 4. It is suggested to eliminate the requirement of "Free of errors and complete" in article 10 (3). If not, please further clarify the definition. The new data would be generated in AI training and testing, and the datasets would be enriched after being placed on the market. Few datasets could comply with the requirement of "free of errors and complete", which is inconsistent with the current state and development of the AI industry. Also the act regulates AI systems from the angle of traditional products without considering the dynamic characteristics of the life cycle of machine learning systems development.

2.169. 5. It is suggested to eliminate the requirement to provide source code in article 64(2) and point 4.5 in Annex VII. "the market surveillance authorities shall be granted access to the source code of the AI system" in article 64 does not meet the requirements set out in Chapter 2, Title III. We believe that systematic verification and actual testing, are enough to identify and correct the harmful results effectively, and should be the methods to test whether an AI system accords with its design. Instead of accessing the source code of the AI system, requirements on the related verification and testing are the valid methods to guarantee and improve the safety of AI products. In addition, the obligatory provision of source code also deviates from the common international practice of protecting source code as a commercial secret. 6. It is suggested that article 70 emphasize and specify the confidentiality obligation for all data information from providers, by the EU Commission, by the EU member States and their market surveillance authorities, notifying bodies, and other participating bodies. In this act, AI providers are required to provide a large number of datasets and technical documents. Therefore, the EU shall strengthen the controls on this

⁴⁴ For previous statements follow the thread under [ID 736](#).

information security in some aspects. 7. It is suggested to keep "Penalties" in article 71 inconsistent with the NLF. Penalties under the NLF are usually regulated by member States, such as RED, LVD and EMC, as "The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation". If not, it is suggested to revise the calculation measures of the penalties in article 71, and reassess the fines, to make sure the penalties are proportionate to the performance. For example, it is necessary to consider modifying the fines of "total worldwide annual turnover" to the fines of "turnover in the EU market". In addition, this article is too strict for non-compliance (under Chapter 2, Title III) which may result in fines of 4% of worldwide turnover. It is suggested to classify fines between essential requirements and other administrative requirements with reference to NLF. For example, for the non-compliance with essential requirements in Germany, the fines are about 100,000 euros, and for the non-compliance with administrative requirements, such as incorrect CE mark, unqualified random documents, etc., would be about 10,000 euros in accordance with directive RED under NLF.

2.170. 8. It is suggested to amend provisions in Annex VII with reference to No.768/2008/EC. Conformity based on an assessment of the quality management system and assessment of the technical documentation in Annex VII does not refer to the conformity assessment defined in the new legislative framework. With a view to ensuring the integration of the new legislative framework, it is suggested to amend provisions in Annex VII with reference to No.768/2008/EC, for example, to explicitly cite Module H of No.768/2008/EC. 9. It is suggested transition period is 48 months in Chapter 2, Title III. The presumption of conformity under Chapter 2, Title III shall be carried out by the provider after the publication of the harmonized standards. It usually takes more than 36 months for standards bodies to lay down new standards, and another 12 months is needed to adjust products and systems, conduct conformity assessments and prepare all required documentation.

2.171. In response, the delegation of the European Union provided the following statement. The European Union (EU) would like to thank the P.R. of China for their comments on notification [G/TBT/N/EU/850](#), "Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts". On 8 July 2022, the EU provided a detailed written response to the comments received. The EU would like to address voiced China's concerns as follows. 1. As regards the scope of the definition of AI, the Commission aimed to propose a definition as technologically neutral and future proof as possible so it can be applied to systems resulting from innovation and market developments. The notified draft's definition builds on the internationally recognized definition of the Organisation for Economic Co-operation and Development (OECD), with only minor adjustments, such as the inclusion of "content" (generative AI systems) and the addition of an Annex with the list of techniques and approaches. The Annex aims to provide legal certainty to operators and to support the dynamic character of the overall definition, insofar as the Commission can update the list and clarify its scope when required due to technological and market developments. It is important to note that, in order for a certain system to be classified as AI for the purpose of the notified draft, it is necessary that the system fulfils the "functional" definition in Article 3(1) of the notified draft. In particular, it is necessary that the system "can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with". Such capacity could ensue from the use of a learning approach, but also otherwise by other approaches such as reasoning or modelling listed in Annex I. Recital 6 further specifies that AI systems can be designed to operate with varying levels of autonomy. The impact assessment accompanying the notified draft highlights the objective to cover with the proposed definition not all software systems, but those that pose specific challenges in terms of complexity, opacity, certain level of autonomy or unpredictability.

2.172. 2. While substantially building on the definitions set in relevant existing EU safety legislation (e.g. machinery and cableway installation), the definition of "safety component" is kept wide to cover AI systems having a safety implication for high-risk products, both in an embedded and non-embedded form. As appropriate, the Commission can, in the future, issue guidance on this issue in order to provide the necessary legal certainty to operators. 3. The formulation of the prohibitions of harmful practices in Article 5 uses concepts that are not new to European Union law. They have already been used in other EU legal acts (e.g. Directive (EU) 2019/21612, Directive (EU) 2018/18083). 4. In relation to "free of error and complete datasets", Article 8 specifies that all requirements should be implemented in light of the intended purpose of the system and the risk management framework, which takes into account the acceptable risks and is limited to what is feasible according to the state of the art (Articles 9(3) and (4) of the notified draft). The EU takes note of the suggestion concerning further clarification. 5. The notified draft clearly protects the

source code as intellectual property (see Article 70(1)(a) read in conjunction with Directive 2009/24/EC on the legal protection of computer programs). On that basis, Article 64(2) makes the access to source code dependent on two strict cumulative conditions: 1) there must be a reasoned request on the side of the market surveillance authority, and 2) access must be necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2. These conditions strike a balance between intellectual property rights protection and safety protection to safeguard important public interests, in line with the EU's commitments under the WTO agreements.

2.173. 6. Article 70 already requires national competent authorities and notified bodies involved in the application of the notified draft to respect the confidentiality of information and data obtained in carrying out their tasks and activities. This is also extended to other national public authorities or bodies which supervise or enforce EU law protecting fundamental rights who may gain access to the technical documentation (Article 64(6)). Furthermore, the Market Surveillance Regulation (EU) 2019/10205 applies in its entirety in relation to the market surveillance activities performed pursuant to the notified draft. Article 17 of the Market Surveillance Regulation requires market surveillance authorities to respect the principles of confidentiality and of professional and commercial secrecy and Article 18 clarifies the procedural rights of operators as regards any measure taken by a market surveillance authority. Furthermore, effective judicial remedy and settlement of disputes is regulated by the administrative law of the member State concerned. Enforcement of intellectual property rights in the EU is guaranteed in accordance with Directive 2004/48/EC on the enforcement of intellectual property rights.

2.174. 7. The penalty system in the notified draft follows the model of the New Legislative Framework system but also of other existing legislation, such as the General Data Protection Regulation (GDPR). This implies that member States remain responsible for laying down the rules on penalties, including administrative fines, applicable to infringements of the notified draft. However, some harmonisation elements are provided, e.g. on the capping and types of infringements associated. The reference to the "total worldwide annual turnover" is consistent with already applicable legislation in the field of data protection (GDPR). While 4% is the maximum capping, it is up to the member States to foresee in their national laws the amount applicable to the relevant infringement. 8. The EU takes note of the suggestion to revise Annex VII with reference to Decision No 768/2008/EC, although it notes that it is necessary to account for the specificities of AI. 9. Finally, the EU takes note of the suggestion on the transition period although it notes that it considers the transition period sufficient for the industry to adjust to the new legislation. The EU would like to thank the Chinese authorities once again for providing comments on the notified draft and hopes that these responses sufficiently clarify the points raised.

2.1.3.19 Sri Lanka - National Environmental (Plastic Material Identification Standards) Regulations No. 01 of 2021 (ID 711⁴⁵)

2.175. The delegation of the United States provided the following statement. On 21 January 2021, the Minister of Environment published in the Gazette of the Democratic Socialist Republic of Sri Lanka, the National Environmental (Plastic Material Identification Standards) Regulations No. 01 of 2021 (PMI Regulation). Sri Lanka has not yet notified this PMI Regulation to the WTO TBT Committee. We appreciate Sri Lanka's willingness to engage with our concerns, most recently through the February 2022 comments made by the Ministry of Environment to the United States Government and to US industry. We are encouraged by Sri Lanka's confirmation that it will take necessary steps to notify the PMI Regulation, along with any implementation guidelines, to the WTO TBT Committee before enforcement. While we understand Sri Lanka's regulatory objectives, we request further clarification on the broad scope, vague language, and potentially burdensome labelling requirements of the PMI Regulation. For example, neither the PMI Regulation nor the draft implementation guidelines provide guidance on sizing, placement, or colour of the marks; the manner in which such marks should be printed or affixed to products and/or packaging; or information on how conformity will be assessed. The clarifying language in the draft implementation guidelines raises additional questions regarding the scope of products Sri Lanka seeks to include in the PMI Regulation and does not explicitly exclude plastics used in electronic products.

2.176. Can Sri Lanka elaborate on how it will address these concerns when implementing the PMI Regulation, including whether the PMI Regulation or its implementation guidelines will provide the industry-requested exemptions to these labelling requirements? Can Sri Lanka also clarify the

⁴⁵ For previous statements follow the thread under [ID 711](#).

intended scope of the PMI Regulation, including if the regulation applies only to final products, or if it applies to all constituent plastic inputs and plastic packaging as well? We encourage Sri Lanka to use existing international standards for plastic material identification, including those used in packaging as the basis for any implementing measures for this regulation. For example, ASTM D7611/D7611M and DIN 6120 are widely accepted standards for plastic packaging used by industry on a global basis. The United States appreciates Sri Lanka's consideration of these comments. We look forward to learning more about how Sri Lanka plans to implement the PMI Regulation and its implementation guidelines, as well as Sri Lanka's WTO TBT notification of these measures.

2.177. In response, the delegation of Sri Lanka provided the following statement. We would like to thank the delegation of the United States for its interest on Sri Lanka's regulation on National Environmental Plastic Material Identification Standard No. 01/2021 published through the Gazette No. 2211/50 dated 21 January 2021. Though this regulation has been published, it has not yet been enforced since the implementation guidelines are still to be finalized. The Central Environmental Authority has drafted implementation guidelines in consultation with the industrial sector. My delegation would like to mention that the Ministry of Environment had a bilateral meeting with the Embassy of the United States in Colombo to further discuss this matter in January 2022. After the meeting, the draft guidelines were shared with the Embassy of the United States for their comments.

2.178. In furtherance to this, the authorities are now making consultations with Chambers of Commerce and various industrial groups before they are submitted to the Plastic Expert Committee chaired by the Central Environmental Authority, which would formulate the final guidelines. At the end of such envisaged process, the authorities will arrange to incorporate the final guidelines in the National Environmental PMI standard regulation No. 01/2021. Thereafter, Sri Lanka will take necessary steps to notify the final Regulation, along with the implementation guidelines, to the TBT Committee for Members' comments before its legal enforcement. My delegation has taken due note of the concerns expressed by the delegation of the United States today which will be conveyed to our national focal points for their consideration.

2.1.3.20 Brazil - Technical Regulation 14, 8 February 2018, to set the additional official identity, quality standards for wine and derivatives of grape and wine products as well as the requirements to be acquainted and Technical Regulation No. 48, 31 August 2018 published in the Official Gazette on 10 September 2018, [G/TBT/N/BRA/613](#), [G/TBT/N/BRA/613/Rev.1/Add.1](#), [G/TBT/N/BRA/956](#) (ID 568⁴⁶)

2.179. The delegation of the European Union provided the following statement. The European Union would like to thank Brazil for notifying the draft Technical Regulation on the identity and quality standards for wines and derivatives of grape and wine and to note that the EU written comments were sent to Brazil on 7 December 2021. The European Union would like to ask Brazil about the timing of the next steps of the revision procedure of the Technical Regulation, in particular the estimated dates of the publication of replies to the comments received during the public consultation and the TBT notification process, of the announced public hearing and of the publication and notification to the TBT Committee of the revised draft regulation. The European Union would like to shortly recall its main general concerns and refer for details to its written comments. First, the EU would like to kindly ask Brazil to refrain in the ongoing revision from further enlarging the already long list of analytical parameters, many of them diverging from recommendations of the International Organisation of Vine and Wine. To avoid creation of unnecessary obstacles to trade, it is important to clarify that the new parameters do not need to be certified for imported wines and to guarantee that the Brazilian methods of analysis for the new parameters are consistent with OIV recommendations.

2.180. Second, the EU would like to invite Brazil to aim at resolving in the ongoing revision the longstanding issue of the classification of sparkling wine according to sugar content, which is currently discussed in the OIV, and in the interim, to align with OIV's glucose and fructose method of analysis for the determination of sugar content. As in past TBT Committees, the European Union would like to encourage Brazil to seek international consensus within the OIV framework on issues relevant to our bilateral trade, such as categories of sparkling wines related to sugar content, import documentary evidence and list of analytical parameters for imports. The European Union appreciates the efforts previously demonstrated by Brazil to facilitate the implementation of its wine regulations for importers. However, Brazil is invited to make use to the maximum extent possible of the

⁴⁶ For previous statements follow the thread under [ID 568](#).

recommendations of the OIV when revising the relevant technical regulations and to remove the current requirements that are not in line with the OIV standards on identity and quality of wine and on maximum content limits. The European Union is prepared to work bilaterally with Brazil with regard to the ongoing revision, invites Brazil to take into account the EU written comments and looks forward to the opportunity to review the revised draft regulation.

2.181. The delegation of Peru provided the following statement. Peru thanks Brazil for the opportunity to submit comments on the draft regulation establishing the standards of identity and quality, as well as the complementary rules relating to the labelling and production process for wines and derivatives of grapes and wine, published by SDA Ordinance No. 411 and notified as [G/TBT/N/BRA/613/Add.3](#) of 18 October 2021. In this connection, Peru kindly invites Brazil to respond to the comments sent to Brazil's TBT/WTO contact point by email on 7 December 2021, which we reiterated on 14 February 2022. Peru stated that Brazil needed to bring its standards into line with the Regulation on the Pisco Designation of Origin (RDOP), especially with regard to the analytical parameters. For example, the draft establishes a minimum anhydrous alcohol presence of 150 mg/100 ml for higher alcohols while the RDOP sets it at 60 mg/100 ml of anhydrous alcohol. We would therefore be grateful if Brazil could inform us about the progress made in assessing our comments and the notified draft regulation.

2.182. In response, the delegation of Brazil provided the following statement. Brazil would like to thank the European Union for its statement and recall that the Ministry of Agriculture, Livestock and Supply (MAPA) Ordinance No. 346, published on 1 July 2021, opened public consultations regarding a draft regulation that establishes identity and quality standards, as well as complementary rules for labelling and production process of wine and grape-derived wines. In response to the requests from many stakeholders, Brazil extend the time for comments until 7 December, what has been notified as [G/TBT/N/BRA/613/Add.3](#). Brazil appreciates the comments received from the EU and from other Members on this notification, which are important to improve the regulation of wine, grapes and their products in Brazil. We have replied to the comments and are currently preparing the publication of replies. We also confirm that the draft regulation will be amended following the public consultation and that a public audience will be held so that all interested parties have another opportunity to review it. It will also be another opportunity for comments and suggestions regarding the proposed regulation. We are not able to estimate the dates of the next steps, though. Brazil appreciates the suggestions and comments from the European Union, from the United States and from all other partners for the technical regulation regarding the identity and quality of wine, grapes and their products and is certain that, by conducting this open and transparent regulatory process, all enquiries will be duly addressed and any remaining doubts will be clarified.

2.1.3.21 China - Cybersecurity Law (ID 526⁴⁷)

2.183. The delegation of the European Union provided the following statement. The EU would like to refer to its statements at previous TBT Committees with regard to the Cybersecurity Law, namely that the scope of the requirements is unclear as key terms have still not been specified in sufficient detail. The EU would like to request more clarity regarding several of the implementing measures of China's Cybersecurity Law. For example, the National Information Security Standardisation Technical Committee (also known as TC260) has released the draft of a short (non-binding) guideline on the identification of "important data" (the Identification Guideline). The concept of "important data" was first introduced by the Cybersecurity Law and has more recently been adopted into the Data Security Law. However, the term has never been comprehensively defined. Under the Data Security Law, regional and sectoral regulators have already been tasked with formulating catalogues of "important data" for their respective sectors. The Identification Guideline, released on 13 January 2022, is the first step towards implementing this national classification system for "important data". The EU urges China to proceed with these guidelines as soon as possible and take into account the EU comments submitted during the public consultation.

2.184. The EU has taken note of the publication of the Call for Comments on the "(Draft) Outbound Data Transfer Security Assessment Measures" by the Cyberspace Administration of China (CAC). The movement of information across national borders drives today's global economy. Cross-border data transfers with protection, allow businesses and consumers access to the best available technology and services, wherever those resources may be located around the world. The seamless transfer of information with trust, supports the growth of the global digital economy as well as the

⁴⁷ For previous statements follow the thread under [ID 526](#).

expansion of international trade. Companies need to be able to efficiently transfer data across borders in order to respond to customers' needs, deliver goods and services to consumers, process payments and provide customer support. It is essential that regulatory frameworks for data allow companies to compete globally, foster the creation of new business models and ensure a level playing field, with legal certainty and stability, as well as the protection of personal data. Conversely, the EU understands that the "Outbound Data Transfer Security Assessment Measures" would impose broad data and server localization requirements, notably under the umbrella of national security, covering potentially all sectors of the economy. Such constraints could severely limit cross-border data transfers. Also, we are concerned that they put foreign operators at a disadvantage compared to local ones. The scope of some of the provisions remains unclear and it is not possible to determine which types of data and which kinds of transfers would be covered by the measure. Additionally, some of the terms used in the measure are not well defined. While these terms may be defined in other pieces of legislation, the concerns we have raised there would also apply here. For example, those subject to interpretation, in particular, the vague concepts of "important data" and "critical information infrastructure". It would be important to address these issues to ensure legal certainty. The EU urges China to take on board its comments provided during the public consultation.

2.185. The EU has also taken note of the "Critical Information Infrastructure Security Protection Regulation", which is effective as from September 2021. The Regulations provide long-awaited details about how critical information infrastructure operators will be designated and what their responsibilities will be in order to protect the security of the networks that they build and operate. Since the Cybersecurity Law came into effect in 2017, EU companies have faced uncertainty about whether or not they and/or their customers would be deemed critical information infrastructure operators and therefore face regulatory obligations in data security, procurement, cross-border data flows and other areas. However, the new Regulations do not resolve the overlap between the Ministry of Public Security (MPS)-administered system for network security, known as the Multi-Level Protection Scheme (MLPS, now updated to MLPS 2.0) and the critical information infrastructure protection regime. The EU urges China to clearly 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, as in reality, these two sets of obligations are increasingly being equalled. The EU calls on China to implement the provisions in a non-discriminatory manner, respecting the principles of proportionality, necessity and technology neutrality, and ensuring adequate protection of intellectual property (IP). The EU requests that China notify draft measures concerning any sectoral implementation to the WTO.

2.186. The delegation of [Japan](#) provided the following statement. Japan continues to have concerns regarding China's Cybersecurity Law and would like to refer to the previous statement we made at the last TBT Committee in March 2022. Japan is also concerned with the related regulations and guidelines such as the Guidelines for Identification of Critical Data that China released for public consultation in January 2022. Japan would like to request China to refer to our comments such as our request to clarify the criteria about identification of critical data submitted by the Japanese Government for the public consultation. Japan would like to request that China provide notifications of the enforcement regulations and guidelines to the TBT Committee and consider comments from stakeholders. In addition, Japan would like to request that China provide adequate lead time from the completion of these regulations and guidelines until their enforcement, and to implement these measures in a transparent manner.

2.187. The delegation of [Australia](#) provided the following statement. Australia reiterates our previous position regarding 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 with the final legislation particularly around extra-territoriality, trade retaliation measures, compliance costs for firms and the overall scope. We remain concerned that provisions in these laws have the potential to create inconsistencies with WTO rules. We note that any measure or counter measure taken under these laws should only be applied consistently with China's WTO obligations. We also continue to remain concerned about the lack of clarity when it comes to definitions, jurisdiction and a number of other fundamental elements, to enable businesses operating in China to fully understand and implement their new obligations. We continue to urge China to consider the concerns of business and Members in the implementation of these measures and development of future measures. We look forward to continuing to work closely with China on these issues.

2.188. The delegation of Canada provided the following statement. Canada would like to reiterate its concerns with China's suite of cybersecurity and cryptography/encryption laws and related implementing regulations which create confusion and complicate businesses' ability to comply with all of them, due to their unclear scope, interaction and adherence to the principles of the TBT Agreement. Canada would also like to reiterate its request for a notification timeline for these measures. With respect to the Practical Guidance of Cybersecurity Standards—Technical Specifications for Certification of Cross-border Handling of Personal Information: Canada appreciates China's efforts to clarify Article 38 of the Personal Information Protection Law (PIPL)'s paths to cross-border transfer of personal information, with the voluntary "Certification Technical Specifications" included in the draft of the Practical Guidance of Cybersecurity Standards, published on 7 April 2022. However, this certification, as a parallel path to security assessment, creates additional requirements on cross-border data transfers, compared to domestic treatment of data transfers, which raises significant concerns regarding consistency with the principles of national treatment, necessity and legitimate objective.

2.189. Regarding the Critical Information Infrastructure (CII) Security Protection Regulations, the Cybersecurity Review Measures, the Draft Regulations on Network Data Security as well as the Draft Measures for Security Assessment of Cross-Border Data Transfer, Canada would like to reiterate our views and comments made in November 2021 and March 2022 during the TBT Committee meetings.

2.190. The delegation of the United States provided the following statement. The United States remains very concerned about China's suite of cybersecurity and cryptography measures. As we have said in prior TBT Committee meetings, this is a major concern for US companies, given China's intertwined requirements for conformity assessment systems for security testing, technical regulations, and a multi-level classification scheme laying out requirements including mandatory standards and testing for the purchase of ICT goods across a wide range of commercial sectors. China's Cybersecurity Law entered into force on 1 June 2017, in spite of serious and long-standing concerns from the United States and many other international stakeholders. Since then, China has continued to develop, and in certain cases, finalize related implementing measures that are sometimes general in scope, and sometimes sector-specific.

2.191. We have many concerns regarding China's Cybersecurity Law and related measures, which impose far-reaching, highly trade restrictive conditions on foreign ICT products through "secure and controllable" requirements, enforced by cybersecurity review regime checks. Such requirements are largely based on a planned update and expansion of the Ministry of Public Security's Multi-Level Protection Scheme (MLPS). As one example, China's 25 January 2018 draft measure, "Information Security Technology – Guidelines for Grading of Classified Cybersecurity Protection", appears to repeat and elaborate upon China's MLPS. Most recently, in February 2022, the United States provided formal comments to China on its draft "Security Technical Requirements of Specialized Cybersecurity Products" notified as [G/TBT/N/CHN/1649](#). China's response, while appreciated, magnifies some existing US concerns on protection of trade secrets and CBI, data storage, and cross-border data transfer requirements. Numerous other concerns have been laid out in prior interventions by the United States and other Members at prior Committee meetings.

2.192. Additionally, the United States reiterates its serious concerns regarding China's Cryptography Law, which went into effect on 1 January 2020. The United States is concerned that this law codifies potentially far-reaching, highly trade restrictive cryptography-related constraints on foreign ICT products. Because these issues are technically complex and China's approach appears to be both novel and would have a potentially widespread impact in the commercial sector, the United States requests that China undertake in-depth consultations with the US Government, other WTO Members, and global stakeholders. We also request that China afford subsequent opportunities for interested parties to submit comments on revised iterations of draft standards and all other implementing measures related to the Cybersecurity Law. Given the broad potential impact of these standards and measures and the serious concerns they have raised, it is critical that China act deliberately to collaborate with all interested parties, and take their comments into account before adopting the drafts as written. We will continue to carefully monitor China's implementation of the Cybersecurity law and related measures, as well as the Cryptography Law. We look forward to continuing this important dialogue with you.

2.193. In response, the delegation of China provided the following statement. The Cybersecurity Law aims to safeguard China's sovereignty, national security and public interests in cyberspace, and to protect the legitimate rights and interests of citizens, legal persons and other organizations. It

does not restrict foreign enterprises, technologies and products from entering the Chinese market, nor does it restrict the lawful, orderly and free flow of data. Since the implementation of the Cybersecurity Law, it has played an important role in safeguarding cybersecurity, safeguarding China's national sovereignty in cyberspace, and protecting citizens' legitimate rights and interests. It has effectively enhanced the awareness of cybersecurity, improve the protection skills on cybersecurity, providing a security guarantee for the development of the network industry and technology.

2.1.3.22 European Union - Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR), [G/TBT/N/EU/71/Add.1](#), [G/TBT/N/EU/72](#), [G/TBT/N/EU/72/Add.1](#), [G/TBT/N/EU/845](#) (ID 594⁴⁸)

2.194. The delegation of [China](#) provided the following statement. China thanks the EU for postponing the application date of MDR and adjusting the transitional period of IVDR. However, in view of the important regulatory role of the above regulations on medical devices and in vitro diagnostic medical devices, China proposes the following: 1. We encourage the EU to extend the validity of MDD and AIMDD certificates issued by the notified bodies for another year. The certificates could be effective until 26 May 2025 as long as the certificates are valid before the cut-off date of 26 May 2021 unless major changes happened to the products, the reasons are as follows: At present, notified bodies are faced with unprecedented pressure on MDR certification for medical devices already and are due to be placed on the market. In addition, more audit requirements are added in MDR, leading to a long period of audit cycle and slowing the process of certificates. Therefore, it is suggested to extend the validity of the previous certificate to 26 May 2025.

2.195. 2. We would encourage the EU to consider issuing OBL (own brand labelling) guidelines accompanying MDR, so as to simplify the conformity assessment procedures of new products under OEM/ODM, allowing notified bodies to directly recognize OBL applications with OEM/ODM-MDR certificates, adjusting OBL responsibilities under Article 16-1 (a) of MDR, or allowing ODM to directly provide core technical documents to certificate authority. OEM (Original equipment manufacturer), ODM (original design manufacturer) and OBL are widely existing and evolving into different combination modes due to the international division of labour. In view of protecting the core technologies and intellectual property rights of original equipment manufacturers, the following two common conditions shall be considered in the re-certification: (1) Regarding conditions that OEM/ODM whose original equipment has been approved by notified bodies: OBL could no longer need to provide all technical documents of OEM/ODM products, especially the core technologies of OEM/ODM. China recommends that the notified bodies of OBL could recognize the audit report and certificate issued by notified bodies of OEM/ODM. We consider that mutual recognition among different certification bodies can simplify the conformity assessment procedures. (2) Regarding to conditions that ODM whose original equipment has not been approved by notified bodies: OBL does not need to provide all technical documents of ODM products, especially the core technologies of ODM. OBL could build an index with the core technologies of ODM products. If necessary, ODM can directly provide the core technical documents to the agencies designated by OBL for on-site/off-site audits. (3) It is suggested to modify and simplify the obligations needed by OBL, and strengthen the post-marketing supervision of OBL products. For example, to simplify the document and supervision requirements with reference to the original MDD directive NB-MED/2. 5.5/Rec 5 Conformity Assessment of Own Brand Labelling. It is not reasonable that OBL is required to undertake all responsibilities of manufacturers.

2.196. 3. standardizing the requirements and time limits during the transition period of IVDR among each member when handling FSC for IVDD products. During the transition period, many products are faced with the co-existence of IVDR and IVDD, leading to confusion on certification. The requirements for FSC (Free Sales Certificate) in different EU Members are quite different. 4. speeding up the construction of relevant modules of Eudamed database. At present, there is a huge difference between the functions of EU Eudamed database and those described in regulations. Many function modules have not been opened or are inconvenient to use, for example, Clinical Investigations and performance studies module and Vigilance and post-market surveillance module have not been opened; although the registration module and UDI/Devices registration module have been opened, functions of many sub-modules are still imperfect, such as (i) the database registration information cannot be shared; (ii) enterprises cannot upload product information in batches; (iii) unstable audit of links between importers and manufacturers, etc, bringing many troubles in respect of marketing,

⁴⁸ For previous statements follow the thread under [ID 594](#).

circulation, registration and basic data access of enterprise products in EU, so it is particularly important to improve the availability and software stability of Eudamed database. 5. We would like to reiterate our concerns on protecting the trade secrets of enterprises. At present, the detailed information of importers published by the EU Eudamed database involves the trade secrets of enterprises. In order to protect their own interests, many enterprises add an extra middle layer for shelter, which would increase burdens on enterprises. It is suggested that the importer data could be protected in a proper way (for example, the importer information could be partially blocked).

2.197. The delegation of Japan provided the following statement. 1. Since the MDR's implementation dated 26 May 2021, Japanese manufacturers have been unable to ship new products and medical devices with new features to Europe. In the previous meetings, Japan stated, "We had received reports from many manufacturers undergoing technical document review that there had been no progress for a long period of time since the start of the review and that it is not foreseeable that the review will be completed and certificates issued by the date of application of the MDR, and that more than one year has passed since the start of the technical document review. We would like the EU to investigate the cause of this issue and explain the measures to improve the situation". Japan appreciates the EU's statement at the last meeting that the MDCG is closely monitoring the situation of the examinations. However, we continue to be informed by several manufacturers that more than 2 years and 3 months have passed since the technical document review started. It seems that there has been no improvement. Japan would like to request that the EU continue to monitor the situation and make improvements as a regulator. The expiry date of MDD certificates is 27 May 2024. Also, the products with the MDD certificates can be placed on the market or start to use until 27 May 2025. In view of the delayed certification of MDRs, Japan requests that the expiry date be extended for one year to 27 May 2025 and 27 May 2026, respectively.

2.198. 2. Japan appreciates the update of MDCG Guidance publication plan in May 2022. In the previous meetings, Japan stated, "We request that public consultation be carried out prior to the publication of the MDCG, and that the guidance that is published be made mandatory with a transition period. The mapping plan for EMDN (European Medical Device Nomenclature) and GMDN (Global Medical Device Nomenclature) mentioned in the MDCG guidance publication plan is still not applicable. We request that a publication schedule be set and executed. Post-marketing surveillance and vigilance are required by the MDR. Though the plan for publication has been described, we request that it be published promptly." Japan requests continued consideration of this matter. 3. Strict clinical evaluation is required even for relatively low-risk medical devices classified as Class I, IIa and IIb under the MDR. Japan requests that EU consider simplifying the clinical evaluation requirements for low-risk medical devices like in the case of Japanese pharmaceutical certification or US 510(k) regulations. As requested in the previous meetings, Japan continues to request that EU consider ensuring that the operation is not more trade-restrictive than necessary. 4. In the previous meetings, Japan stated "The publication plan in the EU Official Journal is not disclosed, and they were suddenly promulgated. We request the release of the plan for the development and publication of harmonized standards for MDR and IVDR." Japan requests continued consideration related to the publication plan and setting an adequate transition period for MDR and the IVDR harmonized standard.

2.199. 5. Japan welcomes that Regulation (EU) 2022/112 which amends the transition period for IVDRs entered into force on 25 January 2022, which extends the transition period for three to five years, depending on the risk classification of the device. However, at present, the Japanese IVD industry has reported that it has taken more than 15 months for certification. We are still concerned that many manufacturers will not be able to complete certification by the deadline despite the extension of the transition period. In addition, regarding the fact that there are only seven notified bodies for the IVDR as of May 2022, the European authorities have stated that the number of notified bodies is not an indication of capacity for certification and that the EU does not expect to maintain the same number of notified bodies as existed under the IVD Directive before May 2022. However, at the moment Japan has concerns about the lack of infrastructure necessary for certification. Therefore, Japan would like to request that the EU improve the capacity of notified bodies, including increasing their absolute number, so that certification can be carried out promptly. Meanwhile, four new guidance documents related to IVDRs have been issued since the last TBT Committee in March, and the total number of documents is eight. Japan would like to express our deep appreciation for the efforts of the MDCG (Medical Device Coordination Group) in this regard. Japan continues to request further expansion of the guidance documents and an indication of availability at the earliest possible date. We also continue to request that newly published guidance documents not be made mandatory immediately after publication, but be subject to a transition period of at least one year.

2.200. The delegation of the United States provided the following statement. The United States appreciates the European Union's (EU) continued efforts to apply a robust regulatory framework to ensure the safety of medical devices. Despite the Medical Device Regulation (MDR) coming into force in May 2021, industry informs us that serious implementation hurdles remain that are creating an unpredictable market environment for medical technology manufacturers. These manufacturers report that implementation has been slow, with long delays in securing certificates of compliance. One problem continues to be a lack of sufficient capacity to assess conformity to the MDR in a timely manner. For example, we understand that as of last year Notified Bodies were working to assess the compliance of medical products covered by more than 25,000 CE certificates issued under the old Medical Device Directive. Most of these certificates are set to expire between January and May of 2024 and medical devices covered by these certificates will need to be recertified under the MDR prior to the May 2024 deadline. As of September 2021, however, only around 500 MDR certificates had been issued in total. With companies waiting anywhere from 13 to 18 months on average to have products reviewed and to receive initial certification, it will be impossible for most of the devices awaiting certification to remain available on the market once the May 2024 deadline passes.

2.201. Additionally, with a lack of capacity to assess conformity to MDR even for existing devices already on the market, MDR-designated Notified Bodies do not have the capacity to evaluate new products in a timely manner. This backlog jeopardizes the ability of European healthcare providers and patients to access the most cutting-edge technologies and innovative care that is becoming available in other parts of the world. Some companies are considering deprioritizing the EU market as the geography of choice for first regulatory approval of new devices. The ongoing COVID-19 pandemic is also creating supply chain disruptions and continues to pose challenges with conducting on-site audits and clinical investigations, further delaying the certification process. What is being done to speed up the conformity assessment process and to resolve the backlog of devices awaiting certification? Is the Commission considering providing additional resources or flexibilities to currently approved Notified Bodies to ensure these Notified Bodies have sufficient resources to meet existing demand? If so, what resources are being provided?

2.202. In order to maintain the strong presence of lifesaving medical technologies currently in the European market and broaden the range of new, innovative technologies that are able to enter, the United States implores the European Commission to swiftly put solutions in place that resolve these ongoing challenges. The United States notes that in recent months, CEN and CENELEC issued a few standards that are harmonized with international standards. The United States appreciates this recent development and hopes to see this trend continue. We urge the Commission to use relevant international standards where possible to avoid creating unnecessary obstacles to international trade. As we have previously noted, the European Medical Device Nomenclature (EMDN) system, is not harmonized with the well-established Global Medical Device Nomenclature (GMDN). Contrary to EMDN, GMDN was developed with the support of ISO and the then-Global Harmonization Task Force (now the International Medical Device Regulators Forum) and is widely adopted by the medical device industry and used by over 70 national medical device regulators to support their activity. The United States uses the GMDN as the basis for our Global Unique Device Identification Database (GUDID).

2.203. We are concerned that the Commission's selection of EMDN is undermining the interoperability of the two UDI systems (EUDAMED and GUDID) for tracking and reporting purposes and will pose several significant obstacles to the medical device and healthcare community. Furthermore, the Commission has not addressed interoperability concerns, and has not made any progress on mapping EMDN to GMDN so as to harmonize the UDI systems and reduce uncertainty for industry. An additional consequence of the Commission's adoption of EMDN is that it will encourage other regulators and entities, like the World Health Organization, to adopt EMDN, creating duplicative requirements for the medical device industry, and thus potentially harming public safety. The EU has repeatedly stated in bilateral discussions and in published documents that it intends to map its nomenclature system to GMDN, but we have yet to see any action by the EU that demonstrates an attempt to map to GMDN. In fact, the EMDN is now available in Eudamed and there is no option of mapping to GMDN. Could the EU explain what actions it is taking to map EMDN to GMDN? Could the Commission also explain if there will be additional updates to EMDN? Additionally, can the Commission describe what updates they anticipate?

2.204. The delegation of Australia provided the following statement. Australia remains concerned about the implementation of this measure as outlined in our intervention at the TBT Committee meeting in March 2022. Australia remains concerned about continued market access for Australian

organisations to the European market given the implementation timeframes for MDR and IVDR, in the context of difficulty accessing appropriately designated notified bodies. This also flows through to the capacity of manufacturers outside Australia to access the Australian market as previously outlined. Australia looks forward to the EU's continued engagement on this issue.

2.205. In response, the delegation of the European Union provided the following statement. As announced in previous Committee meetings, the MDR officially entered into application on 26 May 2021. This new Regulation significantly improves and upgrades the regulatory system for medical devices, aligning further with internationally developed principles by the International Medical Device Regulators Forum (IMDRF) and its predecessor, the Global Harmonisation Task Force (GHTF). It is important to remind Members that the shift between the Directives to the MDR is a gradual one, facilitated by a grace mechanism that allows for medical devices in compliance with the Directives to continue to be in circulation until May 2025, in parallel with MDR certified devices. As regards the IVDR and as of May 2022, a staggered set of transition periods for IVDs was proposed by the European Commission. The proposed amendment to the IVDR has since been agreed upon by the European Parliament and Council. A measure explaining the adapted transitional provisions was also notified to the TBT Committee. The length of the transition periods depends on the risk class of devices, with shorter transition periods for higher risk devices and longer periods for lower risk ones. In addition, the notified draft proposes a deferred application of the requirements for "in-house devices", i.e. those made and used within the same health institution. We are happy to report that as of today, we now have 30 MDR designated Notified Bodies and seven Notified Bodies under the IVDR, which is four more since our last update.

2.206. As regards implementation, the Medical Device Coordination Group (MDCG) continues to closely assess the situation on the ground. Given the large subset of additional requirements set out in the new Regulations and the need for both industry and Notified Bodies to adapt to these new requirements, we understand that certification time under the MDR and IVDR is taking longer than certification previously taking place under the Directives. Understandably, it seems that both industry and Notified Bodies are currently in an adjustment period as regards expectations arising from the new requirements, especially those regarding clinical evidence. In certain cases, we also understand that Notified Bodies are requesting follow-up information or testing to be conducted by the manufacturer, so as to ensure the safety of the devices and hence compliance with the new requirements. The turn-around time with the additional requested information by industry sometimes varies, which is inevitably leading to certain delays in the originally foreseen certification timelines. The MDCG will continue to closely monitor the situation on the ground and has established regular contacts with Notified Bodies and industry in that regard. In addition, and within the remit of the current regulatory framework, the MDCG is working on a list of various actions to enhance capacities of Notified Bodies and to avoid shortages of medical devices, as well as to improve the preparedness of economic operators. The sets of actions, which are foreseen for agreement in the coming months, are multifaceted in their nature and will look into but are not limited to Notified Body capacity, the potential benefits of hybrid audits and ensuring that the EU market remains an innovation-friendly jurisdiction. In terms of implementation work, the Commission and member States are continuing work on key implementing acts and guidelines. To date, there have been more than 100 published guidance documents, including several key guidance on the transitional provisions and clinical requirements. In addition, the most recent milestone is the agreement on and publication of the Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications in accordance with Regulation (EU) 2017/746. These common specifications are intended for several types of high-risk diagnostics, such as HIV tests and SARS-CoV-2 tests. The specifications set uniform and rigorous benchmarks for tests across the EU, clarifying the requirements for market actors and protecting EU patients.

2.207. As regards the Unique Device Identification (UDI), allow us to underline the fundamental difference between the UDI and the Nomenclature, which are two topics that seem to be confused in high-level discussions. While the UDI system employed in the EU is based on internationally agreed upon principles, the Nomenclature, also known as the language of use, will be different. This was a decision taken after careful assessment and consideration. The EU would like to stress, once again, that the EU's choice for creating the European Medical Device Nomenclature was founded on the need for a sensibly structured nomenclature that is transparent, open, completely publicly accessible and downloadable for free. There are currently no other nomenclature systems offering these characteristics. It is important to clarify that the choice of this nomenclature does not constitute a barrier. It is essential to avoid misinformation and confusion in this respect. Regarding the mapping exercise which was commenced in 2019 by virtue of a pilot study, the EU investment

in this work was reduced as a result of unsatisfactory results which were non-technical in their nature. Nevertheless, most recently, the EU has been approached on the topic and the work may potentially be reactivated, should we see an interest and active investment by the relevant counterparts. The EU is fully committed to ensuring that the new system provides a higher level of patient protection and counts on trade partners to encourage their manufacturers to meet these new requirements to ensure trade continuity.

2.1.3.23 China - Draft Administrative Measures for Registration of Overseas Producers of Imported Foods, [G/TBT/N/CHN/1522](#) (ID 611⁴⁹)

2.208. The delegation of [Brazil](#) provided the following statement. Brazil would like to once again raise STC 611 regarding new requirements for the registration of overseas producers of imported foods. So far, both bilaterally and at the TBT Committee, the Chinese Government has not been able to clarify the risk analysis that grounded such disproportionate requirements for a wide range of food products. We understand that these requirements constitute unnecessary obstacles not only to our private sector, but also to our regulators, which must operate as the Competent National Authority for a much wider range of products. Not only are the regulators facing an unreasonable increase in their burden, but some of them must also make recommendations on products or producers that are actually subject to inspection by authorities of other levels of government. In April 2021, the General Administration of Customs of China (GACC) published Decrees no. 248 and 249, which deal, respectively, with administration of registration of foreign establishments and management of the safety of imported and exported food. Article 5 of Decree no. 248 requires that the food safety management system of the country where the producer is located has passed GACC's equivalence assessment or review. Could China explain how and when it intends to carry out these assessments? Could China indicate the criteria and procedures used to establish such equivalence, especially for regulators of processed foods and "health foods"?

2.209. The delegation 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 would like to acknowledge China's recent implementation of measures under its Regulation on Registration and Administration of Overseas Manufacturers of Imported Food (Decree 248). Australia notes that China is still managing the transition to the new measures and updates to China's registration systems are occurring sporadically. Australia would like to request that China meets its obligations to provide Members with transparent timeframes for updates and appropriate guidance and assistance to support enterprises in meeting China's registration process and minimise disruptions to trade or confusion at the border. Australia remains concerned over the burden imposed on competent authorities to administer changes within China's registration system. This burden is exacerbated by a number of issues, such as delays and lack of clarity surrounding the registration of food enterprises within China's registration systems. This is causing significant industry concern and, for some commodities, is trade restrictive.

2.210. Australia reminds China that its regulations must not be used to discriminate against imported goods and that delays in processing registration renewals and new applications from overseas food producers may lead to imported foods being treated less favourably than China's domestic product. Australia would appreciate China's transparency on timeframes for processing these applications, in line with its obligations under the TBT Agreement. Further, Australia would also like to raise concerns with the provision under Decree 248 which allows China to livestream audit foreign food facilities at short notice, threatening suspension for non-compliance. Australia encourages China to work with competent authorities and food facilities to conduct audits in an informed, sustainable and reasonable way. Australia urges China to address these issues promptly and remains willing to work with China to minimise trade disruptions.

2.211. The delegation of [Canada](#) provided the following statement. Canada and other Members continue to raise significant concerns and challenges with China's administrative measures for the registration of overseas manufacturers of imported food. Canada would like to refer to its previous interventions on this item, which remain valid. Canada continues to be concerned that the new administrative measures are overly burdensome and unjustified. These measures are broad and overarching in scope and will have a significant impact on Canadian exports to China. Canada notes that the implementation of the online China Import Food Enterprise Registration (CIFER) system,

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

which was not notified by China to the WTO, will create further barriers to trade including significant financial and resource impacts on both industry and foreign competent authorities. Prior engagement by China with trading partners could have limited the disruptions and concerns being raised by competent authorities and industry stakeholders. Despite repeated requests from trading partners, there remains limited engagement, limited information, and minimal guidance from China Customs regarding the implementation of the CIFER system, which is resulting in continued uncertainty and concerns. As a result, exporters are now encountering delayed clearance of their shipments as companies are unable to register or update their registration in the CIFER system.

2.212. The registration process in the CIFER system is overly detailed and confusing, lacking a step-by-step guidance and defined timelines for both competent authorities and industry. As many questions remain regarding the registration process, Canada calls on China to create a single contact or enquiry point for both industry and competent authorities, or to work directly with companies for the completion of their registration. Additionally, Canada expects China to add to the CIFER system, without further delay, all Canadian products and establishments previously approved by China, but currently not on China Customs' lists of approved Canadian products and facilities eligible to export to China. Canada strongly urges China to outline all timelines in a transparent manner and develop clear guidance documents to address the questions and concerns from both industry and competent authorities. Canada remains deeply concerned about the unnecessary impact these measures are having on trade. In conclusion, Canada calls on China to provide Members with additional information and clarification on the new measures and the CIFER system in the very near future.

2.213. The delegation of the European Union provided the following statement. The EU would like to reiterate its concerns regarding the implementation of Decree 248 of the General Administration of Customs of the People's Republic of China (GACC). The EU does not question the wish of China to ensure that imported food products come from legitimate sources. Overall, we share and support this objective. Whilst China has provided guidance information, and engaged in a dialogue with the EU, problems persist with the lengthy and burdensome mechanism set up by China to register exporting businesses, including: (1) cases of shipments being held up at ports in China due to erroneous or missing information in the China Import Food Enterprise Registration (CIFER); (2) cases of establishments in the meat, dairy and fishery sector that were notified to GACC before the deadline of 31 December but remain unregistered; (3) the lack of clarity about the scope and category of products that are covered, which keeps expanding; and (4) the obligation put on competent authorities and businesses to consult CIFER, almost continuously, to be able to follow all the changes made by China to the structure of the CIFER system and to individual registrations, as well as to be informed about the deadlines to re-register individual establishments. Therefore, the EU urges China to: solve implementation issues pragmatically and expeditiously; facilitate new and old registrations by continuing to provide supporting material, guidance documents in English, including on how competent authorities have to verify the establishments that were registered under the fast track procedure; facilitate amendments/corrections to existing registrations; and facilitate the management by competent authorities and businesses of the changes in CIFER, of the information requested by China and of the deadline to register establishments by introducing an automatic e-mail notification system in CIFER. The EU would like to thank China for the openness and ongoing dialogue to solve the technical issues related to Decree 248, in particular the replies received on 1 July, which we are currently reviewing. Important implementation issues remain and need to be solved in order to eliminate all disruptions to trade as soon as possible and before 1 July 2023.

2.214. The delegation of Japan provided the following statement. Japan shares the concerns raised by other Members on China's "regulations on registration and administration of overseas manufacturers of imported food", published as Decree 248 on 1 January 2022. In particular, Japan understands that overseas manufacturers are prohibited from exporting food products without registration in accordance with Articles 22 and 23 of Decree 248, and remains concerned that such registration and administration procedures impose a heavy burden on overseas manufacturers as well as the competent authorities of WTO Members. Japan, thus, requests that China minimize unnecessary burdens and improve the transparency of those procedures. In particular, Japan requests the following: First, China lessen the burden accompanying the procedures to register new facilities and to correct the registered information afterwards, and allow for a smooth registration without undue delay when the competent authorities and manufacturers apply or nominate for registration pursuant to Articles 7 and 9 of Decree 248. China currently requires a wide range of documents and information which Japan believes is excessive, and the registration procedure sometimes takes a month or more to complete.

2.215. Second, China provide written notices to show the results of the registration examination pursuant to Article 14, for example, by notifying the registration number in writing when the registration has been completed so that the applicant can easily understand the status of the procedure. Third, regarding the China International Trade Single Window system which the competent authorities and manufacturers are obliged to use when nominating and applying for registration: (i) China provide a detailed manual on how to use the system, particularly because the interface sometimes changes without prior notice; (ii) add all product codes (HS·CIQ) missing from the product code list shown on the system because the exported food product cannot be registered without a corresponding product code; (iii) enable competent authorities and manufacturers to change the name of the legal representatives and the addresses of the registered manufacturers while maintaining the current registration because, currently, a manufacturer is required to register again when the registered information changes out of necessity; and (iv) enable the submission of letters of proxy via the system, and confirm the validity and scope of the proxy rights when accepting an application pursuant to Article 9 of Decree 248 because electronic copies of the letters of proxy cannot be uploaded via the system, and China does not scrutinize the legality of proxy rights to prevent applications made by unauthorized persons.

2.216. We request that China address these concerns mentioned above, and provide appropriate explanations, time frames, and detailed guidelines on the operation of Decree 248, as well as the registration system, and answer any questions from Japan which remain unanswered. Lastly, even though Decree 248 entered into effect on 1 January 2022, in order to avoid unnecessary burdens while China strives to improve the transparency of those procedures, Japan requests that China (i) adopt a grace period and allow registered facilities to export items regardless of registration per item until 1 July 2023, and (ii) establish a point of contact for interested parties and competent authorities.

2.217. The delegation of The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu provided the following statement. Given the wide range of our food industries that have been or may have been affected by this measure, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu has been closely following the implementation of the measure. Many concerns over the measure remain even after it took effect on 1 January 2022. First, the lack of sufficient information about registration requirements, operational guidelines, and updates of the stages of the procedure is one of the biggest difficulties we face. This issue is even more critical for those facilities that need to file the application by themselves. Without sufficient guidance, the facilities are unable to complete registration, and trade may be disrupted as a consequence. To avoid trade disruption, we urge China to designate an Enquiry Point that can provide effective and timely assistance for facilities to contact directly with concerns about the online registration system. Also, we urge China to hold an information session in the WTO for trade partners to learn more about the General Administration of Customs of China (GACC)'s implementation of the measure.

2.218. Second, there are also concerns over the measure's review and approval procedure. Standard or anticipated processing periods are unknown. So is the stage of the application. In addition, some of our facilities were rejected by the GACC without further explanation, while others cannot correct their application in the registration system. Under Article 5.2.2 of the TBT Agreement, Members shall ensure that the standard processing period of each conformity assessment procedure is published to the applicant and, upon request, the applicant is informed of the stage of the procedure. We request that the GACC comply with the requirements set out under the TBT Agreement, including the transparency requirement and informing the applicant in a precise and complete manner of all deficiencies and allowing corrective actions. Third, other difficulties we face include the ambiguity of HS code categorization and the scope of the products subject to this measure. Some of our facilities reported that their products have faced customs clearance suspension for no reason.

2.219. Ever since China made notification to the WTO in 2020, we have expressed our concerns and sought clarification from China several times through both bilateral channels and this forum; however, we have yet to receive a sufficient and detailed response from China. We therefore once again urge China to offer sufficient and detailed guidelines and designate an Enquiry Point. Also, as any measure of this magnitude requires far more time for industries to implement, we urge China to offer a longer grace period for implementation so as to avoid serious trade disruption. We also suggest that China temporarily allow entry of all products from registered facilities. This additional time will allow facilities to accurately enter or update the product information in their online registration.

2.220. The delegation of the United States provided the following statement. The United States remains deeply concerned with this measure, published as Decree 248 on 12 April 2021, and implemented on 1 January 2022, and continues to question the food safety and public health benefits, and whether such benefits are based on science or risk. The United States notes that the lack of guidance provided by China and China's implementation and enforcement of the measures continues to cause considerable confusion for exporters and competent authorities. The changing application of these administrative measures is directly leading to disruptions in trade. US agencies continue to face administrative burdens as they work to resolve issues with shipments held up at ports in China.

2.221. We reiterate statements raised in every meeting of this Committee since February 2020: any measure of this magnitude requires far more time for producers, exporters, and competent authorities to implement. Therefore, we again ask that China take the following steps to facilitate trade: First, the General Administration of Customs of China (GACC) should continue to use existing government-to-government facility registration processes, as outlined in Article 11 of Decree 248, and not require facilities to enter information online, where such pre-established processes exist. Second, allow entry of all products from registered facilities without requiring extensive registration information or competent authority intervention for modifications. Third, provide a central point of contact at GACC for facilities to contact directly with concerns about the online registration system. Facilities should be able to communicate with this point of contact in English from outside of China, and the point of contact should not refer general registration questions to satellite GACC offices at individual ports. Fourth, hold an informational session in Geneva for trading partners to learn more about GACC's implementation of the Decrees.

2.222. We note that GACC's requests for additional detailed information from facilities and competent authorities, such as process-specific food safety plans and photographs on an establishment-by-establishment basis, create additional administrative burdens for exporters and may possibly be unnecessary or unjustified. We look forward to China's response to these specific requests and comments.

2.223. The delegation of the Republic of Korea provided the following statement. The Republic of Korea supports Brazil, Australia, Canada, the European Union, Japan, Chinese Taipei, and the United States in raising this Specific Trade Concern. Korea respects China's efforts to ensure consumer safety and appreciates China for continuing bilateral cooperation. However, Korea would like to once again express our concerns under this STC, as China did not duly address the concerns that various Members including Korea have raised regarding Decree 248, which was promulgated on 12 April 2021. To meet the General Administration of Customs (GACC)' requirements, Korea put efforts to register the newly added product categories under Article 7 of Decree 248. However, the GACC's measures is creating unnecessary obstacles to trade because it is taking considerable amount of time for the registration to finalize. While Korea respects the policy objective of Decree 248, we would like to ask China to streamline or expedite its registration process. Moreover, we suggest that China take a more efficient and pragmatic approach with its measures by allowing companies of the product categories outlined in Article 7 to register their respective establishments on the GACC website. For the purpose of ensuring transparency, Korea would like to express our concern that China did not allow a reasonable time period between its notification date and the date of which the regulation entered into force. As China's new measures is significantly affecting bilateral trade, we would like to ask China's response to Korea's requests.

2.224. The delegation of Türkiye provided the following statement. With regards to the current STC, we reiterate our support to the Members that brought this item to the agenda. We believe that China as other Members has the right to take necessary measures to ensure food safety as well as prioritize the protection of human health and safety. At the same time, those measures should not create unnecessary obstacles to international trade. We observe that Decree 248 covers a wide range of food items and the implementation still need further clarifications. We think that this practice, which does not classify products based on a risk assessment, in fact does not fully meet the human health concerns targeted by this legislation. Therefore, we ask China to review the list of items in a more risk-based approach, and if it is possible only include items that are high-risk products. On the other hand, the regulation of the overseas importer's registration process imposes a great burden on both the exporters and the competent authorities of the exporting countries. The companies which are exporting the selected food items mentioned in the Decree 248 are expected to register by submitting necessary information. These companies might need a transition period to complete their registration with accurate information, and in some cases to update their applications. We think that

the companies' registration should be treated in a more flexible approach and might be granted for an extra time. Therefore, we ask for a grace period not less than 18 months. Türkiye believes that this aforementioned regulation seems to be restricting trade more than necessary. Therefore, Türkiye would like to ask China to review this legislation from a risk-based perspective and narrow its scope of products, in addition to extend the grace period for this regulation.

2.225. The delegation of Switzerland provided the following statement. Switzerland shares – and supports – the concerns expressed by other Members regarding decrees 248 and 249 published by the General Administration of Customs of the People's Republic of China (GACC). Switzerland supports China's objective to ensure that only safe food is imported. However, we regret that the measures still include all food categories irrespective of their risk-profile and seem to be more trade restrictive than necessary to ensure the safety of imported food products. We therefore reiterate our concerns expressed in previous meetings. Furthermore, Switzerland strongly encourages China to allow entry of all products from registered facilities until 1 July 2023. This additional time would enable facilities to accurately enter or update product information in their online registration.

2.226. The delegation of Mexico provided the following statement. The delegation of Mexico once again refers to Decree 248, notified to the Members of this Committee on 16 November 2020 in document G/TBT/N/CHN/1522, which entered into force on 1 January 2022. While efforts have begun to ensure that the registration of Mexican companies exporting to China is carried out in a satisfactory manner, we have identified that concerns remain about potential effects on international trade, since we have been made aware of recent issues in the process for the registration of Mexican companies. In this connection, we reiterate how important it is for the measures adopted by Members of this Committee to comply with the international commitments contained in the TBT Agreement. We also ask the delegation of China to provide a point of contact that may offer assistance to companies that have experienced difficulties in registering. Lastly, the delegation of Mexico thanks the delegation of China for giving its consideration to this statement.

2.227. The delegation of Chile provided the following statement. The delegation of Chile appreciates the opportunity to address this specific trade concern and would like to refer to what was said on the matter in the Committee on Technical Barriers to Trade last March.

2.228. In response, the delegation of China provided the following statement. 1. The revision of the Draft Administrative Measure for Registration of Overseas Producers of Imported Foods is based on law, the process is open and transparent, and complies with international rules and common practices. GACC has made amendments to this measure and notified to WTO, provided Members with a commenting period, fully considering Members' comments, and followed the requirement of the transitional period. 2. While aiming to strengthen food safety supervision, the measure also takes full consideration of trade facilitation. All categories of food specified in the Food Safety Law are included, among which, "official recommendation registration" is adopted for the overseas production enterprises of 18 categories of food, while "self-application by enterprises" with relatively simplified procedures is adopted for the overseas production enterprises of food other than the 18 categories.

2.229. China welcomes the suggestions for China to offer more clarifications as to the implementation of the measure. As a matter of fact, a lot of preparation works have been carried out in this direction. 3. To ensure the smooth implementation, GACC has issued the rules of interpretation, the guide for registration applications, supporting documents and forms for registration applications, and the operation manual for a registration information system. In September 2021, China contacted Members which exported food to China, informed them of the relevant requirements and procedures for the registration of overseas enterprises, and made reasonable arrangements to speed up the auditing process. As for the implementation of the rules, the GACC has been in close contact with the competent authorities of various Members and other relevant parties. GACC answered their concerns about registration through video conferences, telephone calls, emails and letters. GACC has held video-conference with 152 Members, organized training for more than 2,000 overseas enterprises through industry associations, and answered all the questions of overseas relevant parties. 4. Since the implementation of the regulations, by the end of June of 2022, more than 100 Members have provided the list of enterprises recommended for registration, a total of 73,743 overseas manufacturers engaged in 32 food categories are registered. Right now, according to our observation, the implementation of this measure is going in an ever smoother way.

2.1.3.24 India – Toys (Quality Control) Order, 2020 (IND/131); Amendment in Policy Condition No. 2(iii) to Chapter 95 of ITC (HS), 2017- Schedule-I (Import Policy) (IND/143), [G/TBT/N/IND/68](#), [G/TBT/N/IND/131](#), [G/TBT/N/IND/143](#) (ID 632⁵⁰)

2.230. The delegation of the European Union provided the following statement. As stated in previous TBT Committees, the European Union is concerned about India's Toys Quality Control Order (QCO) and in particular the certification requirements introduced by the Bureau of Indian Standards (BIS). The EU refers to its previous statement but would like to highlight that European industry continue to report the difficulties to work through the QCO. Since its adoption in 2021, the European companies are facing serious challenges especially because of the factory inspection requirement to obtain the necessary BIS marking. In order to comply with the regulatory order, the European companies have submitted the necessary applications well in time to furnish Indian authorities with the necessary information to enable factory audits by BIS auditors. However, factory audits were not performed. Only recently, the European industries are experiencing some improvements thanks to more travel possibilities for factory certifications, and we appreciate that from India. However they indicate that the QCO remains challenging and the process is still very burdensome and complex. In addition, a huge concern is related to the fact that the import policy ([G/TBT/N/IND/143](#)) is being applied on top of the QCO.

2.231. The EU would like to recall that on-site factory audits and verification testing requirement is burdensome, expensive and unnecessary. Also, without any alternative, the requirement for the QCO is inconsistent with international product safety practices. 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.

2.232. The delegation of the United States provided the following statement. The United States supports and echoes the statements made by other Members on this STC. In the last four WTO TBT Committee meetings, the United States has urged India to provide a means by which US companies can resume shipments of toys to India. We note the inability to secure factory inspections required by a Quality Control Order (QCO) is not unique to the toy industry. At the March meeting, we heard other Members report that companies in industries including chemicals, paper, and automotive face the same barrier shipping goods to India. The last shipment of toys to India by a US company was nearly two years ago and if inspections of toy factories do not begin immediately, US companies are unlikely to ship any toys to India in 2022. In light of repeated confirmations from India that toy products produced by US-based entities are not the source of safety concerns, we urge India to consider means by which US companies can comply with the QCO without further delaying US companies' exports of toys to India.

2.233. The delegation of Canada provided the following statement. As stated in previous TBT Committees, Canada continues to remain unclear regarding the objective of India's requirement that toy manufacturing sites be inspected by the Bureau of Indian Standards personnel to verify, among other things, production processes and plant layout, and to collect product samples. India has previously stated that its main concern is safety of toys and that many "foreign" toys in India failed a safety test and electrical inspections. However, Canada continues to question the necessity of inspecting toy manufacturing facilities to ensure toy safety. Could India please provide a rationale how inspecting the toy manufacturing sites is going to demonstrate that the health and safety requirement of a toy is met? And if the purpose of the factory inspection is in fact product testing, what would be India's rationale for not allowing this testing to be done by International Laboratory Accreditation Cooperation (ILAC) accredited labs? The Canadian industry continues to raise great concerns with India's compliance requirements for the Quality Control Order. Recently the industry has reported that while some factory audits are happening overseas and the shipment of toys has resumed, Indian officials are still testing at the ports of entry in addition to the testing at the factories. Could India please provide a rationale for the necessity of this double testing requirement of products?

2.234. Canada would like to reiterate that the on-site factory audits and verification testing requirement is onerous, unnecessary, and expensive. And failure to provide alternatives is inconsistent with international product safety practices such as ISO 17067. Additionally, verification and testing must be performed by a lab accredited by the Indian accreditation body, only a few of which exist outside of India. In contrast, international safety norms allow product testing to be done

⁵⁰ For previous statements follow the thread under [ID 632](#).

by any laboratory accredited to international standards by an accreditation body that is an ILAC-MLA signatory. Further, because costs of the on-site audit, including travel to and from the factory by Indian government auditors must be paid by the manufacturer, the on-site audit requirement treats domestic manufacturers more favourably than foreign ones. Canada kindly urges India to consider allowing product testing to be done in the country of manufacture by ILAC-accredited labs and to remove the requirement for factory audits overseas. Canada looks forward to working with India to ensure access to safe, high-quality toys from Canadian firms.

2.235. In response, the delegation of India provided the following statement. As per the provisions of the QCO, the products specified therein shall bear a Standard Mark under a valid licence from BIS as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. Under this Scheme, factory inspection is a mandatory requirement for the purpose of granting of licence. As per the product certification scheme of BIS, the availability of in-house testing facilities with manufacturers is required to operate a licence. However, BIS has allowed relaxations for toys manufacturers, including permitting sub-contracting of tests to BIS-recognized laboratories. As per the product-specific guidelines for toys, sub-contracting of tests other than physical, mechanical and electrical safety is allowed. Sufficient capacity for testing of toys is available in BIS laboratories and laboratories recognized by BIS under its laboratory recognition scheme (BIS LRS) for testing as per the relevant Indian Standards. Clause 12 of BIS LRS deals with the recognition of overseas laboratories. The decision regarding recognition of overseas laboratories will be taken by BIS taking into account the MRA (Mutual Recognition Agreement) with the concerned nation. Foreign inspections were on hold due to the prevalent restrictions on international travel imposed. As the COVID-19 restrictions have eased out, BIS has started carrying out inspection where confirmation for travelling of fully vaccinated BIS officers has been received. BIS has nominated officers and applicants are asked to remit the inspection charges for carrying out inspection. On receipt of inspection charges, inspections are being planned. Preliminary inspection for more than 100 applications has already been carried out. However, in some cases inspection are being delayed due to difficulty in issuance of VISA.

2.1.3.25 European Union - Non-renewal of the approval of the active substance mancozeb, [G/TBT/N/EU/712](#) (ID 627⁵¹)

2.236. The delegation of Brazil provided the following statement. Brazil would like to convey once again its concerns regarding the non-renewal of the approval of the active substance mancozeb, according to European TBT notification [G/TBT/N/EU/712](#). Mancozeb is a substance whose use is approved for many different crops by the Brazilian Health Regulatory Agency, including soy. MRLs for soybeans in Brazil are set in 0.3 mg/kg. Around 11% of the soy produced in Brazil is exported to the EU. Therefore, restrictions on mancozeb will significantly impact the income of Brazilian farmers. The availability of an alternative to mancozeb in the short to medium term is also limited by the fact that other substances of similar use have already been banned in the European market, such as chlorothalonil. Mancozeb is an important substance for the management of fungicide resistance to control soybean rust. It is used as a crop protection additive, intended to increase the effectiveness of other fungicides, minimizing resistance, and prolonging the life cycle of other molecules. In light of the insufficient transitional period granted by the EU, such crops could not have their treatments changed in time for exportation to the EU market before the entry into force of the regulation. Brazil would like to urge European authorities to consider establishing transition periods that are adequate to the production cycle of the affected crops. Brazil also respectfully asks the EU to align MRLs with limits established under the framework of Codex Alimentarius, 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.

2.237. The delegation of Colombia provided the following statement. Colombia reiterates its concern regarding the measure notified by the European Union in document [G/TBT/N/EU/712](#) of April 2020 relating to the non-renewal of the approval of the active substance mancozeb. As we have already noted, the EU has adopted measures resulting in the non-approval of the use of plant protection products, which is affecting exports from Colombia. Measures on the suspension or non-approval of the marketing of numerous active substances and the subsequent reduction of their MRLs to the minimum detection limit are being taken without any sound scientific evidence and without proof that such measures are the least trade-restrictive means of achieving an appropriate level of protection. We have already referred to the importance of this plant protection substance on previous occasions. In this connection, we would like to ask the EU to provide clarification on the relationship

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

between the notification in document [G/TBT/N/EU/712](#), on mancozeb, and the notification in document [G/TBT/N/EU/797](#), regarding the REACH regulation with respect to substances that are carcinogenic, mutagenic and toxic for reproduction. We would also like to recall that, even though in this and various other cases we have requested the EU to provide information on the deadline for the adoption of the standard and on the implementation of maximum residue limits, the EU has failed to respond to these requests.

2.238. We recall that Article 2.12 of the TBT Agreement provides that "Members shall allow a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member". In line with the above, the information available indicates that EFSA has initiated the procedure for revising MRLs for mancozeb and similar substances. In the previous Committee, the EU indicated that the scientific opinion would be published in the first half of 2022. In this regard, and taking into account that the procedure currently being followed by EFSA is different from the international public consultation process that should be followed under the TBT Agreement, we urge the EU to notify the relevant standards at a conveniently early stage and to take into due account Members' comments, in line with Article 2.9. We also request that this Committee be informed of the steps to be taken in such cases. In this case, too, producers and exporters have questions and concerns regarding inspection and control mechanisms and procedures. The EU has failed to provide clear answers on how to make carrying out foreign trade operations more predictable, on inspection mechanisms, or to demonstrate compliance with requirements. Lastly, we once again invite the EU to follow the recommendations for good regulatory practices, under which standards must be based on clear and objective information, and which promote open dialogue with stakeholders, transparency and the minimizing of market distortions.

2.239. The delegation of [Paraguay](#) provided the following statement. This concern and the non-renewal of the approval of the remaining substances were already discussed extensively both in this Committee and in the SPS Committee because of the subsequent reduction in the MRLs. Paraguay therefore refers to its previous statements and reiterates its cross-cutting concern with regard to the EU's decision not to renew the approval of these substances without a proper risk analysis and without complying with scientific principles. We draw attention to the most recent emergency authorization of this substance. As with previous emergency authorizations, the applicant country, in this case Finland, presents the same arguments as Paraguay and other Members in favour of the use of this substance: the lack of available alternatives for protection 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 can be combated effectively only using this substance. What the emergency authorization does not mention is the large number of fungi against which this fungicide is used and how prevalent most of these are in countries like Paraguay that have climatic conditions and pest-pressure levels that are very different from those in the European Union, and that these fungi can be safely and effectively controlled by substances such as mancozeb.

2.240. 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. Emergency authorizations are not intended to facilitate trade, unlike import tolerances, but we have not received answers to repeated written questions, submitted on numerous occasions, on the specific mechanisms used to ensure that products with temporary MRLs are kept within the borders of the authorizing Member and on the consistency between this authorization and the alleged concerns about the food safety impact of using these substances, in relation to which 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. The EU also mentions in its responses, such as those contained in document [G/SPS/GEN/2038](#), that 90% of emergency authorizations are granted for products approved for use in the EU, and that most of these are covered by existing MRLs, but our questions seek clarity on those that are not.

2.241. We also heard that emergency authorizations "are used only where it is necessary to do so because of a danger or threat to plant production or ecosystems which cannot be contained by any other reasonable means". We agree with this statement, but unfortunately the lowering of MRLs for this and other substances by one of the world's largest food importers leaves our producers and those of other Members without possible quick fixes like the emergency authorizations available to EU Members. 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 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 European Food Safety Authority (EFSA) is conducting on the MRLs for mancozeb, on the current status of the analysis, since an outcome was expected in the first half of this year, and on how comments submitted by Members will be taken into account. 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 granting or refusing such authorizations "is the responsibility of the EU member States". Lastly, Chair, 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.

2.242. The delegation of Australia provided the following statement. Australia recognizes the European Union's right to regulate the manufacture and use of plant protection products in agriculture to address risks unique to its settings. However, Australia reiterates its concerns about the proposed non-renewal of Mancozeb and the potential impact on maximum residues limits (MRLs) and effects this may have on trade, including wine exports to the EU. Australia notes the EU has recently made several plant protection product non-renewal decisions and subsequent changes to relevant MRLs which are impacting Australia's trade with the EU. We seek further clarification on how this decision will impact future decisions around MRLs. In particular, we understand the European Food Safety Authority (EFSA) has been reviewing the existing MRLs for dithiocarbamates, and we welcome any information on EFSA's scientific opinion, which was expected to be published in the first half of 2022. Australia notes that our competent domestic authority and Codex have determined MRLs for dithiocarbamates that ensure the continued protection of human, animal and environmental health while allowing trade to continue.

2.243. The delegation of Costa Rica provided the following statement. Costa Rica wishes to express its support for the concern raised by Paraguay, Brazil, Australia and Colombia in relation to the draft Implementing Regulation notified by the European Union, under which approval for the use of Mancozeb would not be renewed. We support the statements of the delegations that have already taken the floor.

2.244. The delegation of Chile provided the following statement. The delegation of Chile echoes what was recently presented in the room. The active substance Mancozeb is of great importance for Chilean agriculture and, given that Mancozeb does not have a replacement product of similar effectiveness and characteristics, the non-renewal of authorization by the EU is of great concern to our agricultural export sector.

2.245. The delegation of Ecuador provided the following statement. Ecuador reiterates its concern regarding the non-renewal of mancozeb. As we have already mentioned on previous occasions, this fungicide is used for many strategic crops produced in Ecuador and the region, including bananas, cocoa and broccoli. This compound is important for pest management in countries with tropical climates – like Ecuador – in which pest behaviour follows patterns that are very different from those prevailing in countries with four seasons, meaning that chemical pesticides for agricultural use that have mancozeb as their active ingredient are vital for agricultural production. I must point out that the way in which this substance is applied in banana production means that the use of mancozeb is the most effective and environmentally friendly phytosanitary control method for Black Sigatoka, bearing in mind that the latter is considered to be the most destructive disease for banana and plantain crops; it is thought to pose the highest economic risk for such crops and can cause yield losses of up to 50%. Ecuador is concerned that there are currently no approved and properly registered alternatives to this substance that are as effective as mancozeb. As a result, prohibiting the use of mancozeb – without effective alternatives – could have a very significant economic impact on small-, medium-, and large-scale producers in my country.

2.246. Ecuador urges the EU to take into consideration the relevant scientific information emanating from international specialized agencies recognized by the WTO, such as the Codex Alimentarius, which has information relating to this substance. We would like to recall that the economies of Latin American countries have not yet recovered effectively from the impact of the COVID-19 pandemic,

which has led to a reduction in the agro-export supply markets of these countries. Therefore, continuing to suspend the use of compounds solely on the basis of the precautionary principle will result in a loss of production and obstacles to the marketing of products, further affecting the already hard-hit economies of countries such as Ecuador. For these reasons, Ecuador calls on the EU to consider alternative measures that are less trade-restrictive, to identify substitute substances that would enable existing trade to continue, to base its measures on conclusive studies, not only the precautionary principle, and to establish transition periods of at least 36 months for the registration of alternative substances, in view of the current shortage of tools available to control pests.

2.247. The delegation of Uruguay provided the following statement. Mancozeb is an active substance that is authorized and widely used in a safe manner in many countries, including Uruguay, for the control of diseases and pests in various national fruit and vegetable sector products, including apples, pears and citrus fruits. It is particularly important for the control of apple and pear scab, which is the main disease affecting apple and pear production and is caused by fungus of the genus *Venturia* spp. In this connection, we support the concerns and requests raised by other delegations, particularly with respect to the possibility that, as a result of the ongoing dithiocarbamate review process, the European Union may significantly reduce the corresponding MRLs, even lowering them to the limit of determination, without having any conclusive scientific evidence that substantiates such a decision in line with the WTO SPS Agreement. We would appreciate an update of the current status of the ongoing review process of these substances, including the expected date of completion, the reasons for the apparent delay and the date on which a notification of the changes to the MRLs might be submitted to the SPS Committee. Against this backdrop, like other Members, Uruguay recalls the importance of taking due account of international standards, guidelines and recommendations and the scientific information produced by international standard-setting bodies recognized at the WTO, such as the Codex Alimentarius, and of allowing a reasonable transition period if a decision is made to change the MRLs.

2.248. The delegation of Argentina provided the following statement. Argentina maintains its general concern regarding the hazard-based approach used by the EU as regards regulating pesticides, without identification of risk, which is an unnecessary technical barrier to trade. In the case of mancozeb, this is a broad-spectrum fungicide used for growing fruits, vegetables and field crops. Although Argentina shares the EU's concern over strengthening the protection of human health and the environment, we would once again like to underline the importance of complying with Articles 2.2 and 2.4 of the TBT Agreement, which stipulate that "technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective". We are particularly concerned by the number of substances banned by the EU Commission, which 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.

2.249. In response, the delegation of the European Union provided the following statement. We have provided detailed explanations on this issue in previous TBT Committees. On 17 April 2020, the European Union notified to the TBT Committee a draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance Mancozeb, in accordance with Regulation (EC) No 1107/2009 on the placing of plant protection products on the market (the "EU Plant Protection Products Regulation").⁵² Implementing Regulation (EU) No 2087/2020⁵³ entered into force on 4 January 2021. 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 did not meet the approval criteria as outlined in Article 4 of Regulation (EC) No 1107/2009, the approval of this substance was not renewed. EU member States had to withdraw existing authorisations for plant protection products containing Mancozeb at the latest by six months from the date of entry into

⁵² 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.

⁵³ Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of the approval of the active substance mancozeb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 423, 15.12.2020, p. 50.

force of the Implementing Regulation (by 4 July 2021). Possible grace periods granted by EU member States, in line with Article 46 of Regulation 1107/2009, expired, at the latest, on 4 January 2022, after 12 months from its entry into force.

2.250. The EU would like to inform Members that EFSA has started a review of the existing Maximum Residue Levels (MRLs) for dithiocarbamates (group of substances of which Mancozeb is part). We informed Members at the last TBT Committee meeting that interested parties had been invited to actively contribute with relevant information to this MRL review through the main authorisation holder, as described in document [G/SPS/GEN/1494/Rev.1](#).⁵⁴ The EFSA scientific opinion on dithiocarbamates is expected to be published in the second half of 2022. For advice on alternatives to Mancozeb, the EU pesticides database⁵⁵ 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 (REACH⁵⁶), following the classification of the substance as CMR (carcinogenic, mutagenic or reproductive toxicant) 1A or 1B under that same Regulation.

2.1.3.26 India - Quality Control Orders for Chemical and Petrochemical Substances,
[G/TBT/N/IND/116](#), [G/TBT/N/IND/121](#), [G/TBT/N/IND/122](#), [G/TBT/N/IND/123](#),
[G/TBT/N/IND/124](#), [G/TBT/N/IND/125](#), [G/TBT/N/IND/126](#), [G/TBT/N/IND/127](#),
[G/TBT/N/IND/128](#), [G/TBT/N/IND/129](#), [G/TBT/N/IND/130](#), [G/TBT/N/IND/132](#),
[G/TBT/N/IND/133](#), [G/TBT/N/IND/134](#), [G/TBT/N/IND/135](#), [G/TBT/N/IND/136](#),
[G/TBT/N/IND/137](#), [G/TBT/N/IND/138](#), [G/TBT/N/IND/139](#), [G/TBT/N/IND/140](#),
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[G/TBT/N/IND/151](#), [G/TBT/N/IND/152](#), [G/TBT/N/IND/153](#), [G/TBT/N/IND/154](#),
[G/TBT/N/IND/175](#), [G/TBT/N/IND/176](#), [G/TBT/N/IND/177](#), [G/TBT/N/IND/186](#),
[G/TBT/N/IND/187](#), [G/TBT/N/IND/191](#), [G/TBT/N/IND/193](#), [G/TBT/N/IND/199](#),
[G/TBT/N/IND/201](#), [G/TBT/N/IND/202](#), [G/TBT/N/IND/203](#), [G/TBT/N/IND/204](#),
[G/TBT/N/IND/205](#), [G/TBT/N/IND/206](#), [G/TBT/N/IND/208](#) (ID 630⁵⁷)

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

2.252. The delegation of the United States provided the following statement. As of July 2022, India's Ministry of Chemicals and Fertilizers notified 44 Quality Control Orders (QCOs) to the WTO TBT Committee. Each QCO appears to identify substances that correspond to or fall under the 72 identified chemicals and petrochemicals for which India intends to mandate compliance to standards set by the Bureau of Indian Standards. In particular, we continue to highlight US industry's concerns regarding the Polyethylene Material for Moulding and Extrusion (Quality Control) Order, 2020 (Polyethylene QCO), notified as [G/TBT/N/IND/191](#). While we appreciate the Ministry's delay of the Polyethylene QCO's enforcement date, US industry remains concerned about the measure's labelling requirement, which mandates the marking of the smallest unit-level package of polyethylene product

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<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/SPS/GEN1494R1.pdf&Open=True>

⁵⁵ https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en

⁵⁶ 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).

⁵⁷ For previous statements follow the thread under [ID 630](#).

delivered to the customer. Under this requirement, these markings must include "designation codes" identifying an array of technical information, including a product's melting point, density, processing method, and application. Can India explain the intended objective and audience for these new labels?

2.253. We reiterate US industry's comments that other markets have neither applied such labelling requirements to polyethylene products nor experienced any perceived need for such information, given the technical knowledge of the customers involved in the commercial transaction. We remain interested in hearing how India has considered industry input on alternative, cost-effective, and mutually beneficial ways to fulfill India's regulatory objectives. How has India considered these proposed alternative options? We continue to report US industry's concern that, as proposed, requiring the labelling and affixation of information in print, with alphanumerical code unique to India, on either the polyethylene product's bag or its smallest unit-level packaging delivered to the customer will impose administrative burdens leading to inefficiencies, delays, and additional costs for exporters. We are concerned about possible confusion on the part of the Indian customer in deciphering the code as the product moves through the chain of custody, as well as confusion on the part of any third country customer to whom such labelled products might be exported to from India. Given Indian dependence on imports, particularly with regard to specialty grade resins, such labelling may disrupt Indian imports of, and access to, essential materials used by Indian health care, pharmaceutical, and other high value Indian export-critical sectors.

2.254. The delegation of the European Union provided the following statement. The European Union would like to support the delegations of the United States and Chinese Taipei. India continues to define and introduce specific standards and certification requirements for a number of products – under the umbrella of the Quality Control Orders (QCOs). The QCOs require physical audit at manufacturers' premises by an auditor of the Bureau of Indian Standards (BIS) in order for products manufactured in third countries to receive the approval for exports to India. The EU deeply regrets that India repeatedly refused to consider meaningful alternative options to foreign audits – which were suspended for over two years due to the SARS COV-2 pandemic – such as virtual audits or audits conducted by internationally recognized third agencies/entities. The EU welcomes the fact that applications for inspections are processed gradually. However, the EU would like to stress the benefits that virtual audits and recognition of laboratories outside India would have for India and its partners. It would further help BIS in reducing its backlog of pending applications. The EU would therefore like to take this opportunity to request Indian authorities to consider preparing rules for international recognition of laboratories by the BIS, as foreseen by legislation in place. This would speed up audits, and lower the cost of mandatory testing for foreign manufacturers.

2.255. The EU would like to reiterate its stance that the QCOs in question have a protectionist orientation. The increasing number of QCOs across sectors is sending worrying signals to EU industry, EU investors, and EU member States. Once these QCOs come into force, they will cause extra burden and economic cost to the EU industry that will have to undergo cumbersome procedures to obtain necessary permissions and/or licences for products already certified under established international standards. Furthermore, the foreign manufacturers have to make necessary modifications in their tooling systems for the ISI mark, which could cause temporary shutdown of some production lines. In this context, the QCOs add little value for Indian consumers, making the reason of their introduction not evident. Quality Control Orders pertain to a wide range of chemical and petrochemical products under the HS chapters 28 and 29. The EU systematically takes note of all Indian TBT notifications pertaining to Quality Control Orders (QCOs) for chemical and petrochemical substances. The EU welcomes announced delays in the entry into force of some of these QCOs. However, the EU would like to underline that some QCO notifications do not have a determined date of entry into force. For example, some Orders have a precise date of entry into force of the Order, whereas some other Orders state that the Order shall come into force on the expiry of 180 days from the date of its publication in the Official Gazette. The EU requests India to provide structured information regarding the planned time for the adoption of these measures.

2.256. Furthermore, the EU noticed that there is an increasing number of TBT-notified Indian QCOs on chemicals and petrochemicals that are not implemented. The European Union wishes to seek reasons for repeated postponement of implementation of notified measures in this sector. Given the confusion this situation creates, the EU would like to call, once more, on India to provide an updated list of chemicals and petrochemicals, which have already been implemented and of those that are yet to be implemented, together with copies of relevant Quality Control Orders. The European Union would like to recall its request for clarifications explaining the reasons for establishing India-specific Quality Control Orders when these chemical and petrochemical products already comply with

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

2.257. The delegation of Singapore provided the following statement. Singapore echoes the concerns raised by Chinese Taipei, the United States and the European Union, and we would like to reiterate our concerns expressed at the previous meetings of this Committee. Singapore remains concerned that India's Quality Control Orders for chemical and petrochemical substances could affect foreign chemical manufacturers' access to the Indian market, given the onerous requirements for industry stakeholders to comply with the new measures, some of which are not aligned with international standards. We understand that some industry players have put forth alternatives to meet the requirements of the Quality Control Orders, and we would like to respectfully request for India to positively consider these alternatives, to smoothen the operational implementation of the Quality Control Orders, and to ensure that the mandatory requirements are not too onerous and challenging for the industry to comply with. We also respectfully urge India to align its Quality Control Orders with international standards to reduce the industry's compliance costs, and to ensure that the measures imposed are not more trade-restrictive than necessary.

2.258. In response, the delegation of India provided the following statement. As per the provisions of the QCO, the products specified therein shall bear a Standard Mark under a valid licence from BIS as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. Under this Scheme, factory inspection is a mandatory requirement for the grant of licence. Licence to use the Standard Mark on a product is granted after assessing the manufacturing and testing capabilities through factory inspection of the manufacturing premises. During this visit, conformity of the product to the requirements of the relevant Indian Standard is also established through in-house factory testing or testing at a third-party testing laboratory or a combination of both. At present, there is no provision in BIS (Conformity Assessment) Regulations, 2018, to undertake virtual inspection for conformity assessment activities as an alternative. Foreign inspections were on hold due to the prevalent restrictions on international travel imposed. As the COVID-19 restrictions have eased out, BIS has started carrying out inspection where confirmation for travelling of fully vaccinated BIS officers has been received. BIS has nominated officers and applicants are asked to remit the inspection charges for carrying out inspection. On receipt of inspection charges, inspections are being planned. Preliminary inspection for more than 100 applications has already been carried out. However, in some cases inspection are being delayed due to difficulty in issuance of VISA.

2.259. In accordance with the Code of Good Practice of WTO-TBT Agreement and as a policy, BIS tries to align Indian Standards with International Standards of ISO and IEC, where available and to the extent possible, considering the specific climatic/environmental conditions and technological development in the country. Around 94% of Indian Standards, for which corresponding ISO and IEC standards are available, are harmonized with their ISO/IEC counterparts. In response to the statement of the US and Singapore, the details of QCOs and the relevant standards are available on the BIS website.⁵⁸ As regards the point made by the EU about standards being voluntary, whereas mandatory standards being technical regulations, India requests the EU to refer to India's reply in its previous statements of TBT meetings.

2.1.3.27 India - Order related to requirement of Non-GM cum GM free certificate accompanied with imported food consignment, [G/TBT/N/IND/168 \(ID 651⁵⁹\)](#)

2.260. The delegation of the European Union provided the following statement. The European Union would like to refer to its previous statements on this matter. The EU considers that the Order is disproportionate and that it creates unjustified barriers to trade, as the Indian requirement goes beyond what is necessary to achieve the stated objective and puts an additional burden and costs on EU exporters. India should explain why it considers it necessary to impose such a burden on trading partners with a high prevalence of non-GM food on their domestic market and a robust

⁵⁸ <https://standardsbis.bsbedge.com/> and <https://www.bis.gov.in/index.php/product-certification/products-under-compulsory-certification/scheme-i-mark-scheme/>

⁵⁹ For previous statements follow the thread under [ID 651](#).

regulatory regime governing the use of GMs. The EU underlines that in addition to the fact that only a limited number of the food crops referred to in the Annexure are authorized to contain GMs, there are very strict traceability and labelling requirements applicable to food that contains GMOs. These requirements allow for a strict and effective separation between non-GM and GM products, with the exception of those containing GM ingredients in a proportion of less than 0.9%, provided that the presence is adventitious or technically unavoidable. This means that the EU's tolerance limit is even stricter than that indicated by FSSAI in its clarification dated 8 February 2021, i.e. 1%.

2.261. The EU as well as India are both parties to the Cartagena Protocol on biosafety to the Convention on Biological Diversity. The EU adopted Regulation 1946/2006 on transboundary movements of genetically modified organisms. According to Article 12(2) of this Regulation, exporters of GMOs intended for direct use as food or feed or for processing must accompany their exports with a document stating that the export contains or consists of GMOs. This obligation for accompanying documentation of GMOs provides the necessary reassurance to the importers and to the authorities. Therefore, we consider that the additional certification of non-GM food is not needed and is unjustified.

2.262. The delegation of the United States provided the following statement. The United States reiterates its serious concerns with India's measure mandating "non-GM (genetically modified) origin and GM free certificates" for certain agricultural imports into India, notified on 2 September 2020, as [G/TBT/N/IND/168](#), and a later notified entry-into-force date of 1 March 2021. India has asserted that the measure is neither discriminatory nor trade restrictive because it is applied to imports from all countries, and because India and various trading partners are issuing their own certificates. The United States must stress that neither broad application nor various modes of compliance offer justification for such a trade-restricting measure; rather, they highlight the parallel issues of uneven market access and inefficiency in biosafety regulation exacerbated by the measure. We once again urge India to rescind this measure and engage with the United States and other trading partners to find a science-based, trade-facilitating alternative. The United States has previously proposed technical cooperation with the Food Safety and Standards Authority of India on numerous occasions; we once again extend this offer to work together to develop a mutually beneficial solution.

2.263. The delegation of Japan provided the following statement. Japan would like to reiterate concerns raised at previous TBT Committee meetings, regarding India's measure which requires 24 agricultural products imported to India to be accompanied by a certificate stating that they are not of genetically modified origin and do not contain genetic modification. Japan considers that this measure, having negative impact on agricultural trade between India and other WTO Members, is more trade-restrictive than necessary. 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, requiring those items to be accompanied by non-GM origin and GM free certificates is more trade-restrictive than necessary. Japan requests India to withdraw the requirement to attach certificates for foods that are properly controlled in the origin country.

2.264. The delegation of Australia provided the following statement. Australia thanks India for its ongoing engagement and cooperation regarding the use of the non-GM origin and GM free certificate, as well as India's previous responses provided in the TBT Committee. Australia shares the view that GM use in agriculture needs to be safe, and we are strong supporters of robust, risk and science-based regulation of GM. Further to Australia's previous statements on this issue, Australia reiterates that it is common international practice to maintain regulatory oversight and controls on agricultural crops subject to genetic modification. As such, requiring GM assurances on a consignment-by-consignment basis does not improve regulatory outcomes. In order to ensure that trade is not subject to unnecessary costs and additional regulatory burdens for both Australian exporters and Indian importers, Australia requests that alternate arrangements which recognize the regulatory systems in place by countries to control GM exports be implemented. Australia maintains appropriate regulation of GM-crops and is able to provide assurances of which crops are and are not subject to GM. Australia appreciates India's cooperation in agreeing to a pathway forward during FSSAI's recent visit to Australia on this matter. The agreed pathway moves this matter towards more open trade, in accordance with the principles of the recently signed Australia-India Economic Cooperation and Trade Agreement (AI-ECTA). Australia looks forward to further collaborative engagement with India on this matter.

2.265. The delegation of Paraguay provided the following statement. My delegation would like to thank the delegations of the United States and the European Union for placing this concern on today's agenda and reiterate its support for it. Several months ago now, we, together with other Members, asked India, through our representation in New Delhi, to reconsider this policy on the grounds that it is not consistent with its obligations to this Organization. We reiterate that we continue to await a response from India to our concerns and requests, and hope to have an update as soon as possible.

2.266. The delegation of Canada provided the following statement. Canada would like to reiterate our concerns regarding the implementation of India's August 2020 Order, which mandates that a non-genetically modified or GM-free certificate accompany imported consignments of 24 imported food products. Canada remains concerned that India's Order will disproportionately impact the ability of GM-producing countries to export to India and unnecessarily restrict international trade; we have raised these concerns during previous TBT Committee meetings as well as at the SPS Committee and in the Council for Trade in Goods. While Canada welcomes India's recent decision to accept Canada's non-GM attestation on bean exports, this is only one of the 24 commodities impacted by the Order. We continue to have concerns with the potential trade impact on other crops covered by the Order. Canada continues to request that India to consider a less burdensome approach to meeting the Order's stated food safety goals. As previously stated, the robust, science-based regulatory frameworks developed in countries around the world, including in Canada, should be considered as they assess the risks of GM food products prior to their approval and commercialization. These products are authorized for commercialization only once they have received appropriate safety approvals.

2.267. Until a satisfactory solution is found and to minimize potential trade disruptions, Canada again requests that India suspend the implementation of this measure and that trade be permitted to continue without a certificate requirement. This would allow for further engagement with Members to discuss and consider an alternate, less trade-restrictive measure to meet India's intended objective. Finally, given the Order's stated objective "to ensure the safety and wholesomeness of articles of food imported into India", Canada once again reiterates its request that India notify the non-GM Order to the SPS Committee. We remain available and would welcome the opportunity to pursue further discussions on this issue in a bilateral setting.

2.268. The delegation of Uruguay provided the following statement. Uruguay recognizes India's right to take measures to guarantee food safety and the health of its population. However, Uruguay wishes to recall that there is consensus internationally that genetically modified products, approved by exporting countries on the basis of Codex recommendations in relation to the risk assessment methodology, are equivalent to their conventional counterparts. Therefore, in Uruguay's view, there would not appear to be any technical justification for the implementation of the certification measure proposed by India, taking into account the legitimate objective, cited in the Order in question, of ensuring the safety and wholesomeness of imported food. In the light of this objective, we wish to ask why the delegation of India still has not notified this measure to this Organization's SPS Committee, as it has to the TBT Committee. Uruguay wishes to stress that it is important for Members to establish measures based on scientific principles and, in particular, to apply such measures with the objective of minimizing the negative trade effects, in line with the provisions of the TBT and SPS agreements. Lastly, like Paraguay, we wish to reiterate that we continue to await a reply to the joint note submitted by a number of countries, including Uruguay, in New Delhi in January 2021, a year and a half ago.

2.269. The delegation of New Zealand provided the following statement. New Zealand acknowledges and supports measures that focus on legitimate objectives, including the protection of human health and safety. New Zealand remains concerned that India's requirements regarding non-GM certification for specific foods is imposing further restrictions and costs on existing trade in goods covered by the measure. New Zealand continues to encourage India to accept a country-wide assurance as an alternative to consignment-based non-GM certification.

2.270. The delegation of Argentina provided the following statement. We would like to thank the EU and the US for including this specific trade concern on the Committee's agenda and request that Argentina's support for it be put on record. With regard to this measure, Argentina reiterates its concern and again stresses that the measure has no scientific explanation to support it. Argentina is concerned that this requirement would set a precedent for other products or even their derivatives to be included in the future, and that this requirement could be a barrier to trade. We therefore request India to consider reviewing this measure.

2.271. In response, the delegation of India provided the following statement. The requirement to regulate the import of GM food is not new. It already exists under the Environment Protection Act (1986). This requirement is already notified to WTO and is neither discriminatory nor trade restrictive as it is uniformly applicable to imports from all countries. The FSSAI order on 21 August 2020 made it mandatory for the 24 identified commodities to be accompanied with a Non-GMO origin cum GM-free certificate issued by a competent national authority of the exporting country. On similar lines, India has issued such certificates for its exports to other countries. The Government of India has authorized Export Inspection Council (EIC) as the nodal agency for issuing Non-GMO certificates for export consignments. EIC is issuing more than 9,000 Non-GMO certificates for the export of primary food crops as well as processed food products for export to several countries. It may be noted that the said Order is not trade restrictive as the consignments of the identified commodities are already being accepted for import to India along with the Non-GM origin cum GM-Free Certificate in the prescribed format. Section 7 of The Environment Protection Act (1986) and its Rules prescribes that no person shall import or export genetically engineered organisms/substances or cells except with the Genetic Engineering Approval Committee (GEAC). DGFT Notification No.2 (RE-2006)/2004-2009 dated 7 April 2006 on "Import of Genetically Modified Food" states that import of GMOs/LMOs for Food will be governed by the provisions of the Environment Protection Act, 1986 and Rules 1989. GEAC has so far not approved any of the crop varieties of Genetically Modified/Engineered origin listed on the Order mentioned above. The requirement of a Non-GM certificate for import of 24 food crops is an assurance required from Competent Authorities of exporting countries that the food crops exported to India are of Non-GM origin and GM-free. As of date, several trade partners like the USA, UK, Australia, Canada, Türkiye, Iran, China, EU, including Italy, Germany, France and Thailand, are already providing requisite certificates.

2.1.3.28 Kingdom of Saudi Arabia - Technical Regulation for limiting and restricting hazardous materials in electrical and electronic equipment, [G/TBT/N/SAU/1166](#) (ID 666⁶⁰)

2.272. The delegation of China provided the following statement. We support Saudi Arabia's restrictions on hazardous substances in electrical and electronic products, however, after careful study, the draft regulations proposed by Saudi Arabia are inconsistent with international practice. especially the provisions on conformity assessment procedures create unnecessary obstacles, China would like to raise concerns as follows. 1. According to Article 5 and Appendix 3, suppliers need to obtain a conformity certificate (Type 1a) from an approved certification organization. However, according to the practice of global implementation of RoHS, it is usually the manufacturer to prepare technical documents for products to prove their conformity in the light of international standard IEC 63000 and to provide a conformity declaration. In response to the testing report requirements described in the notified regulations, a full product testing report means that companies need to test every single component, at the homogenous material level, which is extremely time-consuming and resource-consuming. On the contrary, the international standard IEC 63000 allows manufacturers to work with their supply chains to compile technical documentation as evidence of compliance, which is a common procedure or method for restrictions on hazardous substances implemented and accepted by the international community. Therefore, it is recommended that the conformity assessment procedures would comply with current global practices, and the preparation of technical documents would comply with IEC 63000.

2.273. 2. The applicable scope of the regulations of this notification is electrical and electronic equipment, but the batteries and accumulators (HS code 8506 and 8507) are included in Appendix. Based on the differences between batteries and electrical and electronic equipment, and with reference to the current management and control across the world, it is recommended that this regulation excludes batteries and accumulators from the scope of this regulation. 3. Regarding the allowable percentage of hazardous substances in electrical and electronic equipment or devices specified in the Appendix, the percentage of many materials (copper alloys, steel alloys, and high-temperature solders, etc.) is currently unable to meet the limitation set in regulations due to immature technology or no alternative materials. It is recommended to refer to Annex III of the EU Directive 2011/65/EU (RoHS) or the "Exemption List for Application of Restricted Substances in the Compliance Management Catalogue" issued by the Ministry of Industry and Information Technology of China to clarify the corresponding exemptions.

⁶⁰ For previous statements follow the thread under [ID 666](#).

2.274. The delegation of the United States provided the following statement. The United States thanks Saudi Arabia for its continued engagement on the "Technical Regulation for the Restrictions of Hazardous Substances (RoHS)." We were pleased to receive the June response from Saudi Arabia's Standards Organization (SASO) regarding our concerns to the Kingdom's RoHS regulation. In its response SASO expressed its intent to accept a Supplier's Declaration of Conformity (SDoC) as it begins to implement the RoHS regulation. As we understand it now, the decision to accept SDoCs under the RoHS regulation aligns the Kingdom's conformity assessment requirements under the regulation with those of other WTO Members and should resolve a potentially significant trade barrier. We thank the Kingdom for its fulsome engagement - with governments and with private sector stakeholders - and for taking our comments into account. We also note and appreciate the decision to provide a staged implementation of the regulation, based on product category, which began earlier this month. Given the broad scope of the measure, and a significant change in conformity assessment requirements as the measure is taking effect, we look forward to seeing the revised regulation and guidance as soon as possible. We may have additional questions and comments for SASO as those revised regulations are published and the requirements are implemented. We thank SASO, in advance, for its continued engagement, and we appreciate SASO's willingness to take our comments into account.

2.275. The delegation of the United Kingdom provided the following statement. The United Kingdom thanks Saudi Arabia for the constructive engagement on notification [G/TBT/N/SAU/1166](#), which sets out its technical requirements for the restriction of hazardous substances in electrical and electronic equipment. We would like to thank the Saudi Standards, Metrology, and Quality Organization (SASO) for holding the workshop with stakeholders in May and for providing a written response to our subsequent questions. The United Kingdom notes that, according to this written response, Saudi Arabian authorities will now accept a Supplier's Declaration of Conformity. The United Kingdom welcomes this change. If implemented as described, acceptance of Supplier's Declaration of Conformity will be consistent with common international practice. It will also provide businesses with a less burdensome means of demonstrating compliance with the technical regulation than third-party conformity certification. Where several regulations that require a Declaration of Conformity apply to a product, it is common international practice that the manufacturer is allowed to merge all these declarations into one document. We would be grateful if Saudi Arabia could confirm that Saudi Arabian authorities will accept a single Declaration of Conformity to cover all relevant legislation.

2.276. The United Kingdom appreciates that SASO stated in their written response that they will amend the implementation guidelines to reflect the acceptance of a Supplier's Declaration of Conformity. We would encourage Saudi Arabia to also amend the technical regulation itself to reflect this change, and notify the updated text of the technical regulation and the amended guidelines to the TBT Committee in an addendum notification. We would like to reiterate our thanks to Saudi Arabia for delaying the implementation date and for developing guidelines to support industry in complying with the measure. We will contact you if we have any further questions. The United Kingdom thanks Saudi Arabia for their continued productive engagement, and we look forward to future correspondence with Saudi Arabia on this matter.

2.277. The delegation of the European Union provided the following statement. The European Union thanks Saudi Arabia for its availability to discuss this issue bilaterally. The EU appreciated the postponement of the application of the Technical Regulation for Restriction of Hazardous Substances (Saudi RoHS) by six months (until 5 July 2022) and the phased implementation dates for product categories notified to the TBT Committee on 10 February 2022 ([G/TBT/N/SAU/1166/Add.1](#)). The practical implementation of the Saudi RoHS Regulation will be followed with interest. The EU welcomes the Guidance document to industry on the Saudi RoHS and would appreciate information on any further plans to involve trade partners and stakeholders in the practical implementation of the Regulation, as well as eventual measures to monitor its compliance. As regards conformity assessment, the EU welcomes the confirmation, in the bilateral meeting, that Saudi Arabia has decided to accept Supplier's Declaration of Conformity by the manufacturer or its authorized representative for products included under the scope of the Saudi RoHS, as it is done in common international and EU practice. The EU stresses that this is an important development and invites Saudi Arabia to notify the relevant measure to the TBT Committee and to update the Guidance document to industry accordingly.

2.278. The EU understands that Saudi Arabia will introduce expiry dates for the items included in the list of substances excluded from the application of hazardous material limits (Annex 1a to the Technical Regulation). Saudi Arabia will introduce, in addition, mechanisms to amend the list of

substances excluded from the application of hazardous material limits, as well as the list of restricted substances (Annex 1b to the Technical Regulation), for their alignment to the EU RoHS. The EU welcomes those developments. The EU highlights the importance of promoting GCC harmonized requirements and their uniform application and the mutual recognition of conformity assessment results in the region, instead of the proliferation of separated national RoHS regulations. In this context, we would like to enquire about the timeframe for adoption of the draft GCC Technical Regulations for the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment, notified to the TBT Committee in March 2018 ([G/TBT/N/SAU/1048](#)). The EU understands that, once adopted, the GCC RoHS Technical Regulations will replace national RoHS provisions in the region. The European Union welcomes any workshop or information session with stakeholders and remains available to further discuss technical issues bilaterally.

2.279. The delegation of [Switzerland](#) provided the following statement. Switzerland would like to support the interventions made by previous speakers on the Kingdom of Saudi Arabia's Technical Regulation for limiting and restricting hazardous materials in electrical and electronic equipment. We reiterate our concerns from previous meetings of the WTO TBT Committee and remain concerned that these requirements may have a negative impact on trade for a wide range of products. Switzerland appreciates the Kingdom of Saudi Arabia's recent efforts to allow for a smooth implementation of the measures, such as the postponement of the application of the measures, the phased implementation, the issuance of a guidance document or the useful engagement with interested Members and stakeholders. We also understand the Kingdom of Saudi Arabia's legitimate objective to protect the environment and public health and safety. Switzerland encourages the Kingdom of Saudi Arabia to ensure that these requirements do not create unnecessary obstacles to trade. We would in particular welcome any clarifications as to the acceptance of supplier's declaration of conformity which is common international practice. Furthermore, the implementation of the requirements still lead to uncertainties for manufacturers and conformity assessment bodies, such as regarding the scope or the process for testing the products or critical components. Finally, we encourage the Kingdom of Saudi Arabia to continue engaging with interested stakeholders and providing clear and transparent guidelines in order to support the implementation of these requirements.

2.280. In response, the delegation of the [Kingdom of Saudi Arabia](#) provided the following statement. Saudi Arabia would like to express appreciation for the concerns addressed by China, the United States, the United Kingdom, the European Union and Switzerland for their valuable comments on the Technical Regulation for Restriction of Hazardous Substances. The Saudi Technical Regulations are developed in line with international practices and TBT good regulatory practices (GRP). As far as conformity assessment procedures for products included in the scope of the RoHS Technical Regulation, we would like to inform you that a supplier declaration "Self-Declaration" of conformity for products supplied either by the manufacturer or the legal representative of the manufacturer will be accepted, and the competent authority in Saudi Arabia is in the process of publishing this decision. Finally, Saudi Arabia is always pleased to engage in bilateral discussions through conducting workshops and meetings to clarify the regulations and receive feedback and enquiries, which will be revised and considered.

[2.1.3.29 India – Draft Food Safety and Standards \(Import\) Amendment Regulation, 2020, G/TBT/N/IND/180 \(ID 667⁶¹\)](#)

2.281. The delegation of [Mexico](#) provided the following statement. The delegation of Mexico refers to its statement at the previous meeting of this Committee in March 2022 on the draft Food Safety and Standards (Import) Amendment Regulation, notified by the Government of India to the Members of this Committee on 25 November 2020 in document [G/TBT/N/IND/180](#). During the meeting in March, the delegation of India indicated that it would publish the detailed guides for the registration of companies, and will allow enough time for compliance with the measure. However, as things stand, we do not have any more information on the development of the measure or the setting of a date of entry into force. We would therefore be grateful if any updated information in this regard could be shared with us. We also reiterate the great importance of this measure for Mexico's industry and Government, as well as our interest in being able to follow it up in a timely manner. The delegation of Mexico thanks the delegation of India for giving its consideration to this statement.

⁶¹ For previous statements follow the thread under [ID 667](#).

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

2.283. The delegation of the [United States](#) provided the following statement. The United States remains concerned with India's draft measure, notified to the WTO TBT Committee as [G/TBT/N/IND/180](#). As the United States has noted in previous TBT Committee meetings, this draft regulation leaves many unanswered questions for foreign food manufacturing facilities, competent authorities, and other stakeholders. The draft regulation states that India may identify categories of "risk" for food products "from time to time... for which inspection or audit of foreign food manufacturing facilities producing such categories of foods shall be mandatory." We are concerned about the lack of detail regarding the scope of this proposed technical regulation and the scientific and technical information India will use to determine the specific "risk" for food product categories. We again ask that India please provide further information on this measure and its plan for implementation.

2.284. The delegation of [Japan](#) provided the following statement. Japan shares the concerns with other Members on India's introduced amendment regulation on food safety and standards. The regulation would impose additional burdens on business operators who plan to export food products to India. However, there are many unclear points yet to be explained by India including definitions of "food manufacturing facility", scope of "food" subject to the regulation, and the registration procedure for facilities inspection and audit. Japan requests India to submit TBT and SPS notifications and provide WTO Members with the opportunity to comment on the detailed regulation regarding the scope of food, facilities registration procedure, and so forth. Japan urges India to sincerely address Member countries' concerns and comments to ensure the new rule does not create unnecessary trade barriers.

2.285. The delegation of [Australia](#) provided the following statement. Australia recognizes the right of the Indian Government to take measures necessary to protect public health. Australia thanks India for their engagement on this issue between the Food Safety and Standards Authority of India (FSSAI) and the Department of Agriculture, Fisheries and Forestry (DAFF), including with FSSAI officials on their recent visit to Australia. FSSAI has previously advised that the proposed regulations will not apply to all food establishments. FSSAI also advised that requirements will only apply to manufacturers of specific commodities based on a history of non-compliance detected at the border. Australia would welcome written confirmation of this advice from FSSAI. Australia respectfully recommends the regulation be amended to clarify the categories of food included. The proposed measures should be linked to the risks posed by the imported food and aligned with Codex international food standards, guidelines and codes of practices. Australia believes that food standards should be grounded in sound scientific and risk-based principles. Australia is happy to work with India to support a more risk-based approach to food safety and looks forward to further engagement on this proposed regulation.

2.286. The delegation of [Canada](#) provided the following statement. Canada would like to reiterate concerns raised at previous TBT Committee meetings regarding India's draft amendment to its Food Safety Standards (Import) Amendment Regulation pertaining to the registration, inspection and/or

audit of foreign food manufacturing facilities producing food products destined for India. While Canada recognizes India's right to take necessary measures to protect public health and safety, a number of elements contained in India's proposed amendments remain ambiguous. As previously stated, it is unclear what criteria would be used to determine the level of risk for food products imported into India, what circumstances would instigate an audit or an inspection of a foreign manufacturing facility or, how such actions will be taken given the ongoing travel restrictions resulting from the pandemic. In addition, Canada remains concerned with the measure's target commodities, source-countries, implementation plan, audit rates, compliance actions and appeals. We are of the view that India's approach in these areas could create unnecessary obstacles to trade. Canada notes that India has yet to respond to comments submitted to India's Enquiry Point on 21 January 2021. We would appreciate if India could provide an update as to when it expects to provide the requested details. In closing, Canada recalls its request to India to notify these amendments to the SPS Committee given that India's proposed regulation covers food safety measures aimed at protecting human health and safety.

2.287. The delegation of New Zealand provided the following statement. New Zealand acknowledges and supports measures that focus on legitimate objectives, including the protection of human health and safety. However, New Zealand would like to understand more about the intentions of the proposed requirements in relation to the proposed requirements in relation to the registration and auditing of foreign food manufacturing premises, particularly around why this is a requirement for foreign manufacturers only. New Zealand would appreciate clarification on the full scope of products to which this measure applies. We also request further detail regarding how the measure will be implemented, including what timeframe will be established to ensure exporters have adequate notice to comply. We note that, without further detail, these requirements generate uncertainty for manufacturers and exporters.

2.288. The delegation of Argentina provided the following statement. We would like to thank Mexico, the EU and the US for including this specific trade concern on the Committee's agenda and request that Argentina's support be put on record. We would like to point out that Argentina has submitted timely written queries to the Indian Focal Point and is still awaiting a response. It is worth mentioning that the publication of the draft regulation has prompted Argentine stakeholders to engage in continuous consultations as to its scope, without there being any official response so far, which creates uncertainty for our exporters. Argentina's Agro-Industrial Attaché Office in India held a meeting with the Director of the FSSAI in New Delhi in March this year and we discussed this regulation. The response that we received was that the implementation of the regulation was still under review, as comments had been received from all stakeholders. The FSSAI also made it clear to Argentine officials in Delhi that the implementation of the measure would be communicated well in advance. However, this was a bilateral conversation. There was no written communication of any kind regarding all the queries that Argentina formally submitted in writing. We therefore urge India to submit responses to our queries and to provide notice of the measure in time for comment.

2.289. In response, the delegation of India provided the following statement. Based on the intension to determine the compliance status of foreign food manufacturing facilities with the FSSR requirements and food standards, the FSSAI came up with the regulations named FSS (Imports) First Amendment Regulations, 2021, regarding registration and inspection of Foreign Food manufacturing facilities intended for export to India. As prescribed under the said regulations, Food Authority may, based on the risk associated, specify the categories of food products and accordingly, Foreign Food manufacturing facilities falling under such categories and desirous to export such article of food to India shall register with the Food Authority before exporting to India. However, the detailed guidelines/SOP including the scope of this regulations is under consideration. Therefore, in pursuance of the said regulations, FSSAI is in process of making such guidelines that would include procedural information and guidance for the foreign food manufacturers to comply with the said regulations. Moreover, once the SOP will be finalized the same will be separately published, and sufficient time considering the request for implementation shall be provided for the compliance purpose.

2.1.3.30 India - Pneumatic tyres and tubes for automotive vehicles, [G/TBT/N/IND/20](#), [G/TBT/N/IND/20/Add.1](#), [G/TBT/N/IND/40](#), [G/TBT/N/IND/40/Rev.1](#) (ID 133⁶²)

2.290. The delegation of [Indonesia](#) provided the following statement. The Indonesian Government is extending our gratitude to India for responding to the concerns conveyed by Indonesia regarding the policy of import restrictions on tyre products at the TBT Committee meeting in March 2022. However, Indonesia regrets that until now it has not found an adequate solution to overcome these problems. Indonesia is fully aware that India has imposed import restrictions on tyre products with certain types and size categories that can be produced by tyre manufacturers in India. This policy was implemented shortly after India imposed a temporary import ban on tyre products to India for a period of 6 months as stated in notification no. 12/2015-2020 dated 12 June 2020, regarding Changes in Tyre Import Policy. The implementation of this policy has the potential to hamper tyre exports to India considering that the choice of tyre products that can be exported is very limited and even has the potential to eliminate market access for imported tyre products given the various types and sizes of tyres produced by India as one of the world's main producers.

2.291. Although there are no official provisions governing the restrictions on the import of these tyres, importers are required to make a separate statement by electronic mail regarding import restrictions for certain types and categories of tyre sizes that can be produced domestically, where violations of this will be imposed criminal sanctions based on the FTDR Act 1992. In addition, Indonesia sees discriminatory treatment in the application of the said policy, where the policy is applied selectively by targeting certain Member countries that have the potential to become competitors and interfere with market access for domestic tyre products and have de facto hampered product exports Indonesian tyres. In addition to this, we also intend to ask for further clarification regarding the application of a royalty policy or marking fee on tyre products that use the IS Mark. Indonesia is of the view that the imposition of the IS Mark marking fee on tyre products to be exported to third countries has the potential to burden businesses and create unnecessary trade barriers to international trade. The imposition of such marking fees does not have a valid justification and has no relation to the protection of human health, safety or prevention of fraudulent practices. Indonesia perceives that the implementation of these two policies is not in line with the principle of non-discrimination and has the potential to create unnecessary barriers to international trade as stipulated in Article 2.1 and Article 2.2 of the TBT Agreement. In this regard, Indonesia hopes that India can provide further clarification on these two issues and asks India to review or cancel the policy to ensure its conformity with the applicable provisions of the WTO TBT Agreement.

2.292. In response, the delegation of [India](#) provided the following statement. The comments related to the import licensing measures have been already addressed in the Committee on Import Licensing, Committee on Market Access and also in the Council for Trade in Goods. The conformity assessment activities of BIS with respect to product certification are as per Scheme-I of the BIS (Conformity Assessment) Regulations, 2018. As informed earlier on the same concern, the marking fee is uniformly applicable to all manufacturers, domestic or foreign as per the provisions of this scheme. The marking fee is charged for covering the cost applicable to BIS in carrying out the conformity assessment-related works, which includes administrative overheads, cost of surveillance including purchase of market samples and testing charges of the samples drawn from factory/market.

2.1.3.31 China - Regulations for the Supervision and Administration of Medical Devices (Order No. 650 of the State Council), [G/TBT/N/CHN/1022](#), [G/TBT/N/CHN/1023](#), [G/TBT/N/CHN/1024](#), [G/TBT/N/CHN/1025](#), [G/TBT/N/CHN/1026](#), [G/TBT/N/CHN/1029](#), [G/TBT/N/CHN/1313](#) (ID 428⁶³)

2.293. The delegation of the [Republic of Korea](#) provided the following statement. The Republic of Korea recognizes China's efforts to protect the health of its people by enhancing the efficiency of supervision and management of medical devices life cycle, and strengthening corporate responsibility through the Regulations for the Supervision and Administration of Medical Devices. Companies exporting medical devices to China are required to submit a test report issued by a "qualified testing laboratory" in order to undergo marketing authorization under the aforementioned Regulations. However, it remains unclear what the specific definition or scope of "qualified testing laboratories" means under the Medical Devices Regulations. This is the same issue Korea raised at

⁶² For previous statements follow the thread under [ID 133](#).

⁶³ For previous statements follow the thread under [ID 428](#).

the previous TBT Committee meetings, and in its 2022 March TBT meeting response, China provided an explanation of article 75 of the Regulations. As regards to China's response, we request further explanation of what "inspection institutions recognized by the certification, accreditation and drug authorities" mean. Korea recommends China to include "internationally accredited testing laboratories" that are equipped with the appropriate facilities and manpower in accordance with relevant international standards and regulations as "qualified testing laboratories." We view that our request is in line with China's intention to promote innovation in its domestic medical device industry by simplifying China's pre-market review process to enable novel high-quality medical devices to enter its market in a timely manner. Therefore, we request that "internationally accredited testing laboratories" be included in China's definition of "qualified testing laboratories."

2.294. In response, the delegation of China provided the following statement. China regrets that Korea did not make its statements on this topic available in parallel with the meeting and here I would like to make a brief response. The newly revised Regulations on the Supervision and Administration of Medical Devices came into effect on 1 June 2021. According to article 75 of the Regulations, only the inspection institutions recognized by the certification, accreditation, and drug authorities can carry out the inspection of medical devices. Therefore, if Korea wishes to carry out medical device testing, overseas laboratories can contact the above-mentioned competent authorities.

2.1.3.32 India - Mandatory Certification for Steel Products, [G/TBT/N/IND/32](#), [G/TBT/N/IND/32/Add.1](#), [G/TBT/N/IND/32/Add.2](#), [G/TBT/N/IND/32/Add.3](#) (ID 224⁶⁴)

2.295. The delegation of The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu provided the following statement. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu appreciates India for explaining its on-site inspection measures at the previous meeting in March 2022. However, we remain concerned about the application procedures of IS 17404:2020 (electrogalvanized hot rolled and cold reduced carbon steel sheets and strips) certification under the Steel and Steel Products (Quality Control) Order, 2020. Firstly, India is our fourth largest exporting market of the products concerned. The annual export trade volume amounted to more than 3 million US dollars in 2020 and 2021. Since IS 17404:2020 came into force, our companies have faced difficulties in receiving on-site inspection by BIS officials due to ongoing impact of COVID-19 and its associated quarantine policies. The export value sharply declined to USD 215,000 dollars in the first half of this year. It seriously hampered India from importing high quality steel and steel products from our companies and impaired bilateral trade. We strongly suggest that India implement alternative measures during the pandemic, such as accepting test reports and inspection reports from other WTO Members or accept remote factory inspection. Secondly, on-site factory visit/inspection is a costly requirement, which may cause unnecessary trade burden to manufacturers outside of India. We would like to draw India's attention to the trend of the adoption of digital technologies to accelerate the certification process and suggest that India accept remote/virtual inspection as one of the conformity assessment measures.

2.296. The delegation of the European Union provided the following statement. The EU would like to support the delegation of Chinese Taipei. India continues to define and introduce specific standards and certification requirements for a number of products – under the umbrella of the Quality Control Orders (QCOs). The QCOs require physical audit at manufacturers' premises by an auditor of the Bureau of Indian Standards (BIS) in order for products manufactured in third countries to receive the approval for exports to India. The EU deeply regrets that India repeatedly refused to consider meaningful alternative options to foreign audits – which were suspended for over two years due to the SARS COV-2 pandemic – such as virtual audits or audits conducted by internationally recognized third agencies/entities. The EU welcomes the fact that applications for inspections are processed gradually. However, the EU would like to stress the benefits that virtual audits and recognition of laboratories outside India would have for India and its partners. The EU would therefore like to take this opportunity to request Indian authorities to consider preparing rules for international recognition of laboratories by the BIS, as foreseen by legislation in place. This would speed-up audits, and lower the cost of mandatory testing for foreign manufacturers.

2.297. The EU would like to reiterate its stance that the QCOs in question have a protectionist orientation. The increasing number of QCOs across sectors is sending worrying signals to EU industry, EU investors, and EU member States. Once these QCOs come into force, they will cause

⁶⁴ For previous statements follow the thread under [ID 224](#).

extra burden and economic cost to the EU industry that will have to undergo cumbersome procedures to obtain necessary permissions and/or licences for products already certified under established international standards. Furthermore, the foreign manufacturers have to make necessary modifications in their tooling systems for the ISI mark, which could cause temporary shutdown of some production lines. In this context, the QCOs add little value for Indian consumers, making the reason of their introduction not evident. The Steel and Steel Products (Quality Control) Order, 2020 targets 145 steel or steel products and seven goods and articles. Majority of the steel products are already under the QCOs. However, given the regular extensions for some steel and steel products, it remains unclear to the EU, on the exact number of steel products, which are already under the mandatory certification and those, which are still outside the purview of the QCO. The EU would appreciate, if India could provide an updated list of steel and steel products for which the QCOs are in force, together with the list of steel products for which the implementation of QCOs has been deferred. The EU would also like to know whether India plans to further expand the scope of the Steel and Steel Products (Quality Control) Order of December 2020. Finally, does India plan to accept steel and steel products of foreign manufacturers produced in line with international standards, such as ISO, and prune the list of steel and steel products falling under the QCOs?

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

2.299. Mandatory BIS certification for steel products is enforced through notification of QCOs to ensure that the quality of steel being manufactured by domestic producers or imported in the country is as per the Indian standards. The implementation of QCOs ensures the availability of quality steel and steel products to the end-users. It saves the Indian consumers from dumping of spurious and defective steel and steel products. Members are aware that the WTO recognizes the Member's right to implement measures to achieve legitimate policy objectives, such as protecting human health and safety, protecting the environment, preventing unfair trade practices, or national security. The technical regulations / QCOs on steel and steel products have been issued based on such policy objectives. Hence QCOs notified by the government are not trade restrictive but necessary to fulfill a legitimate objective. As far as possible date of enforcement of QCOs is not extended from the first date of enforcement. However, due to exceptional cases, if there are any specific requests for extension, they are examined on merit.

2.300. Foreign inspections were on hold due to the prevalent restrictions on international travel imposed. As the COVID-19 restrictions have eased out, BIS has started carrying out inspection where confirmation for travelling of fully vaccinated BIS officers has been received. BIS has nominated officers and applicants are asked to remit the inspection charges for carrying out inspection. On receipt of inspection charges, inspections are being planned. Preliminary inspection for more than 100 applications have already been carried out. However, in some cases inspections are being delayed due to difficulty in issuance of visa.

2.1.3.33 China - Encryption Law of the People's Republic of China by the Office of State Commercial Cryptography Administration (OSCCA) (ID 534⁶⁵)

2.301. The delegation of [Japan](#) provided the following statement. Japan continues to have concerns regarding China's Encryption Law that entered into force on 1 January 2020 and would like to refer to the previous statement we made at the last TBT Committee in March 2022. Japan would like to

⁶⁵ For previous statements follow the thread under [ID 534](#).

request that China's regulation not hamper the activities of foreign companies or market access to China.

2.302. The delegation of the European Union provided the following statement. The EU would like to reiterate its concern relating to the Cryptography Law that came into force on 1 January 2020. The EU remains concerned about the wide scope of the law, in conjunction with the lack of clarity of a number of foundational concepts as well as the administrative procedures described in the text. These factors have already negatively impacted business confidence. The EU also notes, with concern, that the new law does not recognize China's previous commitment made in 2000 that the cryptography-related regulation would only apply to products whose core function is that of providing encryption – the so-called "Year 2000 Clarification" by the State Cryptography Administration (SCA). The EU calls on China to ensure that legal and regulatory requirements are based on a non-discriminatory basis, do not favour specific technologies, do not limit market access and do not lead to a forced transfer of intellectual property. The EU urges China to guarantee the possibility for foreign invested enterprises (FIEs) to participate on an equal footing with domestic companies in the production, research, development and sale of cryptography products on its market, including participation by chipmakers in standardization bodies, including working group 3 of the TC260 and the SCA's own Cryptography Industry Standardisation Technical Committee (CISTC). The EU requests that applications to these bodies be replied to in a timely manner.

2.303. The delegation of the United States provided the following statement. The United States refers to its statement on the Cybersecurity Law and supports other Members' interventions.

2.304. The delegation of Canada provided the following statement. Canada reiterates the following points from previous meetings of the Committee: China's response to Canada's written comments on China's State draft of Cryptography Administration's cryptography regulations, which Canada provided in September 2020; further clarity, transparency and predictability in China's regulations and laws related to Encryption and Cryptography, including the definition of terms; clarification that international standards will be used; and further precision on the measures' scope; and China's notification of the draft regulations to this Committee.

2.305. In response, the delegation of China provided the following statement. The Law on Cryptography was enforced on 1 January 2020. It clearly stipulates that government agencies shall follow the principle of non-discrimination, and treat all 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 based on voluntary principles and commercial rules in the process of foreign investment. Administrative agencies and their staff are prohibited to force any transfer of commercial cryptography technology by means of administration.

2.1.3.34 European Union - Regulation (EC) No 1272/2008 (CLP Regulation), G/TBT/N/EU/629, G/TBT/N/EU/826 (ID 539⁶⁶)

2.306. The delegation of Brazil provided the following statement. In August 2021, the European Union notified a draft regulation proposing changes to Part 3 of Annex VI of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures (CLP), which introduce a stricter classification of reproductive toxicity to 2-ethylhexanoic acid (2-EHA) from Repr. 2 to Repr. 1B. The reevaluation process was initiated in 2014, when ECHA requested new studies to be carried out, specifically an Extended One-Generation Reproductive Toxicity Study (EOGRTS). A Substance evaluation (SeV) process was then carried on by Spain, which recommended maintaining the previous classification of reproductive toxicity (Repr.2, H361d). At the time, the only modification suggested was the introduction of an explanatory note, which clarified the fundamentals of the classification in question. The competent authorities then opened a public consultation for the submission of comments on the dossier resulting from the SeV and additional information by authorities of other member States and members of the private sector. During this period, Germany and France submitted a reclassification proposal to Repr. 1B, based on analysis of analogy (also called "read-across") with the substance valproic acid.

2.307. The use of read-across relies on the assumption that, due to the presence of similar chemical aspects, the substances in question will have similar effects when exposed to the same tests, and

⁶⁶ For previous statements follow the thread under [ID 539](#).

thus, will reveal the same toxicity. According to our private sector, this does not seem to be the case. The reproductive toxicity studies specific to 2-EHA, which contradict the applicability of read-across with valproic acid, make up the best technical information to support the classification of reproductive toxicity, as they are a direct analysis of the substance, without relying on assumptions of similarity. Studies specific to 2-EHA conclude that the most appropriate classification would be the Repr. 2. The EU has claimed that its analysis has considered studies specific to 2-EHA and not only read-across ones. Brazil is still concerned, though, that the more restrictive classification adopted by the EU is not justified. Brazil would also like to note that, according to the EU, the reclassification of the product as 1B would not entail higher costs associated with the registration process of chemicals. Nevertheless, the reclassification will still have a negative impact on the preferences of importers of the substance, who will have the wrong indication of its actual level of risk. We believe, therefore, that these regulatory changes would be more trade-restrictive than necessary to fulfill the EU legitimate objectives of health protection. Brazil thanks the EU for its statement in our last meeting, clarifying procedural aspects of its legislation and informing that if there would be no objection for the European Parliament and the Council, the measure should be published in the second half of April. In this sense, we would like to ask if the EU could provide an update on the status of the proposal, regarding the current and next steps of the process towards adoption and entry into force.

2.308. The delegation of the Russian Federation provided the following statement. Russian Federation reiterates statements made during the previous meetings of the TBT Committee and CTG with regard to the cobalt classification as a carcinogen 1b for all routes of exposure. We stress that this measure was adopted in the absence of sufficient scientific justification, neither laboratory nor epidemiological, without taking into account grounded comments and opinions of the WTO Members and business community. At the same time, we appreciate efforts of the EU on adoption of the gastric bioelution protocol at the EU and the OECD levels. However, the EU has not adopted this methodology and has not incorporated its use into the CLP Regulation as a regular practice of classifying alloys and compounds that will allow to exclude many cobalt-containing products from the scope of further restrictions which will be developed within the framework of the implementation of this classification decision. We urge the European Union to adopt this methodology as soon as possible.

2.309. In response, the delegation of the European Union provided the following statement. The European Union would like to thank Brazil for the continued interest in this issue and for the written comments concerning the classification of the 2-ethylhexanoic acid (2-EHA) in the 18th adaption to technical and scientific progress (ATP) of the Classification, Labelling and Packaging (CLP) Regulation.⁶⁷ The EU notes that the written reply to the comments of Brazil was sent on 25 November 2021 and the oral reply was provided in the March TBT Committee. Therefore, the EU would like to refer to the written reply and the minutes of the March TBT Committee for details. As to the status of the proposal, the EU would like to recall that the draft 18th adaption to technical and scientific progress (ATP) of the Classification, Labelling and Packaging (CLP) Regulation was presented for a final consultation at the meeting of the Competent Authorities on REACH and the CLP expert group (CARACAL) on 19 October 2021. Based on that consultation, as well as on all previously received comments, including comments from WTO Members, the EU concluded that the proposed classification of the substance 2- ethylhexanoic acid (2-EHA) is appropriate and the 18th ATP was adopted by the Commission on 16 February 2022. Following the two months scrutiny period for the European Parliament and the Council, during which no objections were raised, the Commission Delegated Regulation (EU) 2022/692 was published in the EU Official Journal on 3 May 2022.

⁶⁷ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353 31.12.2008, p. 1), consolidated version available at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1272-20211001>

2.1.3.35 China - Cosmetics Supervision and Administration Regulation and Regulation for Notification of Non-special Cosmetics, [G/TBT/N/CHN/1310](#), [G/TBT/N/CHN/1311](#), [G/TBT/N/CHN/1331](#), [G/TBT/N/CHN/1453](#), [G/TBT/N/CHN/1454](#), [G/TBT/N/CHN/1459](#), [G/TBT/N/CHN/1460](#), [G/TBT/N/CHN/1515](#), [G/TBT/N/CHN/1524](#), [G/TBT/N/CHN/1525](#), [G/TBT/N/CHN/1526](#), [G/TBT/N/CHN/1527](#), [G/TBT/N/CHN/1539](#), [G/TBT/N/CHN/1615](#), [G/TBT/N/CHN/1626](#) (ID 576⁶⁸)

2.310. The delegation of [Australia](#) provided the following statement. Australia respects the right of Members to implement technical measures for legitimate policy purposes and in accordance with obligations under the TBT Agreement. Australia remains concerned that measures under China's Cosmetics Supervision and Administration Regulation (CSAR) and its various implementing regulations, which entered into force on 1 May 2021, are more stringent than necessary to ensure the safety and quality of imported cosmetics. Australia remains concerned that the implementation date for the Good Manufacturing Practice (GMP) regulation, as outlined on notification [G/TBT/N/CHN/1626](#), was given by China as effective from 1 January 2022. Australia continues to request that China provide a transition period until at least January 2023 for cosmetics manufacturers to consider the regulation's requirements and make adjustments to their processes. Australia thanks China for its response to comments on notification [G/TBT/N/CHN/1615](#) on the Provisions for the Supervision and Administration of Children Cosmetics. However, Australia remains concerned that China has maintained its requirement for mandatory animal testing of cosmetics products to be used on children, regardless of the level of risk presented by individual products, and reiterates that we are a reliable supplier of high quality and safe cosmetics products domestically, and to international markets. The Australian Government stands ready to work with China and discuss the CSAR, including subordinate regulations such as those for children's cosmetics.

2.311. The delegation of the [Republic of Korea](#) provided the following statement. Specifications for Cosmetic Efficacy Claim Evaluation ([G/TBT/N/CHN/1526](#)), Specifications for Registration and filing of New Cosmetic Ingredients ([G/TBT/N/CHN/1525](#)), Specifications for Cosmetic Registration and Filing ([G/TBT/N/CHN/1524](#)), and Cosmetics Supervision and Administration Regulation ([G/TBT/N/CHN/1310](#)) The Republic of Korea appreciates China's response to Korea's comments and its bilateral cooperation with Korea on the specifications and regulations under this STC. However, Korea remains concerned since China's response was focused on explaining the implementation of the measures rather than providing an answer to Korea's enquiry, and as Korea's concerns were not duly addressed in China's finalized specifications and regulations. To begin with, exporters to China are required to specify the sources and quality data of all ingredients in their applications, which is an excessive requirement compared to international practices. The required information may contain trade secrets, and are more than necessary to fulfill China's legitimate objectives to ensure product safety and compliance to China's domestic market rules. Korea therefore requests China to provide an evidence-based explanation for its measures. Furthermore, according to Appendix 12-14, businesses are required to disclose information on ingredient safety and this may pose risks to companies' intellectual property and commercially sensitive information.

2.312. Second, China's regulations stipulate that test reports required for cosmetic product registration must be issued by testing laboratories that have obtained the China Metrology Accreditation (CMA). During the 2022 March TBT meeting, China replied that a number of foreign inspection institutions within the country has obtained the CMA certification. However, Korea requests China to offer flexibility by accepting test reports from qualified foreign laboratories located overseas. Third, as per Article 13 of the New Cosmetic Ingredients Authorization and Registration Regulation, exporters are required to provide evidence that proves their test results of alternative test methods are equivalent to the results of *in vivo* toxicity testing method, or animal testing. With respect to this, Korea would like to request China to recognize alternative test methods approved by the OECD or other international organizations without requiring the submission of equivalence evidence. In response to Korea's request, China replied that such requirements apply to both domestic and overseas exporters but Korea would like to highlight that the concern we expressed under this STC is asking China to recognize internationally approved alternative test methods in its Regulations.

2.313. Fourth, regarding the "Administrative Measures on Cosmetic Labelling," Korea requests China to ensure that labelling requirements comply with international practices. In particular, Korea requests China to maintain its current regulation on the requirement of ingredient declaration in

⁶⁸ For previous statements follow the thread under [ID 576](#).

cosmetic labelling. In most countries, cosmetic ingredients are subject to declaration when the substances are at a 1% or higher concentration. However, China's proposed regulation is not harmonized with international practices since it requires substances that are at a 0.1% or higher concentration to be declared, and substances at a concentration lower than 0.1% to be declared as "other trace ingredients". Fifth, under the Specifications for Cosmetic Efficacy Claim Evaluation, China still requires businesses to disclose summarized scientific evidence that supports cosmetic efficacy claims on NMPA-designated websites. Since these information may contain trade secrets, Korea requests China to pare down the information it requires under the Specifications. In the last meeting, China responded that trade secrets protection laws will be strictly complied with when managing the registration and filing of cosmetic products. Regarding this, Korea would like to request China to provide concrete explanation on the measures taken for compliance.

2.314. The delegation of Japan provided the following statement. With respect to "Cosmetics Supervision and Administration Regulation" and its implementing regulations, Japan continues to express the following concerns. 1. "Management Rules for Testing required for Cosmetic Product Registration and Notification" stipulates that microbiological, physical, chemical, toxicological, and human safety and efficacy evaluation tests relevant to cosmetics registration and filing must be conducted by the testing laboratories that obtained CMA (China Inspection Body and Laboratory Mandatory Approval). In the previous meetings, China explained that testing laboratories in China can obtain CMA. However, we understand that testing laboratories located in foreign countries are out of the scope of CMA. Japan would like to request a more flexible framework in which test results obtained by foreign laboratories with the qualifications and abilities equivalent to those of CMA are accepted. 2. "Management Rules for Testing required for Cosmetic Product Registration and Notification" stipulates that tests should be conducted in accordance with China's national standards or relevant regulations. Moreover, "Specifications for Registration and Filing of New Cosmetic Ingredients" and "Specifications for Cosmetic Efficacy Claim Evaluation" stipulate that priority shall be given to test results in accordance with China's national standards or relevant regulations and that various restrictions and conditions are imposed in the case of conducting a test method which is not specified in the regulations. Japan understands the same restrictions and conditions are imposed on imported and domestic products. However, Japan would like to request that China treat internationally accepted methods such as those from the OECD or ISO as equal to China's national standards or relevant regulations, so as not to be more restrictive than necessary in proving safety and efficacy.

2.315. 3. Efficacy claim evaluation method required by "Specifications for Cosmetic Efficacy Claim Evaluation" is an excessive requirement for the purpose of guarantee of the scientific validity or reliability of efficacy claim evaluation and protection of consumer legal interests for the following reasons. "Attachment 1, Requirements of Cosmetic Efficacy Claim Evaluation item" specifies four (4) types of evidence and stipulates in detail which evidence could be used for each efficacy claim. However, types of evidence for each efficacy claim should be judged individually by a company based on scientific validity. Even if formula is very similar, use of "common efficacy claim" evaluation test data is only allowed in exceptional circumstances such as colorants are different in the same registrants or filers, lines, and multi-shades makeup products. Even if slight changes in formula due to regulatory compliance are made, retests are required. This causes heavy burdens on companies. Japan would like to request that China consider expanding the range in which "common efficacy claim" evaluation test data can be used based on international trends and stakeholder opinions. Regarding the test of freckle-removing/whitening products, Japan would like to request China to adopt the approach of "Read-Across", which allows the test to be omitted under certain conditions, that was proposed in Article 16 (freckle-removing/whitening effect cross-reference) of "Specifications for Cosmetic Efficacy Claim Evaluation (Draft for Comments)" in September of 2020. Freckle-removing/whitening is affected by active ingredients included in the cosmetics and the Read-Across approach will help shorten the process from application to permission.

2.316. 4. Article 29 of "Specifications for Cosmetics Registration and Filing" requires "Cosmetic Ingredients Safety Information" issued by an ingredient manufacturer and more detailed information than necessary for the purpose of ensuring safety and quality of final products is included. Requirements for such overly detailed information cause heavy burdens for cosmetic ingredient manufacturers. If the information is not submitted, it is assumed that products already on Chinese market can no longer be sold or products distributed in other countries cannot be sold in China. Moreover, the consistency between information of the raw materials in cosmetic formula and "Cosmetic Ingredients Safety Information" is required. In this regard, when cosmetic companies change cosmetic ingredient manufacturers, it is necessary to re-submit or renew the document even

if the comparability of quality and safety are confirmed by registrants or filers (cosmetic companies). This causes unnecessary burdens for cosmetic companies. Cosmetic companies carry out a safety evaluation of the final product based on the quality standard of ingredients set by themselves and submit the document at the time of registration or filing. Since it is the cosmetics company's responsibility to ensure safety of ingredients and final products including what kind of ingredients are used, it is more trade restrictive than necessary to require the submission of "Cosmetic Ingredients Safety Information" issued by cosmetic ingredient manufacturers. Therefore, in the same manner as international practice, Japan would like to request that China accept that the information of ingredients is submitted when requested by the NMPA after launch, but not at the time of registration or filing, or the information of ingredients in accordance with Attachment 14 is issued and submitted by cosmetic companies.

2.317. 5. "Specifications for Cosmetic Efficacy Claim Evaluation" stipulates that regarding cosmetics for which application for registration or filing has occurred before 1 May 2022, cosmetic efficacy claim evaluation must be conducted and the abstract of an efficacy evaluation of products must be uploaded by 1 May 2023. As mentioned in 3, considering that many conditions and restrictions are imposed on evaluation methods, it is practically impossible to complete an efficacy evaluation of products and upload the abstract by the deadline. Japan would like to request that China extend an adequate grace period of at least one year. "Administrative Measures on Cosmetic Labelling" stipulates that applications for registration or filing of products as of 1 May 2022, must be adapted to the regulations. It also stipulates that products for which application for registration or filing has occurred before 1 May 2022, must be adapted to the regulations by 1 May 2023. Registrants or filers need detailed rules and guidelines to adapt to the new cosmetic labelling system. Japan would like to request that China provide an adequate grace period of at least one year after promulgation of all relevant regulations. 6. Regarding "Interim Measures on the Administration of Overseas Inspections of Cosmetics", Japan would like to continue to request that China consider the following points. Japan would like to request that China clarify which laws and regulations are used to determine conformity and specific purposes for conducting overseas inspections. Japan also asks that China ensure that inspections will not be more trade restrictive than necessary, ensuring that the legitimate objectives under the TBT Agreement are fulfilled. Moreover, Japan requests that China ensures that R&D departments of companies should be excluded from the subject of overseas inspections and confidential information will not be disclosed to persons other than those who are necessary for the legitimate purpose of the inspection.

2.318. 7. The sales certification that proves the products have been sold on the market in the country of production is only imposed on imported cosmetics. Japan requests that China treat imported products no less favourably than products produced in China. Regarding "Administrative Measures on Cosmetic Labelling", which was promulgated on 3 June 2021, Japan would like to continue to express its following concerns. 8. Article 6 stipulates that the content of the Chinese labels, such as information regarding product safety and efficacy, must be consistent with the original labels. Japan appreciates that China continues to accept explanation, in the Chinese label, that the Chinese character "quasi-drug" in the original Japanese label does not mean it is a pharmaceutical product, which was also accepted under old regulations. 9. Article 7 requires the display of "producers", "cosmetics registrants or filers" or in the case of imported products, "responsible person in China" in the label. Japan has concerns that multiple company names and addresses on the label may cause misunderstandings on the part of consumers rather than achieving the aims of this article to inform consumers of the persons responsible for product quality and efficacy. In order to avoid confusion among consumers, Japan would like to ask that the label should indicate only a single responsible person ("cosmetics registrants or filers" or in the case of imported products, "responsible person in China"). Japan would like to request that China delete content that requires the display of producers.

2.319. 10. With respect to the rules for labelling of all ingredients in cosmetics, there is an internationally recognized listing practice that ingredients with a compounding amount of 1% or less are allowed to be listed in no particular order. However, Article 12 stipulates that all ingredients of 0.1% or less must be labelled separately under the title "other trace ingredients" and can be described in no particular order. Japan would like to request that China assure that the rules for labelling follow the internationally recognized practice so as not to be more trade restrictive than necessary. 11. "Specifications for Registration and Filing of New Cosmetic Ingredients" and "Specifications for Cosmetics Registration and Filing" stipulates about nano ingredients. To follow those regulations, Japan considers that a more detailed and concrete standard is necessary to judge which ingredients fall under the definition of nano ingredients. In addition, Japan would like to

request that the standard be formulated in a way that reflects international trends and comments from all stakeholders. 12. "Public notice related matters of Provisions for the Supervision and Administration of Cosmetics Production and Distribution" (No. 140, 2021), which was promulgated on 26 November 2021, requires that, regarding products imported to China from overseas registrants or filers, domestic responsible persons retain samples of each batch of cosmetics. Overseas registrants or filers are responsible for cosmetics. Japan would like to request that China accept that samples do not have to always be retained in China if the testing system can work immediately when problems with imported cosmetics occur. In addition to the above, Japan would like to request that China continue to consider the following points proposed by Japan so far: exemption from submitting toxicological testing documents by certification documents on the quality management system or good manufacturing practice qualification; use of new toothpaste ingredients during the safety monitoring period; submitting the abstract of an efficacy evaluation report for toothpaste

2.320. The delegation of the United States provided the following statement. It is unfortunate that despite the United States and other WTO Members raising significant concerns with the Cosmetics Supervision and Administration Regulation (CSAR) and its implementing measures in the past nine TBT Committee meetings and three meetings of the Council on Trade in Goods, China has not sought to work with the United States and other WTO Members to reach resolution. As published, these measures appear to pose significant risks to companies' intellectual property and are not proportionate to cosmetics' low risk compared to medical products. We also have serious concerns that they may accord unequal treatment to imports. We encourage China to show its intent to resolve these concerns and to facilitate trade, by meeting with industry and WTO Members to discuss the outstanding concerns and to identify a path towards resolution. As noted in previous statements, our top remaining concerns are as follows: First, we remain concerned that the only means China provides importers to establish conformity with good manufacturing practices (GMP) requires animal testing if an importer's government does not issue GMP or manufacturing export certificates. We question China's response that its requirements for imports and domestic products are equivalent. The United States reiterates its request that China consider less trade-restrictive means such as those previously suggested for importers to demonstrate conformity. For instance, accepting conformity with the ISO standard for cosmetics good manufacturing practice (ISO 22716) as sufficient to establish compliance with China's regulatory requirements would be far more effective than animal testing in establishing compliance with the elements of good manufacturing practice.

2.321. Second, the United States remains concerned that CSAR and its implementing measures are overly burdensome with respect to the information that companies are required to provide in order for Chinese regulators to assess product and ingredient conformity. We are disappointed that China will not engage with WTO Members and industry to consider how it might meet its regulatory objectives while paring these requirements back. Third, China has failed to address US concerns and those of cosmetics intellectual property rights holders, including the request that NMPA provide a legally enforceable mechanism to monitor and protect trade secrets and confidential business information (CBI) in cosmetics filings, as identified by companies, within China. Does China have any updates in this regard? Fourth, China continues to require duplicative in-country testing to assess product claims without considering internationally validated methods or data and testing from international labs accredited to Good Laboratory Practices or Good Clinical Practices. Allowing foreign laboratories with facilities in China to conduct this testing does not address this burdensome practice. Fifth, the United States remains concerned with the cosmetics labelling requirements, as they may not allow foreign packaging. We ask that NMPA allow Chinese labelling on the secondary packaging. US companies have also requested 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? We also request that China continue to consider how these trade concerns expressed by the United States and many other WTO Members may be resolved in the implementation of CSAR.

2.322. The delegation of the European Union provided the following statement. The EU would like to support the delegations of Australia, the United States, Korea, and Japan. The EU would like to refer to its earlier statements on this topic, in particular to the statement delivered in March TBT Committee, as the EU's concerns outlined therein remain unchanged. The European Union supports CSAR's objective of ensuring consumer safety. However there is an important concern pertaining to the obligation to transmit confidential information on new products and their ingredients to Chinese authorities. The mandatory disclosure of commercially sensitive information required in the notification and registration process, touching on intellectual property rights (IPR) of companies

involved, remains EU's biggest concern. The EU needs to stress once more that CSAR's requirements go far beyond what is necessary to ensure consumer safety and traceability of the ingredients used in cosmetics. It is also diverging from international practice, as such extensive level of information is not required elsewhere in the world for notification and registration purposes. Unfortunately the concerns previously voiced by the EU were not replied to by China.

2.323. Therefore the EU would like to recall that the following elements of CSAR legislation pose problems to EU cosmetics manufacturers: - Registration of products: Companies must submit a complete list of raw materials used in the finished product. Supplier of raw materials must submit detailed information on the raw material, including the production process. - Notification for new ingredients: There are concerns over the amount of information required under the new notification system and potential issues over the disclosure of such information after a certain period. - Efficacy claims: manufacturers are required to make public a detailed summary of efficacy evaluation, which can reveal business-sensitive information. For certain efficacy claims (sunscreen, skin whitening/spot removal, and anti-hair loss), it is still mandatory to use specified Chinese test methods. Such tests must be carried out by specific testing institutions in China. For new efficacies, if methods are not yet established in China, they must be validated in at least two qualified testing institutions in China to be used to support an efficacy claim in China. Extrapolation of test results between very similar formulations is only allowed under exceptional circumstances (i.e. for colour ranges of a decorative cosmetic, the efficacy test must only be carried out for every one out of five shades). The multiple China-specific requirements for efficacy testing will require significant re-testing of products for which the efficacy was already established in a third country. This affects also many thousands of products that already have been placed on the market in China and for which the claim substantiation needed to be completed until May 2022.

2.324. The delegation of New Zealand provided the following statement. New Zealand welcomes China's endeavours to modernise its regulatory system for cosmetics and appreciates the opportunity to comment on specific elements of China's Regulations. While we welcome the intention to improve safety and quality assurance, New Zealand would like to encourage China to ensure that facilitation of trade is considered in the implementation of the regulations. New Zealand notes that under the measures, non-animal tested cosmetics are able to enter China's market only if a government regulatory authority-issued GMP certification is provided. Yet non-special use cosmetics are considered to be low-risk products in many countries, including New Zealand, and for this reason are not subject to regulator-issued GMP certification. We warmly welcome the introduction of alternatives to mandatory animal testing for imported cosmetics. Yet New Zealand, like others, is disappointed that the measures do not provide for non-government regulatory authority-issued GMP certification or other trade facilitative mechanisms for providing product assurances, meaning that significant and unnecessary barriers to trade for imported cosmetics products still apply for Members who cannot offer regulator-issued GMP certification. We encourage China to engage directly with affected Members, including New Zealand, to identify a trade-facilitative mechanism to demonstrate GMP conformity, without imposing animal-testing requirements. Specifically, and following China's response to New Zealand's question submitted during its recent WTO Trade Policy Review, New Zealand seeks clarification whether the requirement for a regu-issued GMP certificate as an alternative to animal testing requirements can be exempted on the basis that: the manufacture of the product fully conforms with the relevant ISO 22716 standard or higher, assuring the safety of the product, or a product safety risk assessment result is provided from a laboratory accredited by a National Accreditation Body that confirms the safety of the product.

2.325. Additionally, New Zealand requests that China also provide flexibility in respect of product testing requirements. In particular, we encourage China to accept test reports from laboratories situated outside of China that have been accredited by ILAC Mutual Recognition Arrangement signatories. Otherwise, this is a burdensome and unnecessary trade barrier for exporters that send products to China as well as multiple other markets. Building in such flexibility would be trade facilitative and in accordance with international best practice. New Zealand also holds concerns, that we note are shared by a number of members, that China requires more detailed disclosure of product formulas than is required in other markets, including specific sources of each ingredient. New Zealand encourages China to limit such disclosure requirements, particularly in relation to sensitive information, to that which is required to assure product safety in China's domestic market, so as not to compromise intellectual property. New Zealand appreciates our recent constructive bilateral engagement on cosmetics issues and looks forward to engaging further with China on its CSAR measures to address these issues. We would welcome China's response to the concerns raised by New Zealand and other Members in this and other fora.

2.326. In response, the delegation of China provided the following statement. 1. The protection of trade secrets. Submission of cosmetics safety-related information is a common requirement for health-related product safety reviews worldwide. The production process description, raw material production process and other registration and filing materials in the product implementation standards submitted by enterprises are not the contents of government information disclosure. According to the Regulations on the Disclosure of Government Information, administrative agencies are not allowed to disclose information involving trade secrets and personal privacy harming legitimate rights and interests. Therefore, trade secrets and intellectual property rights are not damaged in this regard. China attaches great importance to the protection of trade secrets. Cosmetics regulations require regulators to keep trade secrets when reviewing and releasing information. NMPA, will strictly abide by the principle of protecting the trade secrets during the registration and filing of cosmetics. 2. The problem of cosmetic label labelling. First, the Measures for the Administration of Cosmetics Labels do not require all contents of Chinese labels to be consistent with those of the original packaging labels. The requirement is that the contents of product safety and efficacy claims should be consistent with those of the original labels.

2.327. 3. The claimed efficacy of cosmetics is closely related to the ingredients used. In order to protect the legitimate rights and interests of consumers, preventing "conceptual addition" which is common in the industry, the Measures for the Administration of Cosmetics Labels (Draft for Comments) proposed that ingredients with formula content less than 0.1% (W/W) should be marked with "other trace ingredients" as the guidance language. However, "other trace ingredients" is not the same as "invalid ingredients", cosmetic enterprises add a very low amount of raw materials which still have certain effects, that can be declared in the product label upon fulfilling the relevant requirements for efficacy claims. 4. The cosmetics inspection reports required for registration or filing shall be issued by the cosmetics registration and filing inspection institution to protect the legitimate rights and interests of consumers and to ensure the accuracy of the inspection results. Cosmetics used for whitening, sun protection, and hair loss prevention are administrated as special cosmetics in China. The efficacy evaluation test report of such products should be submitted at the time of product registration. Therefore, an efficacy evaluation test should be completed in cosmetics registration and filing inspection institution. The institutions should obtain cosmetics inspection and testing (CMA) certification. However, China does not prohibit foreign inspection institutions from becoming cosmetic registration and filing inspection institutions. At present, many laboratories of foreign inspection institutions located in China have obtained COSMETIC CMA and undertaken cosmetic registration and filing inspections.

2.328. 5. For the exemption of toxicology tests. Firstly, following the principle of non-discrimination, the Administrative regulations of Cosmetics Registration and Filing Materials set up consistent requirements on imported and domestic cosmetics, for alternatives for animal testing in safety evaluation. For both domestic and imported ordinary cosmetics, while obtaining the relevant production quality management certification issued by government authorities, with the proper safety risk assessment, the toxicology test can be exempted. Secondly, as the skin structure and immune system function of growing infants and children are not perfect, safety assessment only may leave some unknown risks. Moreover, many safety assessment data come from cosmetics of the general population, and the direct assessment of children's cosmetics is not sufficient. Therefore, China believes that children's cosmetics should be evaluated for product safety through both safety assessment and necessary toxicological tests. 6. The basic principles and requirements in "Good Practice for The Production quality Management of Cosmetics" are consistent with that in ISO 22716. It is in line with international prevailing requirements, aiming to standardize the production quality management of cosmetics in China, and to ensure cosmetics safety.

2.329. 7. On the transitional period for the implementation of regulations. Based on the industrial situation and regulatory requirements, China has set up a specific and reasonable transitional period for different situations, so as to ensure the smooth and orderly implementation of the new regulations. While the formulation and implementation of follow-up regulations and technical documents are in process, a reasonable transitional period will also be provided accordingly, so as to ensure a smooth transition between the old and new regulations. 8. Submission of information related to the safety of cosmetic raw materials. Product safety is closely related to the safety of raw materials. Provision of information related to the safety of raw materials when applying for registration and filing is an important measure to ensure product safety. Considering that it is common for enterprises to change the raw material, in order to facilitate cosmetics registrants and record holders to fill in the information related to raw material safety, Provisions on the Management of Cosmetics Registration and Record Materials stipulate that if the raw material manufacturer has

submitted the information related to raw material safety, the registrants and record holders only need to provide the raw material submission code for correlation. 9. The retention sample of imported cosmetics. The purpose of the sample retention system is to ensure the traceability of product quality and safety and to facilitate the inspection of the legitimacy and safety of each batch of products in the case of quality and safety problems and counterfeit products.

2.1.3.36 European Union - Chlorothalonil (pesticide active substance), [G/TBT/N/EU/625](#) (ID 579⁶⁹)

2.330. The delegation of [Colombia](#) provided the following statement. Colombia reiterates its concern regarding the measure notified by the European Union in document [G/TBT/N/EU/625](#) relating to non-renewal of the approval of the active substance chlorothalonil. Despite the many technical and scientific comments submitted within the consultation periods, the regulation under which the marketing approval of the active substance chlorothalonil is not renewed entered into force in May 2020. This decision is already beginning to have implications and consequences for banana producers in Colombia and has repercussions for an extensive domestic agricultural production chain. In addition, through European Commission Regulation (EU) 2019/677 of 9 February 2021, it was decided to set the MRL at 0.01 mg/kg, or the minimum level of detection. This provision entered into force on 2 September 2021. In this case, the EU has also failed to take into consideration the technical comments submitted and the requests for a longer transition period to adapt production processes, which in the agricultural sector are particularly complex. Not only are these measures being taken in a manner that is inconsistent with international standards such as those of the Codex, but they are also being applied in a discriminatory fashion, as, in practice, their implementation and authorization for use differentiate between domestic and foreign producers. This is so in the case of "emergency authorizations", which allow EU producers to continue or resume the use of pesticide substances.

2.331. While we recognize the health and environmental protection objectives involved, these measures are being adopted without any proof that they are indeed the least trade-restrictive means of ensuring an appropriate level of protection for consumers, which constitutes a violation of Article 2.2 of the TBT Agreement. The measures adopted must be based on scientific evidence and international standards and take account of the biodiverse agriculture of tropical countries such as Colombia. Furthermore, producers and exporters have questions and concerns regarding inspection and control mechanisms and procedures. The EU has failed to provide clear answers on how to make carrying out foreign trade operations more predictable, on inspection mechanisms, or to demonstrate compliance with requirements. We request the European authorities to provide further information on these matters to ensure that they are not trade-restrictive measures.

2.332. The delegation of [Paraguay](#) provided the following statement. This concern and the non-renewal of the approval of chlorothalonil and other substances was already discussed extensively both in this Committee and in the SPS Committee because of the subsequent reduction of MRLs. Paraguay therefore refers to its previous statements and requests that its statement at the previous meeting be reflected in full in the minutes of this meeting. 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, 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.

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

⁶⁹ For previous statements follow the thread under [ID 579](#).

2.334. The delegation of Costa Rica provided the following statement. Costa Rica once again supports the comments made by Colombia and reiterates its concern regarding the measure notified by the European Union in document [G/TBT/N/EU/625](#), relating to the non-renewal of the approval of the active substance chlorothalonil. Costa Rica thanks the EU for its willingness to hold a dialogue on agrochemicals policy, taking into consideration international obligations on foreign trade and the agricultural and environmental policy objectives of the member countries of the international community, together with the commitment to leave no one behind in the implementation of its Green Deal policy.

2.335. The delegation of Guatemala provided the following statement. Guatemala maintains its position on this concern, especially because there is no information on scientific evidence of the possible damage to human health caused by consuming fruits and vegetables, particularly those produced in Latin America. We therefore reiterate the importance of conducting a risk analysis. Chlorothalonil is used in the production of bananas, snow peas, sugar snap peas, French beans and coffee. This active substance is used as a broad-spectrum and fast-acting contact fungicide. No molecule on the market is currently as effective for controlling the *Ascochyta* fungus, above all in vegetables. Guatemala's climatic conditions provide this fungus with the ideal environment to reproduce, affecting crops, which have been seriously harmed, and the economy of Guatemalan producers and exporters to the European market. Alternative substances to chlorothalonil include: mancozeb, azoxystrobin, pyraclostrobin, sulphur and difenoconazole. The registration of four of these alternative substances was not renewed for marketing in the European Union, and, as a result, MRLs have been reduced to almost zero tolerance, leaving Guatemalan agricultural production with no options that can effectively combat diseases of fungal origin.

2.336. Unlike European countries, Guatemala is geographically located in the tropics, where there are only two seasons: one rainy and one dry. This provides an ideal climate for pests and diseases to spread throughout the year. As a result, it is almost a certainty that fungi will grow and damage crops. The country is one of the world's leading producers of non-traditional vegetables. In 2019, 32 million kilograms (70 million pounds) of peas and 29.5 million kilograms (65 million pounds) of green beans were produced, making it one of the main exporters of these crops to the European Union. The momentum and growth of the sector have helped improve the quality of life of more than 60,000 families in around 200 of Guatemala's rural communities that make up the sector's production base, generating around 20,000 jobs. Guatemala's banana exports account for 30% of total exports of traditional products from the customs territory. The banana is the world's most consumed and exported fruit. The crops provide over 280,000 direct and indirect jobs. Any changes to their production cycle resulting from an increase in disease due to a lack of alternative substances would affect over 1,120,000 Guatemalans (Independent Banana Producers' Association (APIB)).

2.337. For all of the above reasons, we ask the European Union to consider the similar circumstances of tropical countries when implementing measures, until it has conclusive studies and has aligned itself with the provisions of the Codex Alimentarius. Guatemala therefore requests that: The risk assessment approach and scientific evidence be considered; MRLs that correspond to the reality of tropical countries be set. Tropical countries cannot be required to use the same treatments as European countries, since their climatic conditions are different. For this reason, we ask that the MRLs for chlorothalonil be reviewed, taking into account that no chemical substance on the market can replace this compound and effectively control the *Ascochyta* fungus. Scientifically-based information be provided showing that fruit and vegetables exported from Guatemala or third countries to the European Union are harmful to the health of consumers from these countries.

2.338. The delegation of Ecuador provided the following statement. Ecuador wishes to reiterate its concern in relation to notification [G/TBT/N/EU/625](#) on the non-renewal of the use of the active substance chlorothalonil and document SANTE/10186/2018 Rev.1, through which the EU confirms the non-renewal of the use of this substance. Chlorothalonil is one of the main tools for controlling Black Sigatoka in bananas thanks to its effectiveness, low cost and multisite mode of action, meaning that the risk of resistance is low. It is available in a wide range of products, through many suppliers, and is widely available in the country. Controlling Black Sigatoka (*Mycosphaerella fijiensis*) is the main challenge for banana production in Latin America. To control the disease, strategies of rotating fungicides with different modes of action have been pursued to avoid fungal resistance to these compounds. A limited variety of molecules is available for rotation in spraying schedules. Restricting the use of chlorothalonil will further complicate efforts to prevent pest resistance. Our concern stems from the fact that the non-renewal of the approval of chlorothalonil also resulted in the notification

of document [G/SPS/N/EU/394/Add.1](#), dated 12 February 2021, pursuant to which new MRLs came into force for various active substances, including chlorothalonil.

2.339. Ecuador urges the European Union to consider third country comments on notifications before implementing substance reductions that significantly affect the availability of pest control options for production in tropical and subtropical areas. For an MRL to be banned or lowered, there must be conclusive scientific information demonstrating a real health impact. Reducing the MRL for chlorothalonil could have a very significant economic impact on small-, medium-, and large-scale producers in Ecuador. This is because the banana sector provides jobs for 2.5 million people. Exports of this product account for a significant share of the country's foreign exchange earnings (2.1 billion). This equates to 2% of GDP and 35% of agricultural GDP. Moreover, we wish to recall that no substitute or similar phytosanitary products with the same environmental or toxicological profile are currently available, since the alternatives to chlorothalonil (mancozeb, metiram) are already under review by the EU.

2.340. In response, the delegation of the European Union provided the following statement. As explained at previous meetings, the EU proposed not to renew the approval of chlorothalonil through Commission Implementing Regulation (EU) No 2019/677⁷⁰, adopted on 29 April 2019 and previously notified to the TBT Committee. Following the non-renewal of approval decision, the EU prepared a draft Regulation lowering the Maximum Residue Limits (MRLs) for chlorothalonil, which was notified to the WTO/SPS Committee ([G/SPS/N/EU/394](#)). In view of the concerns identified by EFSA, the EU lowered all MRLs for chlorothalonil to the relevant limits of quantification through Commission Regulation (EU) 2021/155⁷¹ of 9 February 2021. The new values are applicable to all food products since 2 September 2021. Since then, there has been no further developments in the EU on this substance, as not new data 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" member State and the EFSA.

2.1.3.37 Peru - Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA (ID 618⁷²)

2.341. The delegation of Colombia provided the following statement. Colombia thanks Peru for its consideration of the concern regarding the use of adhesive advertising warning labels set out in paragraph 8.3 of the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA. However, we are raising this STC once again, given that DS No. 005-2022-SA extended the deadline for the use of adhesive labels to 31 December 2022. As we are now approaching that date, business owners and trade operators still have many outstanding concerns and questions. Colombia requests that the option to use adhesive labels be permitted indefinitely and that the deadline should not continue to be extended for further periods of time. Furthermore, Colombia considers that the policy under which this standard is being adopted, while understandably seeking to promote and protect public health, should be implemented in a manner that is no more restrictive than necessary and does not subsequently create an unnecessary obstacle to trade. To do otherwise would render the measure inconsistent with Article 2.2 of the WTO Agreement on Technical Barriers to Trade. It also emphasizes that allowing the use of adhesive labels does not distort the purpose of the Peruvian standard, since the warnings, whether included on adhesive labels or printed directly on product packaging, will continue to be clear, legible, prominent and comprehensible, as required by the regulations. Similarly, this technical measure on labelling that is so specific to a particular country primarily affects small and medium-sized enterprises, creating distribution-related logistical disadvantages, as establishments generally require compliance with the standards months in advance to ensure that at the time of sale to the final consumer they are being complied with. Lastly, we welcome the bilateral talks that have taken place at different levels, and the new developments reported by the Peruvian authorities. We also invite you to continue working in a coordinated manner

⁷⁰ 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.

⁷¹ 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.

⁷² For previous statements follow the thread under [ID 618](#).

and to take into account the above-mentioned considerations, allowing the use of adhesives indefinitely to avoid measures that restrict and affect trade.

2.342. The delegation of Brazil provided the following statement. Brazil regrets having to once again express its concerns regarding labelling requirements expressed in the Manual of Advertising Warnings approved by Supreme Decree 012-2018-SA (notified under [G/TBT/N/PER/97/Add.1](#)) and amended by Supreme Decree 015-2019-SA (unnotified). The use of stickers is a widespread practice internationally, as it does not affect the provision of reliable information to consumers. Codex standard CODEX-STAN 1-1985 for pre-packaged goods, Articles 8.1.1 and 8.2.1, explicitly allows for the possibility of using additional labels or stickers, as long as they are attached to the packaging and if the language of the original label is not necessarily that of the consumer for whom it is intended. Brazil shares Peru's endeavour to ensure the highest health standards through technical regulations that help to better inform consumers. Despite Peruvian legitimate concerns with deceptive practices, advances in labelling technologies allow for their safe affixation. We acknowledge that, according to Supreme Decree 005-2022-SA, the entry into force of the prohibition on stickers was delayed until 31 December 2022. However, Brazil would like to respectfully ask Peru to permanently align its labelling requirements with current international standards established under the Codex and withdraw the prohibition of stickers for the products under the scope of the Manual of Advertising Warnings. Brazil considers such postponement a provisional solution and will continue to raise this STC until Peru permanently removes its burdensome requirements for food labelling.

2.343. The delegation of the European Union provided the following statement. The European Union appreciates that Peru further extended the possibility for imported products to use stickers for compliance with labelling requirements for processed foods, until 31 December 2022. However, the EU would like to repeat once again the urgent invitation to Peru to provide for a permanent possibility for imported products to use stickers. The repeated and unforeseeable extensions of the deadline severely disrupt trade because retailers in the Peruvian market stop buying products with stickers several month before each deadline. Such disruptions represent significant losses for importers and producers, as well as disruption of trade flows and unavailability of the affected products in the Peruvian market. The EU recognizes that reliable information to the Peruvian consumer and protection of public health are legitimate objectives. Nevertheless, the obligation to print information on the product package is unnecessarily trade-restrictive and represents a disproportionate burden for foreign producers, in particular SMEs. In the EU and in most countries around the world, stickers are allowed for food products, provided that the information is accurate and the stickers are not easily removable. We invite once again Peru to bilaterally work with the EU on this issue.

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

2.345. The delegation of Paraguay provided the following statement. We thank Colombia, Brazil and the European Union for placing this trade concern on the agenda and request that Paraguay's support also be recorded. Paraguay supports Peru's objective of protecting public health and considers that the provision of information to consumers through labelling is an appropriate strategy. However, we share and support the concerns expressed by other Members with regard to the time limit established for the use of supplementary labels. It should be noted that the use of labels of this kind is widely recognized internationally, as such labels achieve the same public health protection and consumer information purposes achieved by permanent labels. Not accepting them is therefore more trade-restrictive than necessary. We thank Peru for the information received and for extending the grace period until 31 December this year. While we appreciate this decision, it will not solve the underlying problems that our exporters will face. We therefore ask Peru to review this measure and to bear in mind the provisions of Article 2.2 of the TBT Agreement.

2.346. The delegation of Chile provided the following statement. Chile would like to state that it shares the legitimate public policy objective pursued. However, the regulations established in Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Peru, has caused concern among companies and guilds exporting packaged foods to that country, as the acceptance of sticker-based labelling is temporary. Chile would be grateful if Peru reconsidered the established extension period, allowing the use of adhesive labels to be permanent.

2.347. The delegation of Costa Rica provided the following statement. Costa Rica wishes to reiterate its trade concern about progress made in the process to implement the draft Regulation established under Supreme Decree No. 015-2019-SA, which amends the Manual of Advertising Warnings approved by Supreme Decree No. 012-2018-SA of Peru. The food industry has informed us of the negative repercussions on trade that a potential discontinuation of the use of adhesive labels would entail. It should be noted that the use of adhesive labels is widely recognized internationally, as such labels achieve the same public health protection and consumer information purposes achieved by permanent labels. At the CODEX level, for example, Articles 8.1.1 and 8.2.1 of CODEX-STAN 1-1985 – General Standard for the Labelling of Prepackaged Foods, permit the use of supplementary and adhesive labels, as long as it is guaranteed that they will not become separated from the container, or in cases where the language on the original label is not suitable for the consumer for whom it is intended. Costa Rica respectfully requests that the Peruvian authorities consider permitting the use of adhesive labels on a reciprocal basis, given that these labels may be used on Peruvian food products to be marketed in Central America. In view of the above, we respectfully restate Costa Rica's wish that the Peruvian authorities remove the proposal to prohibit the use of stickers and maintain the possibility of permitting their permanent use. We request the Peruvian authorities to provide information on the status of this Regulation, whether the intention is still to ban the use of stickers on labels and the timing of the Regulation's entry into force.

2.348. In response, the delegation of Peru provided the following statement. Peru reiterates that it is committed to its work to protect the health of its citizens and vulnerable groups, such as children and adolescents, through public policies aimed at achieving this goal, in accordance with the country's international trade commitments in this area. In this connection, Peru is seeking to ensure that the information contained in the Manual of Advertising Warnings (MAP) reaches consumers clearly and effectively to enable them to make informed choices. As stated at the previous Committee meeting, Peru, in response to the concerns expressed by some Members and by means of Supreme Decree No. 005-2022-SA, extended again, until 31 December 2022, the period during which the use of adhesive warning labels is allowed, as provided for in paragraph 8.3 of section 8 of Supreme Decree No. 012-2018-SA approving the MAP under Law No. 30021 on the promotion of healthy eating among children and adolescents. Furthermore, it should be noted that the Peruvian Ministry of Health is carrying out the relevant assessments of the matter in order to find a definitive solution in the near future.

Lastly, we reiterate that Peru wishes to honour its WTO commitments and therefore reaffirms its commitment to not preparing, adopting or applying technical regulations that may create unnecessary barriers to trade, as established in the Agreement on Technical Barriers to Trade.

2.1.3.38 Kingdom of Saudi Arabia - Saber Conformity Assessment Online Platform / Saleem Product Safety Program (ID 615⁷³)

2.349. The delegation of the European Union provided the following statement. The implementation of the electronic certification system SALEEM through the web-portal SABER remains a concern for the European Union. While we would like to thank the Kingdom of Saudi Arabia for engaging constructively in bilateral talks and providing some explanations, the difficulties still have a major negative impact on the imports of several products from the European Union to Saudi Arabia. Several European industries coincide in reporting the overly costly, burdensome and time-consuming nature of the conformity assessment requirements. The sector of toys is particularly affected. European toy manufacturers continue to report difficulties related to obtaining a GCC Conformity Tracking Symbol (so-called GCTS) from notified bodies authorized by Saudi Standards, Metrology and Quality Organisation (SASO). The EU refers to its previous statement but would like to recall that the main concerns are related to the following issues: (i) request of test reports; (ii) selection of representative item; (iii) extension of the validity of certificate; and (iv) products imported without GCTS (GCC Conformity Tracking Symbol). In addition, European companies report serious difficulties

⁷³ For previous statements follow the thread under [ID 615](#).

in relation to toys for older children as they are not considered as toys as such and it is impossible to import them through "toy" tariff codes and they don't have a GCTS. On the procedures to obtain the GCTS for toys, there is some small progress. The European Union appreciates that a regular dialogue between GSO, Manufacturers and Testing labs (Notified Bodies) has started. However, any practical agreement still needs to be approved by the GCC member states before Guidance can be adopted. In conclusion, the European Union invites the Kingdom of Saudi Arabia to address these concerns and ensure efficient and less costly procedures for all products included in the new conformity assessment system. The European Union remains available to continue bilateral discussions.

2.350. The delegation of Canada provided the following statement. Canada supports Saudi Arabia's goal of creating an integrated system that efficiently assesses the safety of imported products. Industry stakeholders also support SABER, however, issues continue to persist regarding its implementation. Canada has raised some of these concerns at previous TBT Committee meetings. Industry stakeholders voice that problems include inconsistent application of the requirement by notified bodies and some Saudi Standards, Metrology and Quality Organization (SASO) issues are intertwined with the Standardization Organization for the Cooperation Council for the Arab States of the Gulf (GSO) requirements. These issues continue to pose unnecessary administrative burden, costs and duplicative requirements for stakeholders. We understand the Notified Bodies are working to try and help resolve these issues. We also are aware that some working group meetings among Notified Bodies, GSO, and industry representatives have already taken place. And industry is quite encouraged by this engagement on the part of Saudi Arabia especially given that some issues require direct action by SASO and GSO. Canada kindly asks Saudi Arabia's consideration of providing more detailed guidance to Notified Bodies on how to implement the SABER platform in order to increase the efficiency of the system, reduce compliance costs and ensure consistency.

2.351. The delegation of Switzerland provided the following statement. Switzerland remains concerned over the negative impact of the "Saber Conformity Assessment Online Platform" on bilateral trade with the Kingdom of Saudi Arabia. We would like to support the intervention made by previous speakers on this matter. The registration and certification process seems to remain non-transparent, complex and time-consuming for our exporters. The industry continues to report that the conformity assessment procedures lead to disproportionate fees and in many cases to unnecessary administrative burden, costs and duplicative requirements. In particular for companies exporting quality products in small quantities, this additional burden is prohibitive to enter the market. Switzerland would appreciate if the Kingdom of Saudi Arabia could ensure that the registration and certification process is not more strict than necessary to give adequate confidence that products fulfil the applicable requirements. Furthermore, we encourage the Kingdom of Saudi Arabia to base the documentation and certification requirements on international standards, to implement clear and transparent guidelines and to ensure that the requirements are applied in an equal and uniform manner. Switzerland looks forward to further cooperation on this matter.

2.352. In response, the delegation of the Kingdom of Saudi Arabia provided the following statement. Saudi Arabia thanks the European Union, Canada and Switzerland for raising concerns regarding Saber Conformity Assessment Online Platform / Saleem Product Safety Program and GCC Technical Regulation on Children Toys. "Saber" is an IT Platform that aims to improve the import experience by easing the Conformity process/procedure before the arrival of the shipment. Hence, it is not considered a technical measure under the jurisdiction of TBT/WTO rules. Therefore, the notification process is not required according to the TBT Agreement. According to the TBT/WTO agreement, all Technical Regulations reflected in "Saber" are notified by SASO to all WTO Members through (SPS/TBT E-Ping Platform). Saber itself does not impose additional policies or requirements other than those mentioned in the notified technical regulation. "Saber" has contributed to facilitating and enhancing trade, reducing the cost and time of custom clearance to 1-7 working days compared to 7-15 working days in previous years. As a result, the Kingdom's ranking in the cross-border trade index advanced 72 ranks, confirming SASO's commitment to boosting trade facilitation. Regarding GSO toy regulation, the second version was approved in 2013, and the GCC member states have started to implement it in the interest of the safety of children whose age is less than 14 years.

2.353. The GCC Standardization Organization accepted many notified bodies worldwide to facilitate the application of the children's toys regulation requirements. In the other hand, the E-platform "SABER" does not require additional certificates of conformity as long as the GCC certificate of conformity is valid, therefore, processing shipment certificates through the "Saber" platform would be fast and easy. We would also like to point out that the validity of the GCC conformity certificates

lasts for three years, and then the conformity procedure is considered fair. Concerning toys for people over 14 years old, which are excluded from the scope of the GCC regulation, the Supplier Conformity Declaration through "SABER" only is sufficient. The GSO, along with SASO and other GCC competent authorities, held several opening meetings (the last meeting was held in June 2022) with manufacturers, distributors, exporters, and CBs to discuss all issues and concerns facing the toys industry. All Europe toys industry are invited to these activities to address any challenges they might encounter. In conclusion, Saudi Arabia is always happy to collaborate and engage with all stakeholders, and we look forward to further cooperation on these matters.

2.1.3.39 Colombia - Food Prioritized for its Sodium Content, Certification Requirements, G/TBT/N/COL/238, G/TBT/N/COL/238/Add.1 (ID 609⁷⁴)

2.354. The delegation of Costa Rica provided the following statement. First of all, Costa Rica would like to express its appreciation for the efforts of the Colombian authorities to provide information related to its regulation on front-of-pack nutrition labelling for foods high in sodium. In this regard, we note that we have received information on the reasons and justification for this Colombian regulation. However, Costa Rica would like to take this opportunity to emphasize the importance of harmonizing food labelling schemes, in particular front-of-pack nutrition labelling, on the basis of Codex regulations (Guidelines on Nutrition Labelling CXG-2-1985, Annex 2, adopted in 2021). In this regard, we encourage the use of the recently approved Codex guidance on the subject as a reference to ensure that regulations are consistent with the international consensus and do not establish unnecessary restrictions on trade.

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

2.356. The delegation of Paraguay provided the following statement. We thank Costa Rica for including this trade concern on the agenda and request that Paraguay's support be recorded. Paraguay recognizes and supports the right of the Republic 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 provision of lot-by-lot certificates of conformity would be burdensome and costly for importers and more restrictive than necessary to achieve the legitimate objective pursued by Colombia with this measure.

2.357. In response, the delegation of Colombia provided the following statement. The competent authorities in Colombia have had productive exchanges which have made it possible to clarify a number of the issues that gave rise to this trade concern. We have also shared relevant information on the reasoning behind this regulation on the eAgenda system. Our authorities remain open to dialogue and we will leverage the necessary responses to facilitate compliance with the new regulations. We have taken note of the new comments and expect to provide the countries with a response shortly. Colombia welcomes the comments shared by Costa Rica and the statements made by Guatemala and Paraguay, and reiterates that Resolution No. 2013 of 2020 was issued for public health reasons and is part of a comprehensive strategy that takes into account both the sodium content of processed foods and other sources of sodium, such as the salt added to food preparations in restaurants, at home and in institutions. This is the National Strategy for the Reduction of Sodium/Salt Consumption 2012–2021. The strategy seeks to reduce mortality attributable to high blood pressure and cardiovascular disease by gradually reducing salt consumption from food sources until the WHO recommendation for 2021 has been achieved: 5 grams of salt or 2 grams of sodium per person per day.

2.358. With regard to concerns about the technical and functional role of sodium in the production of prioritized foods, Colombia wishes to reiterate that this aspect was analysed at all of the technical

⁷⁴ For previous statements follow the thread under [ID 609](#).

meetings for the 12 categories of food with industry, academic and government representatives, resulting in agreement on, and the dissemination of, the draft regulations. The following documents shared by Colombia were produced by the Ministry of Health and Social Welfare and provide support for the measures taken through Resolution No. 2013 of 2020 on the maximum sodium content for processed foods.⁷⁵ Colombia would like to point out that the relevant authorities have expressed their willingness to hold technical discussions with the Costa Rican authorities in order to address the concerns raised and ensure compliance with the technical regulations on the maximum sodium content for processed foods. We therefore reiterate our willingness to address this issue bilaterally, so as to facilitate the technical analysis by the relevant authorities of the parties. We will review the comments made in this connection by delegations in order to address the questions raised and provide information to facilitate compliance.

2.1.3.40 Mexico - Draft Amendment to Mexican Official Standard NOM-051-SCFI/SSA1-2010: General specifications for the labelling of pre-packed food and non-alcoholic beverages, [G/TBT/N/MEX/178/Add.9](#) (ID 608⁷⁶)

2.359. The delegation of Costa Rica provided the following statement. Costa Rica would like to take this opportunity to emphasize the importance of harmonizing food labelling schemes, in particular front-of-pack nutrition labelling, on the basis of Codex regulations (Guidelines on Nutrition Labelling CXG-2-1985, Annex 2, adopted in 2021). In this regard, we encourage the use of the recently approved Codex guidance on the subject as a reference to ensure that regulations are consistent with the international consensus and do not establish unnecessary restrictions on trade.

2.360. The delegation of Guatemala provided the following statement. We recognize Mexico's right to protect people's health and to provide consumers with information on the food they buy. We thank Mexico for the response it provided during the previous meeting, which was confirmed in the report of the meeting, in particular its indication that there is no expiry date for the use of a supplementary label as a permanent mechanism. Guatemala would like to ask whether the Government of Mexico will issue a Technical Regulation explicitly stating this, as the Agreement published on 1 October 2020 still has transitional provisions at the end of the publication. The first one clearly states that it will enter into force on 1 April 2021 and expressly excludes the use of supplementary labels on front-of-pack labelling. We recall that CODEX CXS 1-1985, General Standard for the Labelling of Pre-packaged Foods, authorizes the use of a supplementary label that fully and accurately reflects the information contained on the original label.

2.361. The delegation of Paraguay provided the following statement. We thank Costa Rica for including this trade concern on the agenda and request that Paraguay's support be recorded. Paraguay supports Mexico's goal of protecting public health and considers that the provision of nutritional information to consumers is an appropriate strategy. However, Paraguay shares the concern of other countries over the mandatory declaration of added sugar, which is not provided for under Codex guidelines. Paraguay is also concerned that there is no analytical method for distinguishing total sugars from added sugars, which would render enforcement difficult, since this would depend on the information provided by the industry.

2.362. In response, the delegation of Mexico provided the following statement. As has been previously mentioned by Mexico, we are aware that international schemes for the labelling of foods now exist under Annex 2 to the Codex Alimentarius Guidelines on Nutrition Labelling (CXG-2-1985), adopted in 2021. However, at the time NOM-051 was being prepared, there were no international reference standards that could be used as a basis for establishing front-of-pack labelling for pre-packaged food and non-alcoholic beverages. The adoption, modification and/or annulment of technical regulations in Mexico are governed by the standardization process, time-frames and stages established under the Law on Quality Infrastructure, as well as under the General Law on Regulatory Improvement, which includes a regulatory impact analysis applicable to Mexican Official Standards. The Government of Mexico reiterates its responsibility to comply with the international commitments

⁷⁵ National Strategy for the Reduction of Sodium/Salt Consumption 2012–2021

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

Regulatory impact analysis of the draft resolution defining the maximum sodium content for prioritized foods

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

⁷⁶ For previous statements follow the thread under [ID 608](#).

set out in the Agreement on Technical Barriers to Trade and those relative to the free trade agreements to which Mexico is party, as well as to constantly harmonize technical regulations with international parameters, recognizing the legitimate objective of public policy to safeguard the population's health generally.

2.363. The Chair noted that the Committee was running out of time.⁷⁷ He encouraged Members to keep their interventions short and suggested that Members that had uploaded their statements on eAgenda simply refer to them rather than reading them out. The Secretariat would ensure that the full content of the statement would be recorded in the minutes of the meeting even if it had not been read out.

2.364. The Secretariat confirmed that this could be done.

2.365. The representative of the United States noted that they would carry out the Chair's suggestion on a voluntary and case-by-case basis, depending on the importance of the particular STC. The United States stressed the tremendous amount of time spent in the preparation and vetting of questions in advance of the STC discussion and expressed some concern about the notion of limited time being a reason not to fully express an STC, and only referring to eAgenda.

2.366. The Chair confirmed that the proposal was voluntary in nature; Members retained the right, of course, to read out the full statement.

2.367. The representative of Colombia also stated that it would refer to eAgenda on a voluntary basis. She highlighted the importance of dealing in a detailed manner with the STCs, as in many cases new elements and questions were raised, despite a lack of change in the responses over time.

2.368. The representative of Canada suggested that the Chair could encourage Members to use a certain time limit in which to intervene rather than simply referring to statements in eAgenda.

2.369. Whilst acknowledging the time constraints of the Committee, Chile, Paraguay, and Uruguay reserved the right to intervene to the extent necessary.

2.1.3.41 Australia - Maturation requirements for imported alcohol (ID 636⁷⁸)

2.370. The delegation of Brazil provided the following statement. Brazil continues to follow closely Australia's proposal to amend current regulations dealing with alcoholic beverages, and we would like to thank Australia for its response in the Committee's last meeting and for its engagement in bilateral talks. In past meetings, we have shared our concerns with Australian technical requirements applicable to cachaça, the Australian Customs Notice N° 2007/19, which requires that some alcoholic beverages must be matured in wood for a minimum of two years before delivery from Customs control. This covers all beverages under tariff classifications 2208.20.10, 2208.30.00 and 2208.40.00. Even though said Notice only refers directly to brandy, rum, and whisky, it encompasses tariff line 2208.40.00 (rum and other spirits obtained by distilling fermented sugarcane products), under which cachaça is classified in Australia. By granting the same treatment to cachaça and rum, the Australian government does not allow imports of cachaça that are not matured for at least 2 years in wood. Such a requirement does not relate to any quality standard or sanitary requirement applicable to cachaça.

2.371. Following a public consultation in late-2019, the Australian Border Force (ABF) further explored a potential avenue to amend the Customs Act 1901 (Customs Act) that would enable the legitimate importation of certain alcohol products into Australia whilst retaining the maturation requirements for brandy, whisky, and rum. According to a more recent public consultation, the Australian government is developing an approach that is looking to retain Australia's existing maturation requirement for imported brandy, whisky, and rum, but would establish a list of products exempt from this maturation requirement. The proposed list of exempt products would include Cachaça, Pisco and Bourbon. Brazil acknowledges progress in the course of action proposed in the last public consultation. We support the creation of a list of exceptions to the rules set out today in section 105A, thus allowing certain cultural and geographical indications (i.e. Cachaça) that are not traditionally described as brandy, whiskey or rum to be imported into the Australian market. In order

⁷⁷ The intervention was made by Chair at the beginning of the last day (15 July) to address a timing issue.

⁷⁸ For previous statements follow the thread under [ID 636](#).

to avoid any confusion in the Australian market or among Australian consumers, we support that none of the sugar-cane products imported to Australia (matured or unmatured) that are not specifically "rum" should be labeled or marked as "rum". We kindly urge Australia to clarify the following points, which could not be addressed in its previous statements: Could Australia please confirm if this new regulation will also establish new labeling requirements for products other than rum, brandy and whisky? Could Australia provide timeframes for the publication of the final text?

2.372. In response, the delegation of [Australia](#) provided the following statement. We acknowledge Brazil's continuing interest in Australia's review of maturation requirements for imported alcohol and provide the following update on this matter. Australia has concluded its review of the legislative framework for the importation of certain unmatured alcohol products under section 105A of the Customs Act 1901 (Customs Act). We acknowledge that the review process took longer than anticipated due to the impact of the COVID-19 pandemic and the legislative complexities associated with this matter. Taking into account stakeholder concerns identified through public consultations in 2019 and 2020, we are now working with the new Australian Government to make changes to the maturation requirements as necessary and as a priority. The Australian Government will notify the Committee of any proposed legislative changes to section 105A of the Customs Act and any other changes to alcohol import requirements, in accordance with Australia's obligation under the TBT Agreement, once all necessary Australian Government processes have been finalized regarding changes to the maturation requirements.

2.1.3.42 India – FSSAI's Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and the new implementing veterinary certificate for dairy products (ID 633⁷⁹)

2.373. The delegation of the [European Union](#) provided the following statement. The European Union would like to refer to its previous statements on this matter. While the European Union fully supports the importance of labelling the presence of animal rennet, the European Union considers that the new certificate requiring that milk products have not been manufactured using animal rennet is not proportionate and not in line with the TBT agreement. Veterinary certificates are to address sanitary (human or animal) health issues and there is no scientific evidence that cheese produced with animal rennet is harmful to health, or more harmful than cheese produced with artificial/vegetal rennet. Therefore, the European Union would ask India to amend the provisions of that veterinary certificate and allow for a label clearly indicating the presence of animal rennet in the cheese and its by-products, as it was previously the case. This label would allow consumers to make an informed choice.

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

2.1.3.43 Republic of Korea - Revision of Safety Conformation Criteria for Textile Products for Infants, [G/TBT/N/KOR/678](#) (ID 652⁸⁰)

2.375. The delegation of the [European Union](#) provided the following statement. The EU would like to ask the Republic of Korea to provide contact details of conformity assessment experts from the Korean Agency for Technology and Standards (KATS) in order to make progress on resolving this issue with the view to having conformity testing, to the specific Korean rules for infant clothing, be performed outside Korea by internationally accredited laboratories. Contact details from the EU side were provided in March 2022. A meeting took place between the EU delegation in Korea and KATS in May 2022. At this meeting, KATS was apparently suggesting an alternative way forward and committed to providing further information but, as yet, no information has been received so we would appreciate if you could contact KATS in order that we receive this input in a timely manner.

⁷⁹ For previous statements follow the thread under [ID 633](#).

⁸⁰ For previous statements follow the thread under [ID 652](#).

2.376. In response, the delegation of the [Republic of Korea](#) provided the following statement. Korea would like to thank the EU for its concerns and comments regarding the "Requirements for Textile Products for Infants" of Korea, and we would like to take this opportunity to respond to the request, which was raised by the EU at this TBT Committee. In May, an informal meeting was held between the Korean officials in charge and the EU delegation in Korea for a working-level discussion regarding the EU's requests to designate a KC testing institution to be in charge of Korean infant textile products in the EU and to exchange contact points for experts in relation to this. At this meeting, the EU's request for the designation of a testing institution with regard to infant textile products in the EU as a KC testing institution for Korea was discussed. Practically, it would have a limitation under the current Korean laws, to designate a testing institution in the EU as Korea's KC testing institution related to infant textile products. Also, at the Korea-EU FTA Goods and Trade Committee meeting, in April 2022, Korea requested the EU for the designation of an institution in Korea as an Approval Authority that can issue E-mark for automotive tyre certifications. Korea reiterated this matter in May in the informal working-level meeting with the EU delegation in Korea.

2.377. In conclusion, both Korea and the EU have requested each other for the designation of a testing institution within one's own country. In order to address this issue of mutual designation of an institution, Korea mentioned in the working-level discussion, in May, that it would be necessary to review MRA between Korea and the EU. And the EU, also agreeing with this, requested Korea to provide MRA-related materials. Discussions surrounding Mutual Recognition Agreement (MRA) require the participation of various stakeholders (government officials, testing and certification experts, relevant industry, etc.), so that continuous consultations between the two parties are necessary. For this reason, Korea believes that we are in need of a mechanism through which TBT issues between two parties can be discussed formally and efficiently. Therefore, Korea would like to propose to the EU to establish the TBT Dialogue or the TBT working-group based on the Korea-EU FTA. Through the establishment of such a mechanism, Korea expects that TBT issues between the two parties can be discussed/resolved efficiently.

2.1.3.44 European Union - Commission Delegated Regulation (EU) 2019/945 on Unmanned Aircraft Systems and on Third-country Operators of Unmanned Aircraft Systems, [G/TBT/N/EU/628](#) (ID 585⁸¹)

2.378. The delegation of [China](#) provided the following statement. In accordance with the TBT Agreement, which requires that "technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective", it is recommended that the EU could maintain the noise limit at 83dBA, the reasons are as follows: 1. The requirements for noise limits are much higher than the requirements to protect human health. According to the EU Directive 2003/10/EC "The minimum health and safety requirements regarding the exposure of workers to the risks", the 8-hour sound exposure levels are: exposure limit values: LEX,8h = 87 dB(A); upper exposure action values: LEX,8h 85 dB(A) and lower exposure action values: LEX,8h = 80 dB(A). We have derived the conclusion from the formula (provided annex for the derivation process) that: 1) At a sound power level of 81dBA, a drone can meet the arbitrary sound exposure level requirement within 8 hours when a person only needs to be 0.32m away from it. 2) At a sound power level of 83dBA, a drone can meet the arbitrary sound exposure level requirement when 0.4m away from it. 3) If calculated based on a normal flight distance of 3m for recreational drones, the permissible value of sound power for drones can even be increased to 100dBA. The above-mentioned derived formulas were also carried out in unprotected, regular daily exposure to drone noise. In practical application scenarios, category C1 and C2 drones are mostly operated remotely. The control distance between humans and drones can be 7-10km, and there is no situation where a person has to be in close proximity to the sound source for a long time in order to use it, which has a much lower impact on human health.

2.379. 2. If the noise limit is continually reduced, it will lead to a reduction in the drones' performance. Drone noise primarily comes from the rotating propellers. As the requirement of the regulation is to sound power levels rather than sound pressure levels in the direction of impact (e.g. ground), it is not possible to achieve the limits by changing the directivity of the sound radiation, or reducing the noise in a particular direction, etc., which can only be achieved by reducing the weight of the drone or by significantly reducing the rotational speed of the propellers. On the one hand, reducing the weight would make drones impossible to carry a larger, more capable camera and gimbal, on the other hand, reducing the rotational speed of the propellers will lead to larger propeller

⁸¹ For previous statements follow the thread under [ID 585](#).

size and higher torque, resulting in shorter endurance and an increased risk of propeller injury to people in some certain circumstances. To follow Art 2.2 not creating unnecessary trade barriers to trade, China suggests that the EU sets the sound power limits at 83 dBA already fully satisfies the necessary requirements for human health protection.

2.380. In response, the delegation of the European Union provided the following statement. The draft Commission Delegated Regulation on unmanned aircraft systems, and on third-country operators of unmanned aircraft systems was notified to the WTO on 9 January 2019 under [G/TBT/N/EU/628](#). Commission delegated Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft system and Commission Implementing Regulation (EU) 2019/947 on the rules and procedures for the operation of unmanned aircraft were published in June 2019. Regarding the noise requirement, the EU would like to draw the attention of the delegation of China to the fact that those requirements apply to a limited number of products (C1 and C2 UAS). The objective of the requirement is not so much to protect the health of the drone pilot as to reduce noise pollution for citizens. More detailed answer can be provided after a detailed analysis of the Chinese comments.

2.1.3.45 United Arab Emirates - Requirement of G-mark for every toy (ID 702⁸²)

2.381. The delegation of India provided the following statement. India has raised this STC in the two previous TBT meetings and is still waiting for a response from the UAE. India is deeply concerned about the UAE's G-Mark requirement for all children's toys exported to the UAE. It can be issued only by the agencies authorized by the GCC Standardisation Organisation. This requirement of G-mark makes Indian products uncompetitive in the UAE as no agency is authorized to issue G-mark in India. To get G-mark certified products, Indian exporters have to send the entire consignment to the place where it can be G-mark certified. The G-mark needs to be obtained for each toy as per the extant regulation. This process involves additional procedural requirements; it is also cost-intensive and makes the Indian product uncompetitive when placed in the UAE market. Further, during the conformity assessment, the G-mark Notified Bodies (NBs) frequently request physical samples of all products in a group, not only the representative item. Despite the latest GSO guidance specifying test reports are required for only one representative item from a product group. A physical inspection of all items in a product group is burdensome, costly and inconsistent with Article 5.1.2 of the TBT Agreement. As per Article 5.1.2 of the TBT Agreement, Members are obligated to ensure that CAPs are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. CAPs shall not be stricter or applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.

2.382. Hence the UAE is requested to consider that when the G mark is obtained for each and every toy, then the physical sampling should not be insisted by the Notified Bodies for all the products in the group. Such insistence is trade-restrictive and renders high costs and difficulties. Besides, it is also inconsistent with Article 5.1.2 of the TBT Agreement. We urge the delegation of United Arab Emirates to engage constructively on this issue. We are keen to discuss this issue bilaterally as well.

2.383. In response, the delegation of the United Arab Emirates did not make a statement during the meeting. A technical statement was circulated following the meeting.⁸³

2.1.3.46 Colombia – Good manufacturing practices of overseas production establishments, [G/TBT/N/COL/242](#) (ID 697⁸⁴)

2.384. The delegation of the European Union provided the following statement. I would like to refer to our previous statements and the statement uploaded in the eAgenda. I would also like to encourage Colombia to continue the fruitful cooperation with the EU delegation regarding a possible acceptance of Free Sales Certificates issued in the EU member States.

2.385. The European Union would like to thank Colombia for its reply of November 2020 to the EU written comments and for the extensive bilateral discussions. The European Union notes that Article 3 of the Decree no 162 published on 16 February 2021 refers to the possibility to present alternatives

⁸² For previous statements follow the thread under [ID 702](#).

⁸³ [G/TBT/W/772](#).

⁸⁴ For previous statements follow the thread under [ID 697](#).

to the Good Manufacturing Practices certificate upon import to Colombia. EU exporters of wines and spirit drinks already comply with the existing obligation to submit Free Sales Certificates for sanitary register. The Free Sales Certificates state that the product is compliant with the EU legislative requirements, which encompass Good Manufacturing Practices. The European Union therefore considers that Free Sale Certificates issued by EU Member States would comply with the Colombian requirement to provide Good Manufacturing Practices certificate upon import. The European Union would, therefore, like to ask Colombia to confirm this interpretation. As the time left for the entry into force of these requirements is getting shorter, the European Union is increasingly concerned about negative impact this measure could have on its exports of wines and spirits, especially from SMEs, should not all its Free Sale Certificates be accepted. Therefore, the European Union is prepared to continue the bilateral work should there be any need for additional clarifications.

2.386. In response, the delegation of Colombia provided the following statement. Colombia thanks the European Union for working with the relevant health authorities to clarify the concerns raised regarding compliance with Decree No. 162 of 2021, issued by the Ministry of Health and Social Welfare. In this regard, we wish to report that the relevant authorities continue to work with the European Union, through the EU Trade Section in Colombia, on issues related to compliance with Decree No. 162 of 2021, particularly in respect of the acceptance of certificates of good manufacturing practices, thus responding to the concerns raised relating to the acceptance of certificates of free sale (CVL) issued by the competent authorities of the European Union. As a result, the text issued amended Article 22 of Decree No. 1686 of 2012, to ensure equal conditions relating to the certificate of good manufacturing practices (GMP) for domestic producers and producers located outside the national territory, and provided the following four alternatives for complying with the technical regulation: (a) Certificate of good manufacturing practices (GMP), from the manufacturing and/or packaging establishment, issued by the relevant authority of the country of origin, by the accredited certification body or by the authorized third party in the country of origin. (b) Hazard Analysis and Critical Control Point (HACCP) System certificate or document supporting its implementation, issued by the relevant authority of the country of origin, by the accredited certification body or by the authorized third party in the country of origin of the product. (c) Certification issued by the relevant authority, by the accredited certification body or by the authorized third party in the country of origin of the product, stating that the alcoholic beverage and the producer comply with the technical standards, processes or procedures or are subject to monitoring and inspection. (d) Certificate of good manufacturing practices of the manufacturing and/or packaging establishment, issued by the National Food and Drug Surveillance Institute (INVIMA).

2.387. Thus, in order to comply with the requirement in the case of imported beverages, the Decree sets out four feasible options that do not disregard the regulations of the country of origin of the parties concerned, meaning that such parties can assess each of the above options and apply one of them in order to comply with Colombian regulations. The health authorities have indicated that certificates of free sale may be included within the scope of paragraph (c), provided that they comply with the provisions of that paragraph, namely: (i) they are issued by the relevant authority, by the accredited certification body or by the authorized third party in the country of origin of the product, and; (ii) they state that the alcoholic beverage and the producer comply with the technical standards, processes or procedures or are subject to monitoring and inspection. In view of the above, and from the information provided by the European Union, a technical and legal analysis of the guidance provided by Decree 162 of 2021 was conducted. Based on this analysis, working sessions with INVIMA will be held, in order to determine what measures would be taken to comply with the current regulations. We would like to reiterate to the European Union our interest in continuing the joint work that has been taking place between our health authorities.

2.1.3.47 Argentina - Requirement of affidavit along with the product certification from a certified body for export of boards derived from wood, [G/TBT/N/ARG/342/Add.6 \(ID 696⁸⁵\)](#)

2.388. The delegation of India provided the following statement. India has raised this concern in the previous TBT meetings; we thank Argentina for acknowledging the STC and look forward to a detailed reply. Argentina has notified the requirement of an affidavit in addition to a product

⁸⁵ For previous statements follow the thread under [ID 696](#).

certification from a certified body for the export of boards derived from wood. We refer to the statement made in the previous TBT meeting and request Argentina for a timely resolution.

2.389. In response, the delegation of [Argentina](#) provided the following statement. By means of SCI Resolution No. 240/2019, amended by Resolution No. 428/2021, the Secretariat of Domestic Trade approved the Specific Technical Regulation establishing the technical quality and safety requirements to be met by coated and uncoated wood-based fibreboard and particleboard marketed in the territory of the Argentine Republic. The purpose of the measure was to address the problem identified with the presence on the market of low-quality boards that pose a risk to human health, mainly linked to high formaldehyde emissions, low mechanical strength and low abrasion resistance, without the consumer being able to distinguish between these and other boards at the time of purchase. Consequently, the Secretariat of Domestic Trade considered it appropriate to approve a measure to prevent health risks and ensure the safety of users of wood particleboard and wood fibreboard, establishing a mandatory regulation that sets out the technical quality and safety requirements to be met by wood-based boards marketed in the territory of the Argentine Republic. The regulation sets out essential requirements to ensure human safety and product quality, referring to technical standards that establish, among other matters, the maximum permissible limits of formaldehyde that boards may emit or contain, with the aim of protecting the health of the population and consumer rights.

2.390. With regard to conformity assessment procedures, we reiterate what was previously stated about the procedure provided for in SCI Resolution No. 240/2019 and its amendment, SCI Resolution No. 428/2021, which establishes three different stages for the implementation of the measure that do not overlap, given that the affidavit stage ends once the certification stage takes effect. The various requirements at each stage do not imply a duplication of requirements but provide a transition period until the full certification stage. This gives operators and the quality system time to adapt to it. Lastly, it bears repeating that the Argentine Focal Point has no record of the comment submitted by India.

2.1.3.48 European Union - Withdrawal of the approval of the active substance alpha-cypermethrin, [G/TBT/N/EU/770](#), [G/TBT/N/EU/908](#) (ID 694⁸⁶)

2.391. The delegation of [Brazil](#) provided the following statement. Brazil would like to express its concerns related to European notification 770 regarding the Commission Implementing Regulation proposal to withdraw the approval of the active substance alpha-cypermethrin. 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. If the register of said substance is withdrawn and MRLs are automatically reduced, it would significantly affect the income of Brazilian farmers, especially citrus producers. The substance is essential to control greening, a disease affecting citrus orchards worldwide. Greening has been recognized by EFSA itself as a priority pest for control, according to the Commission Delegated Regulation (EU) 2019/1702. The Brazilian citrus industry plays an important role in generating jobs in the countryside. Export of orange juices to the European market represented almost USD 1 billion of exports in the 2019-2020 marketing year.

2.392. Alpha-cypermethrin is also an important component to conduct integrated pest management, once it may be combined with other insecticides to contribute to increase their useful life, ensuring efficient pest control and maintaining the sustainability of crop production. In light of the above, Brazil would like to kindly encourage the EU to adopt MRLs for imported products in accordance with the limits set under the Codex Alimentarius. Also, we would like to consult if the EU may extend the approval of the active substance beyond 31 October, in order to minimize the impact on Brazilian citrus producers. Last, on a related notification submitted last week ([G/TBT/N/EU/908](#)), the EU communicated the review of all existing maximum residue levels for Clothianidin and Thiamethoxam, on the grounds of (and I quote) "an environmental concern of global nature" (end of quote). These two active substances are very important as insecticides used against harmful pests for a wide variety of crops, like soybeans, coffee, corn, tobacco, sugarcane and fruits. We kindly ask the EU to consider extending the 60 days period of consultations and postponing the proposed date for adoption of the review so that comments from Members can be taken into account and negative implications for agricultural producers worldwide can be mitigated.

⁸⁶ For previous statements follow the thread under [ID 694](#).

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

2.394. In response, the delegation of the European Union provided the following statement. As explained in previous TBT Committees, the approval of Alpha-cypermethrin had to be withdrawn, as the Commission Implementing Regulation that renewed its approval in 2019 included the condition that the applicant had to submit confirmatory information as regards the toxicological profile of certain metabolites by 30 October 2020. In addition, confirmatory information had been required for three other points by other deadlines. However, in October 2020, the applicant informed the Commission that it would not submit any confirmatory data. Therefore, as the information required in accordance with Article 6(f) of Regulation (EC) No 1107/2009⁸⁷ on plant protection products was not submitted and the applicant had clearly stated that he will not fulfil his regulatory obligations, the approval for Alpha-cypermethrin had to be withdrawn according to Article 21(3) of Regulation (EC) No 1107/2009. As regards Maximum Residue Levels (MRLs), a review of the whole group of cypermethrins is currently ongoing by the European Food Safety Authority (EFSA). Existing Codex maximum residue limits and import tolerances will be considered in this review. EFSA intends to finalise the review in the second half of 2022. After that, the EU will consider the outcome and follow up on it, if appropriate. If there was a need for a specific measure on MRLs, such a measure would be notified to the WTO/SPS Committee. If Brazil and other Members consider it necessary to ensure that MRLs for Alpha-cypermethrin on relevant crops that were based on previous and now obsolete EU uses remain or should be newly set at higher/different levels, they may wish to submit an application for setting import tolerances according to Article 6 of Regulation (EC) No 396/2005⁸⁸ on maximum residue levels of pesticides in or on food and feed of plant and animal origin. The EU would like to invite Brazil to contact the relevant authorities in Belgium, the Rapporteur member State, and to ensure that the necessary information will be available in due time for the evaluation by the Rapporteur member State and EFSA.

2.1.3.49 Indonesia - Government Regulation 28 of 2021 – Implementing Regulation (for the Manufacturing/Industry Sector) to Law No. 11 of 2020 the "Job Creation Act" (ID 724⁸⁹)

2.395. The delegation of the European Union provided the following statement. The EU refers to previous statements on this matter and also to the statement uploaded in eAgenda. It is quite a complex legislation which affects several sectors. We would like to thank the delegation of Indonesia for the good cooperation. We understand that there are some improvements in implementation so we hope that we continue in this direction.

2.396. The European Union is seriously concerned by Government Regulation No.28 of 2021 and new 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) passed last year. Government Regulation 28/2021 aims to increase the competitiveness of Indonesia's national industry and mainly outlines measure related to raw materials. It also introduces new requirements with regard to product certification bodies (Lspros). We understand that the new requirements affect in principle all products subject to SNI certification and it is very complex to export to Indonesia. Certain sectors appear to be particularly concerned.

⁸⁷ 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.

⁸⁸ 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.

⁸⁹ For previous statements follow the thread under [ID 724](#).

2.397. With regard to the toys sector, articles 38 and 39 create significant challenges. Article 38 prohibits certification bodies (Lspros) from using third-party testing facilities. Article 39 stipulates that product certification bodies (Lspro's) be Indonesian entities, employ Indonesian citizens, residents of Indonesia to assess product compliance to Indonesian National Standards. Regulatory bodies are now giving this article an overly strict literal interpretation as requiring that every step of the SNI certification be conducted by Indonesian nationals residing in Indonesia, etc. We understand this is both required for scheme 1 (batch testing and pre-shipment inspection) and scheme 5 (factory certification). This new approach appears to be implemented despite of no ministerial implementing regulation, which is normally required in the Indonesian regulatory process to implement a Government Regulation. In terms of impact, this means that for batch testing and pre-shipment inspection, samples need to be taken by an employee/Indonesian resident of certification bodies. Due to travel restrictions related to COVID, it was and it is very difficult for certification bodies (Lspros) to send personnel overseas to sample products or to conduct factory audits. As a result, all certification bodies have either stopped overseas sampling or stopped overseas certification altogether.

2.398. In addition, even when international travel would be easier, the new requirements will still add significant costs and delays. The tire industry is also facing major problems. According to our information Indonesia is applying a mandatory certification system for certain spare parts (original and non-original) including tires, safety glazing, rims, primary-batteries and audio/video-components. This implies the audit of the plant where the spare parts are produced (in accordance with ISO 9001) as well as an analysis of the products conducted by Indonesian test institute. This is followed by scheduled conformity of production audits. Currently the Indonesian test institute has suspended both the audit of the plants for new certifications, as well as the conformity assessment inspections. The result is that products requiring a new certifications cannot be imported into Indonesia, and those products which already have a certification will be also banned from Indonesia when their respective certifications expire. The European Union would like to understand what measures Indonesia is putting in place to ensure that EU spare parts can be smoothly imported into Indonesia.

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

2.400. The delegation of the United States provided the following statement. The United States continues to have serious concerns with the Government of Indonesia Regulation No. 28 of 2021, which is the Implementing Regulation (for the Manufacturing/Industry Sector) to Law No. 11 of 2020 of the "Job Creation Act" (GR28/2021), particularly when this measure is already disrupting trade between our countries. US industry is reporting that, in the absence of implementing regulations from the Ministry of Industry, many conformity assessment bodies have halted certification for foreign products, resulting in the halt of exports requiring Indonesian national standards (SNI) testing per shipment. We understand these implementing regulations are still undergoing domestic processes and we urge Indonesia to fulfill its transparency obligations and notify these regulations in draft form to this Committee prior to finalization. We strongly request Indonesia to ensure that all domestic conformity assessment bodies are continuing foreign product certification per previous guidance. We again ask Indonesia to provide a justification for the new requirement that conformity assessment testing to be conducted by Indonesian citizens domiciled in Indonesia. How do these requirements relate to the ability to perform conformity assessment?

2.401. We are concerned that requiring onsite inspections and collection of product samples solely by Indonesian nationals domiciled in Indonesia will effectively halt imports into Indonesia, and already appears to be doing so. Why is Indonesia not allowing remote factory inspections, given travel restrictions and disruptions caused by the ongoing global pandemic that may prevent onsite inspections? Indonesia recently noted to us that they will only accept foreign conformity assessment from labs that have been selected by the Ministry of Industry in Member countries that have signed a mutual recognition agreement. Can Indonesia please elaborate on the necessity and contents of these proposed MRAs? Will further guidance about these requirements be included in the implementing regulations for GR28/2021? We again seek clarification on whether Article 38 requires that conformity assessment bodies must also operate their own testing laboratories for all products required to be certified to SNIs. We again encourage Indonesia to immediately communicate to Indonesian conformity assessment bodies that certification of foreign product shipments can, and should, continue while MOI prepares the implementing regulations.

2.402. The delegation of Canada provided the following statement. Canada joins other Members to raise its concerns with Indonesia's Government Regulation 28 of 2021 – Implementing Regulation (for the Manufacturing/Industry Sector) to Law No. 11 of 2020 the "Job Creation Act", which was published on February 2021 as part of an implementing regulation to the Omnibus Law on Job Creation. Canada understands that Government Regulation 28/2021 introduces new requirements with regard to product certification bodies (Lspros) and SNI certification. More specifically, Article 39 (e) states that "Certification agencies as referred by Article 38 verse (1) are required to ... deploy competent personnel who is an Indonesian national, domiciled in Indonesia, is fluent in the Indonesian language, understands regulations, and has been registered by the Minister". Could Indonesia please confirm whether this means that every step of the SNI certification must be conducted by Indonesian nationals and that they must be domiciled in Indonesia? In addition, Article 38 (4) states that "The appointed certification agencies as referred by verse (3a) must ... have an accredited testing laboratory based on SNI ISO/IEC 17025 or an accredited inspection lab based on SNI ISO/IEC 17020".

2.403. Could Indonesia please confirm whether this means that the Regulation prohibits Lspros from using third-party testing facilities and requires that every Lspro owns and operates a testing lab for all products – across all industries - they certify. Could Indonesia also confirm whether those requirements apply to all products regulated under SNI, which we understand to be over 100 products across all industries? At the last TBT Committee meeting, Indonesia indicated that SNI certifications are conducted through factory inspection and samples are taken on-site by authorized personnel. Indonesia also stated that it accepts testing result from accredited foreign testing laboratories under the mutual recognition arrangement framework and availability of technical regulation agreement between Indonesia and a partner country. Canada is unclear how inspection of factories or product sampling abroad is necessary to ensure that products comply with Indonesian safety requirements. If the purpose of the inspection is in fact product testing, what would be Indonesia's rationale for not accepting ILAC accredited foreign testing laboratories without a mutual recognition arrangement framework in place? The MRAs Indonesia proposes would not be a solution for Canada as, first, we do not have similar regulatory requirements, and second, MRAs would not address the full extent of Canada's concerns given that several stakeholders have their production located outside Canada, where Canada is not in a position to facilitate MRA discussions.

2.404. The requirement for on-site factory inspection, inspection by an Indonesia national, and testing by a person domiciled in Indonesia are all unnecessary barriers to trade. In addition, failing to provide alternatives is inconsistent with international product safety practices. Canada kindly asks that Indonesia pause the implementation of this measure, notify it to this Committee, provide a minimum 60-day comment period for members to comment, and take those comments into consideration before finalising the measure. Canada strongly encourages Indonesia to review the interpretation of Government Regulation 28/2021 and provide more flexibility regarding the requirement for Indonesian nationals, and residents of Indonesia to perform product sampling, factory audits, and testing. Canada also kindly requests Indonesia accept test results from ILAC accredited foreign testing laboratories, and to consider developing clear guidance for industry.

2.405. In response, the delegation of Indonesia provided the following statement. Indonesia thanks the United States of America, the European Union, and Canada for its continuous interest on Government Regulation 28 Year 2021. Indonesia would like to refer to its last statement in TBT Meeting on March 2022, and in our bilateral discussion with the US and EU. Certification process for technical regulations based on SNI in the industrial sector is carried out in accordance with the

provisions stated on the related Minister Regulation. All provisions regarding standard and conformity assessment scheme apply equally for both domestic and foreign manufacturers. Indonesia accepts testing results from accredited foreign testing laboratories under the mutual recognition arrangement framework and availability of technical regulation agreement between Indonesia and its country partner.

2.1.3.50 India - Chemical Fibers and Yarns: PSY, IDY, FDY, POY, PSF, and SMF for use in Cement-Based Matrix (Quality Control) Orders, 2020, [G/TBT/N/IND/185](#), [G/TBT/N/IND/188](#), [G/TBT/N/IND/189](#), [G/TBT/N/IND/190](#), [G/TBT/N/IND/192](#), [G/TBT/N/IND/194](#) (ID 717⁹⁰)

2.406. The delegation of the Republic of Korea provided the following statement. Regarding India's six Quality Control Orders (QCOs) for Chemical Fibers and Yarns (PSY, IDY, FDY, POY, PSF, and SMF⁹¹) notified to the WTO on January 2021 as [G/TBT/N/IND/185](#), [G/TBT/N/IND/188](#), [G/TBT/N/IND/189](#), [G/TBT/N/IND/190](#), [G/TBT/N/IND/192](#) and [G/TBT/N/IND/194](#), Korea submitted comments three times in August and November 2021, and March 2022, concerning the enforcement dates and revision of regulation. In response, the Indian government provided an additional grace period twice, firstly until April 2022 and secondly until October 2022, partially resolving the difficulties of Korean companies. Korea fully appreciates the Indian government for its kindest efforts. We respect the efforts of India to introduce Chemical Fiber QCOs for the health and safety of the Indian people. Furthermore, Korean companies are making their best efforts to faithfully comply with the regulations of India. However, we would like to deliver requests as Korean companies still have unresolved technical difficulties regarding the six QCOs.

2.407. Firstly, the notified BIS regulations are considered excessive compared to international practices. Generally in other countries, the governments do not operate certification schemes for the items under the scope.⁹² And in privately operated certification system (not governmental certification scheme), certificates are issued after the product testing is performed only once either by a designated laboratory or during an on-site factory audit. However, in the case of India, not only does the government implement compulsory certification schemes for these items, but also its regulations require products to be tested twice, during a factory audit and by a local BIS-designated laboratory. The duplicated test requirement causes an undue burden on the relevant industry. Therefore, we request that India streamline the certification process so that chemical fibers and yarns can be certified with a single test conducted by a BIS-designated organization, bypassing the test during an on-site factory audit.

2.408. Secondly, the information on the attachment location for the ISI Mark is not publicly available. If it is required to attach the mark directly to the product, it is practically difficult to comply with the regulation due to the nature of the yarn product. Therefore, we request that India provide information on the method of mark attachment. In case that the mark is to be attached to the product, we request that India mitigate the certification requirements in a reasonable way for manufacturers to accept such as recognizing BIS certification numbers declared in shipping documents as an alternative method⁹³ for the ISI mark attached to the product. Your reply on this matter would be deeply appreciated.

2.409. The delegation of the European Union provided the following statement. The European Union would like express its support to this trade concern raised by Korea. The notified measures require products to be tested twice, including local audits and designated laboratory tests. There is also an additional burden to the EU industry related to registration, bank-guarantee, and certification. The control by the Bureau of Indian Standards (BIS) is seen as disproportionate as the products do not present risk to health and safety, and they are subject to a detailed quality control in the EU before being exported. Furthermore, the notified measures deviate from international standards.

⁹⁰ For previous statements follow the thread under [ID 717](#).

⁹¹ PSY: 100 Percent Polyester Spun Grey and White Yarn; IDY: Polyester Industrial Yarn; FDY: Polyester Continuous Filament Fully Drawn Yarn; POY: Polyester Partially Oriented Yarn; PSF: Polyester Staple Fibres; SMF: Synthetic Micro-Fibres for use in Cement Based Matrix.

⁹² Korea (KC certification) and the United States (CPSIA regulation) require compulsory certification only for children's textile products or skin-contact textile products such as clothing. Other items such as yarns are managed with voluntary certification.

⁹³ Currently, Oeko-Tex, GRS, etc. include copies of their certificate in shipping documents or send the copies to customers separately.

2.410. In response, the delegation of India provided the following statement. The product certification schemes operated by BIS are governed by the BIS (Conformity Assessment) Regulations, 2018 notified by the Central Government. The QCOs issued for PSY, IDY, FDY, POY, PSF mandate a licence from BIS under scheme-I of the said regulations as per the respective Indian Standard prescribed in the QCOs. The requirement of ISI marking on the product/packaging is a statutory requirement under the aforementioned regulations and is equally applicable to both foreign and domestic manufacturers. Further, through the ISI mark only the end user / consumer is able to identify that the product is certified and conforms to relevant standard. The detailed guidelines including Indian Standards and Product Manuals for certification of PSY, IDY, FDY, POY, PSF are available on BIS website.⁹⁴ The scheme of inspection and testing contained in the product manual for each product, available on BIS website, contains the manner of marking of Standard Mark for the respective products.

2.1.3.51 Japan - Inspection system for sports goods and toys and non-acceptance of test reports from Indian test houses (ID 747⁹⁵)

2.411. The delegation of India provided the following statement. India had raised this concern in the previous meeting of TBT. The details of the issue were provided in that statement. We would like to reiterate the questions raised in the previous Committee meetings. We remain concerned with the application of WTO-plus private standards, which seem excessive and not in conformance with the Good Regulatory Practices as understood in the ambit of TBT. We hope to get an early resolution from Japan on this issue dropping trade restrictive practices.

2.412. In response, the delegation of Japan provided the following statement. The Toy Safety Standard (ST standard) is not a mandatory technical regulation. The ST standard is established by the Japan Toy Association (JTA) itself as a voluntary standard, thus any toys to be imported and distributed in Japan don't have to conform to the ST standard. Japan has already informed India that the ST standard is not a technical regulation, and we would like to know further about the details of India's concern. Regarding the Food Sanitation Act, standards are set only for toys for infants, among the goods India has mentioned. The quarantine stations in Japan check the safety of toys for infants and provide guidance for testing as necessary. The quarantine stations in Japan accept certificate of analysis from Foreign Official Laboratories as test results to determine the conformity to the standards for toys for infants. The Ministry of Health, Labour and Welfare registers testing laboratories for which the government of the exporting country recognizes a certain level of inspection ability, and puts those laboratories on the list of Foreign Official Laboratories upon request from the government of the exporting country. As previously communicated, the testing laboratories in India are registered on that list, and the list is published on the website of the Ministry of Health, Labor and Welfare.⁹⁶ Lastly Japan always welcomes bilateral talk with India on this matter.

2.1.3.52 United Kingdom - EC marking certificate for export of home textile items (ID 740⁹⁷)

2.413. The delegation of India provided the following statement. India had raised this concern in the previous meeting of TBT. The details of the issue were provided in that statement. We would like to reiterate the questions raised in the previous Committee meetings. We also remain bilaterally engaged with the United Kingdom and will also appreciate any update on this trade concern.

2.414. In response, the delegation of the United Kingdom provided the following statement. The United Kingdom welcomes India's continued interest in our Personal Protective Equipment requirements and the certification requirements with respect to two textile items (Oven Gloves and Pot Holders). We would like to draw attention to our response from 20 June, outlining that Regulation 2016/425 already states that products which are clearly within the same product family, varying only in regard to certain characteristics and which do not impact on the essential health and safety requirements of the regulation, can reasonably be certified under a common certificate. Where minor changes are made after the original certification is issued, it would usually be acceptable for the manufacturer to apply for the original certification to be varied, rather than a complete, new

⁹⁴ www.bis.gov.in

⁹⁵ For previous statements follow the thread under [ID 747](#).

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https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/yunyu_kanshi/index_00019.html

⁹⁷ For previous statements follow the thread under [ID 740](#).

certification being required. Where changes are made to the product, any differences would need to be considered in terms of whether they affect the conformity of the product being considered. Differences impacting the conformity of a product could include, for instance, if a dye used to change a product's colour was more flammable or contained harmful toxins. This would be a change which impacts the conformity of the individual product. Where changes do not affect compliance, it would be possible to incorporate broadly similar products into a family certification of one or more certificates with reduced testing. We also note that the Regulation, as it applies in Great Britain, is unchanged in substance from Regulation (EU) 2016/425 on Personal Protective Equipment, other than to make it work for the Great Britain market. Therefore, the essential health and safety requirements remain unchanged, as do the arrangements for conformity assessment, and marking (but with UKCA as opposed to CE marking). The essential health and safety requirements that must be met for certification are set out in Annex II Regulation 2016/425. We remain available for further bilateral discussions with India to discuss our regulatory approach.

2.1.3.53 India - Plastic Waste Management (Amendment) Rules, 2021 and 2022 (ID 719⁹⁸)

2.415. The delegation of the United States provided the following statement. On 16 February 2022, India's Ministry of Environment, Forest and Climate Change published in the Gazette of India, the Plastic Waste Management (Amendment) Rules, 2022 (PWM Amendment Rules), which stated that the measure would come into force with immediate effect. India has not yet notified this measure to the WTO TBT Committee. We understand that the PWM Amendment Rules introduce guidelines towards a framework for Extended Producer Responsibility (EPR) on plastic waste management. These guidelines outline targets for EPR volumes, reuse, recycling, end-of-life disposal, and mandatory recycled content (collectively, the EPR targets) for producers, importers, and brand owners of plastic packaging. Can India please provide more information on how it arrived at the EPR targets? According to US industry stakeholders, it will be difficult, if not impossible, to meet many of the EPR targets given the timelines provided. Has India conducted a feasibility study on the EPR targets, and if so, will India share this study and any supporting data? We further understand that subsequent guidance published by MoEFCC indicates that the regulation went into effect 1 July 2022. While we support India's objective to mitigate pollution caused by plastic waste, we have concerns as to the implementation of this measure given the lack of notification and formal input from stakeholders and WTO Members. For example, how does India intend to address the limited availability of recycled material needed to meet its mandatory recycled content targets, particularly given the worldwide shortage of suitable recycled plastics?

2.416. Further, we would appreciate more information regarding existing approved recyclers and recycling collection systems in India. Has India conducted an assessment of its domestic capacity to collect and process materials in a way that supports its goals? We are also aware that US stakeholders have requested further clarification on some of the terms, provisions, and categorizations in the PWM Amendment Rules in order to effectively comply with the measure. For example, stakeholders have noted the need for clarification on: (1) reporting obligations of impacted sectors and the corresponding process administered by the Ministry of Environment, Forest and Climate Change; (2) the EPR fee calculation, especially in cases in which a company is not able to take back or collect the retail packaging; and (3) how producers, importers, and brand-owners can meet their EPR obligations pursuant to section 8.3 by purchasing surplus EPR certificates from other producers, importers, and brand owners of the same category. There also remains uncertainty regarding how certain packaging is classified in the four categories listed in section 5 of the measure. For example, what category (I, II, III, or IV) would packaging such as blister packs and shrink/transport wrap film fall under? Section 17 of the PWM Amendment Rules appears to be a state-level monitoring and reporting mechanism to fulfill obligations established in the EPR. Can India provide information on how state-level Central Pollution Control Boards fulfil this requirement? Given the significant impact that this measure will have on trade, we reiterate our May 2022 Enquiry Point request to notify this measure to the WTO TBT Committee; provide a public comment period of at least 60 days; take submitted comments into account prior to finalizing and implementing the measure; and to provide a reasonable transition period for industry to comply. These steps will allow further engagement with interested stakeholders and provide time for industry to obtain clarity regarding provisions, definitions, and classifications to ensure timely compliance with the obligations outlined in the PWM Amendment Rules.

⁹⁸ For previous statements follow the thread under [ID 719](#).

2.417. In response, the delegation of India provided the following statement. The Plastic Waste Management Rules, 2016, provides the statutory framework for plastic waste management in India. Rule 4 of the Plastic Waste Management Rules, 2016, provide for minimum thickness requirement for plastic carry bags and plastic sheets used in packaging and Rule 9 casts Extended Producer Responsibility on Producers, Importers and Brand Owners for environmentally sound management of Plastic packaging introduced in the market along with the products. The marking and labelling requirement on plastic packaging under Plastic Waste Management Amendment Rules, 2021, is not discriminatory and is not a barrier to international trade. The requirements are applicable in a uniform manner to domestic and international companies. Such marking and labelling requirement have also been put by other countries / regional groupings as well.

2.1.3.54 European Union - Hazard-based approach to plant protection products and setting of import tolerances, [G/SPS/N/EU/166](#), [G/SPS/N/EU/166/Add.1](#), [G/SPS/N/EU/263](#), [G/TBT/N/EU/383](#), [G/TBT/N/EU/383/Add.1](#), [G/TBT/N/EU/384](#), [G/TBT/N/EU/384/Add.1](#), [G/TBT/N/EU/495](#) (ID 393⁹⁹)

2.418. The delegation of Australia provided the following statement. Australia would like to thank the EU for its response to Australia's and other Members' concerns raised during the previous meeting. Australia would also like to thank the EU for notifying Members via [G/TBT/N/EU/908](#) on 6 July 2022 on MRLs for clothianidin and thiamethoxam. Australia understands that the EU is considering lowering existing MRLs for pesticides no longer approved in its jurisdiction due to environmental concerns - such as some neonicotinoid insecticides - to the default value and refusing new requests for import tolerances for these products. By applying EU environmental standards to imported agricultural products, this measure aims to support the EU's ambition to improve environmental objectives globally. While the EU's ambition is commendable, Australia only supports lowering MRLs to default value where a food safety risk has been identified for consumers. Taking into account environmental concerns of a global nature in setting import MRLs, in addition to consumer dietary aspects, introduces arbitrary criteria that are incompatible with current international practice. This approach assumes the EU is better placed to assess the environmental impacts of active substances in third countries than the chemical regulators of those countries.

2.419. Furthermore, this approach fails to recognize the efforts of international scientific panels and standard setting bodies - such as the Joint FAO/WHO Meeting on Pesticide Residues and the Codex Alimentarius - in establishing safe and harmonized levels of pesticide residues in agricultural products. Australia has a robust regulatory framework for agricultural and veterinary chemicals, providing Australian farmers with safe access to the pesticides they need to maintain productivity and profitability while looking after Australia's unique environment. To avoid trade disruption, it is imperative that the EU continues to comply with its obligations under the TBT Agreement when setting MRLs and considering requests for import tolerances. Australia once again requests that the EU respects the conclusions of trading partners' regulators on the environmental impact of chemical substances and limits its assessment of requests for import tolerances to the consideration of dietary risks. Departing from this approach will result in significant trade disruptions. We remain available to discuss our approach to pesticide regulation with the EU and look forward to continued, constructive engagement on this issue.

2.420. The delegation of Japan provided the following statement. Japan echoes the concerns of other Members. Japan considers EU's any plan to lower the MRLs for the neonicotinoid pesticides, clothianidin and thiamethoxam, should be made in a manner consistent with the SPS Agreement which request to adopt SPS measures based on scientific principles and appropriate risk assessment and in a manner not more trade-restrictive than required to achieve an appropriate level of protection. Japan also emphasizes that it is important to respect each Member's right to set its own regulations for environmental protection, by reflecting each Member's unique environment conditions. Accordingly, in case the proposal is aimed to protect the environment, Japan considers that it is important to at least harmonize such measures with the international standards which other Members agree on. Lastly, Japan would request the EU to notify the draft of new regulations in an early stage so that other Members be made aware of them. Japan also requests the EU to provide other Members ample opportunity to comment on the new regulations prior to the introduction.

2.421. The delegation of Costa Rica provided the following statement. As on previous occasions, Costa Rica reiterates its support for the trade concern raised by Australia, Brazil, Canada and Japan.

⁹⁹ For previous statements follow the thread under [ID 393](#).

Costa Rica is concerned about the hazard-based approach adopted by the European Union given that, under the obligations of the multilateral system, all technical requirements must be based on the relevant international reference standard or a risk assessment providing the scientific evidence to support the measure. Costa Rica reiterates its request to the European Union to ensure that the implementation of its regulations is based on the use of risk assessments through the application of criteria supported by sufficient scientific evidence, in line with the commitments established in the TBT Agreement.

2.422. The delegation of [Paraguay](#) provided the following statement. Paraguay reiterates its position and refers to its previous statements by stressing the importance of adopting a scientific approach to the regulation of phytosanitary products based on the risk and not just on the hazard arising from the intrinsic properties of a chemical. In this regard, Paraguay once again requests the European Union to take into consideration information on pesticides provided by the specialized agencies recognized by the WTO, such as the Codex Alimentarius; reconsider its approach and base its decisions on conclusive scientific evidence and real risk weightings, in accordance with relevant international standards and principles; ensure import tolerances; and, where necessary, provide adequate transitional periods. In addition to the systemic concern, my delegation associates itself with the comments of other Members regarding recent notification [G/TBT/N/EU/908](#) of 6 July 2022, which aims to impose European environmental standards on third countries without taking into account the principle of common but differentiated responsibilities, the different climates and production systems or the enormous financial support that European producers receive to comply with these standards. Such an approach also presumes that other Members are not capable of setting their own environmental standards.

2.423. It is surprising that the EU is submitting this notification when only at the most recent meeting of this Committee, it refused to discuss maximum residue limits as it considered that the concerns about them and any details of their implementation should be discussed in the SPS Committee and not in the TBT Committee. It is also paradoxical that, for several of the substances that are banned in the EU and for which import tolerances will not be granted, EU Member States have regularly issued and continue to issue emergency authorizations to keep on using them, citing the lack of effective alternatives, despite the potential harm to pollinators pointed out by the EU itself. We hope that the EU can provide clarity on the consistency between policymaking and implementation within the EU itself as soon as possible. In 2022 to date and 2021 alone, 10 emergency authorizations were issued for the substance clothianidin (Romania, Czech Republic, Belgium, Finland, Spain and Austria) and 31 were issued for the substance thiamethoxam by almost half of EU Members (Czech Republic, Spain, Romania, Slovakia, Lithuania, Finland, Croatia, France, Austria, Hungary, Poland, Denmark and Germany).

2.424. We would like to point out that, although EFSA carries out assessments of the emergency authorizations granted by EU member States, as the EU rightly points out in document [G/SPS/GEN/2038](#), we have found that, in cases where an emergency authorization is deemed to be unjustified, there appear to be no consequences for the Member State. Let me illustrate with an example. In May 2018, EFSA published its assessment of six emergency authorizations granted by Romania for the substances clothianidin, thiamethoxam and imidacloprid to treat maize and sunflower crops against the pests *Tanymecus dilaticollis* and *Agriotes spp.* EFSA found in its analysis that three of these emergency authorizations, including the one to combat *Tanymecus dilaticollis* in maize, were not justified. Since then, Chair, according to the EU's own database, Romania has granted eight emergency authorizations for the substance thiamethoxam and a further four for the substance chlothianidin, with the most recent having been issued on 25 January this year to combat – would you believe it – the same pests, *Tanymecus dilaticollis* and *Agriotes spp.*, in the same crops, namely maize and sunflower, which EFSA had found to be unjustified. We are wondering how a Member State can continue to grant emergency authorizations four years after EFSA determined that an identical authorization was not justified. We also wonder whether the pollinator problem, which is a global concern, according to the European Union, and is the reason why it has indicated that it will not grant import tolerances, is not a concern in Romania, or how Romania could be excluded from the EU's global objectives. We would also like to point out that Romania is a major exporter of honey and the main honey producer in the European Union. Honey produced by the very bees that the ban on neonicotinoids is intended to protect. Therefore, we reiterate our query as to whether emergency authorizations will continue to be issued for these substances for which the EU has said that it will not grant import tolerances. In conclusion, allow me to call for reflection on the impact that this type of measure has on European producers who, as we can see, are demonstrating against it in various countries of the European Union and feel that their interests are not being

served. How much worse is this for Paraguayan producers who, under market conditions, must meet the same requirements to access the market of one of the main importers of foodstuffs?

2.425. The delegation of Brazil provided the following statement. Brazil would like to refer to its previous statements regarding STC 393. We emphasize that regulations on endocrine disruptors should be established according to sound scientific principles, taking all available data into consideration. Serious evaluations must be able to separate chemicals that have the potential to cause harm due to their endocrine mode of action from those substances that do not pose a threat to human health. A solid risk analysis, consistent with Codex guidelines, is important to ensure transparency and predictability in the regulatory processes regarding plant protection products and MRLs. Brazil believes that the European approach to limit the use of pesticides is more trade-restrictive than necessary to fulfill its legitimate objectives under the TBT Agreement. It also disregards risk analyses in the setting of regulatory measures that may have a serious impact on trade.

2.426. The delegation of Canada provided the following statement. Canada would like to take this opportunity to once again echo the concerns raised by many other Members regarding the European Union's (EU) hazard-based regulation for active substances in plant protection products and the setting of import tolerances. Recognizing different growing conditions in different regions, Canada does not insist on any one production method over another and we share the objective of ensuring that pesticides are used optimally and only as necessary. In order to ensure plant health and minimal waste, farmers need to have access to a wide range of effective and affordable plant protection mechanisms, including both chemical and biological options. We have an effective regulatory regime in place to monitor the safe use of chemical solutions when needed, including clear labelling requirements. Using integrated pest management approaches, we support farmers in their own assessment of what is needed according to growing conditions, market demand and other factors. Rigorous regulatory requirements exist, including scientific assessments and monitoring programs, to ensure the health and safety of consumers where pesticide residues can be a factor, as well the health of the environment.

2.427. We encourage the EU to take an approach which does not unnecessarily limit the availability of crop protection tools for growers. Regulatory decisions based on assessments of both hazards and risks for all active substances are the best means to ensure consumer safety while supporting food security and reduced waste. This is ever more important in light of current international supply chain disruptions and food security concerns resulting from the Russian invasion of Ukraine, which threatens farmers' incomes and the wellbeing of populations, particularly in developing and least-developed countries. The EU has stated that it will be changing how requests for import tolerances are established in the context of their current policy objectives, including the hazard-based cut off criteria and other (unspecified) considerations. Canadian growers and exporters have yet to be convinced of the real-world feasibility, commercial viability and compliance with international obligations of the EU's proposed approach for setting import tolerances when a plant protection product has met the hazard-based "cut-off" criteria. Additionally, the EU has indicated that it intends to consider environmental factors in the establishment of maximum residue limits, which would likely apply to import tolerances as well. Canada would appreciate further information on this approach, including on who will determine what environmental factors will be considered and how these will be scientifically justified in the dietary risk assessment.

2.428. Finally, Canada once again requests that the EU consider maintaining MRLs for substances that do not pose unacceptable dietary risks and import tolerances be authorized based on dietary risk alone. We recognize that a dietary risk assessment as part of the re-authorization process would likely be needed, regardless of the results of the hazard screen. We welcome further engagement with the EU on this issue. We also invite the EU to share any relevant information on upcoming regulatory or policy changes to ensure that unnecessary trade barriers are minimized and that measures are consistent with international trade obligations.

2.429. The delegation of Chile provided the following statement. The delegation of Chile thanks Australia and the other Members who requested the inclusion of this specific trade concern on the Committee's agenda. Chile reiterates its position from previous meetings about the importance of adopting a scientific and risk-based approach to regulating plant protection products rather than considering only the hazard of an agrochemical.

2.430. The delegation of [Colombia](#) provided the following statement. Colombia once again shares the concern raised regarding the approach taken by the EU for identifying and prohibiting the marketing of plant protection substances, as well as regarding the announcements to reduce MRLs to the minimum level of detection for several substances. As we have stated in this and previous meetings of this Committee, we reiterate the need for and importance of using risk analysis as a methodological tool for decision-making under the components of assessment, management and communication. Under the EU's approach, risk assessment becomes less relevant, as it bases its decisions to accept or allow the use of substances on a hazard-based approach, disregarding conditions of use and risk scenarios that allow scientifically based decisions to be taken. In light of the above, Colombia considers that the EU proposal must take into account scientific evidence, production processes and methods, the international recommendations of the Codex Alimentarius, and the relevant ecological and environmental conditions in countries that could be affected by the implementation of the measure, in order to avoid creating an unnecessary technical barrier to trade.

2.431. In this connection, we refer to the recent notification [G/TBT/N/EU/908](#) revising and lowering the MRLs for clothianidin and thiamethoxam, following the previous non-renewal of the marketing approval for these substances and the expiry of the grace periods. This case is of particular concern, not only because of the repeated use of the hazard approach to make decisions on plant protection substances, but also because of the use of environmental impact criteria to adopt technical regulations, without relying on scientific evidence on the human health implications. This rule also disregards the Codex standards on this substance and adopts a regulation on the EFSA opinion, under which no information from third-party stakeholders is taken into consideration. Equally worrying is the unilateral application of the European Union's environmental and health standards to imported agricultural and agri-food products, which amounts to an extraterritorial application of the standards governing the methods used to process and produce such products. This extraterritorial application of measures to protect human, animal or plant health, or to protect the environment, is contrary to GATT principles, which provide that standards can only be applied by a State Party in the territory over which it has sovereignty or jurisdiction, and that any exception intended to justify restrictive measures may be adopted to protect legitimate objectives within the territory of the State imposing the inconsistent measure, but not to protect its legitimate objectives in the territory of another State.

2.432. The delegation of [Uruguay](#) provided the following statement. We support the comments made by the preceding Members and reiterate our trade and systemic concern relating to the European Union's use of a hazard-based approach, instead of an approach based on full scientific risk assessments, when making regulatory decisions concerning the authorization of active substances used in plant protection products and when setting import tolerance levels for substances that meet the cut-off criteria in Regulation No. 1107/2009. We again emphasize the need to base such determinations on conclusive scientific evidence, gathered from an assessment of the actual risks, to avoid some of these active substances, which remain important components of pest management systems, having to be withdrawn despite being safe to use. This is due to the fact that an approach based on hazard rather than on actual risk could have a negative and disproportionate impact on production, while contributing little or nothing to the cited aim of protecting public health.

2.433. With respect to the announcements regarding the consideration of environmental impact when assessing MRLs for active substances that are no longer approved in European Union territory, we take note of notification [G/TBT/N/EU/908](#), submitted on 6 July, regarding the substances clothianidin and thiamethoxam. We wish to submit some preliminary observations and questions of a systemic nature: First, we are confused by the fact that this measure was notified to the TBT Committee and proposed for discussion in this forum, bearing in mind that, from the first time this STC was raised at the March 2019 meeting to the most recent meeting of March 2022, three years later, the European Union has stated that, as a matter of principle, concerns relating to the setting of MRLs for pesticides and any specific question related to their application are matters to be debated before the SPS Committee, not the TBT Committee. We note that, as reflected in the European Union's statement under that same STC in the meeting of 13 July, this delegation seems to have changed its position, by stating that only MRL reductions owing to human health-related concerns fall within the remit of the SPS Committee and they must be discussed in that context. The European Union clarified that certain specific MRL reduction measures owing to environmental concerns of a global nature (as is the case of the two substances mentioned above) must be notified to the TBT Committee, and invited Members to discuss such matters in this Committee alone, although it seems to suggest that the SPS Committee would also be informed of such notifications.

2.434. Our initial questions are: Could the European Union clarify this point and, in particular, explain its apparent change of position in this meeting compared to the position it has maintained at least since the meeting of this Committee in March 2019? Are we correct in our understanding that the European Union will keep the Committee apprised of these regulatory changes, even it justifies them in environmental terms? If so, through what channel? Will it use a separate notification or other means? Is the European Union considering an MRL reduction for other active substances on the grounds that they are "environmental concerns of a global nature"? If so, could the European Union provide a list of the substances under consideration? Is the European Union assessing the possibility of reducing the MRLs of active substances based on other grounds or objectives that are also not covered by the SPS Agreement? Could the European Union specify what other grounds or objectives it regards as appropriate justification for reducing the MRLs of active substances?

2.435. Uruguay regards MRLs as a type of measure intended to protect consumer health from the risks posed by ingestion and believes that they therefore fall within the scope of the SPS Agreement. Accordingly, these issues are covered by the multilateral frameworks recognized by this Organization, such as the Codex Alimentarius. We have some doubts as to the legal basis, under both Community law and WTO rules, for reducing MRLs on the grounds of "environmental concerns of a global nature" or for other reasons unrelated to human health. By way of example, we note the MRL definition in article 3 (d) of Regulation No. 396/2005 on maximum residue levels of pesticides: "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". Uruguay wishes once again to highlight the importance for the sanitary and phytosanitary measures adopted or applied by WTO Members, including the European Union, to be consistent with the objectives set forth in Annex A, paragraph 1, of the SPS Agreement and the other substantive obligations thereunder.

2.436. In reference to the objective sought by these measures, Uruguay agrees on the importance of protecting the environment and pollinators. We note, however, that at the multilateral level there seems to be a lack of clarity regarding the definition of "environmental concerns of a global nature" as referenced by the European Union, and regarding the best way in which to address such issues at the international level, especially when dealing with aspects linked to international trade or areas that fall within the jurisdiction of third countries. Accordingly, Uruguay reiterates its willingness to cooperate with other Members, including the European Union, on mechanisms that seek to achieve these objectives by fully recognizing the capacity of the authorities of third countries to adopt the measures that they deem appropriate or necessary to balance the goal of safeguarding food production with other legitimate objectives, such as protecting the environment or human, animal or plant health. As always, Uruguay continues to support the multilateral work undertaken on the Codex Alimentarius to develop a harmonized, risk-based approach to the processing of phytopharmaceutical products that ensures the protection of health, while facilitating international trade in food products. In the meantime, we once again call on the European Union to listen to and address the concerns expressed by a number of Members, and to reconsider its regulatory approach with a view to preventing the unjustified proliferation of barriers to international trade in agricultural products and the serious social and economic consequences of such an approach for other Members, in particular developing and least developed countries.

2.437. The delegation of Ecuador provided the following statement. Ecuador supports and agrees with the points and doubts expressed in the statements made by previous speakers. Ecuador recognizes the importance of protecting human health and the environment; however, we consider that regulatory decisions taken on the basis of hazard-based criteria are inconsistent with international risk-assessment practices. Ecuador urges the European Union (EU) to take into account scientific information emanating from international specialized bodies recognized by the WTO, such as the Codex Alimentarius, which has relevant information on pesticides. Ecuador also urges the EU to take into account the recommendations of the Committee on Technical Barriers to Trade related to good regulatory practices, particularly with regard to carrying out a Regulatory Impact Analysis prior to the issuance of regulatory proposals, which examines all possible social, economic, environmental and health impacts. This is to ensure compliance with the obligation not to be more trade restrictive than necessary to fulfil a legitimate objective, in accordance with Article 2.2 of the TBT Agreement. Lastly, my country once again calls upon the EU to ensure that, in cases where there is a lack of scientific information, EFSA does not make a recommendation on the MRL, since decisions on regulatory measures must be based on conclusive risk analyses that provide real health protection and do not constitute a technical barrier to trade.

2.438. The delegation of Argentina provided the following statement. Argentina once again reiterates its concern regarding this matter 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. The latter include the principles for establishing pesticide MRLs, as well as the many risk analyses that, over the decades, the Codex Alimentarius has conducted to ensure safety in terms of MRL recommendations for different substances and crops. 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.

2.439. In response, the delegation 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 2018/605.¹⁰⁰ This is complemented by a guideline by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), providing more details on how to interpret these criteria.¹⁰¹

2.440. 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 1107/2009¹⁰² on plant protection products. As previously explained, the European Union decided to follow the procedures of Regulation (EC) No 396/2005 for the management of import tolerance requests concerning active substances falling under these cut-off criteria, which include a risk assessment by an Evaluating EU member State and a scientific opinion by the European Food Safety Authority (EFSA). The granting of the import tolerance is then considered in line with risk analysis principles on a case-by-case basis and taking into account all relevant factors. 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.¹⁰³ The EU reiterates its commitment to act in full transparency and keep Members duly informed about further developments.

2.1.3.55 India - Air Conditioner and its related Parts (Quality Control) Order, 2019, G/TBT/N/IND/74, G/TBT/N/IND/110 (ID 598)¹⁰⁴

2.441. The delegation of China provided the following statement. China has raised concerns at 83th-87th TBT meetings regarding the Air Conditioner QCO. In the 87th meeting, India stated that BIS will restart the factory inspection for the foreign manufacturers and require no quarantine and RT-PCR testing for the BIS officers upon arrival. China believes that the above conditions for factory inspection for foreign manufacturers violate the non-discrimination principle of the WTO. Therefore, China would like to raise concerns as follows: 1.1 China would like to request India to provide further information and clarify whether the entry epidemic prevention policy of the Member where the foreign manufacturer is located is a prerequisite for restarting factory inspection. China suggests that India, in accordance with Article 5.1.1 of the TBT Agreement, consider restarting the factory inspection for the foreign manufacturers to ensure that manufacturers in China and other Members can obtain the same access as Indian manufacturers. 1.2 China would like to suggest a further delay of the entry time of the Air Conditioner QCO due to the pandemic. 1.3 We still suggest that India implement alternative measures during the pandemic, such as temporary factory audit exemption for a limited period or virtual audit, or conduct audits through third-party agencies, to address the difficulties of physical inspection resulting from international travel restrictions.

¹⁰⁰ 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.

¹⁰¹ <https://doi.org/10.2903/j.efsa.2018.5311>

¹⁰² 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.

¹⁰³ https://www.wto.org/english/tratop_e/sps_e/thematicsession220322_e.htm

¹⁰⁴ For previous statements follow the thread under [ID 598](#).

2.442. In response, the delegation of [India](#) provided the following statement. The QCO 41/2015-2020 dated 15 December 2020 was necessary to apply standards in reducing risks to human, animal and plant life and health. Besides, it is consistent with India's commitment to the Montreal Protocol. Further, as per the Ozone-Depleting Substances (Regulation and Control) Amendment Rules 2014, the import of air conditioners containing Group VI substances (HCFCs) has been prohibited since 1 July 2015. Presently, the implementation date of Air Conditioner QCO has been extended by one year and will now come into effect from 1 January 2023. At present, there is no provision in BIS (Conformity Assessment) Regulations, 2018 to undertake virtual audits for conformity assessment activities as an alternative. Foreign inspections were on hold due to the prevalent restrictions on International travel imposed. As the COVID restrictions have eased out, BIS has started carrying out inspection where confirmation for travelling of fully vaccinated BIS officers has been received. BIS has nominated officers and applicants are asked to remit the inspection charges for carrying out inspection. On receipt of inspection charges, inspections are being planned. Preliminary inspection for more than 100 applications has already been carried out. However, in some cases inspection are being delayed due to difficulty in issuance of visa. Further, sufficient capacity for testing room air conditioners is available in BIS-recognized laboratories. Bureau of Indian Standards, under its laboratory recognition scheme (BIS LRS), grants recognition to laboratories for testing of products as per the relevant Indian Standards. Clause 12 of BIS LRS deals with the recognition of overseas laboratories. The decision regarding recognition of overseas laboratories will be taken by BIS taking into account the MRA (Mutual Recognition Agreement) with the concerned countries.

2.1.3.56 European Union - Wine labelling requirements – listing of importers for multiple destinations (ID 659¹⁰⁵)

2.443. The delegation of [Australia](#) provided the following statement. Australia recognizes the EU's right to take measures necessary to protect human health and safety, and to ensure wine is labelled in a manner that is not misleading to consumers. Australia thanks the EU for their engagement to-date in this committee and for the clarity they have provided around the EU's wine labelling requirements. This issue remains an ongoing concern and barrier for Australia's wine industry, and we note the Australia-EU Wine Agreement Joint Management Committee also provides an important forum where we may discuss this issue further bilaterally. Further engagement with the EU is appreciated as we continue to work through this issue to ensure a mutually satisfactory outcome.

2.444. In response, the delegation of the [European Union](#) provided the following statement. As explained in previous TBT Committees, the indication of the "importer" is a compulsory indication for wine imported into the EU in accordance with Regulation (EU) No 1308/2013¹⁰⁶ establishing a common organization of the markets in agricultural products and Delegated Regulation (EU) No 2019/33.¹⁰⁷ The importer is a natural or legal person or a group of such persons established in the EU assuming responsibility for bringing into circulation non-Union goods within the meaning of Article 5(24) of Regulation (EU) No 952/2013¹⁰⁸ on the Union Customs Code. Any other indication on the label mentioning the entity that brought the wine into another third country before import into the Union could be only acceptable as an optional particular, provided it does not appear in combination with the words "importer" or "imported by (...)" and is not misleading for consumers as regards the business food operator (i.e. the person assuming responsibility for bringing the wine into circulation in the EU). The EU reiterates that it is not possible to list "importers" for multiple destinations on the same wine bottle label.

¹⁰⁵ For previous statements follow the thread under [ID 659](#).

¹⁰⁶ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007, OJ L 347, 20.12.2013, p. 671.

¹⁰⁷ Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation, OJ L 9, 11.1.2019, p. 2.

¹⁰⁸ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code, OJ L 269, 10.10.2013, p. 1.

2.1.3.57 Indonesia - Import quota and SNI certification requirements (ID 728¹⁰⁹)

2.445. The delegation of [China](#) provided the following statement. 1. It is suggested that Indonesia could notify WTO as regards the changes of relevant measures in a timely manner, providing other members a 60-day comment period and taking Members' comments into account. 2. It is suggested to cancel the restriction that an auditor shall only audit one product category for one factory at a time, and only Indonesian entities employ Indonesian citizens, and residents of Indonesia to carry out certification activities. 3. It is suggested that Indonesia resume remote factory inspection or allow third-party testing and certification bodies to conduct assessments. In addition, China would like to suggest that Indonesia could increase the number of SNI accreditation bodies and testing laboratories outside Indonesia.

2.446. In response, the delegation of [Indonesia](#) provided the following statement. Indonesia thanks China for its interest on Indonesia's import quota and SNI certification requirements. Indonesia would like to refer to its last statement in the March 2022 TBT Committee meeting that all certification process for technical regulations based on SNI in the industrial sector is carried out in accordance with the provisions stated on the related Minister Regulation. All technical regulations based on SNI have also been notified to the TBT Committee which provides a commenting period of 60 days. Indonesia accepts testing results from accredited foreign testing laboratories under the framework of ILAC Arrangement and availability of technical regulation agreements between Indonesia and its country partners.

2.1.3.58 India - Import Policy of Air Conditioners with Refrigerants (ID 748¹¹⁰)

2.447. The delegation of [Thailand](#) provided the following statement. Thailand thanks India for the statement pertaining to our concern on the prohibition of the import of air conditioners with refrigerants in the 86th Committee on TBT meeting. However, Thailand would like to request India to 1) provide evidence that Notification No.41/2015 dated 15 October 2020 issued by the Ministry of Commerce is consistent with the provisions of the Montreal Protocol; 2) clarify the types of refrigerants that are prohibited to import to the country; 3) provide evidence that the regulation to prohibit the production and usage of refrigerants is applied within the country prior to applying to the import of refrigerants from other countries; 4) elaborate plan to cease production of air conditioners with the prohibited refrigerants in the country; and 5) notify the measure to WTO TBT. Thailand would appreciate India's consideration of our concerns and reviewing the measure in a less restrictive manner by taking into account the non-discrimination principles to avoid creating unnecessary barriers to trade.

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

2.1.3.59 Republic of Korea - Regulation for supporting low carbon solar module product (ID 744¹¹¹)

2.449. The delegation of [China](#) provided the following statement. 1. The life cycle assessment (LCA) report submitted by the Chinese Company in accordance with ISO14040 has not been recognized by the ROK, while the report based on the same calculation method has been recognized by EU member States. China hopes that Korean side could clearly explain its implementation criteria for the review of the LCA report. Before formulating/issuing the implementation criteria for the LCA report review, the submitted reports should be reviewed in accordance with ISO and other international standards, and the report review process and requirements should be made public. 2. The ROK side should publish the list of qualified third-party certification institutions for companies' choices. 3. The reviewing time of the report should consider the time needed in other Members, that is, approval shall be completed within 30 days after acceptance, so as to improve efficiency. 4. As

¹⁰⁹ For previous statements follow the thread under [ID 728](#).

¹¹⁰ For previous statements follow the thread under [ID 748](#).

¹¹¹ For previous statements follow the thread under [ID 744](#).

too much trade secret data and industry-sensitive information are submitted which is unnecessary and unreasonable, the ROK side should reasonably set the scope of data submission in accordance with international practice.

2.450. In response, the delegation of the Republic of Korea provided the following statement. 1. The LCA report review process and verification standards are disclosed on the website through KEA (Korea Energy Agency)'s related business regulations and verification guidelines. Since there are no international standards or guidelines for assessing carbon emissions of solar module products, the relevant regulations of the Korea Energy Agency serve as the basis of the report review process. 2. Korea does not publish a list of qualified third-party certification institutions as it may limit the participation of other LCA certification service providers and the freedom of choice for companies. It is also impossible to fully understand the status of global LCA certification service providers as well as their expertise. Therefore, only those with past experience in implementing LCA are regarded as qualified service providers. In addition, to ensure the fairness of the assessment process, chosen LCA service providers must submit confirmation of their independence, transparency and compliance. 3. There are no rules and regulations regarding the LCA report review period. However, the review process initiates as soon as a report is submitted to ensure the process is carried out swiftly. To accelerate the review process, requested documents and data must be submitted in a swift manner. Once the Certification Deliberation Committee grants its final approval, companies will be issued their certification within at least one week. 4. Korea only requires the essential information for assessing greenhouse gas emissions, and does not require any trade or business-sensitive documents. Information on electricity consumption during the manufacturing period of solar modules as well as emissions calculation methods must be submitted as they are essential for evaluating carbon emissions. Therefore, it is impossible to guarantee the reliability of any report and evaluate greenhouse gas emissions without disclosing such essential information.

2.1.3.60 European Union - Regulation (EU) 2022/30 on network protection, safeguards for the protection of personal data and privacy and protection from fraud, G/TBT/N/EU/823 (ID 743¹¹²)

2.451. The delegation of China provided the following statement. Regulation (EU) 2022/30 is a framework rule, which only specifies the scope of products. The regulation lacks detailed descriptions of testing standards and conformity assessment procedures. Manufacturers cannot assess a product's regulatory compliance, and understand the actual impact on the product of testing standards and conformity assessment precisely, which will largely influence the follow-up design plan of the product. As the regulation covers so many different types of products, it has great and complex impacts. After the publication of the standard, manufacturers will need at least 12 months to redesign (if involved), conduct conformity assessment, and prepare all relevant documents required by the regulations. 1. China proposes the EU release relevant testing standards and conformity assessment guidance documents as soon as possible, or at least a publication schedule, ensuring that manufacturers can conduct product regulatory compliance analysis in advance and modify product design in time to meet regulatory requirements. Besides, China hopes that enterprises can take part in the legislative process.

2.452. 2. It is recommended that relevant guidelines could be issued as soon as possible to facilitate enterprises to make compliance preparations in advance. Please clarify the types of equipment complying with 3.3D/E/F in guidelines. For example, Bluetooth headsets, Bluetooth speakers, smart curtains, smart bulbs, and other products without the function to directly connect to the Internet, only connect through Bluetooth modules or through mobile apps, which belongs to indirect networking. Do these devices need to meet the 3.3d/e/f requirements? 3. We noted that there is a detailed Notify Body list of the RED Directive on EU official website. With the enforcement of RED 3.3 d/e/f, we suggest that the EU could re-assess and delegate Notify Body corresponding to the new requirements of RED and could release relevant information as soon as possible. In addition, the regulation only provides transition period of 30 months, please make further market research to ensure the certification resources.

2.453. 4. Cyber Resilience Act proposed in September 2021. The EU states that Cyber Resilience Act will supplement the existing EU legislative framework, including the NIS Directive and the Cyber Security Act. Please clarify the relationship between EU 2020/30 and Cyber Resilience Act. 5. It is our understanding that the EU 5G Scheme compatible with EU 2019/881 is being prepared. While in

¹¹² For previous statements follow the thread under [ID 743](#).

EU 2020/30 5G base stations are subject to 3.3d the network security requirements of the RED Directive. Please clarify the rules for 5G base stations network security and avoid duplication and conflicts of certification results.

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

2.1.3.61 India - Approved models and manufacturers of solar photovoltaic modules order, 2019 (ID 742¹¹³)

2.455. The delegation of China provided the following statement. 1. The Indian F.NO.283/54/2018-GRID SOLAR "Approved Models and Manufacturers of Solar Photovoltaic Modules Order, 2019" distinguishes between imported and domestic products manufacturers, and imported products and manufacturers are treated unfavourably. In terms of review and feedback time, overseas enterprises are discriminated. The overseas enterprise is in less favourable competition conditions, while Indian domestic manufacturers have advantages and are protected. It is not consistent with the National Treatment principle of GATT and Articles 2.1, 5.1 and 5.2 of TBT Agreement. China suggests that the Ministry of New and Renewable Energy (MNRE) of India and the National Institute of Solar Energy (NISE) adjust the measures, and treat domestic and foreign companies equally, besides, the audit process and time schedule should be publicized, so as to improve the certification efficiency.

2.456. 2. In NISE's Documentation and On-Site verification process, the certification standards and process rules are not clear, lack of guidance for the manufacturers, no effective feedback and communication in ALMM audit application process. It is against the transparency principle in GATT and TBT Articles 5.1, 5.2 and 5.6. Clear certification standards and auditing process should be publicized. 3. After charging Chinese companies for high ALMM application and testing fees, on-site inspection and audit have been delayed due to the COVID-19 pandemic. Considering the persistence of the global epidemic and foreseeable travel restriction, It is obviously not possible for on-site inspection of overseas manufacturers. Alternative solutions should be considered, such as entrusting a Chinese certification body to conduct on-site inspection to support the necessary remote video inspection. Besides, we request the Indian side to postpone the implementation of the ALMM Act until eight months after the completion of the on-site inspection.

2.457. 4. The fees charged for ALMM certification were unreasonable. Currently, ALMM certification fee is evaluated and charged according to the total production capacity of the manufacturer, which is much higher than the actual production capacity quota allocated for export to Indian market. Therefore, this measure is against the obligation to control the fee in Article 8.1(a) of GATT, not to create unnecessary obstacles to trade in the TBT Agreement. It is recommended that the Indian side follow the agreement and set a reasonable price standard. 5. From the perspective of the necessity for the formulation of the Decree (The Approved Models and Manufacturers of Solar Photovoltaic Modules Order, 2019 (ALMM) (Compulsory Registration Requirements), the requirements of BIS certification can indeed fully fulfill the purpose of ensuring the quality of photovoltaic modules, and the additional ALMM certification list is unnecessary, burdensome and become an obstacle to trade. 2019 ALMM Decree restricts trade while no further contribution to achieving legitimate objectives, it is against Article 2.2 of TBT. China suggests that India withdraws the ALMM decree.

¹¹³ For previous statements follow the thread under [ID 742](#).

2.458. In response, the delegation of India provided the following statement. 1. The Indian Government vide F.NO.283/54/2018- GRID SOLAR "Approved Models and Manufacturers of Solar Photovoltaic Modules Order, 2019 ('ALMM Order') provides for enlistment of eligible models and manufacturers of solar PV cells and modules complying with the BIS Standards and publish the same in a list called the "Approved List of Models and Manufacturers" (ALMM). The registration process and conditions prescribed are uniform irrespective of the nationality of the manufacturer. In other words, no distinction is made between domestic producers and overseas producers. There are no separate provisions for domestic producers and overseas producers with respect to review and feedback time. There may be some delay with respect to overseas producers due to logistical issues, however, the same cannot be considered as being discriminatory or unreasonable. India requests China to provide more details in this regard. India will review the information and provide its response.

2.459. 2. India has published ALMM Order, Guidelines, Application formats and necessary FAQs on its website.¹¹⁴ The ALMM Order and Regulations are transparent and clearly spell out the process and the documentation requirements for enlistment under the ALMM List. However, India welcomes any suggestions on further improvement of the certification standard and process and will consider such suggestions with an open mind. 3. Foreign inspection visits were on hold due to restrictions on international travel because of the ongoing COVID-19 pandemic. As the situation of COVID-19 improves and the restrictions are eased, inspections will be planned by NISE. There is no provision in ALMM Order or Regulations for remote assessment or any other means for inspection. 4. Under the ALMM Order and Guidelines, a standard fee has been prescribed for all entities which wish to enlist under the ALMM scheme. The said regulation states as under:

2.460. 3.1 The application fee for one model of module /cell shall be Rs. 5,000/- per MW of the total installed manufacturing capacity for solar PV modules and Rs. 5, 000/- per MW of the total installed manufacturing capacity for solar PV cells, of the applicant. However, as a measure of further facilitation to small manufacturers, for PV module manufacturers having total installed manufacturing capacity less than or equal to 50 MW, the application fee for one model of module is Rs.2,500/- per MW of the total installed manufacturing capacity for solar PV modules, of the applicant. 3.2 The "model" as mentioned in (3.1) above, refers to modules / cells of same nominal power output rating. All BIS approved modules/ cells of the applicant with same nominal power output rating shall be treated as one model. 3.3 In case the application consists of multiple models, the application fee shall be as per 3.1 above for one model and additional 1% of this for every additional model. 4.1 The fee has been determined based on total installed manufacturing capacity as ALMM is intended in respect of manufacturer and total capacity and not actual production or export quota. It is also important to note that the said application fee and other charges are uniform, irrespective of nationality of the producer — whether Indian or overseas producers. 4.2 Article VIII(1) (a) of GATT 1947 states that "All fees and charges of whatever character (other than import and export duties and other than taxes within the purview of Article III) imposed by contracting parties on or in connection with importation or exportation shall be limited in amount to the approximate cost of services rendered and shall not represent an indirect protection to domestic products or a taxation of imports or exports for fiscal purposes." 4.3 As stated above, the application fee charged under ALMM regulations is commensurate with the services provided and is uniform irrespective of nationality of the producer. Thus, the application fee cannot be considered as an indirect protection to domestic products or as charges additional levied only on imports. 4.4 Thus, India considers that the application fee charged under ALMM regulations is consistent with Article VIII (1) (a) of GATT 1947 and the said fee is unlikely to cause unreasonable burden or restrictions on international trade.

2.461. 5. The BIS certification requirement deals with quality control of the solar cells and modules. The ALMM Order provides for enlistment of eligible models and manufacturers of solar PV cells and modules complying with the BIS Standards. While BIS certification is with respect to maintaining the quality of the product per se, ALMM certification intends to enlist eligible models and manufacturers, producing the said solar cells and modules. ALMM is thus, aimed to ensure the reliability of the producers of the enlisted models. Thus, ALMM and BIS certifications are reasonable requirements in the larger public interest to ensure quality of the product as well as ensure reliability of the producer. ALMM intends to plug this aspect to ensure protect consumer interests and ensure larger energy security of the country, which BIS does not provide.

¹¹⁴ <https://mnre.gov.in/solar/manufacturersand-quality-control>.

2.1.3.62 European Union - Commission implementing decision (EU) 2017/1357 on a restriction of Standard EN 60335-2-9-2003+A 13-2010 (ID 741¹¹⁵)

2.462. The delegation of China provided the following statement. At present, the safety requirements on air fryers are in standard EN 60335-2-9-2003+A13-2010. However, the European Commission has restricted some provisions of EN 60335-2-9-2003+A13-2010 in its commission implementing decision (EU) 2017/1357, which points out that the provision "exemption from surface temperature rise test for surfaces within 25mm from the edge of the cover and the air outlet" does not comply with 1 (c) of Appendix I of 1(c) of Annex I of Directive 2014/35/EU. The air fryer is a kind of portable electric household appliance that uses convection of hot air and requires internal and external circulation to heat food, the principle of which is fundamentally different from that of a conventional oven. In addition, Germany, one of the initiators of the commission implementing decision (EU) 2017/1357, also separate the safety requirements for air fryer products in the instruction manual for the implementation of the European Electrotechnical Commission (EEC) Guideline No.29 and exempt the surface temperature rise test within 25mm from the edge of the cover and the air outlet of the air fryer. If the EU cannot separate the requirements for air fryers, then most air fryers on the market could not meet the EU market access requirements, which means the harmonized standard is infeasible. a. China suggests that the EU reassess the implementing decision (EU) 2017/1357 and exempt the temperature rise test requirement within the 25mm surfaces of the air outlet of the air fryer. b. China suggests the EU reconsider the products classification according to the working principle of air fryers and develop safety requirements and test method standards that are compatible with them. c. As the EU is also considering improving the standard EN 60335-2-9:2003+A13:2010, China is willing to have technical exchanges and cooperation with the EU on the requirements and test standards related to the classification of air fryers.

2.463. In response, the delegation of the European Union provided the following statement. Thank you to the delegation of China for its interest in the Commission Implementing Decision (EU) 2017/1357 of 19 July 2017 on a restriction of the standard EN 60335-2-9:2003, "Household and similar electrical appliances – Safety -- Part 2-9: Particular requirements for grills, toasters and similar portable cooking appliances", as last amended by A13:2010. The Commission Implementing Decision follows a formal objection by Germany and Norway respectively in June 2014 and July 2014. The formal objections of Germany and Norway stated that Section 11 "Heating" of the standard includes insufficient provisions regarding temperature limits of accessible non-functional surfaces. In particular, the standard allows several exclusions to the temperature limits, authorising the manufacturer to double or not to apply the temperature limit values depending on the size, design or the surface part of the appliance, and requiring at most a warning notice or label. In this respect, Section 7.1 of the standard only requires a warning to be put on the surface with the highest temperature within the parts exceeding the limit values. The colours of the warning label may differ from international warning colours which may confuse the users. Additionally, as a result of the ambiguity of the requirements under the standard, the standard can be interpreted as making it possible to omit the measurement of the temperature rises in certain parts of a given product, which may lead to the disregard of or doubling of the temperature limit values applicable under the standard with regard to the entire product.

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

¹¹⁵ For previous statements follow the thread under [ID 741](#).

contained in Annex 1 point 2 of the TBT Agreement, namely that it is a, "Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory." The EU thanks the delegation of China for its willing to have technical exchanges. We are available to further cooperate on this.

2.1.3.63 United States - Secure equipment act of 2021 (ID 737¹¹⁶)

2.465. The delegation of China provided the following statement. In accordance with the Act, the Federal Communications Commission prohibits authorization of radio communication equipment, which pose a national security risk to the US. Without concrete evidence, the US restricts the authorization of radio communication equipment produced by some Chinese companies which are against TBT rules. Therefore, China proposes that the United States should abide by WTO/TBT rules and treat all the Members' products and enterprises equally, providing fair and non-discriminatory market access for all Members.

2.466. In response, the delegation of the United States provided the following statement. The FCC is charged with issuing implementing regulations, and those proposed regulations are scheduled to be developed and published by 22 November 2022 and they actually have been notified to the WTO TBT Committee. I would like to refer to STC ID 714 which are the implementing regulations. I don't know if we made that clear last time and potentially we should combine those two STCs since they are referring to the same Act and its implementing measure.

2.1.3.64 South Africa - Regulations relating to the composition, production and labelling of wine and spirits intended for sale in the Republic of South Africa, G/TBT/N/ZAF/48/Rev.2/Add.1 (ID 733¹¹⁷)

2.467. The delegation of Mexico provided the following statement. As was mentioned in the statement made for STC 7¹¹⁸, we are of the understanding that it is a concern about the same measure that was included in the previous meeting of the Committee and that now also features in STC 80. Despite this duplication, in order to ensure the traceability of concerns, we are making statements under both items to keep them separate. The delegation of Mexico refers to its statement made at the previous meeting of this Committee in March 2022 on the Regulations relating to the composition, production and labelling of wine and spirits intended for sale in the Republic of South Africa, notified to the Members of the Committee on 20 December 2021 in document [G/TBT/N/ZAF/48/Rev.2/Add.1](#). Firstly, we thank the Government of South Africa for responding to the comments sent during the public consultation period, in which both the Mexican industry and Government participated to share observations on what we consider could have an impact on Mexican exporters of tequila and mezcal, as well as on potential exporters of raicilla and bacanora.

2.468. However, the delegation of Mexico wishes to point out that these concerns remain, since South Africa's response to the comments sent by the Government of Mexico do not address each of the remarks made in Official Circular No. 500/RVL/044/2022 of 11 February 2022. In this regard, we appeal to the good offices of the delegation of South Africa to address the following comments relating to concerns stemming from the lack of inclusion in the Regulations of clear definitions for beverages of Mexican origin: We ask that, separate from the "100% agave" class, there be a clear specific class for tequila that complies with the applicable Mexican regulations, taking into account that tequila has been registered as a certification mark in South Africa since 2004. In order to avoid potential confusion among consumers, we ask that no reference be made in the "100% agave" class to tequila or its classes or categories, even in Spanish.

2.469. We also highlight the request for uniform definitions for Mexico's emblematic beverages, such as mezcal, bacanora and raicilla, which have their own origin, physico-chemical specifications and identity characteristics, as established in the respective Mexican Official Standards. In addition, and with the aim of following up on our concerns in a timely manner, we would be grateful if the delegation of South Africa would provide us with a contact point through which we could regularly

¹¹⁶ For previous statements follow the thread under [ID 737](#).

¹¹⁷ For previous statements follow the thread under [ID 733](#).

¹¹⁸ South Africa - Regulations Relating to the Labelling of Alcoholic Beverages – Revision.

follow up on the development of the Regulations The delegation of Mexico thanks the delegation of South Africa for giving its consideration to this statement.

2.470. In response, the delegation of [South Africa](#) provided the following statement. South Africa is of the view that all concerns that were raised by Mexico were addressed in our communication to Mexico but it seems this is not the view of Mexico. We would like to recall the statement that we made under STC No 7¹¹⁹ to encourage Mexico to engage with us. We are ready to engage in a constructive manner with a view to resolve the STC. We had indicated that our point of contact will be the South African Permanent Mission in Geneva.

2.1.3.65 United States - Energy conservation program: test procedure for circulator pumps, [G/TBT/N/USA/1815](#) (ID 731¹²⁰)

2.471. The delegation of [China](#) provided the following statement. a. China proposes the US clarify "whether the small vertical in-line pumps include end suction close coupled pumps (ESCC)". When an end suction close coupled pump is used vertically, it also meets the definition of a small vertical in-line pump by the Circulator Pump Working Group (CPWG). b. As in the last meeting, US indicated that the proposed definitions can sufficiently address the range of circulator pumps and that schematic diagrams would not provide additional benefit. However, as there is no distinction on coupling methods between "mechanically-coupled pumps" and "close-pumps" in China and other members. China suggests the US appropriately add schematic diagrams to help understand the definitions of "mechanically-coupled pumps" and "close-pumps", so as to avoid misunderstanding. c. For pressure control circulator pumps, the US has given an equation for PERCIRC, please provide scientific evidence for PERCIRC weighting assignments to pressure control type circulator pumps. d. Section 40.6.4.4 of HI 40.6, to which the US refers, only briefly discusses motor pump units or complete pumps. An "integrated design pump" is a pump with associated piping and accessories from which the individual pumps cannot be easily separated. China suggests that the US clarify the efficiency testing method for this type of pump.

2.472. In response, the delegation of the [United States](#) provided the following statement. The United States thanks China for its concerns. We notified Department of Energy's draft regulation to the TBT Committee in USA/1815, and the comment period closed on 18 February 2022. We did not receive any comment from China or any of its stakeholders. The United States will take into consideration all comments received during the open comment period and respond to each substantive comment in the next published rulemaking document on Test Procedures for Circulator Pumps.

2.1.3.66 Mongolia - Draft Law on controlling the circulation of alcohol beverages, and fight against alcoholism, [G/TBT/N/MNG/14](#) (ID 730¹²¹)

2.473. The delegation of [Mexico](#) provided the following statement. The delegation of Mexico refers to its statement at the previous meeting of this Committee in March 2022, regarding the draft Law on controlling the circulation of alcohol beverages, and fight against alcoholism, notified to the Members of this Committee by the Government of Mongolia on 12 August 2021 in document [G/TBT/N/MNG/14](#). During the meeting in March 2022, the concerns that this measure is causing for Mexican exporters of alcoholic beverages were expressed for the first time, and we reiterate the following: It is considered that the ban on sales of these products through electronic channels limits the ability to control and trace lawful sales of alcoholic drinks. The ban on alcoholic beverages with an alcohol content greater than 35% alcohol/volume would have a direct impact on Mexican exports of beverages such as mezcal and tequila, both of which exceed that percentage. The branding-related restrictions are of concern to Mexican exporters, as branding is an international practice intended to inform the consumer of the quality of the products.

2.474. The delegation of Mongolia responded positively to the above-mentioned concerns at a bilateral meeting, at which the following remarks were made. The draft Law has not yet been adopted and was modified as a result of the comments received during the consultation period. In the new version of the Law, which continues to be a draft that is under discussion, the following were eliminated: specific provisions that would result in a ban on online sales; the banning of alcoholic

¹¹⁹ South Africa - Regulations Relating to the Labelling of Alcoholic Beverages – Revision.

¹²⁰ For previous statements follow the thread under [ID 731](#).

¹²¹ For previous statements follow the thread under [ID 730](#).

drinks with an alcohol content greater than 35% alcohol/volume; and branding-related restrictions. The new version has not yet been notified. However, efforts will be made to do so six months prior to the implementation of the Law. In this connection, the delegation of Mexico is grateful for the kind attention paid to concerns and asks the delegation of Mongolia to provide and notify the new final version of the measure as soon as it becomes available, so that it may be reviewed by Members. We would also be grateful if Mongolia could indicate the potential date of adoption of this new version.

2.475. The delegation of [Mongolia](#) was not present in the room.

2.476. The delegation of [Mexico](#) stated that Mongolia contacted them saying it was their national day and they would not be able to participate which is why we included in our statement the responses obtained in our bilateral meeting with the hope that we will get from Mongolia in the next time a revised version of the measure.

[2.1.3.67 European Union - Draft Commission Regulation laying down eco-design requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation \(EC\) No 1275/2008 and repealing Commission Regulation \(EC\) 642/2009 \(and its accompanying annexes\)", G/TBT/N/EU/609, G/TBT/N/EU/610 \(ID 575¹²²\)](#)

2.477. The delegation of the [Republic of Korea](#) provided the following statement. Korea appreciates this opportunity to deliver our opinions on the European Union's "Commission Regulation (EU) 2019/2021 of 1 October 2019, laying down Ecodesign Requirements for Electronic Displays". The Korean government respects the efforts of the European Parliament and the Council to inform consumers and protect the environment by reducing the power consumption of electronic displays. Furthermore, Korean companies are endeavouring to comply with the regulation of the EU. However, in relation to the Tier 2 requirements of the Regulation on Electronic Displays, which is scheduled to be enforced in March 2023, a Korean Electronics Association had sent a position paper to the EU in April, expressing concerns from the relevant industries in Korea. However, the EU replied that it is not considering any review on the Tier 2 requirements. To this, the Korean government officially submitted its comments through the EU's WTO TBT Enquiry Point on 30 June 2022, with regard to the industry's difficulties and requests. Firstly, the regulatory scope of Tier 2 requirements will encompass electronic displays with resolution above UHD-4K and MicroLED displays. Korean manufacturers have been making efforts in improving the technology to reduce the power consumption of the above-UHD-4K resolution display and MicroLED display products. Despite these efforts, it seems that the manufacturers need more time to improve the technology and reduce energy consumption significantly to meet the Tier 2 requirements.

2.478. For 8K Display products, it can be demonstrated by the fact that all models from manufacturers currently in the EU territory do not satisfy the Tier 2 requirements. We are concerned that, if the regulation is enforced as scheduled, none of the above-UHD-4K resolution displays and MicroLED display products can be placed on the EU's markets, limiting the EU consumers' choice of product and hindering the technological development of related industries. In case there is a product among the 8K displays released in the EU that, contrary to our knowledge, satisfies the Tier 2 requirements, we would like to ask the EU to provide such an example. Secondly, it is considered unreasonable to apply the same Energy Efficiency Index limit (EEI limit) to "the displays with resolution above UHD-4K" as those to "the UHD-4K or lower resolution displays". In general, "above UHD-4K displays" consume more energy as they require lighting at least four times brighter than that of "UHD-4K or lower displays". As such, applying the same EEI requirement is overly burdensome to the manufacturers of the above-UHD-4K displays. Just as the EU already applies different EEI limits to the "displays above HD and up to UHD-4K" from the "HD displays and below", we request the EU to apply different and higher EEI limits for "displays above UHD-4K and MicroLED displays" from the "displays above HD and up to UHD-4K". In conclusion, the current Tier 2 requirement has set unrealistic limits based on future assumptions, rather than feasible limits that reflect the actual level of current technological development. As it is stipulated in Article 8 that the regulation shall be reviewed in the light of technological progress, Korea requests that the EU take sufficient time to thoroughly review the EEI limits based on the actual energy consumption data of the electronic displays currently in the EU market, and postpone the enforcement of Tier 2

¹²² For previous statements follow the thread under [ID 575](#).

requirements on displays with resolution above UHD-4K and MicroLED displays until reasonable EEI limits have been newly established.

2.479. In response, the delegation of the [European Union](#) provided the following statement. This measure was notified to the WTO on 9 October 2018 and allowed for 60 days of comments. The energy efficiency requirements for electronic displays have been known since 2019 and are applicable since March 2021, except for displays with very high resolutions which benefit from a specific, temporary exemption until 1 March 2023. A review of this adopted regulation is not among the priorities identified in the Ecodesign and Energy Labelling Working Plan adopted on 30 March 2022, given the geopolitical situation and the acute energy crisis in Europe. Therefore, we encourage display manufacturers to take advantage of the different flexibilities already available under the Regulation. These include allowances for automatic brightness control or specific, advantageous rules on how to measure consumption of displays designed for use with standardised external power supplies.

2.2 Exchange of Experiences

2.2.1 Transparency

2.2.1.1 Report by the Moderator on the Thematic Session on Transparency

2.480. The [Moderator](#)¹²³ for the thematic session on Transparency, held on 12 July 2022 and covering Product Coverage and Domestic Coordination, provided his report. The full report is contained in [G/TBT/GEN/330](#).

2.2.1.2 United States proposal on Article 15.2 notifications

2.481. The representative of the [United States](#) introduced the proposal for a new notification format for Article 15.2 notifications contained in [JOB/TBT/466](#). One of the recommendations from the Ninth Triennial Review was to pursue a change in notification formats to better identify Article 15.2 type measures, which were being updated or newly developed. Members were already submitting such changes, on a voluntary basis, using the notification format for technical regulations and conformity assessment procedures, but without a clear indication. Sometimes, they were labelled as "other", sometimes as a "technical regulation". Therefore, the US proposed to add a checkbox in the notification format to reflect more accurately such measures.

2.482. With a view to improving the number of updates under Article 15.2, giving these updates some structure and consistency, and also to more accurately account for notice and comment opportunities that involve the implementation and operation of the Agreement, the US was proposing that the Secretariat revise the Format and Guidelines for New Notifications (of draft technical regulations and conformity assessment procedures)¹²⁴. Any new, revised or updated administrative, legislative or regulatory actions, including NQI laws and regulations,¹²⁵ that implement Members' obligations or improve the ability of Members in fulfilment of obligations under the WTO TBT Agreement, could be notified with a clear link to Article 15.2. Under item number 3 in the notification template, a checkbox would be included for Article 15.2 notifications. All other information normally contained in the new notification could continue to be included, and the Coherent Use of Notification Formats ([G/TBT/35/Rev.1](#)) could also be applied. The ePing TBT notification submission system could be modified to allow Members to notify actions directly relevant to Article 15.2, and also to facilitate the distribution of the notified measures that contribute to the implementation of Article 15.2.

2.483. When the Article 15.2 checkbox was checked, it could also trigger the Member to submit a revision or supplemental notification in the [G/TBT/2](#)-series when the measure was finalized. The [G/TBT/2](#)-series notification could contain a table of information, where the Member could include the name of the measure, attach a copy of the final measure, the date it was published or approved, the date of entry into force, and the location (a link) where it can be found online. Members had submitted their Article 15.2 notifications in the [G/TBT/2](#)-series upon their adoption of the TBT

¹²³ Mr Jia Jie Loh (Singapore).

¹²⁴ [G/TBT/1/Rev.14](#), page 66.

¹²⁵ This would include new or updated laws and regulations related to standards, conformity assessment, accreditation, and metrology.

Agreement but many had not been updated. The new process would also facilitate updates to these original statements.

2.484. The representative of China expressed his delegation's appreciation for the US proposal aimed at strengthening transparency and shared some preliminary comments. Firstly, China believed that Quality Infrastructure (QI) was an important part covered in the TBT Agreement and that it was of great importance to continuously enforce the quality of relevant notifications. Therefore, China suggested that the Secretariat organize a dedicated event in this area. Secondly, notifications under Article 15.2 and those relating to technical regulations and conformity assessment procedures were subject to different obligations. He asked whether adding an option for measures related to Article 15.2 in the existing notification format would mean that they would also be subject to obligations such as the commenting period and the transition period. Thirdly, he suggested that the US clarify the proposal with examples for a better understanding by Members.

2.485. The representative of the United States responded that these Article 15.2 measures would not be subject to the same obligations as a technical regulation or a conformity assessment procedure. Members, such as Brazil, were already voluntarily notifying drafts of underlying QI laws related to conformity assessment procedures, standards, metrology, and accreditation. Some of these had open comment periods and provided full texts, providing an opportunity for feedback from other Members. Also, the US had notified OMB Circular A119 and Federal Guidelines on conformity assessment principles, with an opportunity to comment, using the commonly used regular notification format. The idea was to better track the notification of such measures, which were related to the implementation of the Agreement under Article 15.2.

2.486. The representative of the European Union thanked the United States for the proposal as well as the clarifications provided. The EU was still reviewing the proposal internally and would revert with comments as applicable.

2.487. The representative of Colombia said that her delegation was still reviewing the proposal. The proposal was a very good initiative to boost transparency and better track relevant information. She asked for clarification on the link between the new checkbox for Article 15.2 in the regular notification format and the reference to the [G/TBT/2](#)-series.

2.488. The representative of the United States responded that many Members had issued their statements of implementation regarding how they would implement and ensure the operation of the Agreement when they first joined the WTO. For example, the US statement was from 1996 and it had not been updated since. However, other Members, including Colombia, had provided updates using the [G/TBT/2](#)-series. While it was voluntary, it was very useful to provide information regarding new measures which helped operationalize the TBT Agreement. For example, it was very useful to provide updates on any underlying laws for conformity assessment, which are key components of NQI. Such updates would be notified under the [G/TBT/2](#)-series.

2.489. The Secretariat explained that the fastest way to access Members' Article 15.2 statements, including any updates provided, was to go to the Fact and Figures – Members' Profiles section of ePing. In terms of document symbol, all Article 15.2 statements were contained in the [G/TBT/2](#)-series. The very first Article 15.2 notification had been received from the Czech Republic in 1995 and circulated as [G/TBT/2](#). From then on, notifications from other Members had been circulated as Addenda to this first one. The ongoing discussions could also allow a revision of this tracking system.

2.490. The representative of Australia said that the proposal had merits and would assist Members in meeting their TBT obligations under Article 15.2. His delegation was still reviewing the proposal, which was consistent with previous discussions and recommendations as part of the Ninth Triennial Review. Australia saw merit in particular in the suggestion to adjust the existing notification by adding a checkbox for Article 15.2 and to use ePing notification submission functions to allow Members to notify actions relevant to Article 15.2.

2.491. The representative of Canada said that the proposal was a very useful contribution to the improvement of transparency given that it related to Members' obligation to inform the Committee of the measures taken to ensure the implementation and administration of the TBT Agreement. As part of the work of the Committee based on the Ninth Triennial Review's recommendations on transparency and as mentioned by Canada in previous meetings of the Transparency Working Group,

Canada was working on a proposal regarding the improvement of the current notification format and associated guidelines. The aim was to improve the information provided by Members on notified measures. Canada looked forward to the next meeting of the transparency working group so that they could further present and discuss their proposal with other Members.

2.492. The representative of Mexico thanked the US for the clarifications provided and said that her delegation was still reviewing the proposal. As preliminary remarks, her delegation understood that the aim was to have a better tracking system regarding the implementation of the Agreement and that adding a checkbox in the regular notification format would not imply any changes to the obligations under the two types of notifications. She also thanked the Secretariat for the clarification provided on how to best access Members' statements on ePing, which should make it easier for Members to review what has already been provided and identify any updates that should be made. The proposal was consistent with the Triennial Review recommendations and Mexico also looked forward to having Canada's input on the regular notifications.

2.493. The representative of South Africa thanked the US for their proposal as well as the useful clarifications provided in response to questions. South Africa was studying the proposal and would be submitting any further points for clarity to the US, for further discussion during upcoming meetings or the transparency working group.

2.494. The representative of the United Kingdom thanked the US delegation for the good proposal and said that her delegation would be coming back with further comments.

2.495. The representative of Brazil thanked the US for their proposal and recalled that Brazil had indeed notified updates to its original Article 15.2 statement and may yet provide further updates subsequent to further review. It was very helpful and constructive that the US had tabled the proposal so that Members could reflect and provide further updates regarding domestic practices and infrastructures, towards strengthening and implementing the TBT Agreement.

2.496. The Committee took note.

2.2.1.2.2 Update on the Transparency Working Group

2.497. The Chair recalled that the meetings of this newly established working group were open to all delegations and were held in hybrid mode. Its first meeting had been held on 6 April, following which the Chairperson had circulated a communication on 12 April 2022, with a brief summary of the meeting and indicating that product coverage in notifications and formats had been identified as two priority areas for further discussion. A second meeting, which had originally been scheduled for 31 May, had been postponed due to intensive preparations for MC12. He proposed that the next session of the working group be held on 13 October. He also encouraged delegations to contact him or the Secretariat if they had any questions or wished to make suggestions regarding the work of the new working group.

2.2.1.3 Secretariat update on the ePing SPS&TBT Platform

2.498. The Secretariat recalled that the new version of the ePing platform had been officially launched on Wednesday 13 July, with the participation of senior officials from ePing partner agencies ITC, UNDESA and WTO. She thanked delegations for their interventions and positive remarks during the launch event, on which a separate document would be circulated. There continued to be high demand for training and outreach activities related to ePing, which also came out strongly during the transparency thematic session held earlier in the week. Therefore, the Secretariat would organize an ePing information session on the margins of the November Committee meeting, where Members could also share their experiences integrating ePing into their domestic outreach mechanisms. At the same time, delegations interested in organizing technical assistance and outreach activities on ePing at the national level were invited to submit their requests through the ITTC process. A new ePing App was available on smartphones (Android and Apple), which, for the moment, could be used to receive alerts and browse notifications. This first basic version had been built mainly to help the private sector access key updates. Members were encouraged to install and provide feedback on the App, which had been developed with significant contributions from ePing partners ITC and UNDESA. She also expressed the Secretariat's gratitude and admiration for their colleague Lotte Drieghe, who

had been a part of the ePing project since its inception and who would be leaving the Secretariat at the end of July. The Committee gave a round of applause for Lotte Drieghe.

2.499. The Chair thanked the three partner agencies for their fruitful collaboration and encouraged all delegations take full advantage of ePing to implement and benefit from the TBT transparency framework.

2.500. The representative of Chile informed the Committee that they were in the process of submitting a technical assistance request for training on the new ePing platform, possibly to take place in early 2023.

2.501. The representative of Mexico thanked the Secretariat for the excellent technical assistance activity delivered the previous week to government officials and the private sector from Mexico. She encouraged other delegations to benefit from such training to make full use of the services of ePing.

2.2.2 Conformity Assessment Procedures

2.502. The Chair recalled that in the Eighth Triennial Review of the TBT Agreement, the Committee had agreed to develop guidelines to support regulators in the choice and design of conformity assessment. And in the Ninth Triennial Review, the Committee noted progress to date and agreed to finalize this work. Since the Committee's last meeting in March, the Committee had held two informal meetings, on 27 April and 29 June. At the 27 April meeting, Members had provided comments on the Elements Paper that was circulated in [JOB/TBT/438](#). Following this meeting, an Aide-Memoire document had been circulated by the Secretariat on 30 May, in [JOB/TBT/465](#). On this basis, a revised elements paper was circulated in [JOB/TBT/438/Rev.1](#) on 14 June. At the 29 June meeting, Members said that the Revised Elements paper was a good basis for further work by the Committee and provided some initial comments on the revised elements paper. The Chair opened the floor for discussion.

2.503. The representative of the United States said that comments ([JOB/TBT/469](#)) had just been submitted in writing and she referred to points made orally at the meeting on 29 June.

2.504. The representative of Australia drew delegations' attention to their written comments in [JOB/TBT/470](#). The submission summarized comments already conveyed to Members verbally at the informal meeting on 29 June. Australia acknowledged the submissions of other Members and thanked them for their contributions. Australia also sought advice and guidance from the Secretariat on the next steps.

2.505. The representative of Brazil, likewise, referred to comments contained in [JOB/TBT/471](#) which conveyed what had been said orally at informal discussions. It was stressed that Brazilian domestic policy and practice was broadly in line with the revised Elements Paper and, therefore, despite the fact that Brazil was not, at this point, submitting more specific points, Brazil confirmed that the current revision of the Elements Paper was a good basis to work on.

2.506. The representative of China noted that his delegation's comments ([JOB/TBT/473](#)) included some specific suggestions and some questions. China wished to keep communication with all Members to establish a good guidance for conformity assessment procedures, to support the regulators in their design or selection of conformity assessment procedures. China was open to any comments on its suggestions and comments, or answers to its questions.

2.507. The representative of India suggested that the discussion be kept open for some more time to that the Committee could get more views, especially on the most recent submissions. India's comments were subsequently circulated in [JOB/TBT/477](#).

2.508. The representative of New Zealand welcomed ongoing efforts to develop *Practical Guidelines to Support Regulators in the Choice and Design of Conformity Assessment Procedures* within the WTO TBT Committee. New Zealand underlined that New Zealand's arrangements for conformity assessment aligned closely with, and in many cases overlapped with, those of Australia. These included, but were not limited to: (i) shared standards and conformance architecture, exemplified by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) and Food Standards Australia New Zealand (FSANZ); (ii) legislative instruments facilitating conformity assessment,

including the Trans-Tasman Mutual Recognition Arrangement (TTMRA) which allowed products approved in one market to be traded in the other; (iii) a common approach to conducting conformity assessment, emerging from broader intersections in institutional design and regulatory policy. New Zealand wished to convey Australia's approach on this basis, as well as in the substantive content of their submissions to date. New Zealand highlighted, in particular, the focus on integrating digital technologies and solutions within conformity assessment procedures – shared by the European Union among others – which carried the significant potential to improve the transparency, evidence-based, and administrative efficiency of conformity assessment procedures. We would conclude by reaffirming New Zealand's support for this important work, looking forward to further opportunities to comment and finalizing the document.

2.509. The representative of Chinese Taipei asked Australia, with regards to paragraph 3.7 under the sub-section on "Traceability in supply chains", to elaborate on the linkages to risk assessment and traceability in supply chains. Considering that there could be multiple sources of input supply in the production process, these inputs could change over time. This could create a significant burden for MSMEs to implement a product traceability system. The complexity and costs associated with supply chain traceability, their impact on MSMEs, and their effectiveness in enhancing product safety needed to be taken into account when choosing and designing conformity assessment procedures. For paragraph 3.10, under subsection "Risk-based: sampling and testing", Chinese Taipei suggested replacing "manufacturers" with "economic operators" which would cover all stakeholders such as manufacturers, importers, distributors, sellers, etc. that play different roles in ensuring the safety of products in the market surveillance system. For paragraph 3.12 under subsection "Authorities", it was proposed to add "importers and/or other responsible economic operators" after "producers" in subparagraph (iii) as these were responsible for placing the product on the market. Chinese Taipei's comments were subsequently circulated in [JOB/TBT/482](#).

2.510. The representative of the European Union expressed appreciation for the continued efforts made by the Secretariat to accommodate the several comments raised by Members; this was sometimes not an easy task. The European Union provided written comments on the previous version of the paper ([JOB/TBT/438](#)) and also oral comments on 29 June. (Written comments were subsequently contained in document [JOB/TBT/455](#).) In general, the EU was of the view that the document was a sound basis to advance the discussions. One point of particular importance was that the guidelines needed to be practical and non-binding but nevertheless useful for regulators; the EU, therefore, wanted to keep the term "appropriate and proportionate". It was recalled that this wording had already been agreed in the Eighth and the Ninth Triennial Review – so this was a matter of consistency; it was important not to take a step backwards. The EU intended to engage constructively with all the Members and asked the Chair for an indication of the timeline.

2.511. The representative of the United Kingdom thanked the Secretariat for their work and drew the Committee's attention to their comments contained in [JOB/TBT/475](#).

2.512. The representative of the Philippines similarly drew the Committee's attention to its comments contained in [JOB/TBT/474](#).

2.513. The representative of Malaysia noted that their comments were contained in document [JOB/TBT/472](#). Malaysia was of the view that the paper was a good basis for work on an important topic; it was not too technical, practical and easily understandable and had a clear flow. Three key comments were contained in their submission.

2.514. The representative of South Africa thanked the Secretariat for the good work. One issue was the term "appropriate and proportionate", which had been removed in the revised elements paper. South Africa wanted to understand the reasons why it had been removed. South Africa understood that Members had raised comments around those terms, some were for it, and some were against. Also, the term "voluntary and mandatory" for conformity assessment procedures had been introduced, and this needed clarification. Another issue was the reference to "best practices" in para. 2.1 – but how would one determine whether an approach was a best practice or not, what were the criteria? The most important point for South Africa was to understand why, in para. 3.6, there was a reference to "moderate risk" with a reference to Annex 1, while, in Annex 1, there was no explanation (it contained a discussion of the types of conformity assessment procedures). Also, in para 3.6, South Africa had a comment on "accommodating the needs of SMEs" – it was unclear how this would be fully implemented. South Africa would also provide comments on para. 3.22, on

"certificates of free sale". We will provide written comments. (The comments were subsequently circulated as [JOB/TBT/481](#).)

2.515. The Chair thanked all Members for the valuable comments and engagement. In terms of the next steps, he said that:

- a. first, since some Members needed additional time to prepare written comments, he proposed to extend the deadline until 15 August. Members wishing to provide comments on the revised Elements Paper [JOB/TBT/438/Rev.1](#) could do so by that date;
- b. second, he requested the Secretariat to prepare an Aide-Memoire document that would reflect all comments on the revised Elements Paper received by 15 August. This Aide-Memoire would be circulated by end-August;
- c. third, he noted that he might hold consultations with some Members to discuss certain aspects of the revised paper; and, based on these comments and consultations, he would ask the Secretariat to prepare, after the summer break, a further revised version of the Guidelines; and,
- d. finally, he noted that he intended to hold an informal meeting on 13 October to continue this work.

2.2.3 Regulatory Cooperation between Members (MSMEs)

2.516. The Moderator¹²⁶ for the thematic session on Regulatory Cooperation (MSMEs), held on 12 July 2022, provided her report. Her full report is contained in [G/TBT/GEN/331](#).

2.517. The representative of Canada recalled that the proposal for Thematic Sessions for MSMEs had come from Canada in the context of the Ninth Triennial Review. Canada thanked the Secretariat for putting together the session and Ms Lizano from Costa Rica for moderating the discussion – as well as all the presenters for their valuable insights on how Members can help MSMEs navigate the various requirements related to technical regulations, standards and conformity assessment procedures.

2.518. The representative of South Africa noted that there was a lot of important information that had been shared at the session and in the moderator's report. One additional point that South Africa would like to underscore was the point that there was no universal definition of MSMEs, and MSMEs. This term was sometimes defined according to specific objectives or according to sectors. And therefore, it was possible that delegations would not be talking about the same companies with regards to either employment, number of employees, or the revenue that they generated – simply because the definition might be different between countries.

2.2.4 Covid-19

2.2.4.1 Update from Secretariat

2.519. The Chair recalled the TBT Committee's mandate on COVID-19¹²⁷, and that the Chairperson had asked the Secretariat to prepare a background document on the work of the Committee to date since the start of the pandemic.

2.520. The Secretariat presented the background document, "Overview of Covid19-related Discussions in the TBT Committee" contained in [JOB/TBT/458](#). The Secretariat's presentation was circulated separately in [RD/TBT/367](#).

2.521. The representative of Brazil found that the presentation was clear and gave a good picture of the measures that Members had taken within the scope of the TBT Agreement during the pandemic.

¹²⁶ Ms Ana Laura Lizano (Costa Rica).

¹²⁷ [G/TBT/46](#), para. 8.4.

2.2.4.2 MC12 outcome on Covid-19

2.522. The Chair drew the Members' attention to one of the MC12 outcome documents that was relevant to COVID-19. The "Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics", contained in document [WT/MIN\(22\)/31](#) provided some important impetus on COVID-19 for the Committee; he drew delegations' attention to paragraphs 24 and 25 of this document, which reads as follows:

24. Relevant WTO bodies [which include the TBT Committee] will, within their fields of competence, and on the basis of proposals by Members, continue or initiate work as soon as possible, to analyse lessons that have been learned and challenges experienced during the COVID-19 pandemic. A stocktaking exercise will be taken of the work by WTO bodies under this declaration yearly at the General Council until the end of 2024, based on the reports of those relevant bodies.

25. Areas of discussion and focus will include, but not be limited to, the topics set forth in Paragraph 23 and other topics raised by Members reflecting their varied experiences during the COVID-19 pandemic.

2.523. The Chair noted that one of the topics of focus mentioned in paragraph 23 document was "regulatory cooperation" and that paragraph 11 dealt with regulatory cooperation in detail:

11. With a view to expediting access to COVID-19 vaccines, therapeutics, diagnostics and other essential medical goods, during COVID-19 and future pandemics, we encourage regulatory cooperation, as appropriate, and the sharing of regulatory information on a voluntary basis.

2.524. In addition, paragraph 20 provided some additional areas of relevance to the Committee:

20. Taking into consideration Members' public health policies and experiences during the COVID-19 pandemic, we acknowledge the relevance of further cooperation within the mandate of the WTO and its rules to boost post-pandemic recovery and trade flows, including on testing requirements and results, recognition of vaccination certificates and interoperability and mutual recognition of digital health applications, while continuing to protect public health and ensuring privacy and personal data protection.

2.525. In this regard, the Chair sought Members' views on two aspects. First, on substance, the Committee had been mandated to continue its work to analyse lessons that have been learned and challenges experienced during the COVID-19 pandemic. In this respect, the Chair noted that the Committee had already agreed to examine and compile best practices in the context of the 9th Triennial Review. Indeed, the Committee had been working on this topic, exchanging and discussing experiences, as summarized in the earlier presentation by the Secretariat. The Secretariat had also listed some practices distilled from the discussion and experiences shared by Members, which could be helpful to further this work. Thus, the Committee already had a head start – and this was an opportunity to make a meaningful contribution to the WTO's response to the COVID-19 pandemic and its preparedness for future pandemics.

2.526. Second, on the process, the Chair's sense was that MC12 had placed additional importance on this part of our work. The Committee has been asked to report annually to the General Council on progress until the end of 2024. The Chairman thus suggested that the Committee strive to continue its work in examining and compiling best practices so that it would be in a position to deliver on this work by 2024. Indeed, standards and regulatory aspects could end up becoming an important contribution to the WTO response to the COVID-19 pandemic, and the organization's preparedness for future pandemics. For the annual reports, the Chair suggested that the Committee ask the Secretariat to prepare a draft for the November meeting based on the factual updates that the Committee had already been regularly provided with by the Secretariat.

2.2.5 Other Matters

2.527. The representative of Colombia recalled her delegation's interest in the Thematic Session on the subject of the regulatory development within the Codex Alimentarius Commission. Colombia

suggested the sharing of national experiences about how different Members had participated in the different committees of the Codex and the different challenges that they had encountered for regulatory development. More generally, being updated on what was going on with the regulatory agenda within Codex, and the priorities and the principle/principal elements which were being developed for the future was important. As far as possible, Colombia invited interested Members to identify issues that were directly linked to the TBT Committee being developed within the Codex framework.

2.528. The representative of the United States expressed interest in the topics raised by Colombia and was happy to work with them in planning the session.

3 TECHNICAL COOPERATION ACTIVITIES

3.1. The representative of the United States drew the Committee's attention to an update contained in document [G/TBT/GEN/329](#).

3.2. The Secretariat announced that it was launching a new capacity-building initiative: The Transparency Champions programme. It aimed to scale up the implementation and benefits of the TBT transparency framework, and foster "champions" for transparency. Participants would benefit from a six-month programme, involving in-person and virtual modules, as well as ongoing support from the Secretariat, mentors and their peers. The first pilot programme would target officials from African countries and would start with an in-person workshop in Geneva from 10 to 14 October 2022. The experience gained from this pilot project would guide the Secretariat in rolling out the programme in other regions.

4 OBSERVERS

4.1 Updates from Observers

4.1. Updates were provided by ARSO ([G/TBT/GEN/332](#)), BIPM (<https://www.bipm.org/en/liaison-partners/wto-tbt>), Codex ([G/TBT/GEN/333](#)), UNIDO ([G/TBT/GEN/334](#)) and ISO ([G/TBT/GEN/335](#)).

4.2 Pending requests

4.2. The Chair noted that an updated list of observers, including pending requests, was contained in document [G/TBT/GEN/2/Rev.17](#). In addition, he noted that document [RD/TBT/1/Rev.9](#) provided an updated compilation of the original communications received by the WTO from the various bodies that have sought observer status in the TBT Committee and whose requests were still pending. The Chair noted that, regarding the pending requests, that there was no new information that would lead him to believe that the situation had changed from where the Committee had stood at the last meeting. He suggested, therefore, that the Committee revert to this matter when Members had the time to further consult among themselves.

4.3. The representative of Türkiye reiterated her delegation's support for the Standards and Metrology Institute for Islamic Countries (SMIIC)'s application for observer status in the TBT Committee. The SMIIC's application to the TBT Committee dated back to 2017. Since then, the SMIIC had maintained its interest on an ongoing basis. During this time, Türkiye had regularly supported its application to the Committee. So far, no progress had been made – and no concrete steps taken. In addition, there appeared to be a lack of recognition of this institution, as well as its activities especially considering its significance. SMIIC was an affiliated institution of the Organization of Islamic Cooperation (OIC), and, of its 43 members, 33 were also Members of the WTO while 8 were observers. The SMIIC aimed at developing quality infrastructure by establishing uniformity in standardization, conformity assessment, accreditation, and metrology activities, thus eliminating technical barriers to trade amongst its Members. In addition, the SMIIC had important activities in the field of halal, which Türkiye noted was arising more frequently on the agenda of the TBT Committee. SMIIC worked on the adoption of a single Halal standard and the establishment of a trustworthy certification system among the OIC countries. With this aim, the SMIIC had already issued halal standards and provided guidelines for halal certification and accreditation. Türkiye believed that SMIIC's expertise had the potential to support halal trade facilitation. In this respect, Türkiye planned to propose a side event to be organized in order to introduce the mission and functions of the SMIIC at the upcoming TBT Committee, in November.

4.4. The Chair said that Members needed to work together to try to find a solution to the matter. As Chair, he remained available and would be willing to meet with interested Members to assist in facilitating discussions if this would be helpful. He encouraged Members to continue the consultations with each other so that the Committee could have a constructive engagement and resolve the matter.

4.5. The representative of the United States stated that her delegation still objected to SMIIC observer status in the TBT Committee.

5 OTHER BUSINESS

5.1. The Secretariat recalled that it was organizing a TBT Symposium on 14 October entitled "Global supply chains overcoming regulatory bottlenecks". More background and the programme is available here.¹²⁸

6 DATE OF NEXT MEETING

6.1. The Chair recalled that the next meeting of the TBT Committee was scheduled to take place from 16 to 18 November 2022. The regular meeting would be preceded by thematic sessions on 15 November, focusing on good regulatory practice and on standards (standards development in Codex). A Follow-up communication with more dates and information was subsequently circulated in ICN/TBT/13.

¹²⁸ https://www.wto.org/english/news_e/events_e/gscforumoct2022_e.htm