SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/51)

New Concerns

China, Índia e Equador x UE – 2004/24/EC on Traditional Herbal Medicinal Products

European Union – Directive 2004/24/EC on Traditional Herbal Medicinal Products

The representative of China raised concerns about the EU Directive 2004/24/EC on traditional herbal medicinal products, which amended Directive 2001/83/EC. It was her delegation's understanding that while the 2001 Directive regulated the manufacture, marketing and distribution of all medicinal products for human use, the 2004 Directive amended the former by introducing a simplified registration procedure for traditional herbal medicine products. While China supported the objective of protecting human health and promoting the use of safe herbal medicinal products, concerns remained that the EU measure was unnecessarily trade restrictive. China also noted that the European Union failed to notify the two measures to the WTO and encouraged the EU delegation to act promptly in this regard, so as to provide the opportunity for WTO Members to comment on the text of the regulations.

The EU delegation was also requested to extend the transitional period for simplified registration to March 2019 (instead of March 2011), in order to provide industries with adequate time to consider the requirements and make the registration accordingly. It was stressed that, to date, only one Chinese enterprise had registered its products through the new procedure – this illustrated the complexity of the new requirements. Furthermore, the representative of China invited the European Union to provide evidence of the scientific basis for not permitting animal and mineral ingredients in traditional herbal medicinal products. It was her delegation's view that herbal medicinal products containing animal and mineral ingredients had been safely used in China and other parts of the world for thousands of years, and they still played an important role in modern health care. Finally, the European Union was encouraged to recognize the Good Manufacturing Practice for medicinal products of China as equivalent, and to provide an update on the current status of implementation of the 2004 Directive and a timetable for amending the 2004 Directive.

The representative of India noted his delegation's concern with the EU Directive on traditional herbal medicinal products. It was India's understanding that the 2001 Directive required that applications for authorization to place a medicine on the EU market had to be accompanied by a dossier containing the results of physiochemical and biological tests, as well as pharmacological, toxicological and clinical trials carried out on the product. These requirements appeared to be cumbersome, particularly for traditional herbal medicinal products, and could constitute an unnecessary barrier to trade. India further noted that the European Union had recognized the complexity of such system and decided to amend the 2001 Directive accordingly, in order to simplify the registration procedure for traditional herbal medicinal products. However, neither the 2001 nor the 2004 Directive had been notified to the TBT Committee.

The representative of India was particularly concerned about the 15 year requirement set out in Article 16 of the 2004 Directive: to be marketed in the European Union, there had to be sufficient bibliographical or expert evidence that a herbal medicinal products had been in use throughout a period of at least 30 years – including at least 15 years within the EU market. It was India's view that these requirement could result in a *de facto* ban on imports of herbal medicinal products from a large number of suppliers of traditional herbal medicinal products, particularly Small and Medium Enterprises (SMEs). When the 15 year requirement was not met – but the product was otherwise eligible for simplified registration – the authorization had to be referred to the Committee for Herbal Medicinal Products. However, the guidelines and parameters on how the Committee would assess this product had not been disclosed. What was the scientific basis and rational justification for the 15 year prior use requirement and was there the possibility of derogating from it? Had the European Union considered other alternative methods or procedures for assessing the safety, quality and efficacy of traditional medicinal

products? What was the coverage of the 2004 Directive and the discipline applicable to the marketing of herbal products not covered by the above-mentioned regulation?

The representative of Ecuador shared the concerns expressed by previous speakers and stressed that the EU measure could have a significant impact on Ecuador's exports.

The representative of the European Union noted that her delegation had met bilaterally with China and India on this issue and confirmed that, with regard to traditional herbal medicinal products, the 2004 Directive amended the standard authorization procedure which was in place for all medicinal products. She further explained that the 2004 Directive provided a simplified registration procedure for traditional herbal medicines, for example by exempting the manufacturer from providing a number of tests and clinical trials which were otherwise required under the normal authorization procedure. Article 16 of the 2004 Directive set the criteria that the products had to fulfil in order to be eligible for the simplified procedure: (a) there had to be sufficient bibliographical or expert evidence that the product had been in use throughout a period of at least 30 years – including at least 15 years on the EU market; and (b) the manufacturer had to provide evidence on the product safety and efficacy. However, when the product met only the second criterion, the authorization could still be referred to a Committee for Herbal Medicinal Products. This Committee would verify if the other requirements were met and would establish a "community herbal monograph"; in that case, the manufacturer only needed to prove the quality characteristics of its product. It was the EU representative's view that the 15 year requirement did not constitute any obstacles for manufacturers to benefit from the simplified procedure. However, she informed Members of the Committee that the European Commission had carried out an internal reflection process on the registration of traditional herbal medicines, which concluded with the drafting of a report. This report highlighted that the Commission was prepared to consider extending the simplified registration procedure to products containing substances other than herbal substances, and that the 15 year criteria could be reassessed. These changes would nevertheless require legislative action.

With regard to the timeline of the transitional period, the representative of the European Union explained that the 2004 Directive gave manufacturers seven years to submit an authorization request for the marketing of products to the relevant authorities. As of March 2011, no authorized herbal medicines could be sold on the EU market as medicinal products – they could, however, continue to be sold as standard products. The European Union regretted that the two directives had not been notified to the WTO. However, interested parties had had exchanges with EU authorities for several years and the EU delegation remained available to further discuss this issue bilaterally.

UE x China - Textiles (G/TBT/N/CHN/20/Rev.1)

China – Textiles (G/TBT/N/CHN/20/Rev.1)

The representative of the European Union expressed concerns regarding China's new General Safety Technical Code for Textile Products. She noted that the Chinese draft measure on textile products set mandatory limit PH values, and values for colour fastness. It was her delegation's view that these requirements did not impact on consumer's health or safety and were therefore more trade restrictive than necessary. The notified draft also provided that textiles could not have a peculiar odour. It was the European Union's view that this requirement could only be verified by a subjective assessment and was not an appropriate means of classifying textile products. The EU delegate further noted that the Chinese draft regulation prohibited the presence of the aromatic Amines 2.4 and 2.6 Xylidine in textiles and set a maximum level of 20 mg/kg for their use of acrylamine dyes. Considering that the EU's REACH Regulation did not prohibit the above-mentioned aromatic substances and set a higher maximum level for the use of acrylamine dyes, the European Union invited the Chinese delegation to provide the scientific evidence on which China's decision had been based. Finally, the EU representative urged China to consider the relevant ISO standards, particularly with regard to test methods, which had the potential to create unnecessary obstacles to trade when deviating from relevant international standards without justification.

The representative of China noted that the EU written comments had been received after the period for comments on the draft measure had expired. However, they were being processed and a reply would be provided to the European Union in due time.

UE e Suíça x China - Textiles and Apparel (G/TBT/N/CHN/427)

China – Textiles and Apparel (G/TBT/N/CHN/427)

The representative of the European Union raised a concern regarding China's new draft regulation on textiles and apparel, notified to the Committee under G/TBT/N/CHN/427. She noted that her delegation had commented on this notification in July 2008 and had asked China to provide further clarification on its measure. In particular, it was the EU's delegation view that certain information to be displayed on textiles – such as the product name, the effective product standards, safety categories and the use and storage precautions – did not appear to be relevant to the objective of informing consumers. The representative of the European Union also stressed that China had first informed her delegation that the draft measure was still under consideration and the mandatory labelling requirements could be modified. It had also been mentioned that the modified draft regulation would have been notified to the WTO. However, in November 2009, the EU delegation had been informed that the notified text was about to be published and that no new notification was envisaged. Finally, in May 2010, the Chinese Enquiry Point had confirmed that the draft measure was still under discussion. In view of this contradicting information, the EU representative requested an update on the status of these issues, including how the comments of her delegation had been taken into account.

The representative of Switzerland shared the concerns expressed by the European Union. She was particularly concerned about the country of origin requirement for imported products. Could China explain the compliance of this requirement with the principle of national treatment contained in Article 2.1 of the TBT Agreement? Could China specify how the country of origin requirement was defined and what was the legitimate objective that this requirement intended to pursue? Could China clarify whether the Chinese standards GB/T 8685 Textile-Care Labelling Code was based on the relevant ISO standard?

The representative of China thanked the delegations for their comments and recalled that 60 days had been provided for comments on this notification. She also informed the Committee that the period for comments had been extended for another month, as requested by the European Union. However, no comments had been received from the European Union within that timeframe. In this regard, the Chinese delegation encouraged the European Union to provide comments within the time period provided so as to give time for comments to be taken into consideration. With regard to the questions from Switzerland, the representative of China said that the labelling requirements would apply equally to domestic products, and therefore the notified measure complied with Article 2.1 of the TBT Agreement. Finally, the representative of China informed WTO Members that the national standard had not yet been published and comments would be taken into account.

Chile, UE, México, Austrália e EUA x Vietnã - Alcoholic Beverages (G/TBT/N/VNM/10)

Viet Nam – Alcoholic Beverages (G/TBT/N/VNM/10)

The representative of Chile raised concerns about Viet Nam's new proposed National Technical Regulation on Food Safety for Alcoholic Beverages, and informed the TBT Committee that her delegation had provided written comments to Viet Nam on the draft regulation. It was Chile's belief that the notified draft regulation would limit certain substances at 100 grams. The representative of Chile expressed the view that 100 grams was a very low limit and particularly difficult to achieve for wines, effectively limiting their market access. She noted the importance of having more clarity with respect to the controlled substances and generic substances in the

products that would need to be limited. Finally, she suggested that the legislation be based on international standards.

The representative of the European Union also expressed concerns over Viet Nam's draft regulation, noting that they had recently received a reply from Viet Nam on their written comments. The European Union was grateful for the open and constructive position taken by the Viet Nam authorities and was analyzing the reply to ascertain whether the European Union's comments had been addressed. She asked Vietnam to confirm that the maximum limit for aldehydes in distilled spirits and mixed spirits would be abolished as indicated in their written reply. She requested confirmation from Viet Nam that the maximum cyanide limit and microorganisms requirement would be eliminated and that the definitions of wine and sparkling wines, as well as the limits on methanol and sulphur dioxide in wines, would be revised to bring them in line with international practices. She also requested clarification from Viet Nam on the administrative requirements specified in the draft regulation, such as compliance announcement, compliance certification, compliance certification stamps and compliance evaluation methods, and on guidelines on implementation. Finally, she requested an update from Viet Nam on when the revised draft regulation would be made available.

The representative of Mexico thanked Viet Nam for replying to their initial comments on the draft regulation. He requested confirmation that the maximum limit of aldehyde would be eliminated from the regulation and asked when the final version of the regulation would be published.

The representative of Australia thanked Viet Nam for replying to their initial comments on the draft regulation and expressed appreciation over Viet Nam's willingness to bring the regulation in line with international standards. Australia joined the European Union and Mexico in requesting clarification on the proposed timetable for redrafting the proposed regulation.

The United States reiterated the concerns they had communicated to Viet Nam in writing regarding the draft regulation. It was the US view that Viet Nam's technical regulation defined a maximum level for aldehydes in distilled spirits of 5mg per litre of alcohol. The United States noted that they supported Viet Nam's objective to ensure the identity and quality of alcoholic beverages sold in Viet Nam, but observed that for nearly all major spirit markets, the identity for distilled spirits was based on the raw materials and production process used, rather than on the chemical composition. The representative of the United States stated that he was unaware of any health, safety, quality, or other concern with aldehyde that could warrant mandating a maximum level. He requested clarification on how often importers would be required to have the product certified; how often testing would have to be conducted; how certification would need to be obtained; how certificate grades differed; and which products required the compliance certification stamp.

The representative of Viet Nam noted that delegations supported the legitimate objective to protect human health and safety through this technical regulation. He informed the TBT Committee that the deadline for making comments on the draft regulation would be extended from 23 May 2010 to 17 July 2010 and ensured delegations that comments and concerns raised would be taken into account; he requested that comments be submitted in writing to the Viet Nam TBT Enquiry Point.

Coréia do Sul x EUA - Conditions and Criteria for Recognition of Accreditation Bodies & Laboratories for the Energy Star Program

United States – Conditions and Criteria for Recognition of Accreditation Bodies & Laboratories for the Energy Star Program

The representative of Korea raised concerns regarding US draft requirements for accreditation bodies and testing laboratories in the Energy Star Program. It was Korea's belief that the additional requirement imposed by the US Environmental Protection Agency (EPA) was duplicative and unnecessary. The representative of Korea urged the United States to reconsider by allowing for the designation of accreditation bodies for Energy Star without an

additional process involving ILAC/MRA accreditation bodies. He also requested more detailed information on the peer evaluation procedures and training programmes. Korea was of the opinion that the requirement to report to the EPA on the result of the ILAC/MRA peer evaluation were against the confidentiality rule of ISO 17011.

Korea was also of the view that the draft requirements were against the spirit of ILAC/MRA. The representative of Korea expressed concern that the draft laboratory requirements would allow the EPA to operate inter-laboratory comparison testing, a provision which, according to Korea, would be unnecessary given that ILAC/MRA Member accreditation bodies already operated internationally recognized proficiency testing. Finally, he urged the United States to notify this measure to the TBT Committee and to allow sufficient preparation time for manufacturers and their accreditation bodies and testing laboratories before implementing the new measure.

The representative of the United States noted that bilateral discussions had taken place with Korea the week prior to the TBT Committee Meeting, after which he felt he better understood Korea's concerns and would communicate them to regulators in the United States. He explained that Energy Star is a voluntary government backed programme dedicated to helping protect the environment by promoting superior energy efficiency products. In order to earn the Energy Star, products had to meet strict energy performance criteria set by the US EPA and the Department of Energy. He informed the Committee that Energy Star currently covered about 3 Billion units, sold across more than 40,000 models, in more than 60 product categories. Additionally, more than 75 per cent of US consumers were aware of the programme and 80 per cent indicated that the logo influenced their purchasing decisions and likeliness to recommend products to others. He was of the view that an 18 year partnership between the EPA and stakeholders had made the Energy Star brand valuable, with most producers seeking to satisfy its criteria. He suggested that the success of the programme demonstrated that WTO Members could satisfactorily achieve legitimate regulatory objectives using a voluntary approach – and not only through mandatory ones.

The representative of the United States next explained the importance of conformity assessment in maintaining the value of the Energy Star brand. He suggested that, given the evolution of the programme, supplier's declaration of conformity (SDoC) that a product meets the Energy Star criteria had proven to be insufficient. In a recent review of the programme by the US General Accounting Office, vulnerabilities and potential for fraud in the current qualification process had been identified. Additionally, over the years, the EPA had found numerous products on the market displaying the Energy Star label that did not actually meet the criteria. He noted that when asked to stop using the Energy Star label, the companies in question voluntarily obliged. He informed the Committee that additional information, including the General Accounting Office report, could be found on the Energy Star website. He declared that the EPA's proposed requirements for accreditation bodies and testing laboratories in the Energy Star program were meant to address these and other issues.

The representative of the United States confirmed that under the proposed modifications, Energy Star would remain a voluntary programme and producers would be able to test outside the United States, whether in their own facilities or in third party laboratories. Furthermore, goods could continue to be shipped to the United States regardless of whether they met the Energy Star criteria. He clarified that the proposed modifications would simply strengthen the conformity assessment procedures to better ensure that products bearing the Energy Star label in fact met the Energy Star criteria. It was the belief of the United States that maintaining a voluntary approach and basing new conformity assessment procedures on international standards was a better way of ensuring Energy Star compliance than potentially stricter alternatives.

The representative of the United States noted that the proposed procedures were based on relevant international standards, guides and recommendations including ISO 17011 and 17025 and Guide 65, and international systems of conformity assessment such as the ILAC/MRA; thus, the United States was not obliged to notify this measure. He informed the Committee however that discussions on the proposal had taken place since 2009 between US regulators and foreign and domestic stakeholders. In December 2009, an enhanced programme plan for

Energy Star, identifying increased testing as a possibility in connection with the Energy Star label, was shared by US regulators with thousands of stakeholders. He noted that comments had been solicited and EPA's responses could be found on the Energy Star website. In March 2010, another stakeholder process had been launched by EPA to develop detailed enhanced testing verification for Energy Star products. The representative of the United States informed the Committee that comments were initially solicited by 30 April 2010, however, WTO Members were encouraged to submit additional comments to the EPA until the end of June 2010.

UE x Colômbia - Shelf life Requirements for Milk Powder

Colombia – Shelf life Requirements for Milk Powder

The representative of the European Union expressed concerns with respect to a Colombian Decree, dated 13 May 2010, which required imported milk powder to have a minimum shelf-life of 12 months, a six month increase over the previous requirement. She noted that this Decree had already entered into force without being notified to the TBT Committee but acknowledged that Colombia had recently notified the implementation rules of the Decree to the SPS Committee, allowing for comments until 10 September 2010. The European Union requested clarification from Colombia on a number of issues including: (i) whether Colombia intended to notify the TBT Committee of the regulation, (ii) whether implementation of the Decree would be postponed during the comment period granted in the SPS Committee, (iii) which legitimate objective was being pursued, and (iv) whether the Decree applied to domestically produced milk powder.

The representative of Colombia acknowledged that they had received and forwarded the European Union's comments to the relevant authorities within the Ministry of Social Protection. He informed the Committee that upon receiving a response from the relevant authorities, Colombia would respond to the concerns raised. In the meantime, he expressed his delegation's willingness to continue bilateral discussions with the European Union.

EUA x China - Regulations of the PRC on Certification and Accreditation (promulgated by Decree No. 390 of the State Council of the PRC on September 3, 2003)

China – Regulations of the PRC on Certification and Accreditation (promulgated by Decree No. 390 of the State Council of the PRC on September 3, 2003)

The representative of the United States expressed concerns over China's regulations on certification and accreditation. It was the view of the United States that China was limiting US suppliers' ability to use competent conformity assessment bodies, including testing laboratories and product certifiers outside of China's territory, to demonstrate their products compliance with Chinese technical regulations. The representative of the United States explained that in order to export to China, US and other foreign exporters had been required to use conformity assessment services provided by bodies designated by the Chinese Government, in the Chinese market. This barred recognition of foreign conformity assessment bodies, including ILAC or IAF accredited bodies. This regulation had put foreign companies at a disadvantage *vis-à-vis* their Chinese competitors for two reasons. First, US exporters had to have their products tested and certified in China, an often duplicative process which imposed additional costs and burdens on US exporters. Second, Chinese producers often had more direct access and closer ties to Chinese testing and certification bodies. In addition, he explained that the regulations had resulted in a loss of opportunities for US conformity assessment bodies to provide conformity assessment services for the Chinese market.

The representative of the United States explained that the CCC mark, China's primary safety and quality certification scheme, fell under the regulations on certification and accreditation. He informed the Committee that over 20 per cent of US exports to China had to obtain the CCC

mark prior to market entry and that there was only one designated certification body in China authorized to issue the mark and one accredited testing laboratory to perform testing and inspection for any given product category under the CCC system. It was the understanding of the United States that, despite China's accession commitment that qualifying minority foreign owned and majority foreign owned joint venture conformity assessment bodies would be eligible for accreditation and would be accorded national treatment, only six foreign invested conformity assessment bodies had been accredited. Furthermore, it appeared to the United States that these six foreign invested conformity assessment bodies had not been permitted to play a role in accrediting products under the CCC system. The representative of the United States noted that one US based conformity assessment body had entered into an MoU with China, allowing that body to conduct one aspect of the CCC certification requirements. However, it was the understanding of his delegation that China had not been willing to grant similar rights to other US based conformity assessment bodies on the grounds that they were only allowing one MoU per country. He noted that China had not provided a rationale for this. He also noted that China had rejected suggestions that it recognize bodies accredited by ILAC/MRA or IAF MLA signatories or that it develop other procedures to recognize foreign conformity assessment bodies, insisting instead that it would accept conformity assessment bodies domiciled abroad only if their governments negotiated MRAs with China.

The representative of the United States recalled that the TBT Agreement encouraged WTO Members to permit foreign laboratories to participate in their conformity assessment procedures on terms no less favourable than those accorded to domestic or other foreign conformity assessment bodies and required Members to accept wherever possible test results, certification and other forms of assurance performed in other Members' territories provided they were satisfied that they offered an assurance of conformity equivalent to their own. Furthermore, Members had to adopt, wherever practicable, international systems of conformity assessment. He suggested that China take positive steps to liberalize its approach to recognizing foreign conformity assessment bodies and expressed his delegation's willingness to engage further in dialogue with China in exploring alternative approaches to reduce costly and duplicative testing and certification requirements for US and other foreign companies doing business in China. He asked whether China was giving consideration to the ILAC and IAF accreditation systems under the CCC mark scheme.

The representative of China explained that the objectives of the regulations were in line with the legitimate objectives of the TBT Agreement, i.e. safeguarding national security, preventing deceptive practices and protecting human health or safety, animal plant life or health, or the environment. It was the view of China that the regulations complied with the non-discrimination principles of the TBT Agreement. The representative of China explained that his country had engaged in mutual recognition bilaterally and multilaterally, including China's membership in IECEE and ILAC/MRA. He explained that China was accepting CB reports issued by the CB testing laboratories of other countries, within the scope of the IECEE scheme. Bilaterally, China had concluded a total of 40 bilateral cooperative documents with 23 countries/areas, identifying ILAC/MRA as a key technical base for mutual recognition between China and other countries. He noted that there were 168 conformity assessment bodies recognized by China, 35 of which were foreign funded bodies, the list of which could be found at www.cnca.gov.cn. He explained that in order to shorten the certification process and reduce burdens for enterprises seeking CCC certification, China had taken a number of measures, including: (i) using online application forms and online acceptance of compulsory product certification; (ii) recognition by the CCC scheme of CB test reports issued under the IECEE scheme and commissioning follow-up inspection of overseas manufacturers after certification to local certification bodies; (iii) reducing the certification fee by an average of 20 per cent; and iv) implementing classified management for key components.

EUA x Coréia do Sul - KS C IEC61646:2007 Standard for Thin-film Solar Panels

Korea – KS C IEC61646:2007 Standard for Thin-film Solar Panels

The representative of the United States raised concerns over Korea's standard for thin-film solar panels. It was the understanding of the United States that since 2008, Korea had required solar panels to be certified by the Korean Management Energy Cooperation in order to be sold in Korea. Additionally, in 2007, Korea had issued a mandatory Korean standard for thin-film solar panels (KS 61646). The representative of the United States pointed out that while the Korean standard appeared to be based on the international standard IEC 61646, which also dealt with thin-film solar panels, the Korean standard only applied to one type of solar panel, amorphous silicon type thin-film solar panels, excluding other types of thin-film solar panels. He explained that as a result, other leading solar panels, including those from cadmium telluride and copper indium selenide, as well as gallium arsenide which was an emerging commercially proven technology, could not be tested or certified under the Korean standard and thus were not able gain the necessary certification to be placed on the Korean market. According to US industry, Korea had been the only country in the world that specifically restricted application of the IEC standard to only one type of thin-film solar panels.

The representative of the United States noted that Korean producers manufactured the amorphous silicon type thin-film solar panels, the only type of thin-film solar panel that was allowed to be sold in Korea. Conversely, foreign producers manufactured the types of panels not covered by the Korean standard and were not able to gain the certification necessary to be sold in Korea. Consequently US companies had left the Korean market. The United States was not aware of any scientific or technical evidence indicating that there had been risks from using the thin-film solar panels not covered by the Korean version of the IEC standard. The representative of the United States noted that while the measure had hurt US companies, it also had the effect of keeping the most innovative solar panel products out of Korea and limiting Korean producers from moving into the next generation of technologies. It was the view of the United States that it would not only facilitate trade to allow other types of thin-film solar panels to be certified to the Korean standard but it would also allow Korea to benefit from the best available technologies in this important area of energy conservation.

The representative of Korea clarified that his country did not maintain their standards on a mandatory basis. All standards had been voluntary in their use and that even without certification, products could be sold in the Korean market. He confirmed that the Korean standard for thin-film solar panels had been largely based on IEC 61646, with the exception of test requirements for cadmium telluride based solar panels and copper indium gallium selenide solar panels which had not been taken into account. He explained that these two types of thin-film panels had not been included in the Korean standard because they used toxic substances like cadmium in their manufacturing processes or in the product itself. He informed the Committee that the Korean Energy Management Cooperation (KEMCO) had recently launched a feasibility study for the environmental and safety impacts of these substances in solar panels. He explained that once the study was complete, in one to two years, the Ministry of Knowledge Economy would take a decision on the inclusion of the other two types of thin-film solar panels in the Korean standard. He noted that comments from the United States would be passed on to KEMCO.

Arábia Saudita x China - Measures on the Environmental Management of New Chemical Substances (G/TBT/N/CHN/210 and Rev.1)

China – Measures on the Environmental Management of New Chemical Substances (G/TBT/N/CHN/210 and Rev.1)

The representative of Saudi Arabia raised concerns regarding China's proposed amendment to the measures on the environmental management of New Chemical Substances, which had been notified to the TBT Committee. While Saudi Arabia supported China's objective of protecting human health and the environment, concern was expressed with respect to a number of issues. With regard to the local testing requirement, it was Saudi Arabia's understanding that the new regulation required chemical test reports to be performed in China, according to Chinese standards. The Chinese delegation was invited to explain the reasons for such a requirement, including whether China would recognize testing conducted in international

accredited laboratories. With regard to the risk assessment requirements, it was the Saudi Arabia delegation's understanding that the Chinese regulation required: (i) risk assessment reports for notification; (ii) risk monitoring as a precondition for a listing in the Inventory of Existing Chemical Substances; (iii) annual reporting requirements for the registrant and the downstream processors; and (iv) a prohibition on the sale or transfer of chemicals to those "who do not have the capacity to take risk control measures". Again, these operations had to be conducted according to Chinese standards. China was asked to provide further information on the above-mentioned requirements, including the applicable risk assessment standards and to clarify what constituted "suitable risk control measures".

With regard to the notification requirements, Saudi Arabia encouraged China to provide information on the specific notification requirements for each classification foreseen by the new regulation. Regarding the Inventory of Existing Chemical Substances, the delegation from Saudi Arabia sought confirmation that chemicals listed in the inventory would not be subject to the requirements set by the new regulation. Could China also clarify what was the status of the chemical substances that had been notified but not yet included in the Inventory of Existing Chemical Substances? Furthermore, the representative of Saudi Arabia noted that the Chinese regulation contained only general language on the protection of confidential information. Could the Chinese delegation provide clarification on the specific provisions for the protection of confidential business information that China intended to adopt? Finally, the delegate of Saudi Arabia noted that the regulation was planned to enter into force on 15 October 2010 and requested the Chinese authorities to postpone its implementation.

The representative of China recalled that 60 days had been provided for comments on this notification and no comments had been received from WTO Members. He confirmed that the notified measures had been adopted in December 2009, officially published in January 2010, and would enter into force 15 October 2010. The representative of China also noted that this was a new issue that had not been previously raised and his delegation had not been made aware of the concerns expressed by Saudi Arabia. However, he stated that given Saudi Arabia's interest, his delegation would be available to discuss this bilaterally after the issue was reviewed in capital.

Previously raised concerns

Argentina, Canadá, Índia, Japão, EUA, Austrália, Arábia Saudita, Cuba, Chile, Tailândia e El Salvador x UE - Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (G/TBT/N/EEC/52 and Adds.1-5; Add.3/Rev.1; G/TBT/N/EEC/295 and Add.1; G/TBT/N/EEC/297; G/TBT/N/EEC/333-6)

European Union – Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (G/TBT/N/EEC/52 and Adds.1-5; Add.3/Rev.1; G/TBT/N/EEC/295 and Add.1; G/TBT/N/EEC/297; G/TBT/N/EEC/333-6)

The representative of Argentina reiterated his delegation's concern with regards to REACH: the regulation was an unnecessary barrier to trade. Besides there was a lack of transparency by not providing straightforward information about how the system worked. Small and medium sized enterprises (SMEs) exporting from Argentina had faced difficulties in coping with and understanding the regulation since it came into existence and faced disproportioned costs in complying with the regulation. While he noted that the European Union had issued explanatory guides to assist in meeting the regulation, these guides were too extensive. Moreover, the update of some explanatory guides would be available after the date in which expires the registration of substances produced or exported in quantities over 1000 tons per annum and of substances which are carcinogenic, mutagenic or toxic (30 Nov.2010). The explanatory guides were not sufficient and technical assistance was essential. The Regulation itself recognized the need to provide technical assistance and capacity building activities in developing countries (article 77 paragraph l of Regulation EC No. 1907/2006).

With regard to the disproportionate costs SMEs faced in complying with the provisions of REACH, the representative of Argentina listed the costly registration procedures, the submission of evidence, the sharing of data, and conformity statements. These requirements put SMEs operating outside the EU at a disadvantage compared with businesses operating within the European Union as these businesses often had to open an office within the European Union or hire a single representative to simplify the procedures. He explained that this imposed additional costs on exporters, which were seen as necessary to continue operating in the EU market. He pointed out that EU businesses and enterprises did not need to comply with these procedures and encouraged the European Union to modify the measure, particularly with respect to the complicated nature of the regulation and the costs involved in complying with it. It was the view of Argentina that if this issue was not addressed, exporters would be excluded from the European chemical substances and compounds market. The representative of Argentina noted that El Salvador would be making a statement on behalf of GRULAC, reflecting the concerns felt throughout the Latin American region regarding REACH. He noted his delegation's support for the forthcoming GRULAC statement. He concluded that Argentina supported the aim of protecting health and the environment but was of the view that REACH constituted an unnecessary barrier to trade.

The representative of Canada noted that her delegation had received a written response from the European Union regarding the *aide memoire* from mid-May and that Canadian officials were currently assessing it. She noted that the European Chemicals Agency (ECHA) had published its Annex V Guidance and she asked how this fast-track guidance update procedure was intended to operate, and how this would affect oils sourced from genetically modified (GM) plants in the interim. It was the understanding of Canada that at the June CARACAL meeting, ECHA had indicated that the Annex V Guidance would be reviewed "with a view to be amended" after 30 November 2010. The representative of Canada asked what ECHA intended to accomplish through those amendments, whether there would be a consultation process, and if so, which stakeholders would be consulted and what the timeline would be.

The representative of India explained that after consultation with Indian stakeholders, his delegation wanted to express its concern with the EU REACH Directive, particularly with regard to the burdensome registration procedures. Regarding the economic rational of the regulation, the representative of India asked why the technical dossier and chemical test reports needed to be prepared separately by each manufacturer for each chemical preparation substance, when the detailed data was already publicly available and no new chemical preparation substances had been produced in the process. Using the example of monomers and polymers, he explained that the approach to determining the selection of polymers for registration on the basis of sound technical and valid scientific criteria was clearly acknowledged; why, therefore, had not the same approach been adopted for other substances? He asked what the justification was for registering all substances without sound technical and valid scientific criteria. Given that the life cycle of a monomer would end when reacted into a polymer, and that information on monomers in polymers did not enable conclusions on the risk of polymers produced, he asked for the rationale in requiring the registration of monomers in the first place.

With regards to difficulties SMEs faced in complying with REACH, the representative of India asked for the EU view on the particularly high costs and the administrative burdens of the Substance Information Exchange Forum (SIEF) membership that these suppliers face. It was India's view that by creating such bodies, which were primarily controlled by the EU domestic industry, and were beyond the control of any regulatory oversight, the EU was placing exporters at a disadvantage. The representative of India asked for information on the number of existing manufacturers in the EU territory, as well as the turnover rate for SMEs, in order to understand the effect of the regulations on SMEs in the EU's domestic industry. India was also of the view that a number of alternatives existed to animal testing, noting that an EU GRC study found that approximately 50 per cent of chemicals under REACH could instead be tested by computer simulation. The OECD was also in the process of drafting guidelines on animal testing. The representative of India asked whether as assessment of such viable alternatives had been considered by the EU as a critical aspect of any chemical regulation that purported to minimize costs and incidence of animal testing.

The representative of Japan expressed his delegation's concern regarding the overlapping regulations covered under REACH and the Restriction of Hazardous Substances (RoHS) Directive. It was the view of Japan that a number of substances were redundantly covered by REACH and the RoHS Directive. Specifically, those covered in the notification according to Article 7 and in the duty to convey information according to Article 33 of the REACH Regulation with regard to the candidate list substances, as well as in Article 4 of the RoHS Directive as substances subject to prohibition or restriction. As an example, the representative of Japan explained that if an article contained an identical hexavalent chromium compound or lead compound, the substance was subject to multiple regulations under both controls. However, the application of the threshold value differed across the two regulations. In REACH, the entire article was the denominator in the calculation while in the RoHS Direction the homogeneous material in the article was the denominator. If the draft RoHS Directive Amendment were to be enacted in the future, substances could be regulated by two regulations with different applications. Japan stressed that such a situation would cause complexity and confusion for non-European exporters of articles to Europe.

The representative of the United States stated that his delegation shared the EU's interest in protecting human health and the environment, but continued to have trade related concerns with REACH and its implementation. Without restating all concerns raised at previous meetings, he highlighted some that were of particular concern to the United States. First, he asked for an update on the EU's efforts to finalize the remaining guidance documents in time for stakeholders to be able to rely on this information in preparation for the first registration deadline. US stakeholders felt that there was a lack of transparency and legal certainty in the implementation process which made compliance planning difficult and limited their opportunities to provide input.

Second, the United States reiterated concerns it had previously raised on the issue of differences in interpretation between the Commission and some member States regarding the 0.1 per cent threshold for the notification and communication obligations with respect to substances on the candidate list. The representative of the United States asked whether the European Union could elaborate on the steps it would take to resolve this disagreement and provide clarification on which rules would govern EU member States' interpretations of the threshold so as to provide legal certainty and predictability to US stakeholders.

Third, with respect to the SIEF issue, the United States reiterated that many SIEFs were not functioning effectively for several reasons and asked what steps the European Union was taking to address these issues in time for companies to meet the first registration deadline. The representative of the United States recalled its previously raised concern that a formal contact group of trade associations had been set up to develop a strategy to help companies meet the first deadline but limited participation to EU stakeholders, excluding US and foreign stakeholders. The United States expressed concern over how foreign stakeholder input was going to be taken into account.

The representative of the United States requested clarification on a number of issues. He requested an update on the latest developments with respect to the impact of REACH on animal testing. Additionally, it was the understanding of the United States that while REACH called on registrants to submit their dossiers before the end of November, press reports claimed that ECHA had indicated it could guarantee processing registrations in time to meet the first registration deadline only if the dossiers were submitted by the end of June 2010. The representative of the United States asked for clarification on this issue, including confirmation whether companies that had submitted their dossiers by the deadline at the end of November would fulfil their legal obligation to register and would be able to continue producing and importing their substances into the European Union. If, in fact, ECHA had taken the position that the deadline was five months earlier than in the actual regulation, the United States felt this would put companies at risk of having to pull their products out of the EU market. Such a significant change in the policy would need to be codified in a formal proposal. The United States understood the motivation in encouraging lead registrants to submit their dossiers early in order to limit last minute submissions which would increase the chances that ECHA would not be able to process the registrations of their competitors in the SIEFs, many of whom where SMEs, in time for their products to remain on the market. He asked what the European Union

intended to do, so that others could still submit them in time, if the lead registrants did delay the submission of their dossiers. He also noted that the United States would submit comments by the 1 December deadline regarding the upcoming review of REACH's scope. However, the representative of the United States asked whether there would be opportunities to submit comments on other aspects of the measure.

The representative of Australia joined others in reiterating concerns about REACH. While she stated her delegation's support of the objectives of the European Union in ensuring a high standard of protection for human health and safety and for the environment, she noted that the overly burdensome and complex regulations unfairly impacted non-EU producers, and in particular SMEs. She explained that non-EU companies continued to require further assistance from EU REACH experts to ensure they understood and complied fully with REACH requirements. While Australia welcomed the development of the REACH guidance documents, the representative of Australia was concerned that these documents continued to be subject to change leaving non-EU companies uncertain about REACH requirements and timelines.

The representative of Saudi Arabia reiterated his delegation's concerns regarding the adverse impact of REACH on trade in chemicals. He explained that the complexity of REACH made it difficult for Members to comply. He explained, as an example, that the registration requirements for monomers and polymers, and for substances "intended to be released under normal or reasonably foreseeable conditions of use" appeared to be overly broad and needed to be clarified. He shared the concerns raised by others that compliance with REACH had created significant costs and burdensome requirements for exporters to the EU market. Furthermore, he expressed concern over the protection of business confidential information within REACH and asked what steps the European Union was taking to address confidentiality breaches. Regarding penalties for non-compliance, the representative of Saudi Arabia asked for an explanation of the penalties provided and an update on the lack of penalty provisions by some EU member States. As a major exporter of chemicals, Saudi Arabia raised concerns that the requirements imposed by REACH in terms of its coverage, costs and procedures appeared to be more strict than necessary to achieve the EU objectives.

The representative of Cuba shared concerns raised by others regarding the costly requirements exporters faced. He recalled a study by the European Parliament in 2006 that estimated that complete compliance with this regulation would cost Cuba Eur 2,780,000 per year during the 11 year implementation period. These were the second highest costs that would be faced by an ACP grouped country, after South Africa. He asked for clarity on the case of the Only Representative, the functioning of the substance information exchange forum (SIEFs), the protection of confidential information, and the possible use of a different procedure for the confirmation of pre-registration in each member State of the European Union. He asked the European Union to simplify the burden that this regulation represented for exporters, in particular for developing countries.

The representative of Chile shared the concerns raised by Members regarding REACH. She focused on four concerns. First, in connection with SIEF, she asked about the clause in the dates for availability of access, especially for lithium carbonate and lithium hydroxide. It was Chile's understanding that the access cards contained the technical information, the physical data, and the toxicological characteristics which were necessary for registration. She noted that, in practice, this information needed to be presented to ECHA at the beginning of 2010. However, it was unclear, as previously mentioned by the United States, whether after 1 September 2010, before the official deadline of 1 December 2010; this information would not again be revised. As such a situation could result in the non-compliance of Chilean companies she requested more information about the deadlines, by the first week of July, to ensure the compliance of Chilean companies.

Second, in connection with the implementation of REACH in sectors such as semi-finished steel products and steel products, which would be subject to the registration requirements, the representative of Chile noted that uncertainties existed regarding the pre-registration process. While some may decide to enter into REACH provisionally, the ECHA authorities would have to look at the article and the respective SIEF would remain dormant. She noted that Eurofair, the association comprising European steel producers, had different interpretations of the issue to

that of ECHA. For example, Germany could consider semi-finished products as finished products, thus falling under REACH, creating legal uncertainty. She noted that different interpretations of REACH by the various EU member States would have an enormous adverse effect on foreign companies.

Third, the representative of Chile raised questions on classification, labelling, and packaging (CLP). She explained that some EU companies were not required to notify the classification of their products to ECHA until January 2011. However, some foreign companies that would not have come under the regulation for REACH registered substances would have had to comply with everything according to this legislation. It remained unclear whether notification could be given, an issue that was raised as critical for Chilean companies registered under REACH and subject to the CLP. She asked for clarification on this issue.

Fourth, the representative of Chile noted that technical assistance for non-EU countries regarding both REACH and CLP, was almost non-existent. Explanatory notes on the internet were useful, and a formal request for training procedures existed, but she suggested video conferencing could also be used. Additionally, she asked for information on what the European Union was doing regarding confidentiality breaches, referring to a case where registered Chilean companies received unsolicited emails from a consulting firm. Finally, she noted her delegation's support for the statement that would be made on behalf of GRULAC.

The representative of Thailand echoed the concerns raised by others on the difficulties SMEs had had in complying with REACH. While Thailand supported the objective of human health and environmental protection, the representative of Thailand urged the European Union to consider ways to ensure that the measures was not more trade restrictive than necessary.

The representative of El Salvador made a statement on behalf on the Group of Latin American and Caribbean countries (GRULAC). GRULAC recognized the right of Members to establish technical regulations on procedures to evaluate conformity based on scientific evidence with a view to protecting human health and the environment. However, she explained that the complex nature and costs involved in the process, and the lack of precise information, particularly in Spanish, represented unnecessary trade barriers particularly to SMEs. She requested that the European Union offer prompt and effective technical assistance as part of special and differential treatment to SMEs. She stated that GRULAC reserved its right to come back to this measure with new concerns in the future.

The representative of the European Union responded to the questions and comments raised. She reminded India that an explanation about the rationale and objectives of REACH had been addressed in previous Committee meetings. Regarding Argentina's statement that the businesses outside the EU had to open an office within the European Union or hire a single representative she noted that it was not correct that the appointment of an Only Representative was mandatory, since REACH only applied to importers in the European Union. As the importer was the one responsible for registration, an Only Representative was only necessary when third countries' manufacturers did not want to provide the necessary data to the importers.

Next, she noted that the polymer and monomer question had been resolved by the European Court of Justice which had confirmed that article 6 paragraph 3 of the REACH regulation, which had provided for the registration of reacted monomers in polymers, was valid. It was found that the registration obligation enabled better knowledge to be obtained of polymers and address certain health and environment risks such as monomer residues.

The representative of the European Union went on to suggest that instead of repeating the same issues in every Committee meeting, she would focus on issues of current relevance for the REACH Regulation, and especially on those regarding the first registration deadline of 30 November 2010. She explained that the functioning of the SIEF was *a priori* the responsibility of industry. However, the European Commission and ECHA had continued efforts to help industry in making the SIEF function. Additionally, an ECHA Stakeholder Day had taken place 19 May 2010 regarding the registration deadlines; she noted that information from the day was available on the internet. She informed the Committee that the next ECHA Stakeholder Day, which would be held on 4 October 2010, would focus on registration and the second step of the

dossier evaluation; it would again be open to all stakeholders and accessible online. She explained that a couple of "webinars" had also occurred, providing information on how to prepare a registration dossier and submit to ECHA. The recordings for these webinars had been published. Additionally, a new practical guide (number 9), on how to do registration as a member who joins a submission, was also available on the website. She stated that these readily available tools were a form of technical assistance, meant to assist both EU and non-EU manufacturers. Other information was also specifically addressed to SMEs, to assist them in complying with REACH. She stressed that if countries had specific training needs, they could contact the EU delegation in their territory.

Regarding the functioning of the SEIFs and the upcoming registration deadline, the representative of the European Union noted that a Directors' contact group, chaired by the European Commission, had developed certain practical recommendations, including on issues of importers and Only Representatives. These recommendations were first communicated by ECHA on 16 April 2010, and more recommendation would be made public in the future. One recommendation was to the lead registrant to set a cut-off date in order to avoid the situation where companies that did not participate in the SIEF discussions, submitted important information at the very last moment, disrupting the planned submission. This recommendation was meant to address concerns, also raised by Members at the TBT Committee meeting, that certain participants were dormant in the SIEF, by encouraging companies to start work now on collecting the data needed so that the lead registrant could submit the dossier correctly. The representative of the European Union explained that this contact group had been set up rapidly and thus had not involved EU member States or foreign countries. However, all recommendations were made public and if foreign countries were interested to be represented by the International Chemical Council Association joining, the European Union would be open to discussions. She noted that following these recent efforts, the number of lead registrants that had registered had again increased, to 2574 by mid-June.

Regarding the concerns from Chile that a consulting firm had contacted other participants in the SIEF, the representative of the European Union noted that the issue had been raised before and that steps had been taken in this regard: ECHA had reacted with a press release dated 30 July 2009. Regarding Chile's other questions, she mentioned that her delegation would follow-up bilaterally.

Next, she explained that on the ECHA website, a list was now available of all chemicals that companies had indicated as being planned to be registered by 30 November. She asked Members to pass this information on to their industry so that manufacturers, particularly downstream users, could consult the list and check to make sure that their substances, which had to be registered by 30 November, were included in the list. This was important since if a substance had not been registered, it would be illegal to manufacture or sell it in the European Union. She explained that the list would be updated regularly.

Regarding Canada's reference to the new Annex V guidance, the representative of the European Union explained that this guidance had been published on 1 April 2010 and provided explanation and background information on how different exemptions from the obligations to register applied. With the completion of this guidance, all guidance documents important for the registration deadline of 30 November were available, with most of them being available in all 22 EU member State languages, including Spanish. Regarding when the guidance would be revised, she stated that those relevant for registration would not be amended before 30 November 2010. In fact, ECHA had taken the decision to postpone amendments to 10 guidance documents in order to give companies and industries time to focus on registration until 30 November.

With regards to the 0.1 per cent issue and member States' different interpretations, the representative of the European Union noted that in consequence no update of the guidance documents was planned for the moment. She referred to the last EU statement made in the TBT Committee where it had been explained that a final interpretation of the REACH Regulation could only be given by the European Court of Justice. Addressing Saudi Arabia's request for an update on the absence of sanctions in certain Member States, she noted that there was only one member State who had not yet adopted sanctions for its whole territory, but all others had

done so. Regarding the US question on animal testing, she referred Members to the ECHA press release on a new practical guide on avoiding animal testing, published on 2 June 2010.

The latest developments regarding the candidate list and the substances to be included in Annex 14 were outlined next. The representative of the European Union recalled that at the last Committee meeting there had been 29 substances on the candidate list and that ECHA had identified 8 new potential substances of very high concern, with public consultation on-going. As of June 2010 there were 38 substances on the candidate list: the 29 substances already of the list, acrylamine which was added after a court case, and the eight new substances which had still been under consolation at the time of the last TBT Committee meeting.

Regarding Japan's question on the relation of the REACH Regulation with the RoHs Directive, she stated that these two Directives were being applied in parallel. She further explained that there was no overlapping, as referred to by Japan, since Articles 7 and 33 of REACH referred to information requirements while Article 4 of the RoHs Directive referred to restrictions. Also, regarding the potential overlapping of regulations, she stressed that the European Commission would review the scope of REACH (done in accordance with Article 138 paragraph 6 of REACH) by 1 June 2012 in order to assess whether to amend the scope to avoid overlaps with other relevant Community provisions. She noted that the review was already underway, and that stakeholders were being provided with the opportunity to share any relevant experience they had regarding overlapping scopes or gaps between REACH and other EU legislation. A website had been created to receive comments, www.reachscope.eu, and would be operational until 1 December 2010. She invited Members to submit comments.

Finally, she updated the TBT Committee on the draft regulation amending Annex XVII of the REACH Regulation (notified under G/TBT/N/EEC/297) which had been mentioned at the last meeting. She stated that similar to the situation at the time of the last meeting, the proposal was still under review and had not yet been adopted. The only development to report was that the European Commission and EU member States were currently analyzing the opinion of the ECHA Risk Assessment Committee, on the use of boric acid in photographic applications.

Japão, Rapública da Coréia, EUA e China x UE - Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) (G/TBT/N/EEC/247 and G/TBT/Notif.00/310, Corr.1)

European Union – Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) (G/TBT/N/EEC/247 and G/TBT/Notif.00/310, Corr.1)

The representative of Japan understood that in the draft amendment of the RoHS Directive 2002/95/EC, Article 4 on Prevention had been transferred to Annex IV, and new candidate substances were listed in Annex III. Japan sought confirmation that Annexes III and IV were indeed part of Directive 2002/95/EC, thereby requiring the European Union confirmation on the procedures for the insertion or deletion of listed items in the annexes. Japan requested that the European Union notify any schedule of amendments to Directive 2002/95/EC.

The representative of the Republic of Korea welcomed the exclusion of brominated flame retardants (BFRs) and PVC from the RoHS Annex IV list of restricted substances. However, the representative of Korea expressed concern that DEHP, DBP, BBP and PVC remained on the Annex III Priority List. Their inclusion could present incorrect signals of their dangers to many stakeholders, especially non-experts. The Republic of Korea was of the opinion that the risks associated with these substances required vigorous scientific investigation. Until investigative results were generally approved, they requested the European Union to exempt the proposed substances from any list.

The representative of the United States reiterated his delegation's support for the RoHS objective for protecting health, safety and the environment, but trade-related concerns remained. If adopted the proposal would likely impact upon many producers. The United States therefore sought an update from the European Union on what consideration was being given, as part of the process, to the input provided by producers and other stakeholders. Although the representative of the United States recognized the Commission's efforts on information gathering in order to inform the development of its proposal, including through impact assessment, he believed that had a thorough impact assessment been conducted, it would have been a useful tool to have better informed the Council and Parliamentary scope proposals. This in turn could have led to a very different outcome by the Environment Committee. The United States continued to hear concerns from stakeholders about the proposals for an open scope as, for example, the current proposal's not clearly defining excluded categories.

European Union efforts to articulate the relationship between REACH and RoHS, through their proposal for a revised RoHS Directive, was acknowledged by the United States. Nevertheless, they were of the view that the text could benefit from greater clarification. It was noted that the new substances identified in their proposal, itemized substances which might also appear on the REACH candidate list of substances of high concern for authorization and subject to REACH assessment. If the purpose of a link with REACH was to align approaches, the US concern was that evaluation conclusions would differ – given that the same substance would be evaluated under two separate measures, by different agencies, having different objectives and using different criteria.

The United States requested the European Union to elaborate on the timeframe for revising the RoHS Directive. A REACH process for discussing scope issues existed and many stakeholders would want to submit specific comments on the relationship between REACH and RoHS, prior to the December timeframe. Should the recast process complete before December, any comments could prove to be moot.

The United States held the view that the operation of the RoHS Directive would be improved through a transparent exemption process that provided fixed timeframes for decisions; a meaningful opportunity for all interested parties to comment; and an explanation of the basis for decisions. The United States voiced its concern that given the potentially wider scope of the measure, as the number of exemption requests would likely increase, and European Union resources might not be adequate. The United States held the view that the operation of the RoHS Directive would be approved through a transparent exemption process that provided fixed timeframes for decisions; a meaningful opportunity for all interested parties to comment; and an explanation of the basis for decisions. The United States voiced their concern that given the potentially wider scope of the process, as the number of exemption requests would likely increase, European Union resources might not be adequate.

With respect to additional substances, the United States urged that any decision to include additional substances be science-based, taking into account any end-uses and all available scientific and technical information with respect to substances not currently restricted and for which the Environment Committee had called for further evaluation. As well as for those substances for which the Committee had called for a ban, the United States requested information on the identified potential risks to health and the environment, together with information on the processes through which those risks had been identified.

The representative of China reiterated that his delegation had repeatedly raised concerns on both European Union Directives, bilaterally and within the Committee. He acknowledged previous speakers for raising issues and registered China's continued concern with regard the directives and their implementation developments.

The representative of the European Union informed the Committee that the proposal was in the first reading of the legislative process by the European Parliament. The Environment Committee had adopted its report on the Commission proposal on 2 June 2010. The report retained 160 of the 300 amendments tabled by parliamentary members within different parliamentary committees. The report of the Environment Committee was to be discussed at a

plenary session of the European Parliament in October 2010. It was expected that during that session, the Parliament would adopt its opinion on the Commission's proposal. The next stage of the procedure would be a discussion in Council by the European Union Member States on the text voted upon by the Plenary. The EU Member States would review the amendments and indicate whether they were agreeable. If agreement was found between the Parliament and Council, and should the Commission agree, the legislative process would conclude with the finalization of the text. If a compromise could not be reached the text would be re-submitted to Parliament and Council for examination under a second reading.

Regarding substance, the Environment Committee had indeed proposed extending the scope of RoHS to all electrical and electronic equipment, including cables, consumables and accessories until 1 July 2014. The Environment Committee had also proposed certain exclusions from RoHS, in particular means of transport; large-scale fixed installations; and equipment manufactured for research and development purposed. They had also proposed changes to the ways and rules through which exemptions were granted. It was noted that the Environment Committee had not retained the amendment aimed at enlarging the number of substances that would be restricted under RoHS, but rather proposed enlarging the substances list in Annex III by adding 29 candidate substances from the REACH candidate list.

Which amendments would survive the plenary vote remained unclear and, in the view of the European Union, it would be premature to surmise on any amendment. Within the legislative process the Commission would signal concerns raised by WTO Members to the Parliament and to the Presidency of the Council of the European Union. The representative of the European Union informed WTO Members that should the Commission's initial proposal be substantially amended, the revised text would be notified to the TBT Committee. Also, WTO Members will be updated on developments of the legislative process at the next meeting.

EUA x UE - Regulation on Certain Wine Sector Products (G/TBT/N/EEC/15, Corr.1-2, G/TBT/N/EEC/57 and G/TBT/N/EEC/252 and Add.1 and Add.2; G/TBT/N/EEC/264 and Add.1)

European Union – Regulation on Certain Wine Sector Products (G/TBT/N/EEC/15, Corr.1-2, G/TBT/N/EEC/57 and G/TBT/N/EEC/252 and Add.1 and Add.2; G/TBT/N/EEC/264 and Add.1)

The representative of the United States informed the Committee that it continued to have serious concerns regarding European Union measures that severely restricted the ability of non-European Union wine producers to use common or descriptive and commercially valuable terms that the EU claims are traditionally associated with European wines. This was particularly problematic as some terms had no common definition across all European Union member States, and to their knowledge no efforts had been undertaken to monitor or limit the use of those terms within the European Union. Negative trade impacts remained a concern, along with previously raised issues, and discussion continued with stakeholders.

The representative of the United States understood that discussions between the EU and industry were ongoing with respect to several terms upon which the European Union continued to claim exclusive rights, citing the recent example of the United States Government and industry filing objections to Cyprus' request that the English term 'special reserve' be designated as a traditional term. Cyprus' application provided no indication that the English term 'special reserve' is a name used widely within the Community, nor a reputed name in Cyprus. The United States queried whether this application may have been prompted by a recent European Court of Justice ruling that found that traditional terms were now protected in languages other than the one for which protection was originally identified. Further, the United States requested the provision of an update on the discussion over specific terms and how the European Union intended to address the request from Cyprus.

The representative of the European Union acknowledged the continued interest by the United States in European Commission wine labeling legislation, noting that their authorities were in regular contact with Wine of America, the National Association of American Wineries. The

European Union had provided the necessary information to EU industry in order to assist them in submitting their application. It was noted that the Commission was currently examining both the application by Cyprus and the comments received, including those from the United States.

UE, Japão e República da Coréia - Pneumatic tyres and tubes for automotive vehicles (G/TBT/N/IND/20 and Add.1; G/TBT/N/IND/40 and Rev.1)

India – Pneumatic tyres and tubes for automotive vehicles (G/TBT/N/IND/20 and Add.1; G/TBT/N/IND/40 and Rev.1)

The representative of the European Union voiced appreciation to India for their recent decision to postpone implementation of the new Indian Order on Tyres and Tubes for Automotive Vehicles for an additional six months. Nonetheless, the European Union remained concerned that tyres produced according to United Nations Economic Commission for Europe (UNECE) Regulations were not considered as equivalent. Moreover, the European Union had some concerns regarding the implementation of the Order. The European Union had been alerted by economic operators that the burdensome certification procedure had made it extremely difficult to receive necessary certification within the required timelines. For instance, detailed information was requested concerning raw material, manufacturing machinery, the name of the maker, the number of installed machines, as well as test equipment. The European Union sought clarification as to why the Indian authorities required this information. Furthermore, applicants were required to pay a royalty fee calculated on all tyres marked with the Indian logo, whether imported or not, obliging economic operators to either pay high fees or produce tyres for the Indian market alone. The European Union urged India to ensure that the calculation on which royalty fees was based was on the total value of actual imports to India. Additionally, India was urged to accept test results from UNECE accredited laboratories.

On certification, the European Union sought clarification that the procedure required tyre manufacturers to have complete in-house testing facilities. The European Union had been alerted that certain applications from economic operators had been rejected on this basis. Clarification was sought as to what type of testing such in-house facilities would perform and whether they would complement tests by the Bureau of Indian Standards (BIS) accredited laboratories. In the view of the European Union, all above-mentioned elements created unnecessary obstacles to trade and were not in compliance with the TBT Agreement. Therefore India was urged to take the necessary steps to ensure their procedures were less burdensome and more cost effective for economic operators.

The representative of Japan stated their regret that India had expanded the scope of tyres targeted by this Regulation. Japan's concern was that the Regulation contained considerable uncertainties, creating a barrier to trade of tyres and tubes. It was pointed out that a TBT Notification on the expansive revision of the Regulation should have been submitted. Due to the revision, many additional plants would require audit applications. The representative of Japan requested India to further postpone the implementation of the Regulation so that industry had sufficient time to prepare for the revision. Regarding the BIS Indian Standards Institution (ISI) mark, it was Japan's understanding that the Regulation required manufacturers to pay license fees for all ISI marked tyres, including those exported outside India. They pointed out that the license payment obligation needed to be limited to tyres imported to India.

The representative of the Republic of Korea stated that notwithstanding the welcome postponement of the Regulation, several concerns remained. On the obligatory ISI marking of tyres (Article 3.1), they again called upon the Indian authorities to consider the significant amount of time expended and the increase in costs for both manufacturers and consumers. They reiterated that these concerns could be eliminated by the acceptance of international marks of conformity. On the requirement of information disclosure (Article 5), the Republic of Korea remained of the view that the necessity for confidential information needed to be made exempt. Korea had serious concerns over the leaking of manufacturers' confidential industrial and technological information.

The representative of India stated that in extending the Regulation timeframe to November 2010, they had provided more time than that stipulated by the TBT Agreement. On the non-acceptance of international standards, the representative of India informed the Committee that the BIS had undertaken comprehensive analysis of not only UNECE standards, but those of the International Organization for Standardization (ISO) and American Standards (ASTM) as well. They believe the ISO to be a relevant international standards-setting body, whose benchmarks had framed this Regulation. With regard to royalty fees, the representative of India informed the Committee that the fees had recently been amended by BIS to ensure that the unit value of the fees were equivalent for both the domestic and import markets.

Brasil, Canadá, Turquia, EUA, Tailândia, República Dominicana, Equador, Colômbia, Cuba, Austrália, Arábia Saudita e China x UE - Regulation on Classification, Labelling and Packaging of Substances and Mixtures (ATPs and CLP) (G/TBT/N/EEC/151 and Adds.1-2; G/TBT/N/EEC/212 and Adds.1-3; G/TBT/N/EEC/163 and Adds.1-2, Add.1/Corr.1)

European Union – Regulation on Classification, Labelling and Packaging of Substances and Mixtures (ATPs and CLP) (G/TBT/N/EEC/151 and Adds.1-2; G/TBT/N/EEC/212 and Adds.1-3; G/TBT/N/EEC/163 and Adds.1-2, Add.1/Corr.1)

The representative of Brazil reiterated his delegation's concerns regarding the first adaptation to technical progress (ATP) to the EU regulation on Classification, Labelling and Packaging of Chemical Substance (CLP Regulation). Brazil considered that the classification of nickel compounds under the first ATP had been based on an inadequate application of read-across methodology. It was the view of Brazil that major flaws in the process had been related to the absence of data, the criteria used to group substances, and the disregard to some OECD recommendations on read-across. The representative of Brazil recalled that, on previous occasions, that European Union had informed the Committee that the first ATP would only have implications for the labelling of nickel compounds. However, the classification of nickel compounds as carcinogenic had led to additional restrictions under other EU Regulations such as REACH. Brazil was concerned that this new classification would have significant commercial effects which would go beyond the labelling requirements.

The representative of Brazil expressed his delegation's regret that the European Union had not provided adequate opportunity for Members to comment on the first ATP, noting that the difference between CLP and DSD regulations justified a new consultation period for the first ATP. Due to the fact that a comment period had not been granted, Brazil was of that view that important transparency flaws existed in the process of elaborating and publishing the first ATP to the CLP. While Brazil did not dispute the EU's objective of protecting human health and environment, it did dispute the necessity of the measures used for achieving those legitimate objectives as there was no sound scientific evidence on the risks posed by the reclassified nickel compounds. The representative of Brazil stressed his delegation's concern regarding the compatibility of the first ATP with Articles 2.2, 2.4 and 2.5 of the TBT agreement.

The representative of Canada raised her delegation's longstanding concerns with the EU's classification of nickel containing substances. She recalled that at the last TBT Committee meeting, Canada had circulated a Room Document which contained a list of concerns and questions regarding the issue. She thanked the European Union for their response in mid-May. Additionally, she noted that Canadian officials were also currently reviewing EU comments received 9 June 2010 regarding document G/TBT/N/EEC/297. It was Canada's view that given the potential of a negative impact on nickel producers and exporters, it was essential that any classification of substances be based on transparent, sound science. The same principles needed to be applied to measures that relied on these classifications. Regarding Borates, the representative of Canada noted the concerns raised by other Members regarding the proposed identification of Boric Acid as a Substance of Very High Concern (SVHC) and explained that Canada also had an interest in resolving such concerns, ensuring that the assessment and management of substances were scientifically based, conducted in an appropriate and transparent manner, and proportionate to the risk that substances posed. She expressed

Canada's interest in the EU's proposed classification of borates and the perceived risks associated with inhalation exposure in the workplace and asked what other risk management options the European Union had considered.

The representative of Turkey maintained its position on the classification of borates with regard to the lack of legal and scientific basis. He expressed concern with recent steps taken in the classification of borates. It was Turkey's understanding that the classification was based of the evaluation of hazard and the determination of concentration limits with respect to danger for human reproduction. Therefore, when limits were not exceeded, it was presumed that substances would not damage human health. Similarly, he explained that exceeding concentration limits did not automatically lead to risk. He noted that besides authorization (Annex XIV) and restriction (Annex XVII), lists under REACH were determined according to risk analysis. While there where no other borates products exceeding the concentration limits or which were found to pose a risk to consumers, the downstream impact had been to add borates to Annex XVII of the REACH regulation and Annex XV dossier to add borates to the candidate list. He stated that it did not seem plausible to rush for the restriction of borates since there were no borates sold to consumers that posed a risk. He noted that as time passed and new studies on the chemicals were undertaken, the issue was becoming more complicated. He asked the EU to re-evaluate this issue in light of these new concerns and new studies.

The representative of the United States reiterated his delegation's concerns on the initial classification of certain borate and nickel compounds under the Dangerous Substances Directive and their translation into the CLP regulation. With respect to borates, the United States noted that, in light of the risk assessment commissioned by the European Union, borates usage, in the cases examined, posed either a negligible or non-existent risk to the general public. As a result, the European Union had initially proposed that the placing on the market and use of borates containing substances in household cleaners, detergents and certain photographic mixtures would not be restricted. However, due to member State disagreement, the European Union had not adopted this exemption. It was the understanding of the United States that this issue had once again been referred to ECHA's risk assessment committee, which had found that normal use of photographic compounds was safe. The representative of the United States asked what would happen with the results of the initial risk assessment which resulted in the EU proposal, and whether the European Union would go forward in placing restrictions on these substances despite the results of the risk assessment. He urged the European Union to adopt a risk-based approach to determining exemptions for the use of products.

With respect to the recent decision to place certain boric compounds on the candidate list, the representative of the United States asked whether the results on the Chinese mine workers study, as well as other studies submitted by the European Borates Association, would be taken into account. He noted that the consideration of the available scientific and technical information was pivotal in assessing the risks of non-fulfilment of legitimate objections. He also noted that the effects of the initial boric classification under other EU measures, many of which were discussed in earlier Committee meetings, appeared to have been confirmed by this new decision to place these boric compounds on the list.

With respect to nickel, the representative of the United States noted that the Danish competent authority appeared to not have completed all the necessary steps of the OECD read-across methodology, raising questions about whether the available scientific and technical information and intended end-uses had been taken into account. It was the understanding of the United States that the European Union believed that certain provisions precluded the following of the necessary steps. The representative of the United States asked for clarification on the exact provisions of the Dangerous Substances Directive that prevented the European Union from following all of the steps of the-read across methodology and whether provisions of the CLP regulation and other EU legislation would prevent them from following all of the steps of the read-across methodology for future analysis of substances. Additionally, he asked what the effects would be regarding the interpretation of the EU's ability to take into account the available scientific and technical information and intended end-users to evaluate substances. He noted that the United States would continue to monitor the potential adverse trade impacts of these classifications and methodological issues.

The representative of Thailand shared the same concerns raised by others regarding nickel classification. She stated that whether for health, safety, or consumer protection, it was important that the classification be based on scientific justifications. She asked the European Union to ensure that its substance classification was based on unquestionable and solid scientific findings and procedural thoroughness.

The representative of the Dominican Republic recalled her delegation's concerns about the EU decision to reclassify nickel carbonate and other nickel compounds in the new regulation on classification, labelling and packaging CLP of the European Union. She stressed that there had been no scientific basis to the first change to the ATP, in effect since 25 September 2009. The Dominican Republic regretted that the European Union had not taken their comments, as well as the comments of several other delegations at the TBT Committee meetings in 2008, 2009 and March 2010, into account.

She reiterated her delegation's concerns with respect to the methodology used by the European Union to classify nickel substances known as read-across. The Dominican Republic was also of the view that the European Union had violated Article 2.2 of the TBT Agreement, which established that Members should ensure that they would not draw up, adopt or apply technical regulations that would have the effect of creating unnecessary barriers to trade. The classification and labelling requirements in this regulation would have adverse consequences for the nickel substance producers and exporters. The representative of the Dominican Republic recalled that in 2007, nickel ion exports from the Dominican Republic represented more than 50 per cent of national exports, with an absolute value of US$1.153 billion. However, due to a fall in the international prices, in 2008, only US$492 million in exports were registered. This had a devastating effect on the industry and the national economy. In November 2009, the company that mined nickel ion in the Dominican Republic dismissed more than 900 employees and was no longer in operation. She noted that nickel ion mining in the Dominican Republic took place in very depressed areas of the country where no other sources of labour or employment existed. The new EU regulations would have made this situation worse. She asked the European Union to reconsider its position and to comply with the provisions of the TBT Agreement.

The representative of Ecuador shared the concerns raised by Brazil and others on the lack of transparency so far in the adoption of the first ATP and the need for the European Union to explain the scientific basis for the reclassification of nickel components CLP.

The representative of Colombia recalled that the scientific basis for this classification had been debated at length in the Committee. He noted that there had been no scientific certainty with respect to the validity of the measures and provisions adopted and that there was no proof of effectiveness with regards to the legitimate objective of the regulation.

The representative of Cuba repeated his delegation's concerns with the classifications adopted by the European Union for more than one hundred nickel compounds. He expressed that Cuba was a faithful defender of human health, the environment and regulations adopted to this end, as long as they were scientifically based. He noted, however, that there had been no data or scientific evidence that justified the classifications in the EU regulation. He noted that the EU's methods had been based on extrapolation, and while Cuba had not been opposed to the use of this methodology, in this particular case, it had not followed international scientific practice as it had omitted steps 5 to 8 of the OECD guide. Furthermore, it was the view of Cuba that the procedures of the European Union were not the most appropriate in terms of the obligations under the TBT Agreement. He noted that the European Union did not take note of the multiple appeals to extend the 60 day term to look at the requests formulated by various Members, including developing countries. It was the view of Cuba that the European Union had not considered the Committee's decision at the Third Triennial Review, that developed country Members would provide a term of more than 60 days for the presentation of comments in order to improve the capacity of developing countries and to accommodate the special and differential treatment clause. Instead, the classifications had been adopted by the Committee on Technical Progress on the day of the Committee just after the expiry of the deadline.

The representative of Cuba noted that while the impact of this system of classification for the nickel industry at the global level was still incalculable, it would cause discrimination against nickel compounds in addition to adverse effects for the marketing the product. Because of this, there were various regulations on protective measures and restrictions and prohibitions on the use of classified substances, including REACH. In September 2009 the European Union notified a proposed amendment to REACH which prohibited the sale of a series of classified substances under the regulation as carcinogenic or toxic for reproduction, including nickel compounds. Adding negative press to this, these classifications could have had a possible domino effect in other markets. Cuba urged the European Union to provide satisfactory replies to the following questions: (i) how did they justify the omission of steps 5 to 8 of the extrapolation methodology or read-across from the OECD; (ii) would they facilitate the opinion of experts or information on which the classifications were based; (iii) did the European Union have data on the water solubility of each one of the nickel compounds included in ATP; and (iv) what specific information would have made the European Union reconsider this system of classification, given the lack of sufficient scientific basis. Cuba sustained that the classification for nickel compounds adopted by the European Union constituted an unnecessary barrier to trade and asked the European Union to revise the first ATP.

The representative of Australia reiterated her delegation's concerns and disappointment regarding the EU's decision to reclassify a range of nickel compounds, noting that the concerns of many WTO Members remained unaddressed. Australia recognized the importance of ensuring the protection of human health and the environment, and therefore supported the development of transparent and sound measures to achieve such protection. However, the scientific validity of the EU's decisions to reclassify the nickel substances remained of concern. The representative of Australia noted that the competent Australian assessment authority had been discussed at past meetings and that concerns along those lines continued to be raised. She noted that Australia had previously welcomed European Union assurances in the TBT Committee that the EU's decision to reclassify the nickel substances would result only in additional labelling requirements and that, as a result the impact on trade in these substances would be limited. However, there was now evidence that there would be a significant impact on trade in nickel compounds resulting from the EU decision. In this regard, she understood that: the proposed EC Green Public Procurement Criteria would exclude the use of stainless steel containing more than 1 per cent nickel in air conditioners and heat pumps; under the revised EU Eco-Label Directive, products incorporating alloy steels and stainless steel containing 1 per cent or more nickel would not be eligible for an EU Eco-label; EU mobile phone producers may be looking to suspend the use of nickel in anti-radiation barriers, and the 2008 London Olympic Games Sustainable Sourcing Code listed nickel, in relation to battery applications, as a material to be avoided.

She further noted that amendments to Annex XVII of REACH would have further prohibited the sale of nickel substances to the general public and would have required these substances and mixtures to be labelled as ‘restricted to professional users'. The consequences of this proposed amendment for nickel producers and users would have been far-reaching and would have confirmed Australia's concerns, as previously raised in the TBT Committee, that the reclassification of nickel substances as category 1 and 2 carcinogenic and mutagenic compounds would trigger a series of downstream regulatory requirements which would impose additional restrictions and prohibitions on the use of nickel substances.

Australia welcomed assurances that a risk assessment would need to be carried out before the European Union sought to impose any type of marketing restrictions, or the setting of maximum exposure levels or bans would be considered. The representative of Australia noted that a risk assessment had been conducted for borates, resulting in the exemption of some borates for certain end uses from the proposed prohibition on sale to consumers, although the United States was continuing to face problems. However, it was not apparent that a similar risk assessment had been conducted for nickel substances. Further, Australia understood, from consulting with their industry, that only three of the numerous nickel substances proposed to be included in Annex XVII were used by consumers. As a major producer and exporter of nickel substances Australia continued to be greatly concerned by the likely significant economic impact on nickel producing and exporting countries, which included developing countries, of the EU's decision to reclassify the nickel substances and to further restrict their use.

The representative of Saudi Arabia shared the concerns expressed by other Members that the requirements imposed by the EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures appeared to be more strict than necessary to achieve the European Union's objectives. Saudi Arabia saw the coverage, costs, and procedures set out in the Regulation as evidence of this. The representative of Saudi Arabia explained his delegation's concern about the scientific assessment under the Regulation. He explained that it was imperative that any such classification be based on internationally recognized science and reliable data, as well as transparent expert assessment procedures, pursuant to the requirements of the TBT Agreement. Like other Members, Saudi Arabia was concerned that the labelling of chemicals under the regulation could be misconstrued or misunderstood as an eco-labelling scheme. Like REACH, this Regulation could have significant adverse trade effects. Saudi Arabia was concerned that this Regulation entailed excessive requirements and would result in unnecessary additional costs for the industry. Saudi Arabia requested the European Union to ensure the consistency of the regulation with the requirements of the TBT Agreements.

The representative of China joined the previous speakers by stressing his delegation's concern with the EU measure, in particular regarding the omission of the OECD read-across steps by the Danish research group, which could lead to incorrect results in terms of the classification of nickel compounds. This could have brought significant adverse trade effects in several areas as illustrated by the delegation of Australia. The representative of China invited the European Union to base its measures on solid and credible scientific evidences, in line with the least trade restrictive obligations of the TBT Agreement.

The representative of the European Union took note that a number of delegations continued to raise concerns over the classification of borates and several nickel compounds in the 30th and 31st ATP. She noted that these concerns would be conveyed to capital. She explained that, over the last years, the European Union had provided detailed replies, in writing and orally, to all of the issues raised in this meeting. Additionally, presentations by EU experts had been given at TBT Committee meetings. Given that there was nothing new to add, she referred Members to the minutes of the last TBT Committee meetings for more details.

Regarding the question from the United States to describe the legal basis in the EU legislation which prohibited the European Union to carry out additional testing, she explained that this had been article 4.3 of the Dangerous Substances directive and article 8 of the CLP regulation. These provisions indicated that a classification had to be done on the basis of the available information. This meant that additional testing could not be required. Under REACH however, the EU authorities, could if necessary for the purposes of registration, ask for the additional testing. In addition, industry could also ask to perform additional testing particularly animal testing for the registration. If this was the case, they were to make a proposal and ECHA would assess it and decide if such testing was needed or not.

Regarding questions on what the European Union needed in order to re-evaluate the classification, she explained that the CLP regulation clearly indicated that the classification would be reviewed when new scientific evidence was provided. Regarding Australia's request for information on the three nickel compounds that were supposed to be found on the market place with concentration levels above those which were authorized, to the EU's knowledge, as indicated in the replies to notification G/TBT/N/EEC/297, there had been no products on the market which contained the classified nickel compounds in concentrations above the authorized levels. She referred to the explanations her colleague had provided under the agenda item 2(i) on the issue of the risk assessment on borates. She reminded delegations, that if there was any information which could challenge the Commission's conclusions on classifications and labelling, that industry could submit such information to the EU and ask that it be submitted to ECHA for revision.

Nova Zelândia, UE e Austrália x Canadá - Compositional requirements for cheese (G/TBT/N/CAN/203 and Add.1)

Canada – Compositional requirements for cheese (G/TBT/N/CAN/203 and Add.1)

The representative from New Zealand reiterated concerns about Canada's compositional standards for cheese and their consistency with the principles and obligations of the TBT Agreement. New Zealand's assessment of the standards was that they were overly restrictive, both in terms of the thresholds imposed for the use of dairy ingredients, and their impact on trade. The standards limited the use of protein sourced from dairy ingredients, when such ingredients were widely used and accepted in cheese production worldwide. He further stressed that these compositional standards were inconsistent with the relevant Codex standard, which did not prescribe limitations on the sourcing of milk proteins for use in cheese manufacture. The delegate requested Canada to provide the TBT Committee with an update on developments with the appeal process following the initial court ruling on the cheese standards and on whether the standards were being enforced pending the outcome of the appeal. He also asked Canada to confirm whether or not its dairy producers were actively lobbying the government to introduce similar standards for yoghurt, and if so what had been the government's response to this proposal

The representatives of the European Union and Australia supported the concerns raised by New Zealand.

The representative of Canada explained that the revised regulations clarified and harmonized the federal compositional standards for cheese. The revised regulations had come into force on 14 December 2008 and applied to cheese manufactured after that date. She highlighted that when developing these regulations, Canada had taken international standards and other countries' regulations into account, as well as the comments received during the WTO's notification period. She informed the Committee that all imported cheeses were deemed to be in compliance with the revised standard. She added that the Government of Canada had not initiated any regulatory process for establishing compositional standards for other dairy products. She noted that hearings of the Judicial Review had been held on 31 March and 1 April 2009. On 7 October 2009, the Federal Court had ruled that the application for judicial review made by the applications be dismissed. The federal court decision was currently being appealed by two of the applicants. She concluded that there was no evidence that the regulations constrained the existing overall usage of milk ingredients, such as milk protein concentrates.

UE x Índia - Drugs and Cosmetics Rules 2007 (G/TBT/N/IND/33)

India – Drugs and Cosmetics Rules 2007 (G/TBT/N/IND/33)

The representative of the European Union reiterated concerns regarding the Indian order laying down a registration procedure of imported cosmetics products. During a recent bilateral meeting, India had informed the European Union that it had revised the draft. She asked whether this draft differed from the previously notified version and whether India intended to notify this new draft to other WTO Members.

The representative of India said that the draft of the new rules, aiming at protecting public health, had been notified in 2007. He announced that the inputs received from the European Union and the United States would be taken into account when finalizing these new rules.

UE e Japão x China - Proposed Regulations on Information Security (G/TBT/N/CHN/278-290)

China – Proposed Regulations on Information Security (G/TBT/N/CHN/278-290)

The representative of the European Union expressed his delegation's disappointment about the entry into force as of 1 May 2010 of the China Compulsory Certification scheme, the so-called CCC-I Scheme, for 13 categories of IT security products pursuant to joint notice on implementation No. 2010/48 of 28 April 2010 issued by the Minister of Finance, CNCA, AQSIQ and MIIT. The European Union regretted that the Chinese authorities had not considered the suspension of the implementation of the CCC-I rules in order to allow for further discussions with interested trading partners and foreign industry in order to address the substantive concerns raised. As had previously been mentioned, the European Union remained concerned that the entry into force of the CCC-I scheme, together with the continued application of the Office of State Commercial Cryptography Administration (OSCCA) 1999 Regulations on commercial encryption and the full implementation of the Multi Level Protection Scheme (MLPS) in the near future would introduce significant restrictions on access to the Chinese market for a wide range of information security products, including products which had purely commercial application and as such were not sensitive for protecting national security.

On the OSCCA regulation, China had indicated at the November 2009 TBT Committee meeting that the regulation was being revised and that OSCCA would be open to an exchange of experiences with foreign governments. The European Union had reconfirmed its interest to work with China on this issue with a view to ensuring a level playing field in China between domestic manufacturers of commercial encryption products and foreign invested companies producing the same products in China or foreign manufacturers, and also with a view to aligning the OSCCA regulation with relevant international standards and practices. The delegate of the European Union requested China to provide an update as to the current status of the revision of the 1999 OSCCA Regulations, as it was the European Union's understanding that the draft text was already with China's State Council Legislative Affairs Office . He also asked China whether it was possible to access the draft, whether interested parties could contribute to the revision process and when the TBT notification of this draft could be expected. He stressed the importance of transparency in the revision process given the high stake for foreign industries and demanded an effective participation of foreign stakeholders in this process.

On the CCC-I scheme, the European Union welcomed the clarifications provided by China regarding the coverage, and in particular that state-owned enterprises would not be covered by the scheme. He asked to receive further clarification on whether semi-public entities, such as hospitals or schools which operated in non-security sensitive sectors, were also excluded from the scope of the CCC-I scheme. He also asked whether entities receiving public funding, for instance from the Ministry of Science and Technology for research and development purposes, would be excluded from the coverage or whether receiving this funding would mean that they would be covered by the definition of government procurement pursuant to the relevant law on government procurement in China.

The representative of the European Union emphasized his delegation's fundamental concerns about the viability of the CCC-I Scheme with respect to its excessive disclosure requirements, which meant that companies would have to divulge sensitive design information, including the source code during the evaluation process. This was compounded by an overall lack of transparency and unpredictability of the system, in particular in regard to those encryption products for which OSCCA would be required to carry out the evaluation of the source code, since procedures applied by OSCCA were not publicly available. He noted that OSCCA did not communicate in writing with foreign stakeholders and companies interested in submitting an application file and thus the latter did not have access to the necessary information in order to adequately prepare such applications. The European Union also remained concerned about the potential *de facto* application of the CCC-I scheme in the commercial area, whereby several state-owned enterprises in the IT field were requiring compliance with the CCC-I scheme as a purchasing condition, which could potentially deprive foreign manufacturers from effectively accessing to the Chinese market. The European Union urged the Chinese government to confirm that this practice would neither be encouraged nor endorsed by Chinese authorities.

With respect to the Multi Level Protection Scheme, the European Union remained concerned about the lack of clarity as to the way the concept of 'critical infrastructure' would be interpreted. The European Union delegate recalled that, if the IT system of a company was qualified as

critical infrastructure, then only products having obtained CCC-I or OSCCA certification could be used in those systems. This opened a back door application of the CCC via the Multi Level Protection Scheme. For this reason, the European Union requested further clarification as to how the notion of critical infrastructure would be interpreted and in particular whether according to such interpretation, state-owned enterprises which operated in non-security sensitive sectors would not be classified as critical infrastructure.

The representative of the European Union also asked for a general update on the implementation of the Multi Level Protection Scheme, and what the current target date of implementation was. Finally, he underscored the European Union's interest in remaining engaged in a technical dialogue with China and announced an upcoming proposal for starting a technical dialogue.

The representative from Japan supported the views presented by the European Union. In their view, the proposed regulations on information security put forward by China were not in conformity with international norms and approaches and Japan remained concerned with the possibility that these measures could negatively affect trade in information security products. Japan requested China to provide further information regarding schemes which had already been implemented especially its measures related to the protection of intellectual property. Moreover, Japan hoped that China would exercise prudence in introducing additional measures regarding information security.

The representative of China explained that China had received comments from all interested parties and given them full consideration. She clarified that China had narrowed down the scope of application to government procurement and postponed implementation. The representative further noted that China had stated repeatedly that it was not appropriate to continue discussions in the TBT Committee on this issue. Concerning the regulation on commercial cryptography, she explained that the revision of the State Council's regulation on commercial cryptography had been put into the State Council's 2010 schedule. Finally, she stated that China would take the European Union's and other interested parties' comments and suggestions into consideration.

The representative of the European Union asked China to explain in greater detail what opportunities existed to provide input into the legislative process at this stage.

The representative of China reiterated that the revision had been added to the 2010 legislation plan. She announced that the comments received from the European Union would be brought back to the capital; China would then evaluated what opportunities would be given to the European Union and other trade partners to be involved in the revision process.

The representative of the European Union requested a statement from China that the draft revised text would be notified at the appropriate stage, as it was a technical regulation and hence the minimum transparency requirement had to be fulfilled. He also enquired about the possibilities to provide input when a legislative proposal was pending with the State Council Legislative Office.

The representative of China reiterated that the comments received from the European Union would be brought back to the relevant agencies.

UE e Japão x Índia - Mandatory Certification for Steel Products (G/TBT/N/IND/32 and Add.1)

India – Mandatory Certification for Steel Products (G/TBT/N/IND/32 and Add.1)

The representative of the European Union reiterated concerns about India's mandatory certification requirements for steel. India had informed the TBT Committee in March 2010 that certain items had been deleted from the list of products that would require certification. The delegate from the European Union enquired whether this deletion was permanent or whether it

was limited to a period of 6 months, as has been indicated by Indian authorities to economic operators. She further asked whether one product, namely galvanized steel sheets, was still on the list and therefore subject to the certification requirements. India had not given any explanation why the widely accepted international standards in this area had not been considered as sufficient to ensure product safety. In the absence of such justification, the European Union urged India to refrain from requiring mandatory certification proving compliance with a national standard.

The representative of Japan echoed the concerns raised by the European Union and requested an update on this measure.

The representative of India explained that the process was on-going and that no decision had been taken yet about deleting specific products. Secondly, he explained that the Bureau of Indian Standards (BIS) reviewed standards on a regular basis and international standards were not normally benchmarked. However, he noted that the end use of galvanized steel was mostly in the rural areas where public health and safety were an important issue, and thus justified a specific standard. He added that in the standard setting process India did benchmark against international standards.

Canadá e Noruega x UE - Seal products (G/TBT/N/EEC/249 and Adds.1-2; G/TBT/N/EEC/325)

European Union – Seal products (G/TBT/N/EEC/249 and Adds.1-2; G/TBT/N/EEC/325)

The representative of Canada noted that on 3 May 2010 the European Union had circulated a copy of the Draft Commission Regulation laying down detailed rules for the implementation of Regulation 1007/2009 on the trade in seal products. Canada had notified the European Union at that time that the five day period for comments left little scope for other Members to submit detailed comments on the proposed measure and for the European Union to fully take those comments into account. Canada had also notified the European Union that its notification of the Draft Commission Regulation was incomplete, since it did not provide any HS or CCCN numbers to indicate which tariff lines would be subject to the regulation. Canada asked whether the European Union was currently in a position to inform Members of the product coverage of the regulation.

The representative of Canada noted that while the European Union's regulation referred to seal products, the scope of the import ban appeared to be much broader, encompassing all products of all species of pinnipeds. That definition included products derived from ivory, from species such as walrus. While the international trade in some pinniped ivory products was regulated by the CITES Convention, trade in those products had not been prohibited. He underscored that these products were of great cultural and commercial importance to indigenous communities in Canada and elsewhere. Canada urged the European Union to reconsider any action which imposed additional regulatory barriers to the trade of sculptures derived from pinniped ivory. Canada recalled that the European Union defended its adoption of the ban on seal products by stating that the fundamental economic and social interests of indigenous communities would not be adversely affected by its seal regulation. Furthermore, Canada requested that the European Union state its objective in banning the importation and trade of products derived from pinniped species other than seals.

The representative from Canada drew Members' attention to the fact that the regulation by the European Union on seal products introduced a requirement for the application of an "ecosystem based-approach" for natural resources management plans. She noted, however, that the regulation provided no guidance on how to determine whether a particular programme met that requirement. Furthermore the implementation rules provided little certainty to certification bodies on how to proceed in order to attest that products met the certification requirements. Canada also reiterated its concerns that the requirements for the establishment of accreditation bodies - and the time it would take the European Union to recognise these bodies - would result in a

complete ban on the importation of seal products as well as other pinniped products for a lengthy period of time.

The representative of Norway recalled that Norway had made several statements to the TBT Committee regarding the notification by the European Union of Regulation 1007/2009/EC on trade in seal products ("the Seal Regulation"), first notified in draft form in document G/TBT/N/EEC/249. Since the last TBT Committee meeting, the European Union had notified a draft "Implementing Regulation" laying down detailed rules for the implementation of the trade restrictions in the Seal Regulation, contained in document G/TBT/N/EEC/325. Norway appreciated the invitation to provide comments to the draft Regulation, which had been submitted by Norway on 4 May 2010. He noted, however, that none of Norway's comments had been taken into account by the European Commission and that no changes had been made to the final proposal submitted to the European Parliament. He stressed that the rules remained ambiguous, unclear, and far more trade restrictive than the legitimate objective could justify. He argued that the new rules established a regime that unjustifiably restricted trade in one of Norway's natural resources, which was harvested in a sustainable and ethical manner. In Norway's view the trade restrictions to be implemented in the European Union on 20 August 2010, as set out in Regulation 1007/2009 and in its implementing regulation, were inconsistent with the TBT Agreement as well as GATT 1994.

The representative of the European Union recalled that during the previous TBT Committee meeting the European Union had indicated that it was of the view that the adopted regulation did not fall within the scope of the TBT Agreement; the European Union therefore considered it inappropriate to discuss it within the framework of the TBT committee. She signalled, however, that the European Union was available to discuss this matter within the framework of the regular bilateral contacts.

UE x Colômbia - Draft Decree Establishing Provisions to Promote the Use of Biofuels (G/TBT/N/COL/96 and Adds.1-3)

Colombia – Draft Decree Establishing Provisions to Promote the Use of Biofuels (G/TBT/N/COL/96 and Adds.1-3)

The representative of the European Union recalled that in the last TBT Committee meeting Colombia had informed the Committee that it was working on a revision of the legislation on flexible-fuel vehicles. In particular, Colombia explained that it had been considering a reduction of the per centage of ethanol in gasoline that vehicles had to be able to use. The European Union requested Colombia to give an up-date of the situation.

The representative of Colombia reiterated his government's readiness to revise the regulation in order to achieve greater flexibility with the respect to the reduction of the percentage of ethanol in the fuel mixture, taking into account the experiences of other countries. He explained that in March 2010 the Colombian inter-sectoral Committee, which approved the management of fuel, had met and noted the importance of revising the standard and strengthening the flex fuel regime with an incentive for the national production of automobiles. He added that this plan was currently being studied by Colombia. With respect to the national policy on this measure and the commitments assumed to deal with this matter, he informed the Committee that the Ministry of Mines and Energy had commissioned a consulting company to make a technical study of flex fuel in Colombia. He announced that on 28 June 2010 the technical proposal of the consultant for the fuel distribution chain which was required for implementation and for the development of the programme would be submitted. He stated that Colombia had a number of international experiences in the production of biofuels, in flex fuels for the automotive industry and the use of a percentage of ethanol in fuel.

EUA x França - Unique Requirements for Ride-on Lawn Mowers

France – Unique Requirements for Ride-on Lawn Mowers

The representative of the United States reiterated his delegation's concerns with respect to the French Ministry of Agriculture's skirt requirements for ride-on lawnmowers, as the measure had never been published as part of an official law or decree, never been notified to the WTO, and had disrupted US ride-on lawnmower exports to France. He explained that the United States had raised its concerns on this issue in previous meetings, including questions about the technical basis for the skirt requirement, the deviation of this requirement from other member States' requirements and international standards, and the lack of transparency.

At the last meeting, the United States had noted that there had been ongoing discussions involving US and European industry, the Ministry of Agriculture, the Commission, and other stakeholders to try and resolve this issue, including efforts to find appropriate language for the European Committee for Standardisation (CEN) ride-on lawnmower standard EN 836. This meeting had contributed to the adoption of a revised CEN standard, with a large majority of members of the technical committee voting in favour. He was disappointed that France's standards body had then appealed this standard which would further delay the publication of the revised standard.

The representative of the United States noted that, in the meantime, the French authorities appeared to have stepped up efforts to enforce the skirt requirement, and US companies felt that they were being unfairly targeted by these efforts. Recently, the French Ministry of Agriculture had called into question test results from an EU "Notified Body" demonstrating full compliance with EN 836 of one US company's ride-on lawnmowers, even though such test results had been accepted by all other EU member States without any problems or challenges. The United States urged the European Commission to review this issue closely and intervene as appropriate to help resolve it both for the benefit of trade in safe, high quality lawnmower products that met the essential requirements, and given the systemic implications of France's actions for the new approach.

The representative of the European Union wished to provide some clarifications with regard to the ongoing process of revising the European harmonized standard and the parallel development of the ISO standard on safety of lawnmowers. In particular, regarding the revision of the European harmonized standard 836 which concerned the safety of powered lawnmowers, the technical committee had decided not to cover the essential requirement 1.3.7 of Annex 1 to the Machinery Directive dealing with the protection of bystanders against the risk of contact with moving transmission parts in the current amendment process. As a consequence, the relevant safety requirement in the current draft amendment only covered aspects relating to the safety of the operator in the driver seat, not of bystanders. The current procedure which had been launched by the *Association Française de Normalisation* (AFNOR), the French national standardization body and member of the European Committee for Standardization (CEN), was precisely addressing the fact that the current amendment failed to address the protection of bystanders. The European Commission could not intervene in this process, as it was governed by CEN procedures. The European Commission only reacted if and when the amended standard was submitted to the European Commission with a request for publication of its references in the Official Journal of the European Union with a view to giving presumption of conformity against the relevant essential requirements of the Machinery Directive. It was only at that stage that the European Commission would take a decision on the publication based on the adequacy of the proposed amendment against the objective of providing presumption of conformity.

The representative of the European Union further explained that there was another parallel initiative in ISO aiming at developing an international standard of the safety of lawnmowers as part of the ISO 5395 series of standards. This process was taking place under CEN lead according to the Vienna Agreement between CEN and ISO. The European Commission encouraged all interested parties to seek an acceptable compromise solution to the outstanding issues regarding the protection of bystanders in the framework of the development of this new international standard which was at the moment in draft stage and which was referenced as ISO/DIS/5395.

Concerning the recent new market surveillance action undertaken by the Ministry of Agriculture in France, the European Commission did not intervene in this process. Market surveillance was

a prerogative of the national enforcement authorities. If a final measure restricting the placing on the market of the product in question would be taken, then the measure would be notified to the European Commission pursuant to the safeguard clause procedure of the Machinery Directive and at that moment, the European Commission would have to take a decision on the justification of the measure. The European Union was willing to provide any further clarification on a bilateral basis. He recalled that the interpretation of essential requirement 1.3.7 by the French authorities had been endorsed by all other EU member States and the European Commission in the Machinery Working Group which was the technical body supporting the implementation of the Machinery Directive. This interpretation was thus shared and supported by all other EU Member States. Current discussions had therefore now to focus on what technical solution would give the best expression to that requirement, taking the state-of-the-art into account.

Canadá, UE, Nova Zelândia, Suíça, Austrália e EUA x Coréia do Sul - Regulation for Food Industry Promotion Act (G/TBT/N/KOR/204 and Suppl.1)

Korea – Regulation for Food Industry Promotion Act (G/TBT/N/KOR/204 and Suppl.1)

The representative of Canada thanked Korea for postponing the implementation date of the proposed amendments to the Food industry promotion act and Regulations to January 2011. As set out in the TBT Agreement as well as in Codex, Canada hoped that Korea would use the delay to include provisions into their regime which allowed for equivalency agreements. Canada would welcome the opportunity to work towards developing an equivalency arrangement with Korea. She explained that Canada was concerned that producers would be unable to ship multi-ingredient products starting in 2011 because they required additional time to ensure that all ingredients were certified to the Korean regime. A further transition period for ingredient certification would be helpful, increasing the likelihood that Korean consumers would continue to have access to a broad range of organic products in the coming years. Canada was concerned that the proposed amendments, which were more trade restrictive than necessary, would prevent Canadian producers from supplying Korean consumers with organic products after 1 January 2011.

In addition, Canada drew the Committee's attention to a multi-country letter from the Governments of Canada, the United States, the European Union, New Zealand, Australia and Chile to the Korean deputy Minister for trade policy, Ministry of Food, Agriculture and Forestry and Fisheries (MIFAFF) which highlighted the shared concerns of all signatories over the proposed changes to the regulations. Canada expected further bilateral discussion with Korea outside the TBT Committee on this issue.

The representative of the European Union joined the delegation of Canada in reiterating its concerns regarding Korea's Regulation for the Food Industry Promotion Act. The European Union appreciated Korea's postponement of the requirements by one year until 1 January 2011, as well as Korea's announcement in the March 2010 TBT Committee meeting that it was undertaking a study on the possibility to introduce an equivalence mechanism in its organic regulatory system, in line with the CODEX guidelines on organic products. In this regard, the European Union asked for an update from Korea about the state of play of the foreseen amendment of its legislation to provide for recognition of equivalence of other countries' organic systems.

Furthermore, she noted that notwithstanding the positive steps undertaken by Korea to facilitate the accreditation process, the approval procedure for foreign certification bodies remained challenging. Of significant concern was the requirement to individually certify each ingredient of processed organic products, as well as the corresponding processing methods. As stated in the past, the European Union judged that this requirement was nearly impossible to comply with, particularly in the case of processed products consisting of multiple ingredients, and would pose serious challenges for the importation of all but the most basic multi-ingredient imported organic products into Korea. The European Union therefore reiterated its demand to Korea to grant

derogation from the requirement to certify ingredients in case of imported products, at least until equivalence recognition was introduced. Finally, in order to allow for minimum distortions of trade of organic products in Korea, the European Union asked Korea to further extend the transitional period after which the existing system would be phased out.

As a cosignatory of the joint letter recently sent to Korea's MIFAFF, the representative of New Zealand supported the comments made by Canada and the European Union. New Zealand welcomed the announcement that a professor at Inha University had been commissioned to undertake a review of Korea's proposed organic regulatory system. This review process and the extension of the implementation date provided New Zealand with the opportunity to work constructively with Korea on provisions in its regime that would allow for equivalence arrangements or other relevant arrangements for both processed organic products and raw organic produce. New Zealand was hoping for changes that would ensure minimal disruption to the market place and would ensure that Korean consumers would continue to have access to a broad range of organic products in the coming years helping Korea meet the objectives of its food industry promotion act.

The representative of Switzerland recalled that at the last TBT Committee meeting, Korea has stated that the MIFAFF was conducting studies on how to install a system to implement measures that was based on equivalency. Switzerland requested Korea to inform the TBT Committee about the outcome of these studies and to extend the transitional period until the installation of such a system.

The representative of Australia shared the concerns raised and confirmed that Australia was one of the co-signatories to the joint letter. Australia welcomed the decision by Korea to allow the revised regulations governing the import of organic food products into Korea to run in parallel with the Korean Food and Drug Administration labelling requirements until 31 December 2010. In addition, Australia asked for an update on concerns that Australia had previously raised regarding the revised regulations, for example: education requirements and auditor numbers. Australia's concerns had been addressed through minor amendments and were supposed to be announced in March 2010. However, as of June 2010, the Australian competition authority for organic exports had not received confirmation of these amendments. Furthermore, as advocated in the June 2009 equivalency recognition request, Australia considered that its organic export system met the policy intent of Korea's new requirements. Australia was aware of the fact that before equivalence recognition of foreign government systems were to be permitted, legislative changes to both the Food Industry Promotion Act and the Environment-Friendly Promotion Act were required. In line with the principles for equivalence agreements as set out in the TBT Agreement, as well as in Codex, Australia encouraged Korea to delay mandating the revised regulations until such a time when provisions allowing equivalence recognition were in place.

The representative of the United States welcomed Korea's decision to extend the implementation date of its processed organic products regulation for one year in order to allow trade to continue to flow. However, the United Sates remained concerned that the regulation did not currently contain a procedure for recognition or equivalence. The United States encouraged Korea to work as quickly as possible to amend the regulation to incorporate language allowing for such agreements. The United States also welcomed an update on the status of that process and the study that was being conducted.

In addition, the representative of the United States raised concern over the difficulty that US producers faced in meeting the revised requirements. A particular concern was the requirement for individual certification of ingredients in processed products. The United States was concerned that many producers would be unable to ship multi-ingredient products starting in January 2011 because the requirement to individually certify each ingredient in processed products would make certification of all but the simplest multi-ingredient organic products extremely challenging, which could be detrimental to exporters, importers, domestic processors, retailers, and Korean consumers. To remedy this situation, the United States proposed a further transition period for ingredient certification until such point as a recognition or equivalence arrangement was established between the interested parties and Korea.

The representative of Korea recalled that during the last TBT Committee meeting, Korea had informed Members that the MIFAFF was conducting a feasibility study on the topic of equivalency. He noted that the MIFAFF was in the course of unifying the two certification systems for processed organic foods and organic foods. Furthermore, he informed the TBT Committee that the MIFAFF was conducting a feasibility study on the issue. He stated that it would be impossible for Korea to grant an additional implementation extension as the MIFAFF had already postponed its implementation date twice. All other comments raised would be delivered to MIFAFF.

Coréia do Sul, EUA, Austrália e Tailândia x UE - Accreditation and market surveillance relating to the marketing of products (G/TBT/N/EEC/152)

European Union – Accreditation and market surveillance relating to the marketing of products (G/TBT/N/EEC/152)

The representative of Korea informed the TBT Committee that following a discussion with the European Union earlier that day, Korea had received answers to their queries. The concern that Korea had raised was that national authorities of EU member States might refuse attestations of conformity issued under accreditation by non-European accreditation bodies not complying with the new EU requirements, but which were signatories to IAF and ILAC MLA/MRA. He asked whether only a government-to-government MRA with the European Union or a sub-contract agreement with an EU notified body would be a way that non-European ILAC and IAF signatories could be accepted by EU member States. If this was the case, he requested the European Union to explain the value of the ILAC MRA and/or IAF MLA in the European Union after the regulation had entered into force on 1 January 2010.

The representative of the United States reiterated serious concerns regarding the European Union's new accreditation framework set forth in Regulation 765. He explained that the measure applied to all sectors, required each EU member State to appoint a single national accreditation body that operated as a public, not-for-profit entity, and prohibited competition among member States' national accreditation bodies within each member State. This meant that only a single, government entity in each member State was permitted to accredit conformity assessment bodies in the European Union.

However, the United States continued to be especially concerned with the Regulation's potential impact on the recognition of non-EU accreditation bodies under the ILAC MRA and the IAF MLA, and the acceptance of conformity assessments performed by ILAC MRA and IAF MLA accredited bodies. Thus far, with respect to ILAC, EA ILAC signatories appeared to be cooperating with non-EU ILAC signatories, confirming the equivalence of their accreditations; given that both sets of bodies (i) maintain conformance with ISO 17011 and related ILAC guidance documents; (ii) ensured that all of their accredited laboratories complied with ISO 17025 and related ILAC documents; and (iii) had been peer reviewed and shown to meet ILAC's criteria for competence

The United States noted that the regulation left to member States the decision of whether to recognize non-European accreditation bodies, as well as the decision as to whether or not accept conformity assessments issued by ILAC and IAF accredited bodies. The United States was concerned that without clear guidance from the European Commission, EU member States might refuse to recognize non-European accreditation bodies and conformity assessments issued by non-European testing and certification bodies; this would undermine the international accreditation system and impede US exports to the European Union.

He noted that the European Co-operation for Accreditation (EA) continued to promote EA I/13, which announced that EA would sign a Cooperation Agreements with accreditation bodies from other countries only if such bodies met the requirements of Regulation 765. The EA had indicated that it would take steps to terminate existing cooperation agreements that were not based on those requirements. Moreover, not only did the EU accreditation bodies appear to recognize the equivalence of their accreditations with non-EU bodies that were ILAC MRA and

IAF MLA signatories, but the Commission had recognized many times that attestations of conformity issued under accreditation by non-EU accreditation bodies could be considered equally reliable as those issued under the accreditation of an EA MLA signatory.

At the last TBT Committee meeting, the European Commission had also noted that there had been no scientific and technical basis for the Regulation 765 requirements noting that they had been mandated by a political decision. Thus, for the United States, there appeared to be no basis under which an EU accreditation body could consider attestations of conformity issued under accreditation by non-EU accreditation bodies that were signatories to these two arrangements and did not meet the Regulation 765 requirements as detrimental to the credibility of the accreditation. The representative noted that under Regulation 765, each EU member State accreditation body appeared to have a monopoly in its own market, yet the member State accreditation bodies could compete with each other in other countries' markets. In the view of the United States this provided additional evidence that the European Union did not have concerns with the reliability of accreditations in the presence of competition between accreditation bodies. If it did, the requirements would limit competition between European Union member States' accreditation bodies in overseas markets as well. He concluded that if the European Commission continued to leave this matter entirely up to the EA and the individual European national authorities, the status of non-EU accreditors in the European market would be thrown into doubt, which could have a detrimental impact on the international accreditation framework. It would also represent a significant step back for the acceptance of conformity assessment results more generally. The United States therefore urged the European Commission to provide guidance to the EA and the individual European national authorities.

The representative of Australia shared the concerns raised by other delegations that Regulation 765/2008 could potentially impede the recognition of conformity assessment procedures accredited by third party accreditation bodies. She noted that Regulation 765 required the national accreditation bodies of European Union member States to assume full legal responsibility for the results of conformity assessment procedures endorsed by foreign accreditation bodies, even though these foreign accreditation bodies might not fully satisfy some of the criteria established in Regulation 765. While Australia recognised that the EA had adopted a resolution that foreign accreditation bodies which were signatories to the IAF/ILAC, but did not necessarily meet the internal criteria of Regulation 765, were "equally reliable from a technical point of view", Australia remained concerned over the potential for European Union national accreditation bodies to refuse to recognise foreign accreditation bodies. Australia invited the European Union to further clarify the operation of Regulation 765, and its interaction with foreign accreditation bodies.

The representative of Thailand supported concerns raised by the previous Members.

The representative of the European Union first referred to the comprehensive explanation of the new accreditation system in the European Union that had been given by the European Union at the previous TBT Committee meeting. He highlighted that the new accreditation framework did not change anything regarding the ability of non-EU conformity assessment bodies to perform conformity assessment in the regulated area. A conformity assessment body not established in the European Union territory could not as such qualify for Notified Body status under EU regulations, irrespective of whether it was accredited or not. He recalled that during the last TBT Committee meeting the European Union had explained the rationale for establishment being an eligibility criterion for notified bodies, and that the EU system involved the use of Supplier's Declaration of Conformity (SDoc) in vast sectors of the economy thanks to the application of regulatory impact assessment (RIAs) tools in the conformity assessment area. Therefore, as previously mentioned, the sectors of the economy in which the EU required mandatory third party conformity assessment were fairly narrow; - however, in these sectors, the performance of the conformity assessment required under EU regulations was reserved for the notified bodies.

The representative of the European Union also stated that the system provided for significant flexibility in the sense that substantial parts of the conformity assessment procedure, such as the testing or any inspection that might be required under any quality management system assessment, could be subcontracted by a Notified Body to a conformity assessment body outside the European Union. In these cases, accreditation from Members of ILAC or IAF would

generally be presumed to establish the technical competence requirements in order to qualify for entering into subcontracting arrangements with an EU Notified Body. He clarified that the only task that could not be subcontracted was the actual issuing of the certificates because, for reasons related to the accountability of the system, only a body which had been designated as a Notified Body could undertake this responsibility. He also clarified that the designation of a Notified Body involved a two stage process: firstly, a technical assessment, which typically was based on accreditation, and secondly a political decision whereby EU member States took responsibility for the operation, supervision and monitoring of this body; this was because, as stated previously, this body would go onto perform third party conformity assessment in the public interest. For these reasons the European Union was of the view that the system could only operate as intended if those bodies were coming fully under the jurisdiction of European Union member States.

On the interface between the EU accreditation system and the international system under ILAC or IAF, the representative referred to the document (EA 1-13:2009, May 2009) that had been quoted by the United States and which set out the current policy of EA as regards its relationship with accreditation bodies in countries which were not members of the European Union or EFTA. He confirmed that the system which was envisaged by this policy document basically foresaw two different frameworks, by dividing accreditation outside the European Union into two categories. First, there were accreditation bodies from countries which were either candidate for accession to the European Union or belonged to the so-called European neighbourhood; these were already integrated in the internal market or were (or would be) linked to it in specific sectors through specific agreements, for instance Agreements on Conformity Assessment and Acceptance of industrial products (ACAAs). This implied that these countries would be treated effectively as EU Member States for EU internal market purposes, which was only possible if they fully took over the EU body of legislation including the underlying quality infrastructure, which comprised full integration in the EU's accreditation system in the relevant sectors. Therefore, cooperation between the EA and accreditation bodies of these countries had a particular nature, due to the necessity for these countries to share the same obligations as EU Member States, thus giving effect to the political objective of economic integration between the EU and the third countries concerned. Second, as for accreditation bodies outside the European neighbourhood, he explained that the policy document EA 1/13 2009 stated clearly that the relationship with those accreditation bodies would be managed through ILAC or IAF. He stressed that that there was no intention to undermine in any way the operation of the existing international accreditation system. Lastly, the EU would consider, also based on the discussions in the TBT Committee, whether further written clarification regarding how EA would cooperate with non-EU accreditation bodies would be useful. The EU would in any event remain available for further bilateral discussions at expert level with interested delegations.

Brasil e Austrália x UE - Poultry Meat (G/TBT/N/EEC/267 and Add.1)

European Union – Poultry Meat (G/TBT/N/EEC/267 and Add.1)

The representative of Brazil thanked the European Union for the information provided during bilateral discussions on the EU regulation 1047/2009 notified under G/TBT/N/EEC/267 and restated some concerns on the issue. He noted that the new EU regulation entered into force in May 2010, without taking into account any of the concerns or suggestions raised by Brazil. He reiterated Brazil's concerns that the EU regulation contained definitions for fresh poultry meat and poultry meat preparations that could lead to serious market access restrictions for foreign producers located far from the European Union market. He explained that the new rules could prevent the use of frozen poultry meat in frozen meat preparations without reasonable justification. According to information provided by the European Union, the new rules would continue to permit that frozen poultry meat be used in poultry meat preparations provided that some temperature limits were respected in the process of elaborating preparations. The representative welcomed this clarification, but announced that Brazil would come back to this issue in the future depending on Brazil's assessment of the feasibility of elaborating preparations within those temperature limits.

He explained that the European Union had also informed the Committee that preparations made from frozen poultry meat would have to be sold frozen, because selling meat defrosted or chilled could mislead consumers which could believe those products were fresh. Brazil therefore restated its suggestion that using the phrase "previously frozen" in defrosted poultry meat and in preparations made with frozen poultry meat which were sold as frosted or chilled.

He noted that in bilateral discussions, the European Union had stated that consumers could erroneously buy defrosted poultry meat as fresh and refreeze it afterwards. He further elaborated that the European Union had also argued that labels such as the ones suggested by Brazil were ineffective. However, Brazil considered European consumers to be capable of understanding the differences between frozen, fresh and defrosted poultry meat, and asked whether the European Union had any empirical evidence to show that labels such as the ones suggested by Brazil did not work. Brazil held the view that the acceptance of the Brazilian suggestion would make the regulation less trade restrictive. Despite the information provided by the European Union, Brazil still believed that the new regulation created *de facto* discrimination in favour of European producers, thus violating Article 2.1 of the TBT Agreement. Because of transportation distances, only European producers would be able to sell poultry meat which was not frozen in the European market. Additionally, only European producers would be able to provide poultry meat for the fabrication of fresh preparations. Finally, Brazil requested the European Union to consider its alternative labelling suggestions. He further informed the TBT Committee that Brazilian authorities and private sector continued to examine the compatibility between Regulation 1047/2009 and the relevant WTO Agreements.

The representative of Australia remained interested in Brazil's concerns.

The representative of the European Union informed the Committee that the bilateral meeting held earlier that day had clarified a number of issues. At the last TBT Committee meeting, Brazil had stated that the EU measures would have the practical effect of prohibiting the use of frozen poultry meat in poultry meat preparations, and had stated that, in their view, there was no sanitary or hygienic impediment to using frozen poultry meat in poultry meat preparations. She stressed, however, that the new marking rules on fresh poultry preparations did not in any way prohibit this use and that there was no impediment in the European Union of using frozen poultry meat to make a poultry meat preparation. She therefore considered that Brazil's understanding of the European Union rules was not correct.

For the purpose of clarification, she explained that frozen poultry meat could continue to be used in poultry meat preparations and such preparations were to be sold at retail level in a frozen state at a temperature not higher than minus 18°C at any time. According to EC Regulation No 853/2004 meat preparations must be frozen to an internal temperature of not more than minus 18°C and this temperature had to be maintained during storage and transport. In this regard, it was important to note that partial rise of temperature was possible in accordance with procedures based on the Hazard Analysis Critical Control Point Process in which certain tolerance might be permitted for a minimum period of time necessary for the manufacture. Therefore, the temperature of frozen poultry meat could be raised to produce a preparation and then be lowered again for sale.

She recalled that at the last meeting, the Brazilian representative had stated that Brazil had suggested that poultry meat preparations made from frozen poultry meat be marketed as "previously frozen". She explained that this option had, however, not been retained by the EU authorities as it would mislead consumers in the sense that they would be buying preparations which were fresh looking, but which in fact had been prepared with frozen poultry meat. On the allegation made by Brazil that the EU rules could be *de facto* discriminatory as foreign producers had to freeze poultry meat in order to export it to the European Union, she replied that a considerable number of poultry meat and poultry meat preparations which were produced domestically were transported in frozen state within the European Union. Finally, she noted that after a thorough analysis of the Brazilian comments, the European Commission had concluded that there should not be a substantial impact since the vast majority of the EU imports from Brazil which were at stake were either poultry products or preparations, for which the marketing standards did not introduce any new requirements.

UE, Indonésia, México, Quênia, Turquia, Chile, Tanzânia, Brasil, Zâmbia, Uganda, Jordânia, Macedônia, Egito, Equador, Honduras, Guatemala, República Dominicana, Burundi, Malawi, Filipinas, Croácia, Moçambique e Zimbábue x Canadá - Bill C-32 amendment to Tobacco Act

Canada – Bill C-32 amendment to Tobacco Act

The representative of the European Union reiterated concerns about Canada's Bill C-32 amending the Tobacco Act, and requested Canada to provide replies to several questions raised by Members at the March 2010 TBT Committee meeting. In particular, the European Union urged Canada to provide some background with regards to its approach to ban a comprehensive list of additives, including certain flavours which might be perceived as appealing to youngsters. Further, the representative of the European Union asked whether Canada could make available scientific studies or other relevant information that established a link between the prohibited additives and attractiveness to youngsters. She also requested that Canada provide assurance to the TBT Committee that the measures envisaged achieved uniform levels of protection in relation to all forms of tobacco, no matter whether imported or domestically produced. Finally, she asked Canada for further detail about any other policy initiatives that it had introduced, or was planning to introduce, in conjunction with Bill C-32 in order to deter smoking among youngsters and increase awareness of tobacco-related risks in this particular population group. Lastly, she noted that the European Union strongly supported Canada's objective of protecting human health and, in particular, deterring youngsters from smoking, which was in line with the WHO Framework Convention on Tobacco Control.

The representative of Indonesia (G/TBT/W/332) responded to the communication to the TBT Committee by Malawi dated 23 March 2010, on the effects of Canada's *Cracking Down on Tobacco Marketing Aimed at Youth Act* on Malawi's exports of burley tobacco (G/TBT/W/329). In this communication Malawi had expressed concerns that Canada's law was inconsistent with Canada's obligations under the WTO TBT Agreement. In particular, Malawi was concerned about the consistency of the law's prohibition on the manufacture and sale of cigarettes, little cigars, and blunt wraps containing certain flavourings and additives enumerated in a Schedule to the law with Articles of 2.2 and 2.8 of the TBT Agreement. In its comments, Malawi compared the approach Canada had taken to reduce youth smoking in its law to similar laws of other countries, such as France, Australia, and the United States. Malawi implied that the regulatory approach taken by these other countries, which banned only products with characterizing confectionary or fruit flavours, was less trade-restrictive than Canada's law and therefore somehow consistent with the TBT Agreement.

In addition, the representative of Indonesia objected to any suggestion by Malawi or any other WTO Member that the manner in which the United States had restricted certain flavoured cigarettes was consistent with GATT 1994, the TBT Agreement or other WTO agreements. Indonesia noted that it had requested that the Dispute Settlement Body establish a panel to hear its dispute with the United States regarding a measure in the Family Smoking Prevention Tobacco Control Act of 2009 that banned the production and sale of clove cigarettes, but allowed the sale of other cigarettes, including menthol cigarettes (WT/DS406/2). He clarified that Indonesia did not disagree with Malawi that reducing youth smoking was a legitimate health objective, or that limiting a ban to "characterizing flavours" was a more precise approach to discourage youth smoking than limiting all flavourings and additives. However, Indonesia argued that an even more targeted ban must be non-discriminatory, based on scientific and technical evidence, and at a minimum, cover those characterizing flavours shown to attract youth smokers. Indonesia maintained that the ban on the sale of clove cigarettes in the United States was inconsistent with various US obligations under the relevant WTO rules and principles, and should not be viewed as a "model" for regulations in other countries intended to restrict the production and sale of flavoured cigarettes arguably designed to attract youth.

The representative of Mexico expressed his disappointment about the answer by Canada at the last TBT Committee meeting on its intention not to notify the law C32 from the parliament. For Mexico, it constituted a dangerous precedent, which cast doubts on the seriousness with which Canada assumed its international commitments. Mexico was still awaiting a specific response

to the questions put at the last TBT Committee and described in paragraph 185 in G/TBT/M/50. Mexico supported the objective of protecting human health, however it questioned the way in which this objective was being approached in Canada and in particular the lack of transparency.

The representative of Kenya (G/TBT/W/330) shared the concerns and questions raised by other Members. He noted that the proposed Canadian law, if implemented in its current form, would effectively ban traditional blended cigarettes which were one of the two major brands of cigarettes widely traded in the world and Kenya's key concern with this legislation. He explained that it was a well known fact that traditional tobacco was normally produced with three types of tobacco, namely Virginia, Burley and Oriental and further blended with additives that the proposed Canadian law was seeking to prohibit. Banning these additives would effectively ban traditional blended cigarettes, even though in Kenya's view, such cigarettes did not exhibit any discernible confectionery, fruit or other flavour perceived to be attractive to the youth. The amendment was therefore contrary to the provisions of Article 12.3 of the TBT Agreement which entailed that WTO Members should ensure that their technical regulations did not create unnecessary obstacles to exports from developing country Members.

Furthermore, Kenya held the view that the proposed legislation was inconsistent with other provisions of the TBT Agreement namely Articles 2.2, 2.8, 2.9 and 12.3. Although the proposed law was intended to address a specific concern, it was unnecessarily trade restrictive. In the opinion of Kenya the issues in the legislation could easily be resolved through other equally effective means that were less trade restrictive and consistent with Canada's obligations under the TBT Agreement. The representative asked Canada to answer three questions: First, on what basis had the additives been included in the schedule, and how were they particularly appealing to the youth. Second, would Canada consider amending the schedule of products and additives affected by the ban to ensure that the ban only applied to cigarettes exhibiting discernible confectionery or fruit flavour. Third, what specific evidence had Canada relied upon in relation to its claims that blended tobacco products were more toxic, more addictive and more attractive to youth.

The representative of Turkey reiterated his delegation's concerns regarding the measure at issue and referred to comments made by Turkey in previous TBT Committee meetings. While fully supporting the objective of the legislation, Turkey was of the opinion that the current legislation was more trade restrictive than necessary. By means of this measure, Canada prohibited the use of various additives in certain tobacco products. As these kinds of products, either blended or non-blended, were like products, any measure that would result in favour of prohibiting blended tobacco products was discriminatory in nature. He added that the additives did not give any characterizing flavours to the tobacco product and the decision was made without considering their effects on final products. In addition, there was no scientific evidence and the measure was not proportionate with its objective. Turkey therefore requested Canada to provide responses to Turkey's comments and urged Canada to reconsider its decisions and amend the measure in accordance with their TBT commitments.

The representative of Chile supported the concerns raised by other delegations. Chile had sent a letter expressing its concerns to the Canadian embassy in Chile and was still awaiting a formal response. In this letter, Chile supported the objective of the law and the Canadian authorities in their attempt to reduce smoking among young people. However, in Chile's view, the scope of the law was much broader than that and it *de facto* prohibited the import, manufacturing and marketing of American blended tobacco and cigarettes. Chile therefore supported the comments made by other Members and regretted that the measure by Canada had not been notified to the WTO in accordance with transparency guidelines and particularly with Article 2.9 of the TBT Agreement. Notification would have been necessary because the measure would affect products being marketed, including in Chile. Furthermore, Chile held the view that the Canadian measure was not consistent with the obligations stipulated in Articles 2.2 and 2.8 of the TBT Agreement. Chile's concern was that the law was going to have a negative impact on the trade of the tobacco products concerned. Chile was a Burley tobacco producer and Burley tobacco was used in American blended cigarettes. She explained that Chile had about 2,400 hectares of this crop and its cultivation crop employed approximately 1,000 workers. Tobacco companies had more than 25 per cent of its total production exported to over

15 countries worldwide, including Canada. Chile therefore urged Canada to take its position into account with a view to reaching an understanding on this issue.

The representative of Tanzania endorsed the statements made by the preceding delegations. As others, Tanzania supported the legitimate objective of the measure; however, in Tanzania's view, the bill, as currently drafted, was overly broad and violated Canada's trade obligations as a Member of the WTO and could impose serious and unnecessary economic and social hardships on Tanzania's tobacco producers, and affect long term development prospects. Tanzania was not opposed to the purpose of the Canadian Bill C-32 in as far as it aimed at reducing the number of young people smoking, however, the extent of the contribution of the measure to the objective, its trade restrictiveness, and the importance of the values and interests at stake needed be balanced.

The Canadian Bill C-32 banned the use of a long list of different types of ingredients which were used in the production of many tobacco products, as well as in food, including natural components of the tobacco leaf. He noted that the ban applied regardless of the amount used or their effect on the flavour of the finished product. Tanzania's concern was that the Canadian Bill C-32 would effectively place a total ban on traditional blended cigarettes, one of the two major categories of cigarettes in the world. He explained that traditional blended cigarettes were produced with three types of tobacco, namely Burley tobacco, Virginia tobacco and Oriental tobacco. Many of the ingredients banned under Bill C-32 were critical components of traditional blended cigarettes sold throughout the world. Their use helped blend the three different types of tobaccos and comprised elements of manufacturers' brand recipes. The type and the amount of ingredients used in traditional blended cigarettes did not impart and/or exhibit any discernible fruity, confectionery, or other flavour that might be perceived as attractive to young people. He concluded that there was an absence of scientific evidence presented by Canada as to how the "attractiveness" of tobacco products could in fact be assessed on any scientific basis.

Tanzania's concern was that Bill C-32 established a dangerous precedent and could have a devastating impact on Tanzania's tobacco leaf export interests, tobacco products trade, and long term tobacco crop development prospects. In particular, it was noted that Tanzania exported significant quantities of tobacco leaf around the world with an approximate annual crop volume of 79 million kilos of which over 90 per cent of that volume constituted Virginia flue cured tobacco. He explained that approximately 98,000 farmers grew tobacco in Tanzania of which 91,000 farmers grew Virginia flue cured tobacco, making tobacco the leading agricultural cash crop generating more than US$ 160 million per annum. Tanzania feared that demand for Virginia flue cured tobacco leaf was likely to fall if manufacturers were unable to use ingredients to manufacture traditional blended cigarettes. Such adverse consequences were avoidable by using less trade-restrictive measures consistent with WTO.

The representative Tanzania continued explaining that the Bill C-32 contravened various articles of the TBT Agreement. Article 2.2 of the TBT Agreement prohibited Members from adopting technical regulations that had the effect of creating "unnecessary obstacles to trade". In particular, it required that "technical regulations should not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create." It further stated, "in assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products." For Tanzania the relevant legal question was therefore whether the ban was more trade restrictive than necessary to meet the stated objective. Furthermore, Article 2.8 of the TBT Agreement stated that "wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics". In Tanzania's view, it was possible to achieve the same objective of reducing the perceived attractiveness of some tobacco products to young people in other non trade-restrictive ways. Other WTO Members had adopted a performance-based standard to regulate tobacco product ingredients. Tanzania was of the opinion that Canada was in violation of Article 2.8 of the TBT Agreement, as Canada had regulated the design of the product, in the form of its composition, without regard to how the ingredients affected the performance of the tobacco product in the form of its characteristic flavour. The "performance-based" approach appeared to be in line with the TBT Agreement, was more precise and more proportionate than

an approach banning a long list of ingredients in any quantity and without considering their effect on the flavour of the final tobacco product. Tanzania therefore urged Canada to consider adopting a similar performance-based approach.

Furthermore, the representative of Tanzania noted that Bill C-32 was not in line with Article 2.9 of the TBT Agreement. Because of lack of a relevant international standard on the production of tobacco products, and because of the significant trade impact of the Canadian Bill C-32, prior to signing the Bill, Canada should have published a notice at an early and appropriate stage, in such a manner as to enable interested parties from other Members to become acquainted with the proposed Bill. Canada should also have notified other Members at an early and appropriate stage, through the WTO Secretariat, of the products to be covered by the proposed bill together with a brief indication of its objective and rationale. Referring to Article 2.10 of the TBT Agreement, he noted that if Canada had considered the sale of flavoured cigarettes as an urgent problem of safety, health, environmental protection or national security, Canada should have notified immediately other Members through the Secretariat of the presence of Bill C-32 and the products covered, with a brief indication of the objective and the rationale of the said Bill, including the nature of the urgent problems.

Tanzania was of the opinion that the implication of Bill C-32 was also inconsistent with Canada's obligations under NAFTA. Article 904(4) of NAFTA stated, in part, that "No party may prepare, adopt, maintain or apply any standards related measure with a view to or with the effect of creating an unnecessary obstacle to trade between parties". In the context of Article 2.2 of the TBT Agreement, Bill C-32 created an unnecessary obstacle to trade within the respective region, and brought to issue Canada's consistency under international trade law and further raised concerns on equitable treatment of Members. Finally, referring to Article 12.3 of the TBT Agreement, he recalled Tanzania's status as a Least Developed Country (LDC) and requested that Canada adapt its domestic objective of reducing the appeal of certain tobacco products to young people with a less trade restrictive approach.

The representative of Brazil stated that despite the fact that Brazil was fully in favour of the objectives pursued by the Canadian legislation, Brazil continued to have concerns about the possible trade impacts of the measure. In particular, Brazil was interested to know whether sugar was one of the ingredients that were contained in the FAO/WHO and US Food and Drug Administration (FDA) lists of additives which Canada had indicated as one of the basis for the regulation.

The representative of Zambia supported the concerns raised by other Members on the Tobacco Act in Canada. He noted that Bill C-32 banned the use of different types of ingredients including those which were essential component of traditional blended cigarettes. The use of some of the banned ingredients helped blend the three types of tobacco (i.e. Virginia, Burley and Oriental) and also helped to replace many of the natural components of the tobacco leaf that the curing method destroyed in some tobacco types. He noted that blended cigarettes were one of the major categories of cigarettes in the world and therefore the ban of these ingredients also effectively banned traditional blended cigarettes, despite the fact that the type and the amount of the ingredients used in the traditional blended cigarettes did not impart any specific fruity or confectionary flavour that might be attractive to young people. In Zambia's view the measure was an unnecessary obstacle to trade in tobacco products and Zambia urged Canada to adopt a less trade restrictive measure to address their legitimate concern.

The representative added that in the current form, Bill C-32 would not only negatively affect tobacco producing countries such as Zambia, but also affect their future development prospects. Zambia had been making efforts to diversify the economy and part of these efforts had been to increase production and exports in agricultural products, which included tobacco. He informed the Committee that 20 per cent of Zambia's agricultural exports were tobacco of which more than 60 per cent was auctioned in Malawi. The auctioned tobacco was used to produce traditional blended cigarettes amongst other types of cigarettes by adding some of the banned ingredients and re-exported to other countries, including Canada. Therefore, Bill C-32 had the potential of negatively affecting Zambia's tobacco leaf exports and the livelihood of hundreds of farmers.

The representative of Uganda (G/TBT/W/331) shared the concerns raised by other Members. He explained that Uganda was one of the major tobacco growing countries in Africa and was thus concerned about the effects of Canada's measure on its tobacco leaf manufacturing and exports. He noted that the law prohibited the manufacture and sale of cigarettes, little cigars and blunt wraps that contained any of the flavourings and additives listed in a schedule appended to the law. Uganda was deeply concerned that this law was inconsistent with Canada's obligations under the TBT Agreement and would have a negative effect on Uganda's long term economic prospects.

Whereas Uganda fully supported the objective of Canada to reduce the incidence of youth smoking, however, Uganda was concerned that the law was far too restrictive to trade than was necessary to achieve this objective. Specifically, Uganda was concerned that the law effectively banned traditional blended cigarettes, which were one of the two major categories of cigarettes in the world. Traditional blended cigarettes were produced with three types of tobacco (Virginia, Burley and Oriental tobacco) and blended with certain additives that the law sought to prohibit, but which were an essential component of traditional blended cigarettes. The additives were applied as manufacturing aids to blend the three different types of tobaccos and as flavourings to confer on each brand its unique tobacco taste. Additives in traditional blended cigarettes did not lend a characterizing fruit or confectionary flavour to the end product. Thus, by banning the additives, the law effectively banned traditional blended cigarettes, even though such cigarettes did not exhibit any discernible confectionary, fruit or other flavour that was particularly attractive to youth.

He informed delegations that Uganda was a significant producer of tobacco leaf in the world, with an approximate annual crop volume of 37 million kilograms of which over half of that volume constituted burley tobacco. He reported that approximately 76,810 farmers grew tobacco in Uganda of which about 36,000 of these farmers grew Burley tobacco. Over 95 per cent of Uganda's total annual tobacco crop was exported to cigarette manufacturers worldwide generating annual revenue of US$ 66 million. Measures which restricted blended cigarettes would, therefore, have a detrimental impact on Uganda's tobacco production and tobacco exports which had been the leading export cash crop for several years.

In Uganda's view the issues that the Canadian law raised could easily be resolved by equally effective but less trade-restrictive alternatives that would address the objective of the legislation but also ensure compliance with Canada's obligations under the TBT Agreement. In conclusion, given the significant repercussion of the Canadian legislation, Uganda requested a response from the Canadian authorities to the list of questions contained in the written communication that had been circulated by the Secretariat the day before as a document. While Uganda fully supported the purpose of this law, namely to address the problem of youth smoking encouraged by candy and fruit flavoured tobacco products, Uganda was of the opinion that the Canadian measure was far too restrictive.

The representative of Jordan explained that his delegation fully supported the objective of Canada's tobacco act, namely to reduce youth smoking. However, Jordan was concerned that the law was overly trade restrictive in proportion to the objective it sought to achieve. Jordan therefore supported the concerns raised by other Members and urged Canada to respond to these concerns.

The representative from the Former Yugoslav Republic of Macedonia supported the statements by other Members and reiterated concerns with the proposed bill. As a producer of traditional tobacco, the Former Yugoslav Republic of Macedonia held the view that there was a way to find a better balance between the obligations which arose from the Framework Convention of Tobacco Control (FCTC) and economical aspects of the tobacco producers which had great social and economic impacts in developing country and developed country. He urged Canada to consider all questions and concerns from the Former Yugoslav Republic of Macedonia.

The representative of Egypt echoed the concerns raised and sought clarification from Canada on how the amended tobacco act was consistent with Canada's obligation under WTO/TBT agreements.

The representative of Ecuador recalled that the Canadian Bill C-32 had the effect of prohibiting the import of the type of cigarettes known as American blend or traditional blend, which was the type of cigarette that blended Oriental, Virginia and Burley tobacco and which was produced and exported by Ecuador. Ecuador recognized Canada's right to pursue a legitimate objective by reasonable measures, however, Ecuador was concerned that Canada had failed to meet the obligations of Articles 2.2, 2.8 and 2.9 of the TBT Agreement. Ecuador was of the view that the measure seemed to be an unnecessary obstacle to international trade because it failed to take into account the need for technical regulations to be based on the performance of products rather than the design and product characteristics. The representative of Ecuador informed the Committee that given the trade effects that the act would have, it could potentially affect the economy of Ecuador since about 1,500 Ecuadorian families, (about 6,000 workers), were dedicated to producing Burley tobacco and its blend, which were marketed in Europe and North America. Ecuador asked Canada to provide an answer to the question how their legislation would affect the domestic production in Canada and thus the importation of tobacco from abroad.

The representative of Honduras expressed his concerns about the implications of the amended tobacco law for its tobacco exports to Canada. While Honduras shared the legitimate objective of the Government of Canada to protect the health of young people, Honduras considered the way in which it sought to achieve this objective as excessive because it created barriers to trade that were more restrictive than necessary. Along the same lines as other Members, Honduras remained concerned about the compatibility of this law with Canada's obligations under the TBT Agreement, and the negative impact that this would have on long term economic prospects. Honduras therefore requested Canada to explain how it had taken into account the special needs of Honduras in drafting and applying the prohibition on use of additives as stipulated in Article 12.3 of the TBT. Furthermore, Honduras raised the question how Bill C-32 was compatible with Article 20 of TRIPS, which stipulated that the use of a trade or service mark in commercial operations with special requirement should not be unjustifiably complicated.

The representative of Guatemala expressed serious concerns about Bill C-32 which had entered into force in Canada on 8 October 2009, and supported fully the comments made by other Members, especially by Mexico, Chile and Kenya. He explained that the concern of Guatemala with respect to this law was twofold. The first had to do with the transparency obligations under the TBT Agreement, under which all Members had to notify and provide sufficient time to other Members to submit their comments for draft technical regulation which could in one way or another affect legitimate commercial interests. For Guatemala, it was a matter of serious concern that Canada had adopted and implemented the bill which had commercial implications without having provided the necessary notification and without taking into account comments by other Members.

Although Guatemala shared the objective pursued by Canada under this legislation, Guatemala was of the view that the manner to achieve this objective was excessive and created hidden barriers to trade which was incompatible with Article 2.2 of the TBT Agreement. Furthermore, the new law discriminated against different types of tobacco which indirectly affected Guatemalan tobacco producers. He reminded delegations that although the Canadian legislation prohibited the use of any additives, it was indirectly prohibiting the tobacco blends and particularly the American blend, which created a precedent globally. As Guatemala was a Burley tobacco producer which was used in these blends, Guatemala was very much concerned about the trade implications of the new law. Guatemala shared Canada's objective to seek to protect the help of young people; however, since Canada did not have any scientific evidence that the use of all additives created flavours which could make the tobacco more attractive for certain parts of the population, Guatemala's view was that the measure was excessive and in violation of Article 2.2 of the TBT Agreement. Guatemala urged Canada to review the regulations under Bill C-32 taking into account the comments made by Members to date as well as respecting the transparency obligations under Article 2.9 of the TBT Agreement.

The representative of the Dominican Republic supported other Members that had expressed and reiterated their concerns regarding the adoption by the Government of Canada of Bill C-32 which prohibited the manufacturing and sale of traditional blended cigarettes. She informed the Committee that Canada had not yet notified the measure to the TBT Committee, despite the

fact that it could have an important impact on the sales of cigarettes, in particular of cigarettes produced with Burley tobacco. The Dominican Republic cultivated different types of tobacco that constituted the traditional blends. The Canadian law would undermine the tobacco production in the Dominican Republic having an impact on the national economy and creating social difficulties and loss of jobs. As stated in the last TBT Committee meeting, she noted that Canada should have notified the measure before adoption as stipulated under Article 2.9 of the TBT Agreement. She recalled that the measure should have been debated and commented on by Members.

The Dominican Republic observed that the law aimed at prohibiting the manufacture and the sale of tobacco products which included cigarettes, small cigars and other tobacco products with certain characteristics such as confectionary fruit or fruit flavours. Although the Dominican Republic understood the objective of this measure, the way in the which the measure had been drafted was overly broad and out of proportion: instead of prohibiting products with specific flavour, it prohibited products that contained at least one of the ingredients in the list of more than five thousand ingredients, which were necessary for the manufacturing of cigarettes made up of the three main types of tobacco. Taking into account the drastic effect that the prohibition of such blended cigarettes with additives without any specific confectionary or fruit flavours, and that the traditional blend only represented one per cent of the total cigarette market, for the Dominican Republic the prohibition on ingredients did not appear to pursue a public health objective, but constituted an unnecessary technical barrier to trade, in violation of various provisions of the TBT Agreement, such as Articles 2.2 and 2.8. Therefore the Dominican Republic urged the Canadian authorities to revise and amend the bill in question.

The representative of Burundi stated that although Burundi understood the legitimate health concerns of Canada in establishing the Bill C-32, Burundi expressed deep concerns regarding this act and associated itself with the statements made by other Members. The proposed amendment to the Canada tobacco act would not only affect Burundi as a tobacco producing country but also was more trade restrictive than necessary. He noted that Kenya, Tanzania and Uganda were partner states in the East African Community and contributed therefore to the regional integration and development efforts of this region. In this regard, Burundi was also affected when those countries were affected. Burundi urged Canada to provide a justification of the act in light of the relevant provisions of the TBT agreements and to take into account all concerns raised in this regard by other WTO Members.

The representative of Malawi stated that his delegation remained deeply concerned about the new regulation by Canada (G/TBT/W/329). As Malawi was the largest producer of tobacco and that tobacco was the leading cash crop in the country. Malawi recommended Canada to consider reviewing the regulation taking into account the questions raised by Malawi and other Members.

The representative of the Philippines shared the concerns raised by previous delegations about Canada's Bill C-32. While supporting Canada's objective to address public health concerns by reducing the incentives for young people to smoke, Bill C-32 appeared to be more trade restrictive than necessary. The Philippines therefore asked Canada to respond to the concerns and questions raised by Members on this legislation.

The representative of Croatia stated that the Amendment to Tobacco Act would effectively ban the manufacture and sale of traditional blended cigarettes and would thereby significantly reduce imports of the burley and Oriental tobacco used in such cigarettes. Since most of Croatian cigarette production was from the blended tobacco and half of Croatia's production was exported, Croatia perceived this measure as trade discriminatory and echoed the concerns raised by other delegations.

The representative of Mozambique joined other Members in expressing its concerns about Canada's Bill C-32. As a tobacco growing country, Mozambique was concerned about the possible effects of Canada's act on its tobacco leaf exports. Like others, Mozambique fully supported the objective of Canada's law aimed to reduce the incidence of youth smoking by prohibiting the manufacture and sale of confectionary and fruit flavoured tobacco products that were designed to appeal to youth, however, Mozambique was concerned that the law effectively

banned traditional blended cigarettes produced with Virginia, Burley and Oriental tobacco, of which two types were grown in Mozambique. He informed the Committee that tobacco was one of the five main export commodities of Mozambique and that Canada's law would have a negative effect on Mozambique's export revenues and economic development. Mozambique therefore appealed to Canada to avoid negative effects that would damage economic prospects of countries depending on tobacco exports.

The representative of Zimbabwe shared the concerns raised by other delegations regarding the impact of the Canada Bill C-32. As a grower of tobacco and manufacturer of tobacco products, Zimbabwe remained concerned about the likely negative consequences of the amendment to the livelihoods of the numerous small tobacco farmers in many of the concerned Members' economies. Had a thorough study been undertaken, including an analysis of the performance aspects of the tobacco products, alternative, less trade restrictive ways to deal with the young smokers problem would have been found to address the concerns of Zimbabwe as well as other Members, while still meeting Canada's objectives to address the health concerns of its citizens. Zimbabwe hoped that Canada would take into account the comments made.

The representative of Canada explained that the *Cracking Down on Tobacco Marketing Aimed at Youth Act* responded to an important public health objective of the Government of Canada. It applied to cigarettes, little cigars and blunt wraps manufactured or sold in Canada, regardless of their origin. She informed the Committee that the act received Royal Assent on 8 October 2009, and most of its measures had already come into force. The section that prohibited the sale of tobacco products containing prohibited additives would come into force on 5 July 2010. Among others, the new act banned the use of certain additives which contributed to making tobacco products more attractive to youth, in little cigars, cigarettes and blunt wraps sold in Canada regardless of their origin. She highlighted that the act did *not* ban any type of tobacco product or types of tobacco. The government of Canada had made these changes to the Tobacco Act to protect young people from marketing practices that encouraged them to smoke. She stated that Canada's obligations under WTO Agreements, including the TBT Agreement, had been taken into account during the Bill's development. Canada was committed to respecting its international trade obligations in meeting its policy objectives.

The representative informed the Committee that at the last TBT Committee meeting in March 2010, numerous questions had been posed by intervening Members. In answering these questions, Canada had grouped the responses into different themes. She noted that several questions had already been answered by Canada in the March 2010 TBT Committee meeting, and were therefore referred to as March 2010 TBT Committee meeting minutes (document G/TBT/M/50).

In response to Malawi's question related to the development of the schedule and selection of included prohibited additives, she noted that Canada had replied to this question during the March 2010 TBT Committee meeting and the response could be found in the respective minutes (document G/TBT/M/50).

In response to questions received from multiple Members regarding the scientific evidence used to develop the list of prohibited additives, she noted that Canada had provided a response at the March 2010 TBT Committee Meeting. In summary, this response had stated that there was sound evidence that certain additives, including flavours, did increase tobacco product attractiveness. The tobacco industry's own documents, made public as a result of litigation, had shown that the use of additives helped to make tobacco products more appealing to young people. In addition, Canada had prepared a list of references of the numerous publicly available studies that had examined the use of additives that increased the appeal of tobacco products. This 14-page list of references was available for interested Members as a Room Document.

In response to questions received from multiple Members regarding the relationship of additives to tobacco product types targeted in the schedule, she reiterated that there was sound scientific evidence that additives, including flavours, were used by tobacco manufacturers to make their tobacco products, including cigarettes with blended tobacco leaves, more appealing. Canada's Act was aimed at prohibiting the use of additives in all cigarettes, little cigars and blunt wraps

manufactured in, or imported into, Canada that contributed to making these products more attractive. To respond to the questions by the European Union and other Members on the treatment of domestic and imported tobacco products, she clarified that the measure achieved uniform levels of protection in relation to all forms of tobacco, no matter whether imported or domestically produced.

In response to Malawi's question regarding the possibility of amending the list of prohibited additives of targeted products, she noted that pursuant to Section 9 of the amended tobacco act, the Governor in Council had the authority to amend the schedule by order; however, no amendments were under consideration at this time. With respect to flavours, limiting the restrictions to confectionary or fruit flavour would only, in Canada's view, not address the problem of attractiveness. For example, Canadian smokers could find that other types of flavour might also make cigarettes more attractive, such as butter flavour.

To respond to a question posed by Argentina during the March 2010 TBT meeting regarding the development of the list of excluded additives including menthol in the schedule of prohibited additives, she noted that this list had been refined during the hearings held by the House of Commons (Canadian Parliament). During these sessions Members of the public, government officials, health advocates, tobacco retailers and tobacco manufacturers had been asked to comment on the schedule of prohibited additives. Typically, except for menthol, l-menthol and l-menthone, the 21 chemicals excluded from item 1 of the schedule "Additives that have flavouring properties" were not expected to either impart or enhance flavour. She informed delegations that the minutes of all deliberations in the two chambers of the Canadian Parliament on the *Cracking Down on Tobacco Marketing Aimed to Youth Act*, including discussions on how the list of excluded additives had been developed, were available to the public online (www.parl.gc.ca). With respect to the exclusion of menthol, menthol cigarettes were used by only 2 per cent of smokers in Canada and their sales had been declining for several years. The *Cracking Down on Tobacco Marketing to Youth Act* had been designed to protect youth from those additives that increased the appeal of cigarettes, little cigars and blunt wraps.

In response to multiple Members' statements related to concerns that Canada's list of prohibited additives was too broad or that Canada should adopt similar approaches used by other countries, she noted that Canada's response was in the record from the March 2010 TBT Committee meeting (document G/TBT/M/50). In summary, she stated that the Canadian approach had been deemed to be the best fit to address the public health problem faced by Canada.

In response to the EU's question on what other initiatives Canada had introduced or would introduce to protect youth, she reminded Members of the other important provisions in the *Cracking Down on Tobacco Marketing Aimed at Youth Act.* She pointed out that tobacco use caused 37,000 premature deaths a year in Canada and was also responsible for 4.4 billion Canadian Dollars in direct health care costs. In addition to the prohibition on certain additives, the new Act contained measures that were meant to protect children and youth from tobacco industry marketing practices that encouraged them to use tobacco products. For instance, the new act required that little cigars and blunt wraps be sold only in packages of at least 20 units, similar to the requirement that had been in place for cigarettes since 1994. These products had been previously sold in Canada in single units or in small-quantity "kiddy-packs" and had been deemed unduly affordable to youth because of their low price. The new act also prohibited tobacco industry advertising that had been taking place in publications that could be viewed by children and youth. She emphasized that the Canadian Government was committed to dealing with youth smoking issues and that it employed multi-faceted approaches, such as policy development, regulations that restricted youth access to tobacco products, mass-media programming, second-hand smoke messages, school-based materials, involving youth in tobacco control activities, and provision of resources and tools for youth to take action.

In response to several Members' questions regarding the notification of the legislation, she referred to Canada's response at the March 2010 TBT Committee Meeting during which Canada noted that when Members had made Canada aware of the lack of notification of Bill C-32, it had already been too late to notify under Article 2.9.2 of the TBT Agreement. She, however, underscored that it had never been the intention of Canada to hide the legislation from

other WTO Members and that Canada had a very transparent legislative process. She emphasized that Canada was very mindful of the comments that had been made by WTO Members at the TBT Committee. In addition, if any technical regulations were to be considered to implement this tobacco legislation, they would be notified to the WTO at an early stage. Finally, she informed the Committee that Canada had taken note of all the statements that had been made during that day, including comments from Tanzania on the NAFTA Agreement, and that the questions would be sent back to capital.

UE x Formosa - Organic Products (G/TBT/N/TPKM/65 and 69)

Chinese Taipei – Organic Products (G/TBT/N/TPKM/65 and 69)

The representative of the European Union reiterated his delegation's concerns with regard to Chinese Taipei's new management system of imported organic products. He appreciated the fact that Chinese Taipei had extended the equivalence recognition to one of the "new" European Union member States (Hungary), on the basis of supplementary information submitted. However, the European Union continued to consider the distinction made by Chinese Taipei between 'old' and 'new' European Union member States' organic systems as unjustified and therefore urged Chinese Taipei to extend its approval to all European Union Member States.

The representative of Chinese Taipei informed the Committee that on 2 February 2010 all required information had been received from Hungary, which, after a thorough review process, had led to the recognition of Hungary's organic regime as equivalent on 21 May 2010. He stated that Chinese Taipei encouraged other new EU member States to provide the same relevant information as Hungary had done in order to facilitate the recognition of equivalence and that Chinese Taipei was willing to discuss the issue directly with the European Union at any time.

UE e EUA x Indonésia - Regulation of BPOM No. HK.00.05.1.23.3516 relating to distribution license requirements for certain drug products, cosmetics, food supplements, and food

Indonesia – Regulation of BPOM No. HK.00.05.1.23.3516 relating to distribution license requirements for certain drug products, cosmetics, food supplements, and food

The representative of the European Union raised concerns with regard to a regulation by Indonesia which limited the granting of distribution licences for drugs, traditional drugs food supplements, cosmetics and foods that were sourced from or contained so-called "un-Halal" substances and/or alcohol to emergency situations only. She stated that there was a lack of clarity with regard to the definition of an "emergency situation", what the evaluation process for granting a license in such cases would entail and what the time frame for awarding a license for emergency reasons would be. While the European Union respected Indonesia's right to regulate the trade in Halal products, it believed that the current voluntary Halal-labelling system was sufficient and less trade-restrictive. The European Union requested from Indonesia an update on its ongoing revision process, and asked that the draft measure to be notified to the TBT Committee to allow for comments.

The representative of the United States remarked that Indonesia had not notified this measure and that the new requirements were unclear in several respects, and could restrict exports of certain food and food supplements, drugs (such as gelatine capsules, vaccines, and cough syrups), and cosmetics products to Indonesia. Because of confusion, the decree could perhaps disrupt trade in critical medicines, such as vaccines, to Indonesia as well as negatively impact trade in other products as well. The Decree indicated that the use of traditional drug products, cosmetics, and food supplements were "in general not emergency" and, thus it appeared that products sourced from, containing, or derived from, certain animal substances would

presumptively not be given a distribution license. The United States asked for confirmation that the decree had not been implemented and for the status of Indonesia's review process.

The representative of Indonesia informed the Committee that the regulation was being reviewed by the National Agency for Food and Drug Control. He noted that the part of the decree that referred to food and beverage was being linked to an existing regulation entitled "Criteria and Assessment Procedures for Food Products". The part of the decree referring to food supplements and therapeutic products was linked to an existing regulation entitled "Criteria Procedures of Registration for Traditional Medicine and Herbal Medicines". Furthermore, the part of the decree referring to cosmetic products was being linked to an existing regulation entitled "Cosmetic Products". He informed delegations that the Indonesian notification Authority and Enquiry Point had sent a letter to the national agency for food and drug control to encourage them to notify its revised regulation in accordance with the TBT Agreement. He confirmed that the regulation was not in yet in force.

EUA x China - WAPI standard requirements

China – WAPI standard requirements

The representative of the United States raised continued concerns about China's requirement that mobile handsets with WiFi be dual enabled with the WAPI wireless standard. He understood that in 2009, China's Ministry of Industry and Information Technology (MIIT) had established a process for approving hand-held wireless devices such as cell phones and smart phones that were Internet-enabled. However, MIIT had indicated to United States government officials in bilateral discussions that it would approve devices that used the WiFi standard *only* if the devices were also enabled to the WAPI standard.

The United States was not aware of any written or published measure providing for this dual enabling requirement, and, to date, China had not notified this requirement to the WTO. Because the measure had not been published, the United States was not aware of written explanations for the basis and technical aspects of the measure. Moreover, there had not been opportunity for stakeholders to comment meaningfully. Furthermore, the WAPI standard with which China was mandating compliance did not appear to have been developed in an open, transparent consensus-based process. Therefore, the United States requested an explanation for why China had not published this particular measure and a technical explanation for why the WiFi standard – which was in widespread use in the global marketplace – was not used to achieve China's objectives. He asked for a copy of the measure and noted that, as previously discussed, applications for approval by companies were not evidence that there were no concerns with the requirement; rather, companies had no choice but to make such applications if they wanted access for their mobile devices in the world's leading mobile handset market.

The representative of China informed the Committee that in order to guarantee the safe operation of wireless networks and to provide a more reliable service, China telecommunication operators wished to provide options for users to choose wireless network products and relevant equipment which supported both WAPI and ISO ICE 802.11i at the same time. In order to meet market needs and promote industrial development, in 2009, the Ministry of Industry and Information Technology had launched a network access test for mobiles which supported WAPI and ISO ICE 802.11i. This was done on the basis of voluntary applications from enterprises. So far, nearly 100 mobile models had passed the test. The representative stated that the implementation of the test of WAPI handset network access met the security needs of consumers and was not contrary to the spirit of the TBT Agreement. Taking into account of industrial and merger needs however, this may be changed in the future if deemed necessary.

EUA x Indonésia - Decree No. Kep-99/MUI/III/2009 relating to Halal certification

Indonesia – Decree No. Kep-99/MUI/III/2009 relating to Halal certification

The representative of the United States said that while the United States respected Indonesia's right to regulate trade in halal products, he was of the view that the regulations for approving halal certifiers needed to be developed in a manner that was transparent and did not disrupt trade. In previous interventions the United States had raised concerns about a lack of notice and clarity in the requirements which had impacted the ability of United States certifiers and producers to be approved through the new process. The United States therefore requested from Indonesia an update on the status of its process for accrediting additional certifiers.

The representative of Indonesia said that following the United States concern about a new decree regarding halal certifiers issued on 22 October 2009, which did not include any certifiers for poultry or lamb, Indonesia had consulted with the Indonesian Assessment Institute for Food and Drugs of the Indonesian Consul of Ulam, who had informed that the recognition was mainly based on requests and intended for re-evaluation proposals done by the Indonesian Consul of Ulam. Therefore the decree only covered the types of slaughters that had been requested so far, but this did not mean that Indonesia Consul of Ulam did not accommodate recognition for poultry or lamb slaughters. Furthermore, on 14 April 2010, the Assessment Institute for Food and Drug and Cosmetic of Indonesian Consul of Ulam had met with the representative of the United States of Department of Agriculture, and the meeting had concluded in a mutual understanding that recognition for poultry and lamb slaughters in the United States could be done through individual applications from slaughterers to the Indonesian Consul of Ulam. Indonesia had also responded to the US TBT Enquiry Point by an official letter and by email on 18 May 2010. Concerning the notification of the revised regulation, Indonesia had forwarded the letter to the Assessment Institute for Food and Drug of the Indonesian Consul of Ulam to encourage them to notify the new regulation according to the TBT Agreement.

UE, México, EUA, Austrália, Chile, Argentina e Nova Zelândia x Tailândia - Health warnings for alcoholic beverages (G/TBT/N/THA/332 and Add.1)

Thailand – Health warnings for alcoholic beverages (G/TBT/N/THA/332 and Add.1)

The representative of the European Union asked Thailand for further information with regard to the scientific evidence leading to the decision by Thai authorities not to use less trade-restrictive, less costly and burdensome alternatives to pictorial health warnings. She asked for a clarification on the scientific data justifying the assumption that the conditions described by the health warnings were generally caused by any level of alcohol consumption, even moderate ones. Furthermore, it was the EU experience that public policies aiming to modify drinking behaviour needed to be approached in a holistic manner, for instance by encompassing education campaigns to raise the awareness level of the public with regard to specific alcohol-related problems. Therefore, the European Union asked Thailand to indicate whether it was considering also other alternatives to mandatory product labelling, such as education and/or information activities.

The representative of the European Union noted that if the Thai authorities nevertheless decided to go ahead with the introduction of these requirements, the European Union requested more flexibility with regard to their implementation – in particular, with regard to the size and placement of the health warnings. The European Union also asked Thailand to allow for a sufficient transition period for economic operators to adapt their labels to the new requirements. Finally, the European Union reiterated its request for Thailand to clarify the relationship between the draft measure and the text notified under G/TBT/N/THA/282.

The representative of Mexico raised concerns about the means by which Thailand's legitimate objective of protecting human health was to be achieved and requested that Thailand consider less costly and less trade-restrictive alternatives, as well additional scientific and economic reasoning behind the provision. He pointed out that exporters would require sufficient time to be able to adapt to Thailand's proposed modifications of the regulation.

The representative of the United States said that the United States had difficulties understanding the scientific and technical basis Thailand had used for the language in the warning statement requirements, and would review the further information supplied by Thailand. He also expressed his delegation's concern that the proposed labelling requirement could interfere with legitimate trademarks on the bottle, as well as with the display of useful information on product labels, including information that was necessary to distinguish one product from another.

The US industry had informed the United States trade representative that the requirement to rotate the warning labels every thousand bottles would require a stop and a change in the production line every three to four minutes, which would be extremely difficult for suppliers to manage and very disruptive to the production process. The United States also asked that the implementation period be extended to allow time for suppliers to make the modifications that were being proposed . Finally, the United States was concerned that a Thai requirement for warning messages in media advertisements for alcoholic beverages had already been implemented, even though comments on these warning messages were still under consideration.

The representative of Australia asked whether Thailand had considered less trade restrictive alternatives and shared the concerns of other Members in relationship to the labels and pictorials, and rotational labels, as well as the already implemented measures with regards to warning messages in advertising for alcoholic beverages.

The representative of Chile was of the view that alcohol consumption in itself was not harmful, and while excessive alcohol consumption was dangerous, moderate alcohol consumption could even have beneficial effects for human health as had been demonstrated by many international studies. She noted that the consumption of alcohol and in particular of wine, had been a common practice for many centuries. The moderate consumption of alcohol had historically always been accepted, as it was not considered to be harmful. Therefore, Chile believed that only excessive consumption of alcohol should be prevented, not the consumption of alcohol *per se*. Furthermore, at a conceptual level, the proposal could potentially serve as a precedent for many food products which all had the potential to harm human health when consumed in excess. Chile believed that the objective of preventing excess alcohol consumption could be attained with less trade restrictive practices. Chile also was concerned by the large size of the labels proposed by the Thai authorities and proposal that warning messages should instead take up less than 15 per cent of the label space.

The representative of Argentina recalled that his delegation had submitted comments and questions to Thailand four months previously, to date without response. Argentina recognized Thailand's legitimate objective to protect human health and specifically to prevent problems connected with a high consumption of alcohol among young people. Nevertheless, Argentina felt that the measure was unnecessarily costly as it deviated from the legislation of all other Members. Argentina joined other Members in requesting further information on the scientific basis underlying the proposed warning statements.

The representative of New Zealand acknowledged that in seeking to address the public health concern of the harmful use of alcohol, Thailand's draft Notification on labelling of alcoholic beverages was directed toward a legitimate public health objective. However, the proposed requirements could be unnecessarily trade restrictive; alternative, less trade-restrictive approaches could be available to achieve the same objective. He also noted that the new requirements would impose significant additional costs and administrative burden on exporters, which could result in a reluctance for exporters to service the Thai market and, therefore, for trade to be reduced. New Zealand was of the opinion that, in line with the "World Health Assembly Strategy on the Harmful Use of Alcohol", a proper balance between policy goals in relation to the harmful use of alcohol and other public policy goals should be achieved. Finally, New Zealand expressed its interest in learning about the background leading to the selection of the proposed labelling approach, including information on what alternatives had been considered to achieve the same objective, for example the development of public education campaigns and consideration of current international practices.

The representative of Thailand said that the notification had been submitted in accordance with the TBT Agreement. In accordance with Article 2.2, the measure pursued the legitimate objective of protecting human health. In accordance with Article 2.1, the regulation would apply to both domestic and imported goods without discrimination. The measure had been notified properly, and in line with Article 10.6, and Members' had been given opportunity to comment. Thailand had initially allowed for a comment period of 60 days, as recommended by the TBT Committee, and had even extended this period by a further 30 days. All comments had been taken into account by the relevant authority, which was the Disease Control Department of the Ministry of Public Health. The measure envisaged a transition period of 180 days after its publication in the Gazette.

The representative of Thailand went on to state that her country did not consider alcohol to be an "ordinary" commodity due to its potential adverse effects on health, as well as on social development and economic growth. Thailand considered the choice to drink an individual right, however felt that the addressing of alcohol-related problems was a public responsibility. The consumption of alcohol had historically not been traditional in the Thai society. The two major religions Buddhism and Islam, which were followed by an estimated 99 per cent of the population, both discouraged and even prohibited the consumption of alcohol. Nevertheless, the Ministry of Public Health did not endeavour to eliminate the consumption of alcohol from Thai Society, and did not oppose drinking *per se*, however, it intended to combat alcohol-related problems in a cost-effective and sustainable way. To achieve this goal, the Ministry had elaborated its measure to include a mix of policy interventions.

The representative of Thailand explained that the ban on small-sized bottles for alcoholic drinks was intended to reduce the occurrence of underage drinking, since small bottles were attractive to minors due to both their relatively cheap price, as well the possibility to be hidden from parents and teachers. Thailand had already banned "tiny bottles" nearly a decade ago. She was of the view that all six pictorial warning messages had high contextual-relevance and were supported by both domestic and international scientific evidence. They were aware of studies indicating that moderate drinking might have health benefits for people with specific characteristics. However, they pointed out that epidemiological evidence showed that no health benefits could be measured at the aggregate level in countries with low prevalence of coronary heart diseases, especially in low and middle-income countries like Thailand. In Thailand, the occurrence of diseases attributable to alcohol consumption had increased by 40 per cent from 1999 to 2004 in terms of "Disability-Adjusted Life-Years (DALY)". The 2004 value was 10.4 per cent of the total health burden, which was twice the global average. Alcohol consumption was now considered the second greatest health risk factor to the Thai population. The market for alcohol in Thailand was characterized by increased consumption volumes, drinking frequencies, product varieties and exposure to direct and indirect alcohol marketing all leading to an increase in alcohol consumption as well as in alcohol-related problems in Thai society.

Evidence showed, according to the Thai representative, that warnings on the packages of commodities entailing potential harm were an effective means to educate the general population about risks associated with the use of the item. Furthermore, the higher the level of alcohol consumption, the higher also the level of exposure to the warning measures. Experience with tobacco packaging had shown that pictorial warnings yielded a higher impact than text-only messages. At present, Thai drinkers exhibited low levels of awareness of the text-only warnings that were currently employed. The experts believed that the location of these messages as well as their small size could be one reason for this. Therefore, the new measure required the pictorial warning messages to occupy between 30 per cent and 50 per cent of the container surface, which would still allow displaying product information in the remaining space. Pictorial messages furthermore were able to reach parts of the population with low literacy rates. Moreover, pictorial warnings would deter children from drinking alcohol. It was the view of the Thai delegation that it was technically feasible to implement a rotation of warning messages. Finally, it was pointed out that the measure was embedded in the national agenda to combat alcohol-related problems, which included an education campaign.

The representative of Mexico remarked that the statement by Thailand gave the impression that the decision of Thailand had already been taken without the consideration of all arguments raised, and of possible alternatives.

The representative of Thailand responded that the alternatives proposed so far included education campaigns in school and for the general population, which Thailand had already implemented. It was in addition to this that the new measure was being proposed; she assured delegations that all concerns would be taken into account.

China, UE, Japão, Coréia do Sul x EUA - Hazardous Materials: Transportation of Lithium Batteries (G/TBT/N/USA/518)

United States – Hazardous Materials: Transportation of Lithium Batteries (G/TBT/N/USA/518)

The representative of China informed the Committee that on 12 May 2010, China's WTO/TBT Enquiry Point had submitted comments on the notification G/TBT/N/USA/518. China was of the opinion that the proposed rules eliminated many regulatory exceptions for lithium cells and batteries from the UN recommendation for the transport of dangerous goods. This would impose stricter restrictions on the transport of cells and batteries and thus would significantly impact the international trade of lithium cells and batteries. China believed that this was not in compliance with Article 2.4 of the TBT Agreement. If the United States insisted upon eliminating these exceptions, China requested that the United States provide sufficient scientific justification.

Moreover, the representative of China noted that the United States was considering requiring a UN symbol to appear on all lithium cells and batteries. However the United States' proposed law did not specify the testing and specification requirements necessary to obtain this UN symbol. Therefore, China proposed that the United States clearly specify the necessary testing and specification requirements and notify these to the WTO. China requested the United States not to implement rules before the specific requirements and procedures had been made clear and other Members' comments had been taken into account.

In addition, the notification provided 75 days for mandatory compliance from the date of publication. This would cause difficulties for the producers of developing country Members to adapt their production to the latest requirements of the United States. Articles 2.12 and 5.9 of the TBT Agreement required Members to allow a reasonable interval between the publication of a technical regulation or conformity assessment procedure and its entry into force; the Doha Ministerial declaration adopted in November 2001 interpreted that a reasonable interval was normally a period of not less than six months. Thus, China encouraged the United States to faithfully implement the Doha Ministerial declaration and to provide a period of at least 6 months for transition. At the same time, China requested the United States to provide special and differential treatment to developing country Members by granting an even longer period for operators in all developing country Members including China.

The representative of the European Union informed the Committee that since the last Committee meeting, the European Union had analyzed the draft and had observed that the new requirements were not in accordance with the UN Recommendations on the Transport of Dangerous Goods and the International Civil Aviation Organization (ICAO) Technical Instructions on the Safe Transport of Dangerous Goods by Air. The United States had explained in the previous Committee meeting that changes had been deemed necessary due to several incidents of aircraft fires. However, the European Union noted that the ICAO Dangerous Goods Panel had also discussed these incidents and that a working paper had been presented. However, none of these incidents had involved lithium batteries that had fully complied with the current ICAO requirements. Thus, simply amending the requirements further and imposing greater restrictions would not necessarily have prevented those incidents from occurring. Some amendments had been introduced, but a majority of the Panel Members had considered that there was insufficient justification to make any substantial changes to the Technical Instructions. It was agreed though that if evidence would subsequently be produced indicating that the current requirements were not adequate, the Panel would re-consider the requirements. The European Union therefore invited the United States to first implement the changes agreed at an international level and to abstain from a unilateral approach. If the United States nevertheless opted for a unilateral approach, the European Union would ask the United

States to provide a transitional period of 18 months, since the new requirements would oblige economic operators to make substantial changes to packaging, processes and logistics.

The representative of Japan raised concerns about the proposed restriction on the transportation of lithium batteries of the United States from a point of view of the harmonization with the United Nations (UN) Recommendation on the Transport of Dangerous Goods and the International Civil Aviation Organization (ICAO) Technical Instructions, as well as the impact on trade. Moreover, the APEC Business Advisory Council had submitted a letter to the United States Ministers responsible for trade, emphasizing the harmonization of regulations on international transportation safety. Japan understood that the United States had received many comments both domestic and foreign, including from Japanese stake holders. Japan requested that the United States seriously consider those comments.

The representative of Korea was of the view that the more effective way to secure safer transportation of lithium batteries was to ensure harmonization and compliance with the international standards and regulations, such as the UN, the ICAO or the IMO. Korea urged the PUMAS (pipeline and hazardous materials safety administration) to provide sound scientific evidence on which the PUMAS had based its decisions.

The representative of the United States confirmed that the pipeline and hazardous materials safety administration in coordination with the US Federal Aviation Administration had published a proposed measure to comprehensively address the issue of safe transport of lithium cells and batteries for aircraft. This represented further steps in the continuing efforts to ensure that the transport of lithium batteries was safe and to prevent catastrophic accidents aboard aircraft; some examples of near misses had been provided in the last meeting. The proposed measures were intended to strengthen the current US regulatory framework by imposing more effective safeguards including testing, packaging, and hazard communication measures for various types and sizes of lithium batteries in specific transportation contacts. Taken together the proposal would eliminate some current exceptions for certain small batteries and in doing so would enhance safety by ensuring that all lithium batteries would be designed to withstand normal transportation conditions, be packaged to reduce the possibility of damage that could lead to an incident, and be accompanied by hazard information that would ensure appropriate and careful handling by air carrier personnel and inform transport workers and emergency response personnel of actions to be taken in the event of an emergency.

While the comment period for the proposed measure had expired on 12 March 2010, United States regulators continued to consider additional comments. In addition to the formal comment period there had been a public meeting which had provided an additional opportunity for stakeholders to comment. Over 100 individuals from companies, associations, foreign embassies and other organizations attended and there had been numerous presentations. All of the materials and analyses used in the development of the proposed measure as well as the statements made at the meeting were available on www.regulations.gov. In terms of the status of the measure, United States regulators were currently still in the process of reviewing all the comments received. The final measure was being developed and was tentatively expected to be issued in late 2010 or early 2011.

The representative of the United States mentioned that one of the issues that had been raised was that perhaps additional requirements were not necessary to the ICAO Technical Instructions. However, the United States noted that the ICAO technical instructions did not cover the smaller batteries that the United States was proposing to cover in its proposal. The proposal therefore would strengthen the current regulations as there was strong evidence that small lithium batteries, especially when packaged in bulk, posed the same risks of ignition as larger lithium batteries.

The representative of the United States recalled that a second issue that had been raised was the allegation that the United States was deviating from relevant international standards. References had been made to the ICAO technical instructions and the UN manual of tasks. The representative noted that United States regulators regularly participated in the work of these bodies and that they considered these documents when regulating. However, there was evidence that neither the ICAO technical instructions nor the UN manual of tasks had been

developed in accordance with the TBT Committee's 2000 decision containing a set of principles it considered important for international standards development. (the TBT Committee Decision). Specifically, the ICAO technical committee that developed the technical instructions and other relevant documents employed a panel of the air navigation commission. Such panels were not open to all WTO Members and paragraph 4 of the directive for the panels of the air navigation commission indicated that panels needed to be kept small, normally between 12 and 15 Members, and that the commission itself selected the countries that it would invite to participate "from those who are known to have the necessary expertise in a technical field of concern". The commission looked for Members that among other things "were able to provide ready access to research facilities and supporting expertise". As a result of these criteria, most of the Members of this body were advanced developed countries and seven of the 13 participating Members including the Chair were representatives of European Union member States. Furthermore, voting was by majority vote, not by consensus and specifically article 15.4 of the working procedures provided that "the panel endeavored to reach unanimous agreement of Members on its recommendations to the commission. However when a recommendation represented a majority decision of Members it was important that a report recalled the views of the minority as well as the view of the majority of Members and the measure of support for each view". Given the large number of EU member States in the committee, they constituted an absolute majority in the meetings. Thus the United States believed that the standards development process clearly favoured the interest of the European Union. In fact, member States met formally as a group prior to every panel meeting to reach a common position; thus the ultimate documents developed by that group were essentially adopted by the panel. The air navigation commission recently rejected the application of another European country to join the panel since that would enhance the current geographic imbalance. The fact that the commission had rejected an application from a WTO Member to join also demonstrates that ICAO did not run an open process as set out in the TBT Committee decision.

Similarly, in the UN committee on the transport of dangerous goods which developed the UN manual, 26 governments were represented, of which 14 were European Union member States who also went together as a block. Given that decisions in this working group were also taken by simple majority and not by consensus, the EU member States effectively dictated the terms of the materials that were developed in that body, so essentially both of these bodies were developing a unilateral EU approach, which was why the United States was declining to adopt all of the portions of that approach. As a consequence of these bodies' apparent failure to follow the openness and the consensus principles of the TBT Committee Decision, the United States did not believe that the documents they developed would effectively respond to regulatory needs in all cases. Due to the majority of European Union member States, the United States did not consider these documents to be globally relevant, and believed that also other countries outside of the European Union would deviate from these regulations according to their specific regulatory needs. The United States would note that if the Committee Decision principles were followed in these bodies and all participants could have their views reflected in the final documents, there would be more widespread adherence to these documents, which would contribute to both global regulatory convergence in these areas and to the achievement of the United States' legitimate regulatory objectives in the area of aircraft safety.

Finally, the ICAO air navigation commission had rules dictating the panel to be very small and the commission was able to reject applications for membership based on criteria which were skewed towards countries with technical expertise in aircraft regulation, making it very difficult for most developing countries to join. The United States believed that many developing countries would be interested in helping to develop a standard for the safe transport of lithium batteries by aircraft through their territories. Unlike many of the countries that did sit on the panel, most developing countries did not produce the subject batteries; thus their absence from the panel and the discussion may also skew the contents of the final documents. He noted that in the Fifth Review (G/TBT/26), the Committee had emphasized that broader stakeholder involvement helped ensure an open and transparent process in line with the disciplines on standardizing bodies set out in the TBT Agreement as well as those contained in the TBT Committee Decision's principles. Thus the United States failed to see how the ICAO commissions' process fulfilled the development dimension of the Committee Decision, since most developing countries were unable to participate in their work. The United States believed

that this issue provided an illustration of why the committee had never designated international standardizing bodies.

The United States further believed that it was clear from this example that the name of the body did not indicate whether or not it developed a relevant international standard; a deeper look into the process by which such documents were developed, including with respect to adherence to the TBT Committee Decision principles, was necessary. The United States hoped that this issue would prompt both the ICAO and the UN to review their respective procedures and to revise them so that they could adopt the code of practice and fulfill the TBT Committee Decision principles.

EUA, UE, Suíça x Turquia - New conformity assessment procedures for pharmaceuticals

Turkey – New conformity assessment procedures for pharmaceuticals

The representative of the United States reiterated concerns about certain aspects of Turkey's new decree regarding conformity assessment procedures for pharmaceutical imports. On 31 December 2009, the Turkish Ministry of Health had issued a regulation, which had gone into effect on 1 March 2010. As of that date foreign producers were required to have their manufacturing plants inspected by the Ministry of Health which would issue a good manufacturing practice certificate unless the country of manufacture was party to a mutual recognition agreement with Turkey. He emphasized that while the United States was not opposed to inspection requirements for pharmaceutical manufacturing facilities, his delegation had a number of concerns.

The United States was concerned that the measure had not been published in the Official Gazette in Turkey in its proposed form, and had not been notified to the WTO. Furthermore, the United States understood from its industry that there was an unofficial stand-still for new regulatory approvals that began before the measure was announced in 2009 which was not reflected in any published document. The United States asked Turkey to explain its health and safety concerns relating to imports from particular countries that had prompted Turkey to discontinue its acceptance of the GMP certificates issued by foreign regulatory authorities, such as the United States Food and Drug Administration (FDA), and to explain why it would no longer accept such certificates. The United States had made several requests for the data which Turkey indicated had substantiated the basis for the change, but to date had not received the information. The United States asked Turkey to indicate at its earliest opportunity any health or safety issues caused by products manufactured in a US FDA certified facility that had harmed Turkish citizens and which had prompted Turkey to discontinue acceptance of such GMP certificates.

The representative of the United States also noted that its industry was concerned that the measure provided a very short (three month) period for suppliers to comply. This, coupled with the lack of notification, had disrupted US exports of pharmaceutical products to Turkey. Some of these products were being used to treat diabetes, heart attacks, osteoporosis and other ailments, so delays would negatively impact patients in Turkey that were in need of these life-saving and/or life enhancing medications. The United States industry had reported that approximately 227 products were awaiting approval and that Turkey did not have sufficient capacity to inspect all of the plants that needed to be inspected in the near future. Given this apparent lack of capacity, the United States was concerned that the process for clearing these products could take several years, effectively preventing imports of these essential medications into Turkey. The United States understood that there had been some follow up discussions between senior officials from the US government in the US-Turkey Economic Partnership Commission. He welcomed opportunity to enhance communication and encourage greater dialogue between MOH and US industry on this and other issues. The United States also welcomed the opportunity to facilitate regulator-to-regulator technical discussions on issues relating to inspection procedures and capacity as well as on information sharing on the methodology used in facility inspections.

Given the procedural deficiency in the announcement and implementation of the new measure, the lack of data substantiating the need for the change, and the apparent lack of inspection capacity, the United States requested Turkey to suspend the measure and to resume recognition of the GMP certificates issued by the FDA to restore patient access to medications. The United States also asked Turkey to notify its measure to the WTO so that interested parties could comment, and these comments could be taken into account by the Ministry of Heath. Finally, and on a more general note, the United States noted that there had been several measures from Turkey in recent years including on biotechnology labelling, medical devices, and inspection procedures for certain IT products where there had been no opportunity for interested parties to comment, and there had been no WTO notification. Therefore, the United States requested Turkey to re-evaluate its internal transparency procedures with respect to increasing the number of stakeholders able to comment and to ensure that measures were properly notified to the WTO.

The representative of the European Union joined the United States in expressing concerns with regard to Turkey's new requirements for pharmaceuticals. According to information received from European Union economic operators, the introduction of the measure on short notice had already led to significant delays in the registration of new pharmaceutical products in Turkey, in particular since Turkish authorities did not appear to have the necessary capacity to carry out all necessary inspections and to deliver the required GMP certificate in reasonable time. Difficulties were further compounded by the requirement for companies to submit extensive documentation in their application file. Finally, the situation of products already on the market and of those that were in the process of being approved when the measure was implemented remained unclear. The European Union noted that the measure had not been notified despite being a technical regulation. Furthermore, the three-month period between publication and entry into force was deemed to be too short for economic operators to be able to comply with the requirements. Therefore, the European Union asked Turkey to revert to its previous practice and to recognize European Union GMP standards and certificates without additional administrative requirements.

The representative of Switzerland shared the concerns expressed by the United States and the European Union and repeated that the measure should have been notified at an earlier appropriate stage when amendments could still have been introduced and comments could have been taken into account. The implementation period of three months was inadequate and did not allow interested parties to become acquainted with the new measure. According to the WTO TBT Agreement, Members needed to ensure whenever possible that results of conformity assessment procedures from other Members were accepted, even when those procedures differed from their own, provided they were satisfied that those procedures offered an insurance of conformity with applicable technical regulations equivalent to their own procedures. He noted that in Switzerland, GMP certificates from WTO Members were in general accepted as proof for the GMP conformity of manufactures of finished medicinal products. This had proven to be workable and Switzerland encouraged Turkey to adopt a similar solution. At the last TBT Committee meeting, the Turkish delegate had mentioned that Turkey's objective was to protect human health by ensuring effectiveness, safety and quality of pharmaceuticals. Switzerland was interested in receiving more information on quality problems with pharmaceuticals manufactured according to international principles. In addition, Switzerland asked whether Turkey had considered that the access barriers to new medicine could even cause a threat to human health. In conclusion, Switzerland invited Turkey to reconsider its new measure and to suspend its implementation.

The representative of Turkey informed the Committee that according to the previous version of the regulation, GMP certificates had either been provided by the Turkish Ministry of Health or the certificates issued by the authorities of the respective countries had been accepted. However, as Turkey had explained at the March TBT Committee meeting, the withdrawal of more than 30 products from the market in the last three years had prompted the Ministry to review its approach to GMP certificates. The Ministry thus decided to undertake a more active role in compliance with the GMP requirement for the sake of protection of human health and life. Therefore, the licensing regulation had been amended in April 2009 and became effective since March 2010 in order to ensure pharmaceutical products were safe, effective and met the quality standards of the GMP regulation.

The representative of Turkey stressed that the objective of the amended procedure for GMP inspections was to ensure the protection of public health and was in accordance with the WTO disciplines. Moreover, both the GMP system and the assessment procedure were in line with international rules and guides and did not impose any additional restrictions or burdens on importers. The Turkish Ministry of Health had been issuing GMP certificates since the 1980s. The Ministry performed GMP inspections and issued GMP certificates every two years for Turkish manufacturers. Thus, the Ministry had adequate capacity to accept all the applications for GMP certificates. Regarding the request for statistics that supported the adoption of a new policy, the Turkish MoH was still working on the information, since there could be an element of confidentiality. The information would be communicated as early as possible.

Nova Zelândia e Austrália x Itália - Dairy products (G/TBT/N/ITA/13)

Italy – Dairy products (G/TBT/N/ITA/13)

The representative of New Zealand said that her delegation remained concerned by the proposed Italian dairy law which had been notified to the TBT Committee in February. This law included provisions proposing a ban on the use of protein in cheese-making, and also provided for the introduction of mandatory country of origin labelling for milk and dairy ingredients. New Zealand understood that the draft legislation was currently the subject of discussion in Brussels between the European Commission and Italy and hoped that deliberations on the proposed law took account of its and other Members' concerns.

The representative of Australia said that her delegation remained concerned about the proposed decree. Her delegation was particularly concerned about the ban on the use of milk protein in cheese-making. Therefore, Australia remained interested in the discussions and development of the decree.

The representative of the European Union confirmed that there were on-going discussions between the Commission and the Italian authorities within the internal notification procedure context. For this reason, he was not able to provide further information on the measure at this stage; clarification would be provided once the internal consultation process had concluded.

Nova Zelândia e Austrália x Canadá - Ice-cream Butterfat Subsidy/Labelling Programme (previously raised under the description "Ontario ice-cream subsidy")

Canada – Ice-cream Butterfat Subsidy/Labelling Programme (previously raised under the description "Ontario ice-cream subsidy")

The representative of New Zealand recalled that this issue had been raised previously in the TBT Committee under the description of "Ontario Ice-Cream Subsidy". The new description reflected New Zealand's evolving understanding of this Canadian programme. The programme had been rolled out nationally, and, in New Zealand's view it could include both a subsidy and labelling element. New Zealand had a number of systemic concerns with Canada's ice-cream butterfat rebate programme. In particular, specific details of the programme had been very difficult to obtain. Due to an apparent lack of transparency in the development, design, and implementation of the programme it was impossible to determine if it was, in fact, an import replacement programme supported by the Canadian Government. Therefore, New Zealand reiterated its request to Canada to provide more detail around the design of the rebate programme, particularly with regard to the role of the Canadian Dairy Commission.

It was recalled that last time New Zealand had raised the issue in the TBT Committee, Canada had noted that the role of the Canadian Dairy Commission was limited to pooling funds for the programme. Thus, New Zealand asked for an explanation of what such " pooling" actually entailed, and whether this indeed was the full extent of the Canadian Government's involvement

in the programme. New Zealand was also aware of various suggestions (including recently in the Canadian media) that the butterfat rebate programme was linked to Canada's "blue cow" labelling programme, which was understood to be a label available for 100 per cent domestically sourced milk in Canada. New Zealand emphasized that, as with other elements with these issues, there was not enough information from Canada to verify this, and therefore requested Canada's clarification on the nature and extent of the linkages between the programme and the "blue cow" labelling programme. New Zealand was also considering raising the issue again at the next meeting of the WTO Committee on Agriculture.

The representative of Australia shared the concerns raised by New Zealand and wished to hear more information from Canada.

The representative of Canada took note of the concerns regarding the Dairy Farmers of Canada ice cream initiative; however, Canada failed to see the relevance of the WTO TBT Agreement. The Dairy Farmers of Canada Ice Cream Initiative was a private contractual agreement between the Dairy Farmers of Canada, which was a non-governmental organization, and individual ice-cream processors. The initiative was a pure industry promotional programme and the government had nothing to do with it. On the questions about media reports, it was not the government of Canada's role to comment on media reports regarding the actions of private entities. On the issue of the involvement of the Canadian Dairy Commission (CDC), the initiative was neither a Government of Canada nor a CDC programme. The CDC merely calculated pooling returns on behalf of producers. Producers decided themselves how they disposed of their revenues. Finally, Canada noted that the WTO Committee on Agriculture meeting could indeed be a more appropriate forum for the issue.