SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/53)

New Concerns

UE x Equador - Certification of Ceramic Tiles

Ecuador – Certification of Ceramic Tiles

The representative of the European Union expressed concern regarding the adoption and publication of Resolution 18 of the "Consejo Nacional de la Calidad" (CONCAL), which laid out the documents that importers of ceramic tiles had to provide in order to obtain the Ecuadorian certification of conformity. She noted that this regulation, adopted on 17 December 2010 brought substantial changes to Ecuador's previous Resolution No. 10-2009.

She asked a number of questions, including: why this regulation had not been notified according to Article 2.9.2 of the TBT Agreement; why supplier's declarations of conformity from enterprises that had been certified according to IS0 9001, and issued by a body recognized by the Ecuadorian Accreditation Body, were no longer accepted; and confirmation that under Article 1 of the resolution, ISO 13006 certificates issued by bodies recognized by the Ecuadorian Accreditation Body would be accepted. She noted that the European Union had been informed that only one laboratory in Ecuador had been accredited to carry out the tests, which could lead to bottlenecks for importers. She invited Ecuador to take the appropriate steps to ensure that an interruption in existing trade in ceramic tiles would be avoided.

She also noted that the time during which existing certificates would be valid had been shortened from one year to 90 or 45 days. Her delegation viewed this decision as arbitrary, and was particularly problematic for products that were already certified but in the process of being imported. She asked Ecuador to consider extending these timelines. Finally, she regretted that her delegation had not been able to submit more detailed comments due to the fact that the Ecuadorian resolution had not been notified.

The representative of Ecuador informed the TBT Committee that his delegation had taken note of the questions raised and would come back with answers at the next TBT Committee meeting.

UE e EUA x Colômbia - Alcoholic beverages (G/TBT/N/COL/121 and Adds.1-3)

Colombia – Alcoholic beverages (G/TBT/N/COL/121 and Adds.1-3)

The representative of the European Union raised concern regarding Colombia's draft decree laying out requirements for the manufacture, processing, packaging, marketing, sale, export and import of alcoholic beverages. While the European Union was pleased that some of their comments, which were submitted in the framework of the original notification, had been taken into account by the Colombian authorities, she noted that the revised version of the draft still contained some provisions which could be problematic, and which could have a significant impact on trade.

In particular, she noted that some quality parameters, such as the restriction on the use of colouring, flavouring and sweeteners in liqueurs were not in line with international practice. Additionally, her delegation was concerned with the definitions of certain terms in the draft Decree, such as whiskey, vodka, rum, and gin.

Regarding the labelling requirements specified in the notified text, she asked whether it would be possible to place the stickers containing the mandatory labelling information locally, before the goods were placed on the market. In addition, she asked if requirement to present a quality certificate at the time of the authorisation of the product applied also to locally produced goods. Finally, she welcome the fact that Colombia had granted a sufficiently long transitional period and asked whether existing stocks at the time of entry into force of the requirements would be subjected to the new regulation.

The representative of the United States requested that Colombia eliminate the three-year ageing requirement for whiskies, as contained in the latest version of the proposed regulation. He noted that while certain types of whiskies might be aged for specific periods, there were no internationally agreed maturation requirements. He explained that this was because the maturation process depended in large measure on the climate in which the maturation took place as well as the barrel technology used. He asked for confirmation that mandatory reporting of the ageing time of rums would not be required and whether Colombia would permit the use of *de minimus* amounts of harmless colourings, flavourings and blending materials for all categories of distilled spirits specified in the proposed measure.

The representative of Colombia noted that the comment period for its notification G/TBT/N/COL/121/Add.2 had been extended until 4 March 2011. He explained that in light of the comments received, the competent authority considered it necessary to revise the draft regulation to ensure better compliance. Finally, he confirmed that comments received by Members would be analysed and that further information would be provided.

UE x Coréia do Sul - Good Manufacturing Practice requirements for cosmetics (G/TBT/N/KOR/301)

Korea – Good Manufacturing Practice requirements for cosmetics (G/TBT/N/KOR/301)

The representative of the European Union expressed concern with Korea's Good Manufacturing Practice requirements for cosmetics (KCGMP), on which the EU had submitted comments on 8 March 2011. While her delegation welcomed the fact that the draft regulation appeared to be in line with the relevant international standard, ISO 22716 on Cosmetics Good Manufacturing Practice, she requested confirmation from Korea that this was the case. If so, she asked Korea to explicitly refer to ISO 22716 in its legislation; otherwise she asked that any differences highlight between the KCGMP and the ISO standard be highlighted.

Second, she noted that Article 30 of the draft regulation provided certain facilities for cosmetics manufacturers complying with the KCGMP – in particular, an exemption from the requirement of conducting batch tests and conducting quality management by lot number. In this context, she asked whether foreign cosmetic manufacturers could also benefit from such derogation if they were recognised as complying with the KCGMP. It was the EU's understanding that only domestic manufacturers would benefit from these derogations. If this was the case, she reminded Korea that the TBT Agreement prohibited discrimination between foreign and domestically produced products.

Third, if the KCGMP requirements were very similar to those of ISO 22716, she asked whether Korea's responsible authority, the Korea Food and Drug Administration (KFDA), would recognize assessments performed or certificates issued by testing laboratories or governmental agencies of third countries proving compliance with ISO 22716.

Finally, she expressed doubts as to whether the Korean Cosmetic Association (KCA), which in her understanding was the only body authorized to conduct an evaluation of KCGMP

compliance, was sufficiently impartial and neutral to conduct unbiased assessments of both foreign and domestic cosmetics manufacturers. She noted that Korea could avoid potential bias in this context by recognizing foreign inspections and certificates, for example.

The representative of Korea clarified that Korea's draft regulation on Cosmetics - Good Manufacturing Practice, put forth by the Korea Food and Drug Administration (KFDA), was part of an effort to harmonize with the international standard ISO 22716. This effort sought to improve the quality of cosmetics and to protect public health from hazardous cosmetics. Hence, the regulation proposed by the KFDA had been largely based on ISO 22716. He explained that the KCGMP was voluntary, and there were no plans to make the regulation mandatory. Furthermore, he noted that the agency responsible was the KFDA and not the KCA.

Regarding the exemption provisions for manufacturers that complied with the requirement, he confirmed that there was preferential treatment to domestic manufacturers. However, he clarified that importers of non-Korea manufacturers' cosmetics products could also receive similar preferential treatment, such as exemption from quality inspection, if the non-Korea manufacturers passed the on-site inspection under Article 9 of the Department Ordinance of Cosmetics. He explained that this order had been running for more than 10 years and that 23 importers of foreign cosmetic manufacturers to date had passed the on-site inspection and enjoyed the benefits. He recommended that the European Union discuss bilaterally with Korea and try to sign an MOU with the KFDA.

UE x Ucrânia - Draft Technical Regulation on the labelling of foodstuff (G/TBT/N/UKR/52 and Add.1)

Ukraine – Draft Technical Regulation on the labelling of foodstuff (G/TBT/N/UKR/52 and Add.1)

The representative of the European Union expressed concern that several provisions of Ukraine's Draft Technical Regulation on the labelling of foodstuff (G/TBT/N/UKR/52), notified in January 2011, differed from the Codex Alimentarius and appeared to be costly and burdensome for operators. She noted that her delegation had recently submitted detailed comments on this draft regulation.

The representative recalled her delegation's comments on a previous notification (G/TBT/N/UKR/45) related to GMOs, and Ukraine's commitment to amend its GMO labelling provisions. In particular, Ukraine had agreed that only foodstuffs containing more than 0.9 per cent GMOs would have to be labelled with the inscription 'with GMO'; there would be no obligation to label other products with the inscription 'GMO free'. Furthermore, she inquired on which grounds Ukrainian authorities had prohibited health claims, whereas the Codex Alimentarius allows and provides guidelines for those claims.

Finally, the representative requested that Ukraine authorities review and clarify requirements for mandatory origin labelling, since as currently formulated, the requirements seemed to apply only to imported products. She also recommended that the definitions of products such as: spread, blended fats, starch and glucose syrup be rendered consistent with Codex Alimentarius.

The representative of the Ukraine noted that while the period for comments on G/TBT/N/UKR/52 closed 1 March 2011, her delegation was still willing to address concerns of Members. She explained that the technical regulation in questions further harmonized Ukrainian regulations with EU directives and international requirements, including with respect to GMO labelling. A grace period of 9 months was envisaged by Ukraine to enable businesses to smoothly adapt their operations to the new rule. She reported that answers to all the

questions received from the European Union had been prepared. They were in the process of being translated by capital, and would subsequently be provided to the European Union.

UE, Japão, EUA e Coréia do Sul x China - Requirements for information security products, including, inter alia, the Office of State Commercial Cryptography Administration (OSCCA) 1999 Regulation on commercial encryption products and its on-going revision and the Multi-Level Protection Scheme (MLPS)

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

The representative of the European Union explained that the title of the specific trade concern reflected the broad scope of his delegation's concerns in this context, some of which had been previously raised. He thanked China for maintaining an open channel of communication with the European Union on these issues, and indicated that his intervention would firstly focus on the revision of the 1999 Regulation on Commercial Encryption Code by the Office of the State Commercial Cryptography Administration (OSCCA). In this regard, he expressed his delegation's hope that the on-going revision of the Regulation would effectively address the concerns raised by the European Union and its industry. This required, *inter alia*, a clarification of the product scope and definitions, the removal of the current restrictions on approvals of encryption products incorporating foreign technology, and the introduction of certification procedures that duly address the legitimate concerns of foreign encryption product manufacturers regarding the protection of their intellectual property rights, including requirements for source code disclosure. In addition, he sought clarification as to the relationship between the OSCCA regulation and other regulations in the area of information security, namely the Compulsory Certification scheme for Information Security Products (CC-IS), managed by the National Certification and Accreditation Administration of China (CNCA), and the Multi-Level Protection Scheme (MLPS) under the leadership of the Ministry of Public Security (MPS). The representative requested an update as to the expected timeline of the revision process and when a public consultation would be held, and also requested that the draft measure be notified to the TBT Committee at the earliest appropriate stage so as to provide interested Members with an opportunity to comment.

The representative of the European Union also expressed concern with regard to the overall opacity of the implementation process of the MLPS. The lack of transparency created an uncertain and unpredictable business environment for foreign ICT equipment manufacturers operating in the Chinese market. He requested a general update on the implementation of the MLPS, including which sectors were being prioritized for assessment, and on the classification of those IT systems which had already been assessed in accordance with the MLPS criteria. In addition, the representative reiterated his delegation's substantive concerns regarding the application of the MLPS in sectors with no obvious relevance to national security, and also the risk of a back door application of the CC-IS requirements through the MLPS for commercial products not covered by its scope. He noted that the CC-IS was currently limited *de jure* to government procurement, yet there was evidence that compliance with CC-IS was required by several large state-owned enterprises, for instance in the banking sector, as a condition for procuring smartcards.

Finally, the representative expressed the belief that there was unexplored potential for closer cooperation between Chinese and other WTO Members, and the global ICT industry in the

information security field. Therefore, his delegation would continue to seek a more comprehensive dialogue with competent Chinese authorities, and he hoped to report some progress in this regard at future meetings.

The representative of Japan expressed support for the EU position, and reiterated that the various schemes and regulations within China regarding information security were not in conformity with global norms and approaches. His delegation was concerned with the negative affect that these measures could impose on trade in information security products. He recalled that delegations had asked China to be prudent in introducing measures regarding information security. He informed the Committee that China was currently considering a new certification scheme for information products that were not subject to the current CC-IS scheme, and he requested that China provide necessary information regarding the scheme, including its purpose.

The representative of the United States echoed the request of the EU delegate that China notify any proposed revisions to OSCCA regulations on commercial encryption so that Members and other interested parties may provide comments. He warned that if the planned revision expanded the scope of the regulations to more information or technology products (for example, by modifying or eliminating the core-function test) the impact would be felt across a broad range of the global information technology sector. In particular, trade disruption could result, such as occurred in 1999 when China issued the first version of these regulations; which was eventually limited in scope to products whose core function is encryption. Furthermore, expansion of the scope could raise questions as to whether the measure was more trade restrictive than necessary, and his delegation would continue to monitor this issue.

The representative of Korea shared the concerns raised by the European Union, Japan, and the United States.

The representative of China explained that the revision of the commercial cryptography regulation by the Office of the State Commercial Cryptography Administration (OSCCA) was on the agenda of the legislation plan of the State Council for 2011. Based on scientific verification and public input, OSCCA was revising the measure under the Legislation Law and the Procedures of the Formulation of Administrative Regulations.

He informed the Committee that the correct name of the measure referred to by other delegations in the context of the MLPS was the Regulation on Classified Protection of Information Security (RCPIS), a basic information security regulation following Chinese laws and regulations, and implemented by a series of standards and management specifications. He noted that in practice, there was no evidence that the implementation of RCPIS had affected the stability of the information and communication equipment market.

The representative explained that five levels of information security protection systems were stipulated in RCPIS, amongst which Level III and above involved systems concerning critical infrastructure and important assets. These critical infrastructure and important assets were vital to maintain and safeguard national security and public interest in fields such as government organs, finance, and banking. He stated that Level III and above covered only a limited scope amongst all information systems employed in China. He observed that only a small percentage of information systems in major industries would be covered by Level III and above. His delegation believed that RCPIS would impose a limited impact upon major industries, similar to the impact of EU information security regulations on the banking sector.

He reported that his delegation had held on the previous day, a bilateral meeting with the Japanese delegation, and that he wanted to continue to work to clarify what global norms were in the information security sector. Also, the representative stated a preference for close cooperation and dialogue in the future as suggested by the EU delegation.

In light of the information provided, the representative of the European Union asked at what stage in the process of the revision of the OSCCA regulation the measure would be notified to the TBT Committee. Also, he asked what modalities were being used to seek public input on this measure, and whether there would be an open call for public comments.

The representative of China replied that the he could not give a concrete timeframe for the TBT notification and the public hearing because the measure was still undergoing an internal research process. However, he pledged to keep bilateral contact with EU colleagues open on this issue to achieving a mutually satisfactory result.

UE x China - Lighting and Light-Signalling Devices for Motorcycles (G/TBT/N/CHN/721 and Suppl.1)

China – Lighting and Light-Signalling Devices for Motorcycles (G/TBT/N/CHN/721 and Suppl.1)

The representative of the European Union stated that in November 2010 China had clarified that motorcycles equipped with automatic headlamps and daytime running lights could not be accepted in China. However, she informed the Committee that China had replied the day before to the EU in writing that it agreed that automatic headlamps and daytime running lights could contribute to world safety and that China was monitoring the EU experience in order to decide if motorcycles equipped with these devices would be admitted in China. The representative underlined her delegation's interest in exchanging information with China so to avoid motor vehicles equipped with automatic headlamps and daytime running lights, which were in compliance with the relevant United Nations Economic Commission for Europe (UNECE) regulations, having to be redesigned for the Chinese market alone.

The representative of China replied that the measure in question specified the technical requirements, test method and inspection rules for the installation of lighting and light-signalling devices for two wheeled motorcycles. He reported that the draft standard had been notified on 8 February 2010, followed by a sixty-day comment period, and that the European Union had submitted three sets of written comments to China's TBT enquiry point, on 30 April 2010, 8 November 2010 and 11 March 2011. He noted that his delegation replied to all three sets of comments, and he hoped the replies addressed most of the concerns raised by the European Union. He was glad that the European Union was satisfied with his delegation's latest reply. His delegation remained open for further technical contact with through TBT enquiry points, as well as other bilateral channels. Finally, he informed the Committee that the standard had been approved and published on 10 January 2011 and would be implemented on 1 January 2012.

UE x China - Provisions for the Administration of Cosmetics Application Acceptance (G/TBT/N/CHN/730 and Suppl.1)

China – Provisions for the Administration of Cosmetics Application Acceptance (G/TBT/N/CHN/730 and Suppl.1)

The representative of the European Union raised concerns with regard to Decree No. 856 issued by the State Food and Drug Administration of China (SFDA), on the "Application and Acceptance of Administrative Licensing for Cosmetics". She stated that this Decree had been issued on 25 December 2009, and had been notified to the TBT Committee on 25 March 2010, just 5 days before its entry into force on 1 April 2010. The representative explained that neither

European industry nor EU authorities had had an adequate opportunity to comment on the draft legislation, which was required according to China's transparency obligations under the TBT Agreement. Furthermore, she noted that industry had been given only three months to comply with the new regulatory requirements.

The representative reported that, following the entry into force of the new requirements, approvals of new cosmetic products in China had decreased from around 1000 per month to a nearly complete standstill. However, she noted that in the past few months the situation seemed to have somewhat improved, with some 370 products reportedly approved between November 2010 and February 2011. Nevertheless, EU industry still experienced significant delays in their application for new product registrations, and the average number of products approved per month under the new requirements was only a fraction of what it used to be under the previous notification system. Furthermore, she suggested that the legislation discriminated between domestic and foreign non-functional cosmetics; while the latter were subject to registration as a pre-condition for their placement on the market, the former would apparently be subject to a notification requirement only, which could be submitted even after their placement on the market.

She expressed appreciation for China's efforts to put in place an efficient and comprehensive regulatory system for the approval of cosmetics. She reported that the European Commission had discussed the issue of the new cosmetics licensing regime at expert level with the SFDA on several occasions, most recently during an expert meeting held in January 2011. Her delegation was grateful for SFDA's openness to discus with EU experts, as well as its efforts to clarify and streamline the new requirements – as exemplified by the issuance of the Guidelines on 'Key Points for Technical Review' of October 2010, which had helped shed light on several issues. Furthermore, her delegation welcomed recent progress by the SFDA in addressing the backlog of applications for product registration.

Despite this evident progress, the representative expressed concerned with the slower pace of the new product approvals as compared to the previous system, that had caused serious delays for the placement of European products on the Chinese market, and had disrupted production and marketing plans for those products. The uncertainty confronting foreign manufacturers was further compounded by the lack of clarity of the new rules in several respects. For instance, she explained that with regard to the registration of new ingredients, there was still uncertainty as to the definition of 'new ingredients'. The representative recalled that in December 2010, the SFDA had issued draft guidelines defining 'new ingredients' as 'any ingredients used for the first time in cosmetics on the market in China'. Nevertheless, she noted that the draft guidelines did not contain a list of existing ingredients, and industry had so far not been consulted in order to ensure that such a list was correct and complete. The representative therefore urged China to develop a comprehensive and accurate list of existing ingredients, in consultation with both concerned foreign and domestic industry.

More generally, she noted that there had been a great number of rules applicable to cosmetics adopted by the SFDA in recent times. The speed at which these requirements were issued, and the often short period given to companies to comply, were posing considerable difficulties to industry exporting cosmetics to China. Her delegation urged the SFDA to adhere to principles of good regulatory practice – for example, through a thorough regulatory impact assessment and public consultation, as well as notification of TBT-related measures to the TBT Committee while measures were still in draft stage, and comments could still be taken into account. Finally, she asked that comprehensive guidance for implementation of all new rules be provided, so to allow industry to comply with the requirements.

Finally, she reported that her delegation had learnt that the SFDA had issued a new rule (no. 454 of 26 November 2010) specifying further requirements for cosmetics products. This rule would enter into force on 1 April 2011, but had not yet been notified to the TBT Committee. She

reported that the regulation included several requirements, *inter alia*, on testing for product stability or shelf life, which could be problematic for EU industry. She therefore requested that China notify the latest rule, and suspend its entry into force pending notification, to ensure that Member's comments are taken into account.

The representative of China explained that the SFDA revised and issued the Provisions for the Administration of Cosmetics Application Acceptance in response to safety problem that emerged with cosmetics, in particular with child bathroom products and talcum powder in 2009. He noted that during the revision process the SFDA had held forums, workshops, and expert discussions with enterprise representatives, as well as solicited public opinion including those from the European Chamber of Commerce and several European enterprises, and had taken all those comments into account.

He stated that in order to strengthen supervision on cosmetic materials, the measure required that enterprises submit safety evaluation data on potentially harmful substances. Based on risk assessment and taking into account comments from the European Chamber of Commerce, L'Oreal, P&G, Johnson&Johnson, Unilever, and Chanel, the SFDA had issued the Guidance on Safety Assessment of Potentially Harmful Substance in Cosmetics on 23 August 2010. He noted that this guidance was in line with the 6th Revision of the Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation by EU Scientific Committee on Consumer Products. The representative pointed out that the SFDA guidance had clearly defined potentially risky substances in cosmetics, basic procedures for safety evaluation, requirements on evaluation data (and the relevant submission form), and data review principles.

In addition, he informed the Committee that SFDA had issued documents outlining key points and guidance for the technical review of cosmetics. Meanwhile, the representative noted that fruitful training had been carried out for cosmetics enterprises, including those from the European Chamber of Commerce. He reported that cosmetic registration and recording was proceeding smoothly, and qualified products, including those from EU cosmetic producers, had been recorded and approved. With respect to the new SFDA rule flagged by the European Union delegate, he promised to deliver comments to the SFDA. Finally, he agreed to follow up on a letter from the European Union delegation suggesting a July 2011 meeting between SFDA and the European Commission in Brussels.

UE e Japão x China - Administration on the Control of Pollution Caused by Electrical and Electronic Products (G/TBT/N/CHN/140, Add.1 and Rev.1)

China – Administration on the Control of Pollution Caused by Electrical and Electronic Products (G/TBT/N/CHN/140, Add.1 and Rev.1)

The representative of the European Union welcomed the objective of reducing environmental pollution caused by electric and electronic products waste, as pursued by the notified document. She reminded the Committee that the European Union maintained legislation on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and the European Union pursued the same objectives as China of protecting the environment and human health.

However, the representative expressed concerns about the uncertainty that the notified document introduced around the certification procedure that would be introduced for electrical and electronic equipment. First, she observed that the notified draft foresaw the future creation of a catalogue of products that were required to meet the requirements. It was unclear when and according to which criteria the catalogue would be set up. Therefore, the representative

requested confirmation from China that the introduction of products in the future catalogue would be notified to WTO Members under the TBT Agreement, and that an appropriate time for comments would be given.

Secondly, she stated that her delegation understood that the notified draft required that the products introduced in the future catalogue would need to be certified according to a system endorsed by the State. The representative questioned why such a third party certification was necessary for proving compliance with the restrictions on the use of certain hazardous substances in electrical and electronic equipment. She explained that the risk that the requirements aimed to control only appeared when the products entered the waste phase, and were not present in the consumer use phase. She therefore considered this third party pre-market certification to be an overly burdensome requirement that constituted an unnecessary obstacle to trade according to Article 5.1.2 of the TBT Agreement. A system of supplier's declaration of conformity (SDoC), coupled with post-market surveillance would, in the view of the representative, be a more proportionate option, and would achieve China's objective of reducing pollution without placing unnecessary burdens on economic operators. She recalled that similar European Union legislation called only for a supplier's declaration of conformity. Her delegation therefore invited China to reconsider the requirement of a third party certification, especially since her delegation was aware that a voluntary certification scheme for six products was already under development in China. Finally, based on the written reply of China dated 2 March 2011 to her delegation's written comments, she understood that China was still considering certification options, and she sought confirmation of this point.

The representative of Japan supported the concerns raised by the European Union. He expressed appreciation for China's reply to comments made by the Japanese government on notification G/TBT/N/CHN/140/Rev.1, however, he sought additional information on a number of points. First, with regard to the national certification system for the control of pollution caused by electronic products (stipulated by Article 21), the representative inquired whether mandatory third party conformity assessment, voluntary supplier's declaration of conformity certification, or other kinds of certification would be used to demonstrate compliance with the regulation. In particular, he sought to confirmation that a voluntary Supplier's Declaration of Conformity (SDoC) could be used.

Second, the representative noted that Article 3(1) of the draft regulation stipulated that "electrical and electronic products refer to equipment and related products". He therefore suggested that objective related products, as well as excluded products, be listed in a separate list or Annex. He highlighted automobiles, batteries, any parts and materials incorporated in "equipment and attached products", any jig tool (e.g., a die), and materials used in production of "equipment and attached products" as products that needed to be excluded under the definition of the electrical and electronic products.

The representative of China stated that the measure in question (Administration of the Control of Pollution Caused by Electrical and Electronic Products) was notified on 21 October 2010, and that his delegation had received comments from the United States, EU, and Japan; replies were provided through the TBT enquiry point earlier in March 2011. Given the concerns expressed by China's trade partners, he saw a need to provide further clarification.

He explained that the management catalogue for the Control of Pollution Caused by Electrical and Electronic Products was presently being drafted, and would be notified to the TBT Committee in due course. The representative also stated that mandatory, voluntary, or other kinds of certification could be employed for the purposes of conformity assessment. These options ensured non-discrimination under the requirements for both domestic and imported products. The representative also noted that the Chinese government would honour MRAs reached between China and other countries. Related standards and the procedures of conformity assessment would be developed in line with WTO rules and international practice.

He informed the Committee that at present only six hazardous substances, including lead, mercury, were limited in electrical and electronic products. The representative assured the Committee that any changes to the prohibitions of hazardous substances would be notified to the WTO TBT Committee.

UE e EUA x India – Food Safety and Standards Regulation - Food labelling requirements (G/SPS/N/IND/69)

India – Food Safety and Standards Regulation - Food labelling requirements (G/SPS/N/IND/69)

The representative of the European Union stated that India had notified a draft regulation on food safety and standards to the SPS Committee (G/SPS/N/IND/69) in July 2010. In comments to the SPS notification, her delegation noted several trade restrictive aspects of the regulation, as well as deviations from Codex Alimentarius. In addition, her delegation observed that the Indian regulation included TBT related aspects, such as labelling and packaging requirements, and consequently, she asked that India also notify the regulation to the TBT Committee. She explained that a number of the Indian packaging and labelling requirements could be considered burdensome and more trade restrictive than necessary. For instance, the obligation to label certain aspects in capital letters appeared to be too strict and went beyond practice of Codex Alimentarius. In this context, her delegation requested an opportunity to discuss these aspects in detail with India, and therefore kindly reminded India of the need to notify the text to the TBT Committee.

The representative of the United States agreed with the EU position that this measure should be notified to the TBT Committee. He noted that, for example, Chapter 4 dealt with packaging and labelling regulation requirements, and Chapter 5 set out identity standards for various milk and cheese products, and his delegation believed it to be appropriate to notify this measure to the TBT Committee.

The representative of the United States clarified that there were some elements of the requirements that could have both SPS and TBT components. For instance, he observed that Chapter 4 of the proposal also contained elements related to nutritional labelling, and Chapter 5 contained elements related to different types of quality and identity ingredient issues with respect to various cheese, whey, and milk products. His delegation did not view these as food safety issues, rather as quality and nutritional issues. Therefore, the measure should be notified both to the SPS and TBT Committees, and he agreed to provide further elaboration at the United States – India bilateral meetings later in the week.

The representative of the United States clarified that there were some elements of the requirements that could have both SPS and TBT components. For instance, he observed that Chapter 4 of the proposal also contained elements related to nutritional labelling, and Chapter 5 contained elements related to different types of quality and identity ingredient issues with respect to various cheese, whey, and milk products. His delegation did not view these as food safety issues, rather as quality and nutritional issues. Therefore, the measure should be notified both to the SPS and TBT Committees, and he agreed to provide further elaboration at the United States – India bilateral meetings later in the week

The representative of India believed that the objectives of the measure were well ensconced within relevant paragraphs contained in Annex A.1(b) of the SPS Agreement.

México x EUA - Food Safety Modernization (FSMA) Public Law 111-353

United States – Food Safety Modernization (FSMA) Public Law 111-353

The representative of Mexico stated that the Congress of the United States had approved the Food Safety Modernization Public Law in January 2011, and that the promulgation provided for major changes in the areas of production, transportation, distribution and import of food products into the United States. He explained that the law called for the regulatory activities of the United States Food and Drug Administration (FDA) to be preventive in nature, rather than reactive. These regulatory activities covered the totality of the food production chain, from the farm all the way to the point of sale. Furthermore, he noted that the law involved twelve new regulatory measures, and strengthened the capacity of the FDA for the effective supervision of the entire food production chain through inspection, including of both domestic and imported food. This covered the gathering of records of all involved establishments, and the registration of these establishments with the FDA when they were part of the food production chain. This registration had to be updated every two years, and the representative explained that establishments could be suspended if the FDA suspected that the products of an establishment could be a cause of damaged health or could a pose a risk to health. Additionally, written reports would be made. The representative noted that some imported food would have to obtain certification to guarantee entry into the United States market, and in some cases exporters as well as importers would need to obtain certification. He said that the law provided an obligation for traceability of imported products and also permitted the administrative seizing of products if the FDA believed that some food products had been adulterated or incorrectly labelled.

His delegation shared the concern of the United States for the protection of human health, and recognized the impact that food safety could have on human health; and, Mexico was making efforts in order to attain this objective as well. However, the representative expressed concerns about the possible lack of coherence of this law with the obligations of the United States under Articles 2.2, 2.9, 2.9.4 of the TBT Agreement, amongst others. First, he was concerned that the measure had not been notified nor had time been provided for comments. Some provisions of the aforementioned law could have implication with regard to the commitments of the United States with respect to both the TBT and SPS Agreements, in particular specifications that could be subject to the definition of technical regulations or measure, respectively laid out in Annex 1.1 of the TBT Agreement and/or Annex A.1 of the SPS Agreement. Therefore, the representative believed that the United States was obliged to comply with transparency obligations contained in both Agreements. Moreover, he expressed the view that the measure was excessively restrictive because in his delegation's view, there were other ways of achieving the United States' objectives without unnecessarily restricting trade. For example, Section 207 of the law specified that if the FDA suspected that a food product had been adulterated or improperly labelled, it could lead to the administrative seizure of that product.

The representative called on the United States to ensure that the implementing regulations of the law undergo a public consultation and be notified to the TBT Committee. Moreover, he highlighted the importance of avoiding any impediments in the flow of food trade between Mexico and the United States, in order to ensure due process in the implementation and entry into force of the law. He reiterated Mexico's commitment to establishing measures providing for food safety, yet he underscored the need to do so in a way that respected international obligations and ensured that measures were least trade restrictive as possible. Finally, he inquired whether the United States envisaged including within the law's implementation provisions aspects pertaining to special and differential treatment and technical assistance for developing countries.

The representative of the United States stated his delegation's view that this measure fell squarely within the SPS realm, and it therefore was not appropriate to discuss its contents in the

TBT Committee. He understood that Mexico was concerned that there could be some potential TBT elements in the law's forthcoming implementing regulations, to be issued by the FDA. The representative pledged to review these regulations from the TBT perspective, and should there be any TBT elements, they would be notified to the Committee. He reported that Mexico and the United States had held bilateral discussions on this issue earlier in the week, and he urged Mexico to continue discussion of this issue with the United States' SPS experts.

Japão e UE x China – The Provisions on the Environmental Administration of New Chemical Substances (Amendments) (G/TBT/N/CHN/210/Rev.1)

China – The Provisions on the Environmental Administration of New Chemical Substances (Amendments) (G/TBT/N/CHN/210/Rev.1)

The representative of Japan welcomed the movement forward on the environmental administration of chemical substances, since they demonstrated that the People's Republic of China's was moving towards harmonization with international standards in terms of accepting data obtained in accordance with OECD test guidelines. In particular, this shift was evident in the guidelines for new chemical substances, and the registration of measures on the environmental management of new chemical substances. However, the representative noted that China required test data obtained by Chinese testing bodies pursuant to Article 10-(3) of the Measures, and to Article 4 requirements for chemical substance notification documents and requirements for notification data. He requested that China amend inconsistencies with international standards, and that China revise clauses of the guidance documents.

The representative of the European Union shared the concerns of Japan as to the fact that the Chinese measures on environmental management of new chemical substances required that data for certain eco-toxicological tests be generated by Chinese laboratories. Her delegation considered this requirement to be more strict than necessary, since tests in accordance with available test methods adopted by the OECD, and performed according to Good Laboratory Practices, could be carried out in laboratories outside China in the same way as in Chinese laboratories. This applied equally to tests for degradation and fish toxicity. She therefore urged China to amend the measure so that eco-toxicological tests carried out according to the OECD test guidelines in laboratories outside China would be recognized, including those for degradation and fish toxicity.

Furthermore, the European Union sought clarification as to the distinction between "general chemical substances" and "hazardous chemical substances" as foreseen in Article 50 of the measure. This distinction seemed to be made on the basis of the UN Globally Harmonized System of Classification and Labelling of Chemicals; however, she noted that her delegation could not find any confirmation to this respect in the implementation guidelines. She requested that China confirm that the distinction between types of chemical substances was based on the Globally Harmonized System, in compliance with Article 2.4 of the TBT Agreement. If the distinction was not based on this system, she asked for justifications as to why this relevant international standard in the area of chemicals had not been followed.

The representative of China said that his delegation had held a bilateral meeting on the previous day with Japan concerning measures on environmental management of new chemical substances, and that Japan had expressed a need for further clarification. He therefore explained that the registration requirement and legislation target of the measures were similar to those in the OECD requirements. However, he noted that different target organisms in the different environments of different countries generated different data on the same chemical substances; this was in fact the case with eco-toxicological testing data obtained by testing facilities within Chinese territory. However, China was currently participating in mutual data recognition

activities in OECD. The representative further explained that 27 related national standards were being formulated in accordance with this UN globally harmonized classification and labelling system. He suggested that any further concerns on this point be addressed directly to the Ministry of Environmental Protection of the People's Republic of China. Finally, he noted that relevant documents and requirements could be found on the official website of the Ministry of Environmental Protection.

Japão e EUA x Coréia do Sul - PVC flooring material and Wallpaper and paper linoleum, and toys (G/TBT/N/KOR/303 and Add.1 and G/TBT/N/KOR/304 and Add.1)

Korea – PVC flooring material and Wallpaper and paper linoleum, and toys (G/TBT/N/KOR/303 and Add.1 and G/TBT/N/KOR/304 and Add.1)

The representative of Japan referred to the above-mentioned measures notified by Korea which restricted utilizing specific plasticizers such as DEHP, DBP and BBP in PVC. He said that his government had serious concerns about the lack of scientific evidence on which the new draft requirements were based. Japan was of the view that restrictions on cheap and useful PVC products could have a significant trade impact on many developing countries in the world. He asked South Korea to make publically available the scientific evidence that related to the content restrictions; particularly those for limiting the total amount of certain hazardous chemicals to less than or equal to 0.1 per cent.

The representative of the United States also expressed concern about the proposed content limits of 0.1 per cent for the three phthalates DEHP (Di-Ethyl Hexyl Phthalate), DBP (Di-butyl Phthalate) and BBP (Butyl benzyl Phthalate) in certain uses, particularly for PVC flooring and wallpaper. According to the US industry, these limits effectively prohibited the use of these substances in these applications. He noted that the substances were used as plasticizers in vinyl flooring and wallpaper to make them flexible, durable and easy to maintain. He said that currently the phthalates were restricted in children's toys and childcare articles in the United States and other countries where concern had been expressed about the potential for relatively high exposures in these products to children. The US Environmental Protection Agency (EPA) has expressed general concern about phthalates because of their toxicity and the evidence of general pervasive human and environmental exposure to these chemicals. Moreover, a plan had been published that outlined a number of actions currently being pursued, or that were under consideration by EPA, to better assess exposure and potential safety concerns with phthalates. However, for the measure at issue, if the new Korean regulations were adopted they would be, it was the US understanding, among the first in the world to restrict the use of these substances in flooring and wall coverings. Therefore the United States also asked Korea to provide scientific and technical information that supported applying the 0.1 per cent limit in this context.

The representative of Korea said that almost all houses in Korea used – and had used for centuries – a unique under-floor heating system called "ondol". Due to this system, most of the houses in Korea used PVC flooring materials and wallpaper. When heated, PVC flooring material and wallpaper could emit hazardous substances like DEHP, DBP and BBP. Thus the purpose of the Korean regulation was to protect consumers' health from these hazardous substances. It had already been scientifically proven that DEHP, DBP and BBP were dangerous; they had been categorized as hazardous chemicals. Based on this, the content limit in infants' and childrens' products had been set at less than or equal to 0.1 per cent in many countries, including the United States, the European Union, Japan, and other countries. As houses were utilized by adults, children and infants – this needed to be taken into consideration; regulations had to be extended to any product containing these substances that could have contact with infants and children. This was the rationale behind the Korean draft measure.

Currently, the Korean Agency for Technology and Standards (KATS) was collecting comments from stakeholders and taking them into account.

Coréia do Sul, Japão e UE x Indonesia – Draft Decree of Minister of Industry on Mandatory Implementation of Indonesia National Standard for electroiysis tin coated thin steel sheets. (G/TBT/N/IDN/46)

Indonesia – Draft Decree of Minister of Industry on Mandatory Implementation of Indonesia National Standard for electroiysis tin coated thin steel sheets. (G/TBT/N/IDN/46)

The representative of Korea referred to a draft measure from the Indonesian Ministry of Industry on the mandatory implementation of the Indonesian National Standard for electrolysis on tin-coated, tin steel sheets. While Indonesia's desire to protect consumer safety was understandable, the Korean steel industry had expressed several concerns regarding the proposed regulation. Problems faced by Korean steel manufacturers included, for example, the large number of sampling tests, delayed factory inspection and shipment sampling. The representative from Korea said that this imposed a heavy burden to manufacturers and created unnecessary obstacles to international trade. He asked the Indonesian Ministry of Industry to make efforts to find a constructive solution, including reducing the number of sample tests. The Korean standard for steel product required just three samples, and this system was sufficient to protect consumer safety and to ensure product quality. Additionally, as the new technical guidance for the implementation of the decree had not yet been released, Korean steel manufacturers were having difficulty in preparing to apply for SNI certification for electrolysis tin-coated, tin steel sheets. The representative of Korea therefore invited the relevant Indonesian authorities to provide his delegation with further information and detailed technical guidance, including the date of entry into force as soon as possible. He said that a longer transition period would be helpful.

The representative of Japan noted that his delegation was also seriously concerned about the possible further expansion of mandatory standards for steel imported from Japan; this was steel that was covered by strict quality management systems at steel mills in Japan, certified by ISO 9001. He noted if the scope of mandatory standards was extended, more time and cost would be required to receive and maintain certifications. This was likely to have a serious impact on foreign trade, such as by increasing distribution costs and delaying deliveries at major industries in Indonesia. Indeed, these negative impacts were likely to make industries in Indonesia less competitive in global markets.

The representative of the European Union also expressed concern about the Indonesian measure which rendered Indonesian national standards mandatory for different kinds of steel products. It was the EU view that third party certification for these products was more trade restrictive than necessary. The European Union therefore invited Indonesia to consider accepting Supplier's Declaration of Conformity (SDoC) as proof for compliance. The European Union also wanted to know why Indonesia considered it necessary to impose a mix of requirements coming from different standards and could not refer to relevant international standards.

The representative of Indonesia noted that the draft measure had been notified and bilateral discussions with Korea were underway and concerns were being taken into account. He stressed that the objective of the draft measure was that of protecting consumers. Indonesia would remain open to discussions – he said, moreover, that Indonesia could accept certifications from other countries.

Previously raised concerns

Argentina, Canadá, China, Índia, Japão, EUA, Austrália, Cuba, Filipinas, Tailândia e Venezuela x UE – Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (G/TBT/N/EEC/52 and Adds.1-6; 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.1-6; 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 concerns with the complex nature of the Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH), and stated that the measure was an unnecessary obstacle to trade. He highlighted the serious difficulties faced by Argentine companies as a result of the non-transparent regulations of REACH, and the excessive costs involved in abiding by them. Both issues made it difficult for argentine companies to remain in the European market. He said that concerns with lack of transparency around REACH were accentuated by the failure of the European Union to provide concrete and direct responses to the questions previously raised by Argentina. He said that practical responses to these questions were essential to ensure predictability for Argentine companies operating in the European Union. He also underscored the provisions in Article 77 of REACH that recognised the need for capacity building and technical assistance to help developing countries comply with the regulations.

He also noted that the impact of increased costs was particularly significant for non-European Small and Medium Enterprises (SMEs), which faced higher costs than those of European companies. He cited the example of the regulation that required non-European companies to open an office in the European Union to continue operating in within the Union; or to have a contract representative who represent it at a cost of U$S160,000 per chemical substance. Additionally, he noted that companies needed to also consider studies, the compilation of data, and bureaucratic issues, to ensure full compliance with REACH. The disproportionate cost structure was beneficial for larger companies, and against the interest of smaller and extra-community enterprises. He urged the European Union to establish means for cost reduction for the registration of SMEs to offset this situation, and to ensure compliance of the regulation with the National Treatment principle. He reiterated Argentine support for the objectives of protection of health, and of the environment that REACH sought to achieve. However, he also re-emphasised the concerns raised by Argentina on the difficulties faced by Argentine companies in implementing the regulations contained in REACH, which continued to pose an unnecessary technical barrier to trade. He encouraged the European Union to consider his comments, and provide better solutions so to ensure that Argentine companies were not excluded from the European market.

The representative of Canada raised long-standing concerns over REACH. He highlighted bilateral discussions between Canada and the European Union on the subject, but refrained from discussing the details of the concerns raised therein. He put on record Canada's interest in genetically modified oils, and a lack of clear understanding as to how they would be treated under REACH, and requested further information in this respect. Additionally, with reference to the subject of substances in articles, he once again asked the European Union to ensure that the implementation of provisions was conducted in a manner that was least trade-restrictive. On the subject of Substance Information Exchange Forums (SIEF), he expressed Canada's interest

in understanding how the European Union would ensure that membership to said groups would not be unduly or arbitrarily restricted.

The representative of China noted that his delegation was looking forward to the bilateral meeting with the European Union the following day, but also said he would like to seize the opportunity to express the different concerns that China had with regards to the analytic spectrum of REACH, which were also raised in the previous TBT meeting by China. He also expressed concern about the non-transparent and unreasonable cost-sharing mechanism of some substances' REACH registration, which imposed registration costs of Euro 278,522.56 for1-bromopropane, and Euro 159,051 for oxalic acid, which directly impacted Chinese enterprises.

The representative of India sought clarifications and offered comments on REACH. He first requested that the logic of registration of monomers be clarified, since the lifecycle of a monomer ended once it reacted into a polymer. He noted that monomers were stable in polymers and did not have separate risks of their own. He also noted that the information provided on monomers did not cover the risks associated with polymers. He commented on the creation of the SIEFs and consortia, which were outside the purview of regulatory control, and had the potential to be dominated by EU industry, placing a high burden on SMEs. He underscored some of the concerns associated with SIEFs, such as a high joining fees, non-uniform rules of consortium, penalties for late joining, annual maintenance fees, cost of acceptance letter, and high fees for lead registrants.

The representative sought clarification as to the rationale for registration of the entire tonnage of substances in an article, even if less than 100 per cent of the substance was to be released. He explained that this increased the tonnage ban for registration, and imposed a higher burden on the registrant. Further, he underscored that the definition of SMEs, for the purpose of lower registration costs, was flawed. The definition covered both annual turnover and number of employees, which classified Indian SMEs in the large enterprise category, and increased their registration fee. Additionally, he noted that no special and differential treatment was provided with regard to the cost of sharing data. He also expressed concerns on the prohibition of new animal testing, which made the cost prohibitive, and increased the financial burden for SME registrants. Finally, he expressed concerns over the high costs of sharing data in SIEFs and presented a rationale for encouraging computer simulation of chemical testing, and suggested that the European Union explore this option.

The representative of Japan voiced two main concerns. First, he raised Japan's concerns with the implementation of REACH, including the interpretation of 0.1 per cent threshold. He said that the calculation for the threshold value for substances of very high concern (SVHC) was made based on the whole product, including the assembled product. However, he noted that some EU member states had proposed to amend the interpretation of the article to calculate by parts, such as nuts and bolts, and that discussion was reportedly on-going on the subject.

He commented that the Japanese government recognised that the issue had already been legally judged and that the present interpretation was to be implemented, however, his delegation was still concerned that the opaque action to amend the interpretation without amending the law, a mere three months prior to the implementation, would impact importers as a non-tariff barrier. Additionally, he expressed concerns about inconsistent interpretation within the European Union, which could lead to individual EU members exercising their discretion in stopping importation. He also indicated that the Japanese government had written to the European Chemicals Agency (ECHA) on 21 February 2011, highlighting these concerns and urging the European Union to clarify and implement the current policy with coherence, and ensure that individual EU member states were consistent in implementing the policy.

The representative next raised concerns related to the enforcement of REACH. He explained that the Japanese government had learnt that large-scale inspection had been put in place to

ensure compliance with REACH in the European Union. As part of this inspection, he reported that EU inspectors had in some cases been demanding more information than legally requested. He urged the European Commission and the ECHA to ensure appropriate enforcement of REACH, and to ensure that inspectors did not demand more information than legally requested.

The representative of the United States said that his delegation shared the EU's concerns over the protection of human health and the environment. However, he drew attention to the fact that the European Union had never addressed the trade-related concerns raised by REACH and its implementation. He cited concerns with supply chain impacts, the only representative issue, and the monomers and polymers issue, which had been previously raised at this meeting and past meetings. He was also concerned with different interpretations of the 0.1 per cent threshold for the notification and communication of substances on the candidate list to downstream users. There was a lack of clarity on the subject, and he noted the difference of opinion between the Commission and certain EU member states as to whether the threshold applied to an entire product, or to its individual components. He requested updates and clarification from the European Union, and said that his delegation would continue to closely monitor the implementation of REACH.

The representative of Australia strongly reiterated concerns with REACH, and voiced Australia's support for the concerns raised by other Members on the subject. He referred Members to the minutes of previous meetings for further information on Australia's concerns.

The representative of Cuba highlighted concerns already voiced in previous meetings with reference to the technical progress undertaken by the European Union, in particular, regarding the classification, labelling, and packaging of substances and compounds. He also expressed disagreement with the European Union's reclassification of Nickel compounds, which he noted, was based on an inadequate method and insufficient scientific data. This put the reclassification at the risk of being erroneous, and also undermined the need for a measure adopted in compliance with the TBT Agreement. He also noted that while the European Union had affirmed that the repercussions of the restrictions would be limited only to Nickel compounds, Cuba had observed that they had resulted in strict and expensive prescriptions and had increased costs of transportation and storage. He also noted that stigmatizing of Nickel could reduce its global demand and lead to losses for nickel-using industries. Additionally, he commented that classifications and restrictions of such nature could have repercussions for developing countries such as Cuba, dependent on income derived from Nickel. He hoped that the European Union would act transparently and focus on available scientific information when examining the impact of Nickel on human health, and when making the relevant classifications.

The representatives of the Philippines, Thailand and the Bolivarian Republic of Venezuela reiterated their previously raised concerns with the REACH regulation, as well as the concerns raised by other Members.

The representative of the European Union announced that REACH had passed another significant milestone with reference to implementation, since the deadline for registrations for certain classified phase-in substances, and for substances manufactured or imported in quantities of a thousand tonnes or more annually, had recently passed (30 November 2010). She informed Members that registration had gone smoothly, and that no major problems had emerged in the process. She stated that 24,675 registration dossiers had been received by 30 November 2010, covering a total of 4,300 substances, which had been in line with the volume expected. She also said that to date approximately 86 per cent of registrations had come from large companies and 14 per cent from small and medium enterprises, and 19 per cent of registrations had been made by "Only representatives". She explained that the numbers highlighted that, contrary to comments made by Members at meetings of the TBT Committee, the registration process was not overly complex or burdensome, that the SIEFs were functioning and that SMEs and non-European companies had been able to submit their registrations. Additionally, she noted that

work by ECHA in the evaluation phase had proceeded well. She reported that by the beginning of March, registration numbers had been granted for 20,175 dossiers submitted by the deadline, resulting in a total of 3,483 phase-in substances registered.

The representative noted that the European Commission and the ECHA continued to make all possible efforts to help industry to make the SIEFs function. She recalled that her delegation had several times elaborated on the efforts being made. She stated that there were no issues with regard to the participation of non-European registrants in the SIEFs, as implied by Canada, since they could participate through the appointed "Only Representative". With regard to the question raised by India on consortia activities in SIEFs, she noted that the European Union had previously replied to the question. She reminded the Committee that REACH did not regulate the formation of consortia, and that such activities were entirely voluntary and in the hands of industry. However, relevant work that had been developed in a consortium was part of the information that were to be exchanged in the SIEF and was therefore accessible to all registrants for the same substance, even if they did not participate in the consortium.

In response to the question of cost sharing in SIEFs, she again noted that REACH had left the costs sharing to industry. She explained that in a situation where no agreement was reached between participants, REACH foresaw that costs would be shared equally., Article 30 of REACH also obliged participants to share cost in a fair, transparent and non-discriminatory manner. The representative said that she did not understand China's reference to certain amounts with regard to specific substances, but that she was willing to follow up in the bilateral meeting the next day.

Responding to Canada's question on genetically modified oils and the Annex V guidance document on exemptions, she said that there were no plans to up-date this guidance document immediately, but that Canada was aware of the European Commission's position in this regard and that there had been no changes on that front.

With respect to India’s question on monomers and polymers, she referred to the minutes of the previous TBT Committee meeting for her delegation’s responses. She informed the Committee that the guidance on monomers and polymers was being updated with reference to the calculation of the reacted and non-reacted polymer, as well as the chemical safety assessment.

On the issue of the 0.1 per cent threshold for articles, raised by Japan and the United States, she said that the official position of the European Commission could be found in the guidance document. The substance concentration threshold of 0,1% applied to the article as produced or imported and not to homogeneous materials or parts of an article. She agreed that certain EU member states had expressed a different view on the subject, and referred to her explanations in past TBT Committee meetings to note that in case of such an event, it was up to the European Court of Justice to make a final decision, which would be the final interpretation on the subject.

In response to India's question on the rationale of the one-tonnage criteria for registration of substances in an article, she clarified that this criteria was consistent with the requirements of the registration of substances, and that it focused on the presence of certain substance in the article, and not on the quantity released from the article, in order to ensure coherence with registration of the substances. She also responded to India's question on animal testing and the possibility of conducting computer testing. She explained that the EU aimed to balance animal welfare concerns with the obligation to pursue research for the benefit of human being, animals and the environment and underscored the pragmatism of the approach of the European Union that aimed to reduce animal testing by introducing alternative measures that could eventually replace animal testing. With reference to computer testing, she explained that the European Union had a programme supporting projects on alternative testing strategies, for example, computational modelling and estimation techniques, bioinformatics and computational biology, cell based technologies and integrated testing strategies.

On question of diverging enforcement in different member states, she explained that the enforcement of REACH laid indeed within the competence of EU Member States. She asked Japan to provide more precise information on cases when information had been requested that could not have been legally requested under REACH. She assured that if examples were provided the European Commission could further assess the issues and discuss it with member states if necessary.

On the intervention from Cuba, she noted that it was focused mainly on the classification of nickel compounds and borates through the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (ATPs and CLP) and was not directly relevant to REACH. However, in relation to nickel compounds and borates she informed the Committee that the revision of Annex XVII of REACH was still being discussed and that any changes to the proposed text would be re-notified.

Finally, on the comments from Argentina on technical assistance, she noted that her delegation had previously replied to this query on several occasions, but highlighted that a series of training sessions and 16 webinars were provided in 2010 by the ECHA, which were accessible via the internet and attracted over 10,000 participants. She invited experts to participate in similar seminars offered in the future. She also reminded Members that the ECHA help desk was available to provide responses to concrete requests from industry. Finally, she said that her colleagues had met Argentina's representatives some days ago in Brussels, and that detailed explanations had been provided to the specific questions from Argentina at this occasion.

Japão 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, Add.1 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, Add.1 and G/TBT/Notif.00/310, Corr.1)

The representative of Japan highlighted the difference between G/TBT/N/EEC/247, the proposal for the directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment – RoHS – and the text that had been recently adopted in November 2010. He noted that these differences would have a dramatic impact on countries outside the European Union, citing the example of additional restricted substances. He therefore recommended that the European Union re-notify the latest text.

He also made additional comments on the RoHS recast. First, he expressed concern with procedures to review exemptions under the RoHS recast, within Section 2 of Article 5 and Annex III. He said that the RoHS recast defined the exemptions in Annex III to cover all categories. However, he noted that the applicable terms differ between categories and that the maximum terms of validity were also different in different categories. This, he said, meant that reviews for different categories would take place at different times, and he expressed concern about adverse impact of such a measure. He further explained that the first review of Annex III for categories 1 to 7 and 10 on the list, was scheduled to occur in five years. At the same time, for categories 8, 9 and 11, application would begin in three to six years, while the review of Annex II was scheduled to occur within a maximum of seven years from the start of the application of the directive. He noted, therefore, that the timing of review for categories 1 to 7

and 10 could differ from that for categories 8, 9 and 11; and, that the result for the first review for categories 1 to 7 and 10 could adversely impact the review for categories 8, 9 and 11.

Second, he expressed concern regarding additional restricted substances included in the RoHS recast. He requested the European Union take account of Article 2.1 of the TBT Agreement while considering the assessment of additional restricted substances in the RoHS recast, to ensure fairness for economies outside the European Union. He also noted that a review to add restricted substances to the six substances already on the list would be held three years after the directive came into force. He emphasized that if the review were to lead to additional substances being included the restricted list, exemptions should be provided for substances for which reliable alternative technologies could not easily be found, or for which moving to alternatives would impose negative social and economic impacts.

Moreover, he underscored the necessity of public consultation within and outside the European Union in order to conduct risk and impact assessment regarding waste, recycling, and reuse, for implementation of revised regulations. Lastly, he highlighted the need for allowing sufficient time when putting new regulations into place.

The representative of the European Union provided an update on the status of the recast of the RoHS directive. She confirmed, as stated by the representative of Japan, that the first reading of the European Commission proposal had been adopted on 24 November 2010. She explained that this document had been notified as G/TBT/N/EEC/247/Add.1, on 18 March 2011. She explained that the European Parliament, Council and Commission had cooperated to achieve the first reading agreement on the draft directive. She also said that, following the Parliament's vote on it in the plenary in November 2010, the draft Directive was currently with the Council. Formal adoption by the Council was expected within a short period of time, and the Commission was also in agreement. As a result, the new directive, she said, was expected to enter in force as early as May 2011.

On the subject of the European Parliament's first reading position, she noted that the most significant change had been with regard to the introduction of an open scope to the RoHS, i.e. extending coverage to all electrical and electronic equipment with specific exclusions. In return, if adopted in its current form, the directive would grant a transitional period of eight years after entry into force for products not covered by the old Directive. Additionally, she noted that the list of exclusions from the new scope had been extended significantly, to include, *inter alia*, large-scale stationary industrial tools or fixed installations, means of transportation, certain machinery, active implantable medical devices, and photovoltaic panels.

She also highlighted that the maximum validity period of exemptions from the substance restrictions had been extended from four to five years, with seven years for medical devices and monitoring and control instruments. She explained that exemptions would be decided on a case-by-case basis, and could be renewed. Finally, she also said that Annex III of the original Commission proposal, containing the list of priority substances that could be candidates for future restrictions, had been deleted from the Parliament's proposal. In return, a review mechanism for restricted substances had been developed in more detail. She said that such a review would have to be coherent with other chemicals legislations, in particular, REACH. She informed the Committee that the review would be carried out in consultation with interested parties, including economic operators, and would be based on, *inter alia*, scientific evidence, assessment of the socio-economic impacts, information on the availability and reliability of possible substitutes, and justification for the appropriateness of an EU-wide restriction.

UE, Japão e Coréia do Sul x India – 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 thanked India for the postponement of the entry into force of the order for an additional period of six months. She noted that in the previous TBT Committee meeting the European Union and Japan had expressed serious concerns with regard to the restrictions in the Agreement for the grant of BIS licence in that foreign holders of the licence were only allowed to use the BIS mark on tyres exported to India, and not on tyres exported to other countries. She also enquired if the same restriction applied to Indian producers. If not, she stated that the measure was discriminatory.

She explained that the current global practice was that tyres were marked with a number of different marks for different countries. Therefore, she noted, the result of the Indian requirements was that producers had to produce tyres with the BIS mark alone for the Indian market. This added significantly to the costs for foreign manufacturers, which had to produce special tyre moulds for the Indian market, in addition to reorganising stocks and logistics. She highlighted that on the other hand, Indian producers seemed to be allowed to use the same tyre mould for Indian markets, and for third country markets.

She expressed concern over the issue of royalty fees which were calculated based on the total number of tyres produced and marked with the BIS mark, and not based on the total number of BIS marked tyres which were *de facto* imported into India. The representative noted that if foreign manufacturers followed standard practice and marked all tyres with the BIS mark, it would increase the royalty fees to a level that would make exporting tyres to India unattractive. She also expressed disagreement with the Indian comment in the previous TBT Committee meeting that the measure would not restrict trade or exports to other markets. Indeed, she pointed out that the requirements in the regulations were discriminatory and went against the principles of international trade. She added that the requirements did not contribute to technical safety requirements and only had the impact of obliging manufacturers to produce tyres only for the Indian market, without any justification. She urged India to consider amending these requirements. She also expressed concerns over the low number (only two) of laboratories accepted by Indian authorities for the conformity assessment. She noted that India had not yet addressed this issue in its previous responses. The representative asked for clarifications on what India was doing to overcome the bottleneck of accepted laboratories, and if under the circumstances, India would accept tyres tested in international ILAC accredited laboratories.

She was also concerned that once the order came into force, the local technical Committee would have the power to select a list of tyres that would immediately fall within the requirements of the order as of the decision. She noted that the order did not provide a transition period with respect to the decision. Manufacturers of tyres would need to adapt their production very quickly, which did not appear to comply with the requirements of Article 2.12 of the TBT Agreement. She requested that India provided a transition period of at least 6 months for manufacturers to adapt.

Finally, the representative requested that India provided the response that they promised to the question of whether in-house testing facilities were a requirement for the BIS licence, posed by her delegation the last TBT Committee meeting. She urged India to clarify all issues before the order entered into force.

The representative of Japan raised five points. First, he noted that the Government of India had postponed the date of entry into force of the regulatory act by an additional 180 days to 540 days from the initial entry into force date of 19 November 2009. However, he noted that the number of tyres to be certified was increased resulting in the need for additional factories to be accredited, and the overall number of tyres tested.

He said that while interested companies were preparing to comply with the act and the requirement to test at laboratories designated by BIS, the BIS procedure was lengthy and included handling of the certification, and therefore, he requested a further postponement of 180 days, in line with what Japan had requested in the previous TBT Committee meeting. He also spoke on the activities subject to regulations.

Second, he highlighted that Article 3.1 of the official gazette dated November 2009 prohibited tyres without ISI certification marks from being manufactured, imported, stored for sale, sold or distributed. However, he noted that in terms of activities subject to regulations, there were significant delays between manufacturing and selling or distributing the tyres. He also underscored that several international regulations stipulated enforcement at the time of manufacture. He requested a review of that point and requested that if sale and distribution were subject to regulation, that a three-year lead-time from entry into force on a production basis be provided.

Third, he explained that the paragraph 6.3 that stipulated that tyres with an ISI mark could only be sold in India. However, he noted that India had clarified that the stipulation in the BIS Agreement did not bar exports to other markets. In such a circumstance, he requested that the provision of paragraph 6.3 be eliminated.

Fourth, he noted that paragraph 2 of the BIS Agreement on the use of BIS certification mark impose several charges such as the minimum marking fee, renewal application fees, annual licence fees, marking fees calculated on actual production marked, and any other fees as prescribed but in terms of number of kinds of fees. He commented that the fee was significant by international standards, in particular the fee based on tyre unit was unprecedented by any international measure, and he requested that it be eliminated. Furthermore, he requested a review of other fees, and that they be made equivalent to other countries' regulations.

Finally, he cited Provision 5, a quality control order of the Official Gazette issued on 9 November 2010. This provision enabled Indian authorities to demand information on manufacture, importation, storage for sale, sale or distribution, notwithstanding that such information included confidential business information and know-how, relating to quality management, logistics, and other related systems. Additionally, he noted that this provision could be unjustly used to demand excessive or unnecessary information. He therefore requested elimination of this provision.

The representative of Korea reiterated concerns over the aforementioned measure. He commended the extension of entry into force by the Indian Government. However, he noted difficulties faced by certain Korean tyre manufacturers with respect to delays in factory inspection and sample testing. It seemed impossible to obtain the BIS certification before 18 May 2011, and he once again urged India to accelerate the inspection and testing process. If not, he requested that a longer transition period be provided. The representative echoed the concerns of other Members regarding the prohibition on selling tyres with the ISI mark outside India, noting that it deterred foreign tyre manufacturers from entering Indian markets. Finally, he spoke on the subject of licence fees, and fees for renewal and marking, noting that they were significantly higher than those of other similar certifications, such as the E-mark. He requested that the Indian authorities modify the fee structures forthwith.

The representative of India recalled that the original notification on automotive tyres and tubes was made in July 2006, and that at the time, industry was well aware of the intention of the Government to institutionalise a certification system. He also said that the most recent notification dated November 2010 stipulated entry into force of the regulation in May 2011. He noted that this time period was over five years from the initial notification until entry into force, and therefore well longer then the time periods mandated by the TBT Agreement and the TBT Committee Decisions. He underscored that the provision in Article 3.1 merely endorsed the need for certification of all tyres that were manufactured, imported, stored for sale, sold, or distributed, and that such a clause was an accepted part of any regulation governing a certification system. He also noted that Article 6.3 of the BIS Agreement only stipulated that the ISI marking could only be used for exports of tyres to India, and was not trade-restrictive.

He also noted that the recommendation to allow exports of ISI-marked tyres to other countries was being considered by the BIS. Further, he commented that the marking fee charged was equitable in terms of unit cost of tyres for both domestic and foreign manufacturers. He also emphasized that India was not a signatory to the 1958 UNECE Agreement, and India was therefore not bound to follow all regulations of the UNECE on the automotive sector. Furthermore, he highlighted that the 1958 UNECE was not a relevant international standard setting body since it did not comply with the principles of the 2000 TBT Committee decision. However, he noted that several parameters of the UNECE standards had nevertheless been incorporated into the proposed regulations. Additionally, he explained that the regulations complied with several parameters of the ISO standard, including the tread wear indicator test, the tyre strength test, endurance test, BIT unseating resistance test, among others. Finally, he said that the difference in climatic conditions, geographical terrain and road conditions necessitated the use of domestic standards in India, creating a need for additional tests such as plunger and high-speed tests.

Canadá, Austrália, Turquia, Filipinas, República Dominicana, Cuba e Venezuela 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.1-3, 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.1-3, Add.1/Corr.1)

The representative of Canada reiterated strong concerns with the European Union's classification of substances containing nickel. He understood that the European Court of Justice would soon issue an opinion on the classification of nickel substances, and expressed continued concern on the need for transparency and sound scientific basis for the classification, given the potential to negatively impact nickel producers. He urged the European Union to ensure that the classification did not pose an unnecessary obstacle to trade.

The representative of Australia expressed continued concerns with the European Union's decision to reclassify nickel compounds, and noted that concerns of other Members had also remained unaddressed. He strongly reiterated previously expressed interventions by Australia, and referred to the formal minutes of the TBT Committee for additional information.

The representative of Turkey reiterated her delegation's concerns over 30th and 31st ATP of the regulation of classification, labelling and packaging of substances and mixtures. However, she refrained from repeating Turkey's previous comments, and instead referred to the minutes of

previous meetings. She voiced expectations that the European Union would have noted those concerns and amend the regulation accordingly.

The representative of Philippines also expressed support for the concerns raised by the other delegations on the subject and reiterated concerns raised by the Philippines in past meetings of the Committee. The representative of Thailand also voiced support for the concerns raised by other Members on nickel classification, and requested the European Union to ensure that the reclassification was based on solid scientific findings

The representative of the Dominican Republic also reiterated concerns of the Dominican Republic on the issues of reclassification of nickel containing substances. She voiced two objections on the manner in which the European Union had implemented the methodology for the classification of nickel substances, and noted that she wished to repeat what Turkey had already highlighted in previous meetings in 2008, 2009, and 2010. She urged the European Union to reconsider its position on the subject.

The representatives of Cuba and the Bolivarian Republic of Venezuela reiterated concerns that had already been voiced in previous meetings, and had been expressed by previous speakers.

The representative of the European Union informed the Committee that she had no new information beyond what had already been provided in previous meetings. She referred to the numerous lengthy responses provided by the European Union in previous meetings, which were incorporated into the minutes of those meetings. She did, however, address the issue raised by Turkey at the previous Committee meeting regarding a study carried out in China in a Boron mine. She thanked Turkey for submitting the survey to the European Union and confirmed its receipt. She also informed Members that as per the procedures of the CLP regulation, any changes made to the classification of substances could only be made if the proposal was submitted by a Member State to the ECHA. Therefore, she explained that any interested delegation or industry that sought changes to specific classifications would have to submit a dossier to an EU Member State to trigger submission of a proposal to ECHA. She also clarified that thus far, they had not received any such request from a third country or industry.

Nova Zelândia 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 of New Zealand reiterated on-going concerns with the Canadian compositional requirements for cheese. As stated in previous meetings, her delegation believed that the requirements were inconsistent with the relevant international standard (Codex Alimentarius). She requested an update from Canada on the developments in the domestic court proceedings and domestic industry lobbies in this respect.

The representative of Australia supported New Zealand's concerns on the aforementioned Canadian regulations. He reiterated Australian broad concerns with the measure, and noted that this delegation shared the concerned previously raised by New Zealand on access to milk proteins. He also sought updates on the appeal process in the Federal Court in Canada.

The representative of Canada noted that previously received comments had been taken into account. He explained that thus far, imported cheeses had been found to be in compliance with Canadian standards. On the subject of the judicial process in Canada, he noted that in previous meetings Canada had informed the Committee that the original review was held in April and March 2009, and that the Federal Court had dismissed the application for judicial review in

October 2009. The decision however was appealed, and most recently, the appeal was heard on 9 February 2011, and the Federal Court of Appeal once again ruled that the appeal be dismissed on 28 February 2011. Thus, the judicial review process was concluded. He also responded to the question previously raised by New Zealand, and explained that no regulatory processes had been initiated to establish standards for any other dairy products.

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 previously raised concerns on the Indian order establishing a registration procedure for imported cosmetic products, notified under G/TBT/N/IND/33, and expected to enter into force on 1 April 2011. Her delegation remained of the view that a notification system, instead of a registration or authorisation system, was a less trade restrictive measure to ensure consumer safety. More importantly, she questioned the grounds of the validity period of the Cosmetics Registration Certificates and import licences; those for foreign manufacturers lasted three years, whereas those for Indian manufacturers lasted five years. She also asked the Indian Government to confirm that in this regard, the validity period of foreign manufacturers would be increased by two years, so to be aligned with the rules and conditions that applied to Indian cosmetic manufacturers.

In the event that India chose to continue with its current procedure, she requested that India ensure that the registration certificates would be issued within a maximum period of two months, and that the tests conducted in the country of origin attesting compliance with international cosmetic standards would be accepted.

The representative of India confirmed that this measure had first been published as a notification dated 19 May 2010, and that a subsequent amendment dated 19 June 2010 would bring the rules into effect from 1 April 2011. Therefore, he noted that a reasonable interval between publication and entry into force had been provided. He also said that that notification was based purely on public health concerns of consumers. He emphasized that the provisions of the amendment did not discriminate between foreign and domestic manufacturers. A system of registration of imports of drugs had been in place since 2003, and the draft rules pertaining to the registration of cosmetics had been published in document GSR/63/E dated 2 February 2007. He said that copies of the rules had been circulated to the TBT Committee for comments, and that concerns of both the European Union and the United States had been taken into consideration prior to finalising the amendment. In this regard, he confirmed that the clause that had then been objected to, regarding the inspection or visit of manufacturer premises by the licensing authority of India, or by any authority that had been delegated the power to do so, had been deleted.

UE e Japão x Colômbia – Draft Decree Establishing Provisions to Promote the Use of Biofuels (G/TBT/N/COL/96 and Adds.1-4 and Add.4/Rev.1)

Colombia – Draft Decree Establishing Provisions to Promote the Use of Biofuels (G/TBT/N/COL/96 and Adds.1-4 and Add.4/Rev.1)

The representative of the European Union acknowledged the Colombian notification of 7 January 2011 of the draft amendments to the Colombian legislations of 2007 and 2009 on the use of alcohol fuels in petrol-fuelled motor vehicles. She noted that the draft required all vehicles to use, as of 1 January 2012, ethanol blends within a range of E8 to E12. Furthermore,

the draft required that as of 1 January 2015, conventional vehicles would use E10 to E20 fuels, while flex-fuel vehicles would use E25 to E85 fuels.

She said that the European Union welcomed the proposed revision and the fact that the mandatory shares of bioethanol, as well as the timelines, had been made more flexible. She expressed appreciation for Colombia's quick written reply of 18 March 2011 to her delegation's written comments and for Colombia's explanations about the assessments that had been made on the feasibility of the use of different ranges of ethanol fuels.

However, the representative expressed continued concern over the fact that not all the required ethanol blends would be available in Colombia as of 1 January 2012, or perhaps would not be available in the whole territory. She referred to the European Union's written comments, reiterating that the standard range used worldwide, including in the European Union, was E10. She said that as a result, with the exception of flexifuel vehicles, engines capable of coping with blends greater than E10 had not been developed to date. Finally, she requested information as to how the availability of all ranges of ethanol blends in the draft would be ensured.

The representative of Japan expressed his support for the EU position, and said that given that the development of automotive technologies required time, Colombia's proposed regulations on the use of biofuels did not provide adequate transition time. He underscored that a majority of vehicles on Colombian roads could only adapt to E10 grade of fuel in regular-grade and premium gasoline, and those vehicles would continue to run on Colombian roads even post 1 January. Additionally, he noted that vehicles, which were not technically compatible with the regulatory provisions, would continue to be supplied to the Colombian market post 1 January 2012. He said that it was therefore necessary to ensure that vehicles that adapted only up to E10 fuel would not be excluded from the Colombian market. He expressed concern that the new regulations would place severe limitations on the automobile industry, as well as jeopardise the interests of Colombian consumers.

He requested that the Colombian government ease the E8-E12 regulation to a maximum of E10 and guarantee the continued supply of E10 gasoline to the Colombian nationwide market after 1 January 2015. He also requested that the Colombian government implement measures that were necessary to ensure that users of vehicles did not mistakenly refuel their vehicles with gasoline with which their vehicles could not adapt. Finally, he requested that the Colombian government take into account concerns raised and reiterated by the Japanese auto-industry while formulating the new regulations.

The representative of Colombia acknowledged the concerns raised by Japan and the European Union, and confirmed that they had been passed on to the Ministry of Energy, which was the body responsible for this regulation. He also confirmed that responses to queries had been passed on to Japan and the European Union. Given that the responses had only recently been provided, his delegation was willing to further engage in bilateral meetings with interested Members. Finally, he reiterated that the measure was under revision by various entities in the country.

China x EUA – Consumer Product Safety Improvement Act (G/TBT/N/USA/421 and Add.1)

United States – Consumer Product Safety Improvement Act (G/TBT/N/USA/421 and Add.1)

The representative of China reiterated his delegation's serious concerns over the US Consumer Product Safety Improvement Act (CPSIA). He expressed appreciation for the clarification

provided by the United States on some issues of the CPSIA and information provided on the Consumer Product Safety Commission (CPSC) website. However, he noted that China's concerns had not been adequately addressed. First, he understood that the CPSC would solicit comments from the public as to the scheduled August 2011 reduction of the maximum lead content in children's products from 300ppm to 100ppm. China agreed with purpose of the legislation, namely the protection of children's health, which was a common practice among Members, including in China. However, he reminded the United States that technical regulations should not be made more trade restrictive than necessary to ensure compliance with the TBT Agreement. He shared the opinion of Chinese industry that the new limit was unscientific and inappropriate in the TBT context, since only soluble lead could actually harm children's health. He therefore recommended that the United States make a distinction between soluble lead and insoluble lead while setting new limits.

The representative underscored the need to base more stringent limits on scientific evidence to avoid unnecessary barriers to trade. In addition, he requested a longer transitional period in accordance with the special and differential treatment principle of the TBT Agreement, since toys were mainly produced in developing countries. He also expressed an outstanding concern with regard to the discriminatory treatment against China Inspection and Quarantine (CIQ) laboratories. He first noted that all five stipulations for governmental laboratories in CPSIA were irrelevant to the technical contents of laboratories, and were therefore inappropriate. Second, he commented that Chinese CIQ laboratories were run by independent legal persons who conducted testing and inspection work impartially within the legal framework of China. Third, he noted that the majority of China's laboratories were also accredited according to the ISO/IEC 17025 standards, which fulfilled the criteria of the third party common assessment body within the meaning of CPSIA.

Furthermore, he responded to the US argument that CIQ laboratories enjoyed preferential treatment in comparison to other laboratories, which he characterized as incorrect. In reality, he said that CIQ laboratories only issue test reports within their competencies, and had no right to issue safety and quality export permits. He expressed hope that the United States would remedy the misunderstanding and take concrete steps to allow CIQ laboratories to function in good faith. He also said that China was looking forward to further bilateral discussions with the United States on the subject.

The representative of the United States suggested that China submit comments on the issues raised with respect to the outstanding concerns on the recognition of Government laboratories. He referred to the response of the United States in the previous meeting stating that the CPSC had already recognised at least 14 government joint venture laboratories in China. He also mentioned that US regulators had been in regular discussions with the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) on the issue of CIQ laboratories and had already explained the position of the United States on the subject. He agreed that there were disagreements on the facts, but that the issue was subject to continued discussions between CPSC and AQSIQ. Finally, he noted that since the last meeting, the CPSIA had recognised an additional 20 laboratories based in China, which led to a total of 96 recognized laboratories based in China. On the other hand, he noted that China does not recognise any US conformity assessment bodies.

EUA, Coréia do Sul, 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 the United States expressed serious concerns regarding the EU's accreditation framework set out in Regulation 765/2008. He was concerned that the measure would leave recognition of non-EU accreditation bodies that are signatories to ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum) to the discretion of Member States. The representative reiterated concerns with statements from the European Cooperation for Accreditation (EA) as to potential actions in this matter. He hoped for a resolution to ongoing discussions between EA, ILAC and IAF concerning consistency of Regulation 765/2008 with IAF-ILAC requirements, and again urged the European Union to provide clear written guidance as part of these discussions – clarifying that the measure would not impact recognition of non-EU accreditation bodies, as the European Union had stated in previous TBT Committee meetings.

The representative of Korea shared the concerns of the United States regarding the possible impact of the measure on recognition of non-EU accreditation bodies under the ILAC/MRA (Mutual Recognition Agreements) and the IAF/MLA (Multilateral Recognition Arrangements). He also expressed concerns about acceptance of conformity assessment tests performed by ILAC and IAF member labs accredited by non-EU accreditation bodies. He invited the European Union to ensure consistency with ILAC/MRA and IAF/MLA, and to provide updates on the Regulation.

The representative of Australia reiterated previous interventions on this issue, including with regard to the recognition of conformity assessment procedures from third parties.

The representative of Thailand marked her delegation's concern with the measure.

The representative of the European Union referred to responses in previous Minutes as these concerns essentially reiterated those that had been previously raised. He noted that his delegation had held a detailed bilateral exchange with Korea on this issue, and he hoped that this had met their requirements.

He informed the Committee of the most significant recent developments regarding the implementation of the European accreditation framework: firstly, on the relationship between the EA and ILAC and IAF, he informed that ILAC and IAF were in the process of peer-evaluating EA. Secondly, with regard to the activities carried out by EA, he clarified that one of its main tasks, as the official European accreditation infrastructure, is to harmonize accreditation practices across the European Union. Current priorities for the EA were therefore the training of lead assessors in peer-evaluations, and enhancing the competence of assessors in each regulated sector. He added that this required a great deal of coordination between, on the one hand, the EA and EU Member States' accreditation bodies and, on the other hand, the Member State authorities competent for the designation of Notified Bodies and for the application of related product legislation. The representative highlighted the importance of accreditation bodies being in tune with market realities, in order to be able to assess the competence of conformity assessment bodies to analyze specific products against EU regulatory requirements. He noted that EA has been developing a number of policies, and encouraged interested delegations to consult EA's website (www.european-accreditation.org) to access guidance documents establishing its policy in its various fields of activity. He concluded with an invitation for further clarification through bilateral channels if necessary.

México, Turquia, Honduras, República Dominicana, Jordânia, Cuba, Colômbia, Chile, Equador e Filipinas x Canadá - Bill C-32 amendment to Tobacco Act

Canada – Bill C-32 amendment to Tobacco Act

The representative of Mexico noted that a bilateral consultation with Canada had taken place, that Mexico intended to continue addressing its concerns regarding this Bill, and would therefore pursue additional bilateral consultations.

The representative of Turkey restated concerns expressed at the last Committee meeting, supporting the Bill's objective, but believing it to be more trade-restrictive than necessary. She explained that the restriction on the use of certain additives in effect banned certain types of cigarettes, as these additives are essential components of traditional tobacco blends. She argued that these additives do not give any characterizing flavours to tobacco products and that the decision had been taken without consideration of their effects. She added that blended and non-blended tobacco were like products, and any restriction on additives would constitute *de facto* prohibition of blended tobacco.

She said that no scientific evidence supports either the suggestion that additives used in blended tobacco were attractive to consumers, or the view that blended tobacco products were more harmful to health and more addictive. She viewed the measure as disproportionate, and hoped that the Canadian authorities would reconsider their decision and move towards a less-restrictive measure in accordance with TBT commitments.

The representative of Honduras shared concerns of other Members, citing Canada's obligations under the TBT Agreement and the impact that this measure has had on Honduran tobacco exports to Canada. Though accepting the legitimacy of the policy objective, she argued that the goal had been pursued through an overly restrictive measure. She asked how the special needs of Honduras were addressed within the framework of Article 12.3 of the TBT Agreement when preparing and applying the prohibition on additives, and how the measure was compatible with Article 20 of TRIPS – the use of a trademark within the framework of commercial operations with specific demands, such as the use of an example that would undermine the capacity to distinguish between the goods and services of one company and another.

The representative of the Dominican Republic reiterated earlier interventions, again voicing concern over the adoption of this measure, which effectively prohibited the manufacture and sale of traditional blend cigarettes. She appreciated the legitimacy of the aim but shared the view that the application was too broad and disproportionate, given the coverage of the preparation of products with a special flavour. She argued that many components are used in producing the three main types of tobacco, and that prohibition resulting from the Bill had significant impact given the use of blends of tobaccos to provide different flavours. She repeated her previous request for Canada to revise its law in compliance with the framework of the TBT Agreement.

The representative of Jordan restated comments from previous meetings, supporting Canada's objective of protecting health but questioning the existence of scientific evidence supporting the ban on the additives listed in the Bill. He also argued that no scientific evidence indicated that additives used in the production of tobacco made the product more attractive than other types of cigarettes. He viewed the measure as inconsistent with Canada's obligations under the TBT Agreement.

The representative of Cuba shared the concerns raised in the preceding interventions. He considered the Canadian measures to lack scientific basis, as some banned components did not contribute any characteristic flavour to cigarettes. He explained that Cuba considered the measure to be overly restrictive for the stated objective and hoped for a re-evaluation that would ultimately result in a less restrictive measure. He argued that the measure should not be based design characteristics, and pointed to measures adopted by Members that prohibited different highly aromatised products as examples in line with Article 2.8 of the TBT Agreement.

The representative of Colombia reiterated its position on the issue, particularly the need to discuss these measures in relevant and specialised fora, and avoid discriminatory measures defending a type of tobacco produced by a country.

The representative of Chile supported the aim of reducing tobacco consumption and protecting the health of young people, but underlined concerns that the measure was more restrictive than necessary. She suggested the various guidelines of the World Health Organization (WHO) to be worthy of consideration, underscoring the necessity of scientific evidence. Furthermore, she noted that the Canadian measure concerned only one type of tobacco (Burley tobacco), placing it at a clear disadvantage compared with Virginia tobacco. She sought clarification of Canada's intentions regarding the measure, as it was not notified to the TBT Committee, specifically if a revision or modification of the Bill was planned, as Members did not have the opportunity to comment prior to its application.

The representative of Ecuador restated previous systemic and commercial concerns regarding the measure, in particular that it constituted a *de facto* prohibition of the import and commercialization of Burley tobacco cigarettes. He stated that the measure was more restrictive than necessary and undermined Articles 2.2 and 2.8 of the TBT Agreement.

The representative of the Philippines reiterated previous concerns on the measure.

The representative of Canada explained that C-32 had been Canadian law since coming into effect on 5 July 2010. No modifications were planned, but the concerns expressed by Members at all TBT Committee meetings had been noted. In response to questions, he observed that a number of questions had been answered in previous sessions and referred to the minutes of previous meetings for elaboration upon Canada's views on the scientific basis of the Bill and why it offered the best solution to the stated public health objective. He explained that the intent of this legislation had been to ban the use of certain additives which contribute to making tobacco products more attractive to youth. He noted that he was unaware of any cigarette brands having been withdrawn from the market as a result of the measure since the last provision of this amended Act came into force, and no Members had raised specific concerns regarding bilateral trade.

He emphasised that the Act prohibited the use of certain additives which contributed to making products more attractive to youth regardless of their origin and did not ban any type of tobacco or tobacco product. He informed the Committee that Canada had met with a number of Members bilaterally during the past week, and over several preceding months; he offered to continue to do so and invited communications on any specific concerns.

UE, EUA, México, Austrália, Canadá, Nova Zelândia e Chile 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 for the European Union referred to the Minutes of the previous meeting and to the European Union's written comments on Thailand's notification. She requested an update of the review of requirements announced in October 2010, which Thailand had stated would take account of concerns raised by WTO Members in writing and in past TBT Committee meetings. She also asked for details on when this review would be notified to the TBT Committee, and when the European Union could expect a reply to its comments of March 2010.

The representative of the United States raised previously-aired concerns, including the scientific basis for the text of the alcohol warning requirements, the size of the warning label in

proportion to the bottle, the requirement to rotate the warning statements every 1000 bottles and the proposed implementation period. He hoped that the concerns which were set out in US comments, as well as in responses to Thailand's supporting study were being taken into account, and noted that the United States had requested an update from Thailand.

The representatives of Mexico, Australia, Canada, New Zealand, and Chile, shared concerns raised by previous speakers, and sought an update on the review process, including when updated measures would be notified to the TBT Committee.

The representative of Thailand informed the Committee that the Thai Ministry of Public Health had set up a sub-committee assigned to study the impact of its regulations on alcohol beverages. The sub-committee had yet to start its work, but the scope of the study included the regulation on health warnings notified under G/TBT/N/THA/332, and she said her delegation would keep the Committee updated on developments.

UE, Japão, China e Coréia do Sul x Estados Unidos – 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 the European Union reiterated concerns on the proposed requirements on the transport of lithium batteries in the Hazardous Materials Regulations as far as they went beyond United Nations Recommendations on the transport of Dangerous Goods and the Technical Instructions on the Safe Transport of Dangerous Goods of the International Civil Aviation Organization (ICAO). She referred to the minutes of relevant Committee meetings in 2010 for more information on these points, and requested information on the state of play, as discussions on this proposal appeared to be ongoing.

The representative of Japan expressed concerns over restrictions on transportation of lithium batteries from the US, arguing that inconsistency with United Nations recommendations on transport of dangerous goods and ICAO Technical Instructions would impact upon trade. In addition, he stated that there should be no regulations targeting goods assured of safe transport. He anticipated that the final ruling was imminent, and asked the United States to give full consideration to the opposing views expressed by many governments and private enterprises. He asked that in terms of safety, lithium ion batteries with low State of Charge (SOC) should be exempted. Finally, he noted that the United States Department of Transport website stated that the effect of the regulation would be significant, and hence he sought detailed information about the foreseen dates of notification to the TBT Committee.

The representative of China understood that the primary goal of the regulation was to ensure the safety of flights carrying lithium batteries, and argued that the current United Nations regulation has proved, globally, to be effective enough to ensure flight safety in recent years – thus rendering the formulation of stricter regulations unnecessary.

The representative of Korea explained that concerns over the lithium battery regulation had been expressed in bilateral meetings with the United States, including a delegation to the United States to meet Office of Management and Budget (OMB) officials and raise the issue of lithium batteries. He noted that no update on the progress of the regulation had been received and advised the United States to follow the UN recommendation and ICAO regulation.

The representative of the United States explained that discussions with the regulator and OMB were on-going. He noted that a bilateral meeting with Japan, similar to the aforementioned with

Korea, had taken place since inviting interested Members to engage bilaterally. He added that there was as yet no timetable for the publication of the final regulation, and to his knowledge, no new proposed regulations in this area had been made. When, or if, there were new proposed regulations that would be potential TBT measures, he assured the Committee that they would be notified.

Addressing the issue of ICAO and UNECE standards, he argued that this issue should never have come before the TBT Committee, and should have been dealt with in ICAO and UNECE. In his opinion, the fact that these bodies were not following the TBT Committee decision principles for developing international standards had caused the problem facing the Members. He elaborated upon the functioning of these organisations, stating that developing countries were largely excluded from participating in development processes, decisions were not based on consensus since the EU Member States constituted a voting majority and came to a position ahead of meetings, which effectively excluded the views of others. He suggested that if these two bodies were following the TBT Committee decision principles, it would be more likely that our regulators, and their experts in batteries and aircraft safety, would have been able to reach a sufficient resolution in their technical committees, and this issue would not have reached the TBT Committee. He reasoned that not adhering to the Committee Decision principles caused many issues for the Committee and following its principles could help ensure that consensus standards would be developed in these bodies and more likely to be used by all parties concerned. He hoped that this experience would lead ICAO and UNECE to review their principles for standards development, and to make changes to reduce the likelihood of similar occurrences in future.

UE e EUA x Turquia – New Conformity Assessment Procedures for Pharmaceuticals

Turkey – New Conformity Assessment Procedures for Pharmaceuticals

The representative of the European Union restated concerns with regard to Turkey's Good Manufacturing Practices requirements for pharmaceuticals, which entered into force on 1 March 2010. She reiterated that in order to obtain an EU Good Manufacturing Practice (GMP) certificate, EU manufacturers were already inspected by the competent authorities in EU member states to verify compliance with good manufacturing practices. She said that Turkey had yet to offer any indication as to whether any problems had been encountered with EU GMP-certified products on its markets. In this context, she urged Turkey to revert to recognition of EU GMP standards and certificates without additional factory inspections and additional administrative requirements.

The representative of the United States expressed concerns similar to those raised in previous meetings on the lack of transparency in the development and implementation of this, and other measures, by Turkey. He explained that the United States was not against inspection requirements in principle, but the manner of implementation had caused significant market disruption, to the detriment of both US exporters and Turkish consumers. He urged the Government of Turkey to consider measures to alleviate the blockage of imports of pharmaceuticals, including processing registration files submitted prior to March 2010, giving priority to innovative drug applications that provided new therapies and allowing producers to submit an application while GMP inspections were pending. He hoped to hold further technical discussions with Turkey to discuss these issues and resolve concerns in the near term, restoring market access for pharmaceuticals.

The representative of Turkey stated that the general requirements for the manufacturing of pharmaceutical products were first introduced in 1984, and its Ministry of Health began

conducting GMP at the national level in 1995, and therefore Turkey had considerable experience in this field. She explained that the document required its licensing application for pharmaceutical products. She explained that the aim of the regulation was to protect human health through the provision of safe pharmaceutical products.

Citing the preamble of the TBT Agreement, she said that no country should be prevented from taking measures necessary to ensure the protection of human health. Given that pharmaceutical products are concerned with human health, and that the aim of this measure was the protection of public health, she argued that it was consistent with WTO rules and in accordance with the relevant guidelines and recommendations of the WHO. She added that Turkey's system did not envisage any restrictive effect of additional administrative burden for importers, and that its Ministry of Health had accepted and processed applications for GMP certificates. She informed the Committee that of the complete applications received, four had been processed and completed, and another five complete applications were in process.

Finally, the representative also explained that the Ministry of Health was developing a classification system for pharmaceuticals based on scientific criteria. Additionally, she urged Members to consider the option of an MRA, and said that Turkey remained willing to continue to communicate and work constructively with interested Members.

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 reiterated concerns on the Italian proposal on dairy products. She argued that it was inconsistent with relevant international standards and Codex, and that the stated objectives were already sufficiently covered by EU law. She requested an update on progress and asked for confirmation of the European Commission's opinion as to whether the proposed ban on protein would be consistent with EU law provided it applied to Italian products alone.

The representative of Australia shared New Zealand's concerns over this measure, particularly Article 5, which proposed a ban on the use of milk protein concentrate (MPC) in cheese making. He sought an explanation from the European Commission on the legitimate objective under which such a measure could be justified. He said that Australia was unaware of any scientific evidence of Chile using MPCs of insufficient nutritional value or in any non-compliant with food safety and public health requirements. He asked for an update on discussions between the European Commission and Italy on this measure.

The representative of the European Union informed the meeting that discussions between the European Commission and the Italian authorities on the proposed measure were ongoing, and therefore remained an internal procedure. She did offer further clarification for any interested delegation once the internal consultation process had concluded.

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

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

The representative of India requested an explanation of the rationale behind the decision to not notify the enactment of EU Directive 2001/83/EC relating to medicinal products for human use and the subsequent Directive 2004/24/EC on traditional herbal medicinal products (THMP). He

explained that the requirement to provide extensive documentary evidence on physiochemical, biological, micro-biological and pharmacological tests, as well as data on quality and safety requirements for the purposes of obtaining marketing authorization or registration (under the 2001 Directive or the 2004 THMP Directive respectively) may be unnecessary obstacles to trade, may not be based on scientific principles and may be maintained without sufficient scientific evidence. He expressed concern that the Directive was excessive and not limited to what could be deemed reasonable and necessary, in effect denying market access to India's ayurvedic products.

He argued that the current THMP Directive requirements had set out a complex procedure for registration of multi-ingredient products, given that a complete dossier is required for registration; polyherbal products may pose special problems as in such cases the quantification (and stability testing) of each component was not possible for practical reasons.

He thought that the Common Technical Document (CTD) format under the THMP Directive seemed acceptable for single herbs, but possibly inappropriate for multi-component traditional medicinal formulations. Furthermore, he stated that it could be near impossible to provide information with respect to multi-component traditional medicinal formulations in the CTD format, even if the products were otherwise eligible as THMP. He argued that the 2004 Directive therefore imposed a *de facto* ban on imports of such products and may be inconsistent with GATT Article XI.

He said that toxicity data should be required on a case-by-case basis, e.g. where there is reason to believe that the herb may be toxic or there is an alert on the herb. Data should not be required across the board for herbs known to be generally safe, that are included in the Generally Recognised as Safe (GRAS) list. Requirements on geontoxicity data and bioessays of ingredients in poly-herbal formulation had apparently resulted in low numbers of applications for traditional-use registrations. He argued that insistence on quantitative determinations (bio assays) in polyherbal compounds was technically unfeasible for any polyherbal formulations with more than three or four ingredients – further insistence on genotoxicity data without hazard assessment indicated the excessiveness of the Directive.

He explained that a large number of traditional herbal medicinal producers were small and medium-sized enterprises and the prohibitively high cost of registration under the Directive would create a barrier to market access for such enterprises. These costs comprised analytical and galenical development, stability testing, dossier compilation and dossier submission. He cited estimates in the range of more than €150,000 for a single ingredient product.

He stated that the EU Directive did not recognise ayurvedic products that complied with the provisions of the Ayurveda Pharmacopoeia of India, which were certified by bodies accredited by members of ILAC/IAF Mutual Recognition Agreements. In addition he explained that the scope of the THMP Directive was limited to herbal products, and many ayurveda, siddha and unani products contain a combination of ingredients which were of mineral and animal origin, yet these were denied registration. He requested an update on the status of these products under the Directive.

He raised the issue of a supplier being required to show 30 years of traditional use, including 15 years of traditional use in the European Union in order to establish efficacy of the medicinal product. He postulated that this requirement would prove so difficult to fulfil that it would be a *de facto* ban on imports of THMPs, thereby resulting in a complete denial of market access. He said that Article 16(c)(4) of the 2004 Directive prescribed an alternate process of a Committee referral for seeking registration of traditional herbal medicinal products, when the product had been in use in the European Union for less than 15 years. However, the guidelines and parameters on how the Committee would assess the product were not detailed. He argued that the derogation [from the requirement of demonstrating 15 years prior use in the European

Union] indicated that the condition of 15 years prior use was not sacrosanct and may not have been based on scientific evidence – and as such had no rational justification.

He asked if the EU had considered alternative methods or procedures for ascertaining the safety, quality, and efficacy of traditional medicinal products, including THMP while formulating its procedures under the 2001 and 2004 Directives. He requested clarification of the classification of herbal medicinal products under the 2004 Directive, as it provided for the registration of over-the-counter products, and also on the status of marketing of other herbal products outside this category.

Under these circumstances, he asked the European Union to extend its transitional period by another ten years; the existing transitional period of the Directive would end in March 2011, after which it would come into force.

The representative of China shared India's concerns, but acknowledged the European Union's openness on the issue.

The representative of Ecuador shared the points raised in previous interventions. As already stated in previous meetings, he explained that Ecuador exported medicinal products based on herbs and the requirements of these Directives (namely chemical, microbiological and pharmabiological evidence, as well as details and data on quality and safety) for import authorisation and EU market registration would be excessively costly and difficult to comply with, especially for small and medium-sized enterprises in developing countries. He added that herbs from Ecuador would be particularly affected, and that the process of the wording and implementation of this Directive would constitute a barrier to trade under Articles 2.9.1 and 2.9.2 of the TBT Agreement.

The representative of the European Union noted that bilateral discussions had taken place in the past with some of Delegations, and offered to continue providing information in further meetings. She recalled that Directive 2004/24/EC introduced a simplification for the registration of traditional herbal medicinal products – if a product was eligible for simplified registration, the manufacturer was exempted from providing a number of tests and clinical trials which were otherwise required under the standard procedure. She stated that eligibility for the simplified procedure was dependent upon usage over a period of 30 years, including at least 15 years within the EU. She added that this could be demonstrated via bibliographical or expert evidence and it was accepted that "medicinal use" did not exclusively mean "use as an authorised medicinal product", this proof of 15 years medicinal use in the European Union may be submitted even in the absence of marketing authorisation.

Expanding upon this point, she said that herbal medicines may contain toxic substances that would be harmful for patients, despite being natural products. The 15 years use in the European Union requirement allowed sufficient monitoring of side effects, increasing confidence in the absence of tests and trials. However, she explained that if the 15 years requirement was not met, but the product was otherwise eligible for simplified registration, the product should be referred to the Committee for Herbal Medicinal Products for the elaboration of a monograph. Once a monograph was completed, the manufacturer would not have to demonstrate 15 years of use – this requirement therefore did not constitute an obstacle to benefitting from the simplified procedure. The 2004 Directive foresaw a transition period of seven years for manufacturers to submit registration requests for their products to the relevant authorities.

She clarified that as of March 2011, herbal medicinal products not authorised or registered could no longer continue to be placed on the EU market, however, herbal products may be classified and placed on the market as food products provided that they did not fulfil the definition of medicinal products and complied with applicable food laws. She cited Directive 2002/46/EC on food supplements and Regulation (EC) No. 1924/2006 on nutrition and health

claims made on foods as the relevant legislation concerning herbal products marketed in the form of food supplements.

Finally, she said that the European Commission had started an internal review process in 2008, on the registration of traditional herbal medicines. This had concluded with the drafting of a report which expressed the European Commission's preparedness to consider extending the simplified registration procedure to products containing substances other than herbal products, and that more experience with and information on the requirement of at least 15 years use had to be gathered with a view to assessing its necessity. Any of these changes would require legislative action.

UE e EUA x Colômbia – Shelf life Requirements for Milk Powder

Colombia – Shelf life Requirements for Milk Powder

The representative of the European Union reiterated concerns on the adopted measure, which required imported milk powder to have a minimum shelf life of at least 12 months, 6 months more than the previous requirement. She expressed concern that this extension would harm exports of milk powder to Colombia. Given a combined transport and quarantine time of two months on average, if shelf life is counted from the date of commercialisation, export of the product would be practically impossible without incurring additional costs to extend the shelf life of the milk powder via specific and costly treatments. She explained that the European Union had invited Colombia to clarify several elements of this proposal at the last Committee meeting, particularly what risk the authorities intended to address by the extension of the shelf-life requirement. She said that this query remained unanswered and requested further information from the Colombian representative.

The representative of the United States encouraged Colombia to notify the measure, and requested clarification on the 12-month shelf life requirement for these products.

The representative of Colombia explained that the measure had recently been notified as an amendment to a previously notified decree, in G/TBT/N/COL/67/Add.3 on 27 Jan 2011. The new decree extended the shelf life for milk powder, as well as the process of the product in Colombia. He noted that comments on the notification had been included on 3 April 2011, and that no comments had yet been received from Members on the draft resolution. Finally, the representative emphasised that his delegation had previously responded to the concerns of Members regarding potential discrimination of this measure.

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

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

The representative of the United States reiterated concerns that China does not permit US suppliers to use competent conformity assessment bodies, including test labs, product certifiers and inspection bodies, located outside Chinese territory to demonstrate compliance with its compulsory certification requirements. He raised concerns following an indication in an earlier intervention that these requirements could be extended to other products through China's Restriction on Hazardous Substances (RoHS), as at least 20 per cent of US exports to China were currently affected by these issues with respect to conformity assessment.

He said that numerous US industry interests; including medical devices, information technology, the US Chamber of Commerce, US-China Business Council and the telecommunications sector had submitted a letter to the USTR and other US agencies, listing conformity assessment and the lack of recognition of bodies outside China as one of the top issues facing US exports to China. He argued that requiring China Compulsory Certification (CCC) related procedures to be performed by a single Chinese conformity assessment body often led to the imposition of additional costs, burdens and delays on US exporters, particularly SMEs. He cited Decree 390, stating that in each area there should be at least two certification bodies, yet in many cases only one existed and none of them were located outside China – US companies were thus obliged to arrange and fund travel for pre-market inspections at the manufacturers location, submit to subsequent annual inspections after receipt of the CCC mark and also pay for product testing and certification, which would already have been done in the United States.

He explained that there were also issues with changes in requirements and inconsistent post market surveillance, which were raised during a bilateral meeting held in the margins of the last Committee meeting. He added that the US had been encouraged to arrange a meeting with the Certification Accreditation Administration of the People's Republic of China (CNCA) during its last visit to Washington, but the CNCA had been unwilling, leading to the issue continuing to be raised in the Committee. He said that the United States favoured bilateral discussions, and hoped that China would consider ILAC and IAF as the basis for recognising Conformity Assessment bodies. He noted that the Chinese Accreditation Authority under ILAC rules had a duty to promote the use of the ILAC MRA in China, and enquired as to what steps had been taken towards this goal. He compared this situation to the US Consumer Product Safety Commission's recognition of 96 bodies based in China, stating that this growing disparity would increase the seriousness of the issue – he hoped that China would start to recognise US conformity assessment bodies in the near term.

The representative of China invited interested Members to review the Minutes of previous TBT Committee meetings for detailed clarification of the CCC scheme as this was a longstanding topic of interest. However, he sought to clarify the accreditation of foreign laboratories under the CCC scheme. First, he explained that the Chinese CCC system was a mandatory market access requirement in terms of conformity assessment procedures, rather than commercial inspection and certification, and therefore different in nature from third-party inspection required in the US CPSIA. Second, the Chinese CCC system facilitated trade by allowing foreign conformity assessment bodies to participate in the implementation of the CCC system through mutual recognition agreements and multilateral systems. He added that China had recognised 168 conformity assessment bodies under CCC, including foreign conformity assessment bodies such as the UL laboratory of the United States. Furthermore, China automatically accepted all testing results of CB laboratories located in other countries, including the United States.

UE e 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 European Union raised concerns with Korea's requirements for certification of photovoltaic panels, in particular the standard for thin-film solar panels, which did not allow certain types of thin-film solar panels to be tested or certified. She explained that this prevented such technology from qualifying for government incentive schemes – which was a *de facto* ban from the market. She added that the European Union had been engaged in bilateral discussions with Korea, though there was no significant progress to be reported. She

requested an update on a study undertaken by the Korea Energy Management Corporation (KEMCO) on the environmental impact of thin-solar panels other than those using amorphous silican (A-Si), and the foreseen timeline for the completion of the study.

The representative of the United States referred to past interventions discussing concerns with the KEMCO process for certification and the fact that the Korean standard for thin-film solar panels only applied to a certain type of solar panel. He noted that the only type of thin-film panel that could be certified by the Korean Energy Management Corporation was manufactured by Korean firms, and those manufactured by foreign companies were not covered by the standard – thus they were unable to gain certification and access the Korean market. He said that the United States was not aware of any scientific or technical evidence indicating a risk from use of thin-film solar panels not covered by the Korean standard. He explained that the alleged concern was over the presence of cadmium in the panels or their production process, but argued that the concentration levels were lower than regulatory levels and also lower than cadmium levels in batteries on the Korean market. He questioned the need to delay certification while working on a feasibility study assessing the safety of thin-film solar panels and urged Korea to amend its standard and enable all thin-film panels to demonstrate that they met the requirements for certification.

The representative of Korea reiterated that KS and its related certification were not mandatory; any cadmium telluride (CdTe) and Copper Indium Gallium Selenide (CIGS) were allowed to enter the Korean market without KS certification. He stated that other Members had been notified at the last Committee meeting, and that the feasibility study was ongoing, with publication expected by June 2012. Following completion of the study, he explained that the MKE would decide upon the inclusion of the aforementioned thin-film panel types in KS61646, and subsequently Members updated.

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 reiterated concerns, specifically with regard to mandatory requirements concerning pH values, level for colourfastness and odour of textiles, referring to the Minutes of past meetings for details. She thanked China for additional information submitted in writing in February 2011, but expressed disappointment at the lack of accompanying scientific evidence to support these mandatory requirements. Without these, she explained that it appeared that these measures had no scientific basis.

The representative of China stated that the revision of the national standard on textiles was notified to the TBT Committee on 10 February 2010. He welcomed the EU's comments, dated 16 April 2010, 3 September 2010 and 13 January 2011, noting that China endeavoured to issue detailed written responses. He added that the last reply had included the details of a contact person, with a view to engaging in a more in-depth technical exchange. He invited the European Union to refer to this person directly on technical matters and clarification of the new standard. He informed the Committee that the standard had been approved and published on 14 January 2011 and would be in force from 1 August 2011.

UE, EUA, Japão e China x Índia – New Telecommunications related Rules

India – New Telecommunications related Rules

The representative of the European Union thanked India for making available their experts to discuss with the European Commission and EU industry concerns with the above mentioned rules. Meetings held in Delhi built a shared understanding of the rules, and also helped elaborate her delegation's concerns.

He recalled that in March 2010 the Department of Telecommunications of the Indian Ministry of Information and Communication Technology, had published new rules on security clearance for telecommunications equipment. Subsequently, in July 2010, a mandatory template agreement for security and business continuity had been issued, which formed part of private commercial contracts between telecommunication service providers and vendors of all telecommunication related equipment, products, and services.

The representative further recalled that his delegation had expressed a number of concerns with the template agreement at the past TBT Committee meeting and in a number of subsequent bilateral meetings. The concerns included: (i), the obligation that vendors deposit their source code in an escrow account that would be accessible to officials from the Department of Telecommunications; (ii), the mandatory transfer of technology to Indian companies; (iii), the unlimited liability foreseen on vendors in case of any security breach; (iv), the requirement to substitute Indian engineers for foreign engineers for the maintenance of networks; and, (v), the apparent exemption of telecommunication equipment and products manufactured in India from the application of the new rules, meaning that only imported equipment and foreign vendors would be covered. He also noted that the since the template agreement mandated compliance with specific security standards, as well as testing and certification requirements, it was in his delegation's view both a technical regulation and a conformity assessment procedure within the meaning of the TBT Agreement.

He reported that in August 2010 the Indian Prime Minister's office had decided to give telecommunication operators a choice between compliance with either a security clearance on a case-by-case basis according to a self-declaration system subject to assessment by the Department of Telecommunications, or the new system of prior security clearance based on the rules of the new template agreement. The dual regime had been initially granted for a period of 60 days, and then extended for additional 60 days, and subsequently had been extended on 14 March 2011 until further notice, pending review of the new security clearance policy by the Department of Telecommunications, in light of the concerns raised by foreign partners. The representative expressed his delegation's appreciation for the extension of the dual regime, since it created a more predictable framework for the business community and for trade in these products, as well as, more generally, for India's commitment to finding a solution capable of fulfilling its legitimate security needs without restricting international trade.

Finally, the representative requested an update on the timeline and content of the aforementioned policy review by the Department of Telecommunications, inquired whether a stakeholder consultation was foreseen, and requested that the revised draft be notified to the TBT Committee. Lastly, he reiterated his delegation's availability for discussion and experience sharing with the competent Indian authorities in the framework of the India-EU bilateral ICT dialogue.

The representative of the United States recalled that his delegation had, at the last TBT Committee, described the Indian measure and provisions of the template agreement that would become a mandatory element of commercial contracts between telecommunication service providers and vendors of all telecommunication related equipment, products and services. He noted several concerns with the measure raised by US industry, including the requirement that companies deposit their source codes in escrow, mandatory technology transfer to local telecommunication companies, and burdensome and irrelevant testing and certification requirements.

He understood that the government of India was considering eliminating the requirements for the provision of source code and technology transfer, and revising other portions of the regulation, to address concerns raised by trading partners and industry. He requested an update on the current status of the measure, and inquired whether a revised template agreement would be forthcoming; if so, he requested that the revised agreement be notified to the TBT Committee.

The representative recalled that India had argued at the November 2010 Committee meeting that the measure was not subject to the TBT Agreement, since its objective was national security. However, he noted that Article 2.2 of the TBT Agreement specifically listed national security as a legitimate objective, and he therefore expressed the view that the measure was covered by the TBT Agreement and subject to its disciplines, including notification, which he believed to be appropriate in this case.

The representative of Japan expressed concern with the possible security related amendments to the unified access service licence agreement, and supported the interventions of the EU and US delegates. He highlighted the requirements for technology transfer from foreign to domestic firms, and for deposit of source code in escrow, as contrary to WTO rules for the protection of intellectual property rights, and harmful to foreign firm's ability to access the Indian market.

He explained that Japan shared Indian's commitment to ICT network security, and understood its importance for both the business sector and national security. However, he noted concerns with implementation of the measure, and he encouraged India to take full account of the problems identified by concerned industry. Finally, he recalled that in mid-February his delegation was led to believe that the proposed amendments to the unified access service licence agreement would shortly be made public, and he requested an update as to the latest developments.

The representative of China echoed the concerns raised by the EU and US delegates. He expressed support for India's objective of telecommunication security, but was concerned about the vague certification environment and the standards elaborated within the Indian rules. He called for greater transparency, and requested an opportunity for stakeholders, including equipment vendors, to comment on the measure. Finally, he emphasized that all vendors should be treated fairly under the rules, in accordance with the principle of non-discrimination.

The representative of India reiterated his delegation's belief that the provisions of the unified access licence agreement for telecommunication services were not a technical barrier to trade within the ambit of the TBT Agreement. Rather, he said that the provisions fell within the security exemptions of Article XXI of GATT 1994, and the TBT Committee was therefore not an appropriate forum for discussion.

He did, however, refer to the concerns related to technology transfer. He noted that transfer of technology was an integral element of international agreements, and also a key element of technological development in developing countries and LDCs. He recalled that both the Doha Ministerial Declaration and the Hong Kong Ministerial Declaration recognised the importance of technology transfer in the context of trade. He also reminded Members that the TRIPS Agreement recognized transfer of technology as one of the objectives under Article 7, and in Article 66, an obligation was placed on developed country Members to provide incentives to their enterprises and institutions that promote and encourage technology transfer. He reiterated the importance of technology transfer for technological development, and stated that, in the view of his delegation, it was a central parameter of the measure under discussion.

Finally, he informed the Committee that the Department of Telecommunications was working to simplify the procedural aspects of the licensing agreement. He noted requests for additional

information from the European Union, United States, Japan and China, and he pledged to consult capital and revert to the requests at the next Committee meeting.

UE e EUA x Indonésia – Labelling Regulations (Ministry of Trade Regulation 62/2009 and 22/2010) (G/TBT/N/IDN/47)

Indonesia – Labelling Regulations (Ministry of Trade Regulation 62/2009 and 22/2010) (G/TBT/N/IDN/47)

The representative of the European Union thanked the delegation of Indonesia for notifying to TBT Committee the regulations of the Indonesian Ministry of Trade concerning the obligatory labelling of goods, allowing other Members to submit comments in this regard within a 60-day period. She noticed however, that these regulations had already entered into force at the time of this meeting. She also expressed her delegation's hope that the European Union's written comments sent on 3 February 2011 would be taken into account and that the regulations were going to be revised, if necessary. She recalled that during the previous TBT Committee meeting, the European Union had requested a clarification about why imported products could not be labelled or re-labelled in Indonesia before they were actually placed on the market and why a preapproval procedure of the label was considered necessary.

She added that the European Union had also asked for clarification regarding the exemption procedure for importers. She noted that Indonesia had replied to this request by explaining what these regulations were providing for, but that it had not given any explanation as to why these requirements were deemed necessary. Thus, she expressed her delegation's hope that this explanation could be provided during this TBT Committee's session, as well as in a written reply to the request sent by the European Union.

The representative of the United States observed that his delegation had similar concerns, and that in the United States' view Indonesia's labelling measure as currently drafted could significantly disrupt trade. He expressed his delegation's respect for Indonesia's desire to have all packaged food and many industrial products sold at the retail level bearing a label in Indonesian language. He added that the United States hoped to continue working with Indonesia to resolve this issue, in particular concerning the question of whether a supplemental label could be applied post-customs. He indicated that due to the rise of global supply chains and the use of consolidated shipments, it would be very costly and burdensome for companies if the label were required prior to the shipment of the products to Indonesia. He suggested instead that, for instance, supplementary labels could be applied at the importers selected warehouse in an in-country location, after the product had cleared customs but prior to distribution within Indonesia. He stated that this would be the best way forward, recalling that this was also the way Indonesian products were allowed into the US market.

The representative of Indonesia took the floor and explained that the Ministry of Trade of the Republic of Indonesia Regulation No. 62-22-2010 was aimed at ensuring consumers' right to obtain correct, clear and precise information, as well as providing consumer protection. He explained that the intention of the Indonesian authorities was not to create any trade barriers or increase costs for importers. Rather, their intention was to address the risks arising from the practice of labeling products after port entrance, but before being placed on the Indonesian market. He also explained that, for instance, the measures included exemptions for goods that were packaged directly in front of the consumer, and for goods listed in Attachments 2 and 3 of the regulations. He finally stated that his delegation would welcome further discussions with EU and US on this matter at a bilateral level.

EUA e México x UE – Proposal for a Council Regulation on the Indication of the Country of Origin of Certain Products Imported from Third Countries (SEC(2005)1657)

European Union – Proposal for a Council Regulation on the Indication of the Country of Origin of Certain Products Imported from Third Countries (SEC(2005)1657)

The representative of the United States recalled that at the last Committee meeting, his delegation noted that the EU Parliament had recently voted to approve a proposal of the Parliament and Council regulation on the indication of the country of origin on certain products imported from third countries, which would require that certain consumer products imported from third countries be labelled with their country of origin. He added that the list of specific products that required marking was in the opinion of the United States' very broad. He indicated that the United States acknowledged that there could be legitimate reasons for requiring country of origin labelling. However, he added, these regulations should not discriminate based on origin, observing that the draft of the EU measure appeared to only require products imported from third countries to be labelled. Thus, he indicated, products from the EU as well as Turkey and members of the EEA agreement would be excluded from the country of origin labelling requirement. In the view of the United States, such requirement should not apply only to imported goods or only to imported goods of some countries. Therefore, he requested a clarification from the EU delegation as to the reasons supporting the decision to apply this new requirement only to imported products, and moreover, only to imported products from some countries. The US representative also inquired about whether the EU Commission could provide the United States with an update on the status of the measure in the EU Parliament and on whether and how it would solicit the input of WTO Members and other stakeholders.

The representative of Mexico indicated that his delegation continued to analyse the scope, objectives and impact of this EU regulation. He added that in the opinion of the Mexican delegation, some of the provisions contained in this regulation could affect Mexican exports to the European Union. Thus, his delegation reserved their right to continue to analyse this concern and to express its views during future meetings.

The representative of the European Union replied to these comments by indicating that indeed, a 2005 EU Commission proposal for a regulation on the indication of country of origin for certain products was under discussion in the EU Parliament and Council. She added that the EU Parliament had introduced a number of important amendments to the EU Commission's proposal, in particular, a limitation on the scope of application of the draft regulation to a list of end consumer goods, as well as the inclusion of a sunset clause. She also mentioned that the Council of Ministers was examining the EU Parliament's amendments but that there was no date yet set for the adoption of a common position. She also expressed her delegation's view that considering that it was highly possible that the text resulting from the first reading by both institutions would significantly modify the Commission's original proposal; it was premature to enter into a detailed discussion about this regulation in the TBT Committee.

UE x EUA – California Code of Regulations: Chapter 53 Safer Consumer Product Alternatives (G/TBT/N/USA/579 and Corr.1)

United States – California Code of Regulations: Chapter 53 Safer Consumer Product Alternatives (G/TBT/N/USA/579 and Corr.1)

The representative of the European Union indicated that her delegation would appreciate an update on the planned revision of Chapter 53 of the California Code of Regulations on the Safer

Consumer Product Alternatives. She recalled that during the previous TBT Committee meeting, the United States had notified the planned revision of this Code of Regulations on 26 October 2010, but had withdrawn the notification some days later. She mentioned that the European Union had discovered that a newly revised text had been submitted to public consultation in the territory of the United States on 16 November 2010. She added that the period for submitting comments on this modification had been 15 days. Nevertheless, she indicated that this information had never been transmitted through the TBT notification procedure. She clarified that the European Union had not learnt of any new developments in this regard since November 2010, and that her delegation was interested in knowing if the proposal was still under discussion. Moreover, she stated that the European Union was also aware that several US States were preparing legislation on the control of chemicals and chemicals in articles. Thus, she expressed her delegation's desire to get confirmation about whether these State legislations, when containing technical regulations or conformity assessment procedures, would be notified under the TBT Agreement, and whether a comment period of at least 60 days would be given.

The representative of the United States replied recalling that during the previous TBT Committee meeting, the United States determined, after reviewing the measure, that the proposal was neither a technical regulation nor a conformity assessment, and that for this reason they withdrew the notification. He added that this proposal had gone through a number of drafts over many years and that the public consultation held in November 2010 was simply the latest iteration in a long process. He mentioned that at that moment, several advisory panels to the California Department of Toxic Substances Control (DTSC) were holding a series of meetings to discuss the appropriateness of revising the draft measure. He observed that the advisory panel meetings were open for any interested stakeholders to participate. He reported that, based on the outcome of these meetings, the advisory panels were going to submit their recommendations to the DTSC on how the measure could be revised. Finally, he stated that based on these recommendations the DTSC would submit a new version of the measures for public comment. However, the US delegation was not aware of any specific dates for the submission of the new proposal for public comments. He announced that the United States was going to review the proposed measure to determine if it constituted a technical regulation or a conformity assessment procedure, in which case the United States would notify it under the TBT Agreement if appropriate. He noted that the European Union had drawn attention toother regulations that might be under development in other US States, and he announced that the United States was going to continue monitoring these regulations, and notify them if appropriate as well.

EUA x Turquia – Communiqué SUT 2010 regarding documentation requirements for medical devices

Turkey – Communiqué SUT 2010 regarding documentation requirements for medical devices

The representative of the United States recalled that during the previous TBT Committee meeting the United States had introduced this issue and noted that it had serious concerns regarding Turkey's new medical device reimbursement regulation Communiqué SUT-2010. The United States' essential concern was that medical devices were already regulated by Turkey's Ministry of Health. However as of June 2010, all producers of medical devices used in specific areas, specifically traumatology, orthopaedic arthroplasty and spinal procedures were also required to comply with a second regulation administered by Turkey's Social Security Institute (SGK). He stated that during that session his delegation raised several transparency concerns, noting that the measure was never notified to the WTO; that there was no chance for stakeholders to comment about it; and that no time period for implementation had been established.

He reiterated previous concerns about the purpose of the new measure for this second regulator to require companies to provide additional documents, given that Turkey's Ministry of Health already regulated these products for safety and efficacy and did not require companies to provide these additional documents. He questioned the necessity of having a second regulator laying down technical requirements for medical devices that were already regulated by Turkey's Ministry of Health. In addition, the United States expressed its desire to know the basis on which the specific devices regulated by the SGK measure were selected. With respect to the documentation requirements themselves, the US representative noted that producers needed to provide written evidence that each group of products was certified by the regulator in the country where the products were manufactured or from which they were imported, and that they were used in that country. According to the United States, this situation was problematic because sometimes certain devices were manufactured in countries where they were not used. Thus, producers could not obtain the required certification in those countries. Therefore, producers essentially were forced by the measure to ship their products to another country where the producer could obtain a certificate. In the United States' opinion this seemed to be unnecessary, time consuming and the cause of additional costs. Moreover, he recalled that many medical device regulators around the world did not provide documentation on product usage or proof of reimbursement. Thus, in the United States' view it was not clear what purpose this information served. Therefore, the representative urged Turkey to notify this measure under the TBT Agreement for comments; to meet with the industry stakeholders to hear their concerns; and to take action to eliminate or modify any of these unnecessary documentation requirements so that suppliers could continue to place their products on Turkey's market provided that their products satisfied the technical requirements of the Ministry of Health.

The representative of Turkey explained that in Turkey, medical devices were regulated under three individual legislations. The first was the regulation on medical devices, the second was the regulation on in-vitro medical devices, and the third was the regulation on active implanted medical devices. She added that medical devices, either domestically produced or imported, had to comply with these technical regulations in order to be marketed in Turkey, and that the CE mark was assumed to be the indicator of that compliance.

She also explained that while medical devices with the CE mark could be freely marketed in Turkey, Turkey's Social Security Institute (SGK) would choose among them those in relation to which it would pay reimbursements. In this selection process, the SGK based its decisions primarily on public interest considerations, ensuring that patients were provided high quality products. Secondarily, public expenditure and budgetary targets are also considered. She clarified also that the SGK was part of Turkey's public social security system, and that it covered the health expenditures of 80% of population, accounting for approximately 56 million people. Thus, in Turkey's view, the documentation requirements established by the SGK should be assessed from this perspective. Most of the documents requested by the SGK were required by relevant legislation, in particular in relation to the CE marking. Other documents were required to indicate the prices paid by the social security institutions in the originating country, to assist the SGK to establish its own price criteria. The representative of Turkey highlighted that these document requirements were applied equally to both domestic and imported products. In addition, in Turkey's opinion these documents were already required by the authorities of the countries where the products originated. She therefore concluded that no new documentation requirement or new conformity assessment system was created by the measure.

Índia x Itália – Law on "Provisions concerning the marketing of textile, leather and footwear product" (G/TBT/N/ITA/16)

Italy – Law on "Provisions concerning the marketing of textile, leather and footwear product" (G/TBT/N/ITA/16)

The representative of India requested an update from the European Union on the current status of this labelling law and on whether the various comments submitted by India had been taken into account when finalizing this law. He clarified that India's specific trade concern regarding this law was that it required compliance at each stage of the production process which went against the basic premise of an industry that was based on global and multiple sourcing. In India's view this requirement was onerous for exporters, especially from developing countries, and was more trade restrictive than necessary to fulfil the legitimate objectives.

Moreover, India was concerned about the requirement established by this law to provide employment-related information, which in India's opinion, constituted information referring to non-product related process and production methods which were fields not covered by the TBT Agreement. He added that India believed that this information was clearly unwarranted as it sought to interlink labour issues with trade, altering the conditions of competition to the detriment of imported goods. Thus, in India's view this requirement was inconsistent with the provisions of GATT. Similarly, according to India, the reference to compliance with regulations on environment was another issue of concern and was clearly a trade barrier that would affect exports from developing countries. Finally, he asked the delegation of the European Union whether Italy had considered other less trade-restrictive regulatory alternatives to fulfil its objectives.

The representative of the European Union recalled that during the previous TBT Committee meetings, her delegation had reported that the Italian authorities had decided, due to on-going internal discussions in the European Union, to postpone the application of this law. Consequently, the law would be effective only after the adoption of the Inter-Ministerial decree pursuant to Article 2 of the law in question. She confirmed that discussions about the implementing measure were still taking place in the European Union, and that this circumstance made it impossible to provide further clarification at this stage. She announced, however, that once the internal discussions were finished, the EU delegation would provide India and the TBT Committee with further clarification.

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 expressed his delegation's conviction that the United States shared Indonesia's goal of ensuring that food products labelled halal complied with Indonesia's requirements. However, he indicated his delegation's belief that Indonesia's objective could be accomplished without disrupting trade. In his view, avoiding the creation of trade disruptions required additional transparency including ensuring that suppliers and certifiers were aware of the existence of new requirements; allowing them to review and comment on those requirements in draft form; taking into account those comments by the relevant authorities; as well as having a reasonable time period to comply with new requirements. He noted that halal certification related to food production processes, not food-safety issues. The United States also expressed its appreciation for the recent visit by Indonesian authorities to the United States, resulting in the approval of US-based halal certifiers. Finally, the representative expressed his delegation's desire for future engagement and cooperation on this issue between both governments.

The representative of Indonesia expressed his delegation's gratitude to the United States for raising these concerns about the Decree of the Majelis Ulama Indonesia (MUI) on halal certification. He reported that further consideration would be given by the MUI to this issue, and that his government would communicate to the relevant US authorities any developments

regarding their concerns on this matter. Finally, he invited the United States to continue discussing this issue bilaterally.

China x UE – Toys

European Union – Toys

The representative of China reiterated China's longstanding concerns with the European Union's new Toy Safety Directive. He noted that this directive had entered into force on 20 July 2009, and that EU member States had to finish transposing the Directive into their domestic legislation before 20 January 2011. China recognized that protecting children health and safety was a legitimate goal. However, China's representative expressed his delegation's disappointment about some of the requirements established by this new directive since they were, in China's view, more stringent than necessary and inconsistent with existing international standards.

He noted that the international standard ISO 8124-3:2010 on Safety of Toys specified maximum acceptable levels and methods of sampling and extraction prior to analysis for the migration of the elements antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy materials and from parts of toys. However, he continued, the EU directive significantly expanded the list of regulated substances to 19 types of metals, and added restrictions in relation 66 kinds of aromatic compounds and many other substances classified as carcinogenic, mutagenic, and reprotoxic (CMRs) substances. In China's opinion, overly extensive and unnecessary chemical requirements would substantially increase costs to toy manufacturers, in particular for small and medium enterprises (SMEs), leading to unnecessary barriers to trade.

He also expressed China's hope that the EU would rectify and adhere to current international standards, so to avoid the creation of unnecessary chemical restrictions. In this context, China suggested eliminating the limits to non-toxic or low toxic metals such as Zinc, Nickel, Manganese, Boron and Cobalt, which had already been scientifically proved to have negligible effect on human health. In addition, China welcomed the principle set forth in the directive stating that "all modifications of the Directive do not impose unnecessary burden and costs on industry, especially on small and medium sized enterprises, or administrations". Thus, the representative of China invited the EU to take into account the special and differential treatment principle enshrined in the TBT Agreement, and to grant a longer transitional period to developing countries by postponing the implementation date of this directive to the year 2015. He added that further exemption provisions were anticipated based on available scientific evidence. Finally, he thanked the EU delegation for the informative bilateral discussions both countries had held in the past, and welcomed further contact between authorities of each side.

The representative of the European Union indicated that Chinese and European Union authorities had a comprehensive regulatory dialogue on toy safety matters, and that the last meeting on this issue had taken place in Beijing in November 2010. He explained that both countries planned further seminars and training events in China in the autumn of 2011, and that in the meantime the EU authorities kept regular channels of communication with their Chinese counterparts, in the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ), and in the Chinese local inspection and quarantine offices. He added that his delegation had been providing the Chinese authorities and industry with guidance documents and clarification papers on the development and implementation of the new Toy Safety Directive. He announced that the new Toy Safety Directive would be applicable as of 20 July 2011, except for the chemical requirements section for which a longer transitional period was established, namely, until 20 July 2013.

He also reported that the majority of EU Member States had already published the national provisions implementing the new Toy Safety Directive in their respective jurisdictions. Moreover, he explained that one of the main changes to the pre-existing legal framework on toy safety involved requirements for the use of chemicals in toys. Thus, one of the goals of the EU toy safety directive was to enhance those requirements for substances that were carcinogenic, mutagenic or toxic for reproduction (CMR), and heavy elements in toys like lead or other heavy metals and allergenic fragrances. He specified that these requirements had been established taking into account the best scientific evidence available at that time, and that the directive foresaw the possibility to amend certain chemical requirements in order to ensure the constant alignment of the directive with the latest scientific evidence. He also indicated that the EU authorities were open to receiving any additional scientific evidence, and that they would carefully examine it with a view to determining whether a proposal for amendment was justified. In order to facilitate the implementation of the new rules, the European Commission had prepared a number of guidance documents, and a very comprehensive guide was already available. In addition, more specific guidelines on the technical documentation for the safety assessment procedure, including the chemical safety assessment, were under development and were soon to be finalized.

Moreover, existing standards were also being revised at that moment and, with the exception of new standards related to chemicals, all revised standards were going to be published before the entry into application of the new Toy Safety Directive (expected publication date: late spring 2011). He also stated that work on new standards on chemicals was well underway and the publication of the new standards was expected before July 2013. He noted that, in conducting these activities, EU standardization bodies worked in close coordination with the relevant technical committee in ISO, and their counterparts in other major trading partners, including China and the United States. He reported that experts from China's Standardisation Administration (SAC) had been invited to participate as observers in the work of relevant CEN technical committees, and that there was also regular coordination with the American Society for Testing and Materials (ASTM). In his opinion, this coordination effort would hopefully contribute to a greater global alignment of standards in the field of toy safety.