SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/46)

New Concerns

China X EUA - Consumer Product Safety Improvement Act (G/TBT/N/USA/421)

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

The representative of China raised concerns about the US Consumer Product Safety Improvement Act of 2008. While China supported the objective of protecting consumer safety by developing new technical regulations, it was concerned about a possible violation of TBT obligations, both with respect to the regulation itself and to the process through which it had been developed. He stressed that the Act could have a significant effect on trade and that it should be notified to the WTO in the draft stage to allow for comments, which needed to be taken into account.

The representative of China further noted that the Act required that total limits of lead in products should be reduced from 600 ppm to 100 ppm within 3 years. However, the total lead content included both soluble and insoluble lead. Insoluble lead, as it could not be absorbed, was not harmful to human health. Therefore, setting limits on total lead content would create an unnecessary obstacle to international trade and would violate the least trade-restrictive principle of the TBT Agreement. Other provisions in the Act could also have a significant effect on trade, for example those related to the criteria for accreditation of third party certification bodies. He requested the United States to notify the Act and to take comments into account.

The representative of the United States noted that the document G/TBT/N/USA/421 contained the notification of the first of several implementing measures of the Consumer Product Safety Improvement Act of 2008. He explained that the Consumer Product Safety Improvement Act - also known as CPSIA – had been signed into law in August 2008. CPSIA gave the US Consumer Product Safety Commission (CPSC) new regulatory authority and enforcement tools to protect public health and safety. Specifically, CPSIA contained several provisions designed to strengthen protection against unsafe products intended for children's use. He noted that, reflecting the need for suppliers to adjust to the new measure, many of the requirements contained in the CPSIA would be introduced and implemented on a rolling basis over the coming year.

The representative of the United States further pointed out that the notification referred to the implementing measures relating to third-party testing for children's products, as well as establishing accreditation requirements for independent third-party testing facilities to test for conformity with the new maximum lead-paint levels set by the Act. Additional implementing measures, including for small parts, cribs, and other CPSIA requirements, would be developed and published according to the timetable laid out in the statute and would be notified to the WTO. Given the seriousness of the public health incidents, there had been strong support in the US Congress for expedited implementation of some measures. Therefore, on lead and other issues, Congress had directed CPSC to implement on a very short timetable.

It was further explained that, under US law, every manufacturer of a product subject to a consumer product safety regulation enforced by CPSC was required to certify that the product was compliant through a supplier's declaration of conformity (SDoC). SDoC had been recognized by the TBT Committee as the most trade facilitating of all conformity assessment procedures. For those products intended for children, CPSIA mandated that each manufacturer would also have its products tested by an accredited independent testing laboratory. Based on that testing, the manufacturer certified that the product met all applicable CPSC requirements and also specified the accredited laboratory that had performed the testing. It was noted that

laboratories operating anywhere in the world could be accredited, and that the current list of accredited labs was posted on the CPSC website.[1]

Furthermore, it was noted that under the Act, CPSC was given the authority to either accredit laboratories for doing the required testing of children's products, or to designate accreditation bodies to accredit testing laboratories. CPSIA also contained special provisions to ensure that laboratories controlled by the manufacturers of children's product and government-owed laboratories were properly "firewalled" to ensure strict standards of independence and no undue influence. CPSC's implementing rules on accreditation relied on the existing international technical infrastructure. For example, ISO 17025 accreditation by an ILAC-MRA accrediting body would serve as the baseline criterion for CPSC acceptance of any laboratory - whether a commercial third party, a government laboratory, or a manufacturer-owned laboratory.

Finally, the representative of the United States stressed that CPSC had made many efforts during the development of this legislation to reach out to the key trading partners to ensure full understanding of its provisions, and that it stood ready to engage with any government laboratory to work through issues related to the additional criteria.

China X UE - Proposal for a Regulation of the European Parliament and of the Council on Cosmetic Products (G/TBT/N/EEC/186 and Corr.1)

European Communities - Proposal for a Regulation of the European Parliament and of the Council on Cosmetic Products (G/TBT/N/EEC/186 and Corr.1)

The representative of China noted that, while his delegation understood the objective of protecting human health, there was concerned about possible inconsistencies of the notified measure with the TBT Agreement. Written comments had been sent to the European Communities and a written reply had been received. However, the reply had not fully addressed the concerns expressed. First, Article 10 of the draft regulation prescribed the information that should be submitted by the supplier prior to placing cosmetic products on the market. The European Communities had replied that it aimed at giving relevant information to the member States' authorities and anti-poison centres in case of necessity. However, his delegation believed that the required information was not related to cosmetic safety and that it would significantly increase costs for manufacturers. He requested that the scope of the information to be submitted be limited to product safety and that the least trade restrictive obligation of the TBT Agreement be fulfilled.

Second, the draft regulation stipulated that "with regard to substances which are classified as CMR1 or 2 substances [carcinogenic, mutagenic and reprotoxic substances], there should be a possibility to use such substances in cosmetic products if such use has been found safe by the SCCP. Such substances should be continuously reviewed by the SCCP [the Scientific Committee on Cosmetic Products]". The representative of China stressed that, according to Article 6.1 and 6.2 of the TBT Agreement, test data and results issued by laboratories which had been approved by the accreditation bodies of other Members such as China should also be accepted. Finally, he sought an update on the status of the proposed regulation, in particular with respect to the time of adoption and to whether Members' comments could still be taken into account.

The representative of the European Communities recalled that comments from China on the EC notification had been received in March 2008 and a comprehensive reply had been provided on 1 August 2008. She pointed out that the notified proposal consisted of a codification and recast of Council Directive 76/768/EEC relating to cosmetic products and the 55 subsequent directives amending this Directive. The codification and the recast version was done in order to improve

[1] www.cpcs.gov

clarity and legal certainty for cosmetic products. The concept of cosmetic product safety assessment was not new in the European Communities. The current cosmetic directive already contained the requirement to undertake such an assessment prior to the placing on the market of the product. However, the information to be contained in this safety assessment had never been specified. A crucial element of the recast was the clarification about the information that had to be contained in the cosmetic product safety assessment. This would provide evidence of the safety of the cosmetic product placed on the market and also help member States carry out their market surveillance, thus contributing to legal certainty.

With respect to the substances whose use was banned or restricted, the representative of the European Communities stressed that these substances had been assessed by the Scientific Committee for Consumer Protection, an independent scientific body advising the European Commission. Most of the scientific opinions at the origin of the restrictions could be found on the publicly available database on the internet site of DG Enterprise and Industry of the European Commission.[2] Finally, she informed the Committee that the proposed regulation had not been adopted and that it was undergoing its first reading in the European Parliament and in the Council.

UE X China - Brake linings for automobiles (G/TBT/N/CHN/366 and Suppl.1)

China - Brake linings for automobiles (G/TBT/N/CHN/366 and Suppl.1)

The representative of the European Communities raised concerns about the above-mentioned measure, which laid down mandatory requirements for brake lining of cars. Her delegation had sent comments to China seeking clarification of the scope of the measure, in particular if the draft applied only to replacement brake linings or also to brake linings which were part of the original vehicle. Her delegation considered that brake linings which were part of the original vehicle or replacement brake linings which were identical to the original linings used on the vehicle should not be covered by the measure. These brake linings had already been checked at the time of the type-approval of the whole brake system and there would therefore be an unnecessary duplication of checks.

The representative of China noted that his delegation had fulfilled the transparency obligations by notifying the draft measure and providing a comment period of sixty days. A reply to the comments sent by the European Communities would be provided through the Enquiry Point.

UE X EUA - Olive Oil (G/TBT/N/USA/395)

United States – Olive Oil (G/TBT/N/USA/395)

The representative of the European Communities referred to the proposed revision of the US standards for grades of olive oil and olive pomace oil. Written comments had been submitted to the United States, which pointed out that some of the items covered by the proposed standards, such as aspect, colour, odour and flavour were requirements or limits of certain chemical components in the oil were not in line with the Codex standards for olive oil and olive pomace oils. She invited the United States to provide a written reply to the comments and looked forward to continued discussion on this issue.

The representative of the United States noted that the proposed grade standards for olive oil and olive pomace oil had been notified on 4 June 2008 and that the final date for comments was 1 August 2008. Comments had been received from domestic and foreign producers, consumers, trade associations, and government agencies. All comments on the proposed standards were in the process of being evaluated by the USDA Agricultural Marketing Service (AMS). Upon

[2] http://ec.europa.eu/enterprise/ .

completion of this review, AMS would draft and publish final standards which would explain the consideration given to each of the comments received.

The representative of the United States further noted that the use of these standards was voluntary, as indicated in the Federal Register notice of 2 June 2008. Further, the proposed parameters for linolenic acid and campesterol were more liberal than the International Olive Council (IOC) standard, so it was difficult to understand how the US standards could inhibit trade. In terms of the substance, the Unites States believed that the proposed standards were in accordance with current international guidance from Codex relating to specific levels of fatty acid composition of linolenic acid. The Codex Standard[3] for olive oils and olive pomace oils specifically stated that, pending further discussion by the Codex Committee on Fats and Oils, national limits could remain in place for linolenic acid.

Moreover, the representative of the United States pointed out that IOC was not recognized as a technical expert body by Codex, but as a Non-Governmental Organization (NGO) with observer status. His delegation believed that current IOC grading standards for fatty acid composition were flawed in that they did not account for fundamental climatic and geographical factors that could affect key components of fatty acid and sterol composition such as linolenic acid and campesterol. The IOC levels were based on historical data from Europe that did not account for agro-climactic conditions in other regions of the world that caused certain components of olive oil to vary from region-to-region. If compliance with the IOC standards were mandated, this would restrict global trade in olive oil since only olive oil from the European Communities would qualify. He stressed that the IOC grading standard reflected input exclusively from its members in European and Mediterranean countries. Therefore, it was no coincidence that the governments of Argentina, Australia, and New Zealand, as well as industry groups from Australia and Argentina, had provided written comments in support of the proposed US standards, which took into account that olive oil was not produced in only one region of the world.

India X UE - Napropamide (G/TBT/N/EEC/203)

European Communities – Napropamide (G/TBT/N/EEC/203)

The representative of India raised concerns about the non-inclusion of napropamide in Annex 1 of Council Directive 91/414/EEC and about the withdrawal of the authorization for plant protection products containing this substance. Indian industry believed that the measure was not based on concrete scientific evidence and on an appropriate risk assessment. He stressed that the Indian industry had provided all available scientific findings in favour of inclusion of napropamide in Annex 1 for continued authorization of plant protection products containing this substance. He noted that, while Denmark had accepted these finding, they had not been duly considered in the report of the European Communities Food Safety Authority. His delegation believed that this measure was more trade restrictive than necessary and thus in contravention of the basic principles of the TBT Agreement. He urged the European Communities to examine this issue and to reconsider the non-inclusion of napropamide in Annex 1 of the Council Directive 91/414/EEC.

The representative of the European Communities noted that a response had been sent to the Indian Enquiry Point. If further clarification was necessary, this could be pursued bilaterally.

[3] Codex Stan 33-1981 (rev. 2-2003)1

Índia X EUA - Detection of contaminants in fuel containers

United States – Detection of contaminants in fuel containers

The representative of India raised a concern with respect to the detection of contamination in fuel containers of casting and fencing material being exported from India to the United States. The contamination was said to be caused by Cobalt 60, an isotope causing radiation in stainless steel capsules. As a result, all exports of steel and castings from India were currently being checked for contamination. He pointed out that the main problem was that there was no tolerance limit supplied by the United States for contamination of Cobalt 60. His delegation's understanding was that there was no international standards in this area. In the absence of an international standard, how did the United States fix the tolerance limit at zero? Indian industry believed that the zero limit was more trade restrictive than necessary and thus against the basic principle of the TBT Agreement. He invited the United States to provide a risk assessment to justify the limit.

The representative of the United States stated that further clarification from India was needed before his delegation could provide a response. He also noted that the fact that there was no international standard on a particular matter did not mean that Members could not regulate.

Colômbia, Equador, Peru, México e Costa Rica X UE - Novel foods (G/TBT/N/EEC/188)

European Communities – Novel foods (G/TBT/N/EEC/188)

The representative of Colombia introduced his delegation's concerns with respect to the EC measure on novel foods (circulated as document G/TBT/W/298, dated 4 November 2008).

The representative of Ecuador shared Colombia's concerns. While his delegation recognized the effort made by the European Communities to take into account interests of Andean countries and other developing countries, concerns remained about the current regulation. For example, clarity was needed on what constituted a "generation" as well as on other matters, such as the limitation to commercial operators. He stressed that data on the safe use of foods varied in different countries and that data protection should not be included in this legislation. He urged the European Communities to take into account the interests and requests of the Andean countries expressed on various occasions, in particular during the revision of the legislation which was being carried out by the European Parliament.

The representative of Peru shared the concerns expressed by Colombia and Ecuador regarding the amendment of the regulation on novel foods, and noted that his delegation had expressed concerns at the last meeting of the SPS Committee. Peruvian authorities had also received a response from the European Communities to the concerns expressed, which was being examined.

The representative of Mexico shared the views expressed and noted that his delegation had raised concerns about this measure in the SPS Committee.

The representative of Costa Rica supported the comments made by previous delegations and also noted that concerns had been expressed by his delegation in the SPS Committee, and that the matter would be raised again in that Committee.

The representative of the European Communities explained that the European Communities had launched a revision of the novel food legislation with a view to simplifying it and facilitating market access for third country operators by providing a centralized risk assessment, an authorization framework and strict timelines for the authorization procedure. With respect to

the new procedure for the authorization of traditional food, she informed the Committee that the novel food regulation was being discussed in the European Parliament as well as in the Council.

With respect to some specific issues raised, for example the definition of "traditional food" or of "generation", the representative of the European Communities pointed out that these would be defined in the implementing rules which had not yet been elaborated. Comments would be taken into account when these implementing rules were prepared. In addition, technical guidance would also be developed to assist food business operators and other interested parties, in particular small and medium sized enterprises, when submitting an application. Although time for comments had elapsed, she encouraged interested delegations to submit comments in writing to the EC Enquiry Point so that they could be taken into account.

Japão X Taipé Chinesa – Green Mark Products

Chinese Taipei – Green Mark Products

The representative of Japan raised concerns about Chinese Taipei's green mark products. He pointed out that there was no perfect method of excluding lead from foreign materials in additives, paint and degradation control agents. Regulations concerned, such as the Restriction of Hazardous Substances (RoHS) in other countries, including EC member States, set lead reference values at 1,000 mg/kg. However, Chinese Taipei's green mark regulation set its lead reference value in industrial products at 2mg/kg; many products were not able to meet this standard. In some cases industrial products had been forced to undergo multiple examinations. It was his delegation's request that these reference values be promptly amended.

The representative of Chinese Taipei stressed that the green mark regulation was different from RoHS, and that applying for a green mark was a voluntary practice. There was no zero tolerance provision. She noted that the issue could be discussed with Japan bilaterally.

UE, Argentina, Canadá e Suíça X EUA - Requirements to combat illegal logging (G/TBT/N/USA/424 and Corr.1)

United States – Requirements to combat illegal logging (G/TBT/N/USA/424 and Corr.1)

The representative of the European Communities noted that the notified measure established new requirements to combat illegal logging; it was an amendment to the Lacey Act that had been included in the 2008 Farm Bill and which had been recently approved by the United States Congress. The new measures, which would come into force in April 2009, required the submission of an import declaration for most plant and plant-related products. The import declaration would include, *inter alia*, information on the plant species, country of harvest, value of importation or quantity of the plant used. The Animal and Plant Health Inspection Service of the US Department of Agriculture had launched a public consultation on these new measures, inviting interested stakeholders to submit comments by 8 December 2008.

While the European Communities shared the US commitment to fight illegal logging, concern was expressed with regard to the potential negative impact on EC exports to the United States. The new measures could potentially impact a wide range of products. Detailed comments would be transmitted within the framework of the consultation that was launched in the Federal Register. The United States were urged to take the comments into account in the ongoing discussions on this proposal.

The representative of Argentina shared the concerns expressed. He pointed out that the new measures required an import license for plant products and products derived from plant species including sports products, musical instruments, furniture, textiles and manufactured products

made from plant resin. It was his delegation's view that the regulation was not necessarily intended to protect endangered species but rather to protect domestic markets from imports.

The representative of Canada shared some of the concerns expressed and noted that comments would be submitted to the Untied States.

The representative of Switzerland echoed the views expressed and noted that comments would be submitted. She stressed that the scope of the products that would require a declaration under the Lacey Act was very broad and that it only applied to imported products.

The representative of the United States explained that the Lacey Act had initially been signed into law in 1900 and that it was the United States' oldest national wildlife protection statute, which had served as an anti-trafficking statute protecting a broad range of wildlife and wild plants. The Lacey Act was amended with the passage of the 2008 Farm Bill and the purpose of the amendment was to combat illegal logging and to expand the Lacey Act anti-trafficking protections. While his delegation understood Members' concerns, he noted that the United States and other countries shared a desire to assist countries in combating illegal logging and associated trade, and the amended Lacey Act provided a new tool for that effort.

The representative of the United States further pointed out that any actions taken to implement the amended Lacey Act would be done in a manner consistent with the US international trade obligations. The careful and measured approach to implementation that the United States was taking would demonstrate that the planned import declaration would be developed and implemented so as not to be an undue burden. His delegation was actively engaged in consultations with a wide range of stakeholders regarding all aspects of implementation. Particular attention was put on the declaration and the plan for phased-in enforcement. He drew the Committee's attention to the fact that the requirement to file the declaration would not be immediately enforced and that implementation would begin no earlier than 1 April 2009. In addition, there would be a phased-in approach over time to enforcing declaration requirements, with an initial focus on products more closely linked to illegal logging. When in force, the declaration would not require information on legality, but would require information on the country where the plant material was harvested.

Finally, the representative of the United States noted that a Corrigendum to the original notification had been submitted to clarify a few points, in particular that the measure was not a technical regulation, and to inform about the delay in the enforcement of the measure.

EUA X Coréia – Import Review Process for Functional Cosmetics

Korea – Import Review Process for Functional Cosmetics

The representative of the United States raised a concern regarding Korea's import review process for functional cosmetics. He pointed out that the applicable Korea Food and Drug Administration (KFDA) regulations appeared to treat imports differently than domestic products in at least two significant areas. The first was the quality testing process. While domestic companies could combine their internal quality tests with the KFDA-mandated tests, importers had to test their active ingredients in Korea in order to get KFDA approval, in addition to their internal quality controls. He further noted that, in addition to the KFDA approval process, there was a requirement for the final product - a sample of every imported batch, even different colours of the same product - to undergo a second round of testing in Korea before being allowed to be sold. This second round of testing imposed significant costs on importers that their domestic counterparts were not burdened with, and should be abolished.

The second area where Korea appeared to treat imports differently than domestic products was the involvement of the Korean Pharmaceutical Trade Association (KPTA) in the customs

clearance process. It was the United States' understanding that, as part of an agreement Korea had recently reached with the European Communities, importers would no longer have to submit the quantitative detailed formulas of their products to KPTA. The United States welcomed and appreciated this as a positive step and expected that this would apply to all Korea's trading partners. However, from the US perspective, the entire step of reporting information to the KPTA was redundant, unnecessary, and subjected imports to a requirement that domestic products were not affected by. Only importers needed to go through the step of having the KPTA review and approve their documentation - ingredients, product names, product classification - in order to sell their products in Korea. KPTA could hold up the entire customs clearance process while it asked for supplementary information.

The representative of the United States also recalled that concerns had been raised in the past about Korea's implementation of its requirement for exporters to submit proprietary business information to KPTA, a private association comprised of the companies that US companies were competing against in the marketplace, without providing for adequate penalties and enforcement for disclosure of proprietary information. He urged Korea to give consideration to abolishing the Korean Industry Association involvement in the process of bringing imported cosmetics to the Korean market. Finally, he noted that bilateral discussions had recently taken place and understood that Korea was reviewing the measure: his delegation looked forward to continued discussions with Korea in the context of that review.

The representative of Korea pointed out that there was no discrimination between importers and domestic manufacturers regarding conformity assessment procedures. With respect to the inspection for domestic manufacturers, there were numerous inspection procedures, including during the manufacturing phase. In terms of confidentiality, according to internal regulations of the KPTA, there was a strong protection clause order to protect confidential commercial information. He took note of the concerns expressed by the United States and stated that bilateral discussions could be intensified in order to accommodate these concerns.

Canadá, Cuba, China, Equador, Colômbia e outros X UE - Dangerous Chemical Substances; Draft Commission Directive amending, for the 31st time, Council Directive 67/548/EEC (G/TBT/N/EEC/212)

European Communities – Dangerous Chemical Substances; Draft Commission Directive amending, for the 31st time, Council Directive 67/548/EEC (G/TBT/N/EEC/212)

The representative of Canada raised concerns about a draft regulation on the 31st Adaptation to Technical Progress (ATP) to the Dangerous Substance Directive 67/548/EEC (G/TBT/N/EEC/212). Her delegation regretted that, despite the previous commitments to review the classification and labelling of nickel substances in light of any new relevant scientific findings or interpretations, the European Communities had not take into account the concerns expressed by industry and trading partners. In particular, although industry stressed that the proposed classification for nickel carbonates was not based on sound scientific analysis under the 30th ATP, the European Communities decided to classify more than one hundred nickel substances under the 31st ATP using mainly the same data. With the implementation of this proposal, nickel substances would be treated as proven human carcinogens, and many of them would also be classified as reproductive toxicants and mutagens, among other hazards.

The Canadian representative stressed that her delegation was not taking a position on the toxicity or carcinogenicity of particular nickel-based substances; rather, there were concerns that the issues raised by industry had not been taken into account nor had sufficient time to conduct the necessary research been given. Some other specific concerns on the 31st ATP were raised by his delegation. First, Australian officials and the nickel industry had pointed out that water solubility, which the European Commission relied on, was not sufficient to delineate a category for read-across. Second, Canadian industry had expressed concern that water solubility was not

a predictor of bioavailability. Third, industry was concerned that the European Communities' reliance on "expert judgement" as part of the OECD read-across methodology was flawed because the supporting information for the "expert judgement" had never been made available. The European Communities was therefore requested to provide the full supporting information for its "expert judgement".

Furthermore, Canada had been informed that the European Communities had scheduled a meeting of the Technical Progress Committee (TPC) on 19 November 2008, in which EC member States would be asked to vote on the 31st ATP. In this regard, the representative of Canada asked the European Communities to confirm the date of this meeting and explain how they planned to take into account the comments submitted by trading partners, given that the comment period for this notification closed on 18 November 2008. Finally, the representative of Canada encouraged the European Communities to identify the downstream consequences of its proposed technical regulation. She reiterated concern that the European Communities would use the same methodology as a model for future classifications of other substances under REACH.

Canada exported over US$8 billion worth of nickel and nickel substances to the European Communities each year. It was therefore critical that any restrictions imposed on nickel substances be based on sound science and did not represent an unnecessary barrier to trade. The representative of Canada requested that the 31st ATP be withdrawn, and that the delay in adoption allow sufficient time for information submitted by industry to be properly considered. Alternatively, Canada urged the European Communities to remove all nickel classification proposals in the 31st ATP and allow nickel classification to proceed under REACH.

The representative of Cuba was concerned that the European Communities proceeded with the 31st ATP in spite of the considerable criticism directed at the 30th ATP on account of the read-across methodology, which was again being used as the basis for classifying more than one hundred nickel compounds.[4] It was also recalled that communications regarding these classifications had been sent to various European Commission authorities in Brussels by the ACP Group and by a group of developing countries in conjunction with other developed countries in February and March 2008, respectively, as well as in a further letter sent by the ACP Group at the end of October.

The Cuban representative pointed out that the technical consultation held on 4 November 2008 by the European Communities was considered by Cuba to be a somewhat tardy endeavour. Given the complexity of this issue, the consultation should have taken place earlier and indeed several such consultations should have been held. Moreover, the European Communities' responses at that consultation were not considered convincing. In particular, it was noted that not a single scientific publication had been mentioned or distributed, nor was there mention of any research centre or researcher in a position to back up the European Communities' theories about the classification of nickel compounds. In this regard, Article 2.2 of the TBT Agreement provided that "in assessing such risks, relevant elements of consideration are, *inter alia:* available scientific and technical information, related processing technology or intended end-uses of products".

The Cuban delegation also noted that, at the above-mentioned consultation, the EC had asked the Members about the implications for and impact upon their countries and industries of the Dangerous Chemical Substances Directive. These were precisely key factors which the European Communities should have ascertained and assessed when developing the draft Directive. In this regard, the representative of Cuba drew the Committee's attention to Article 2.2 of the TBT Agreement, which also provided that "Members shall ensure that technical

[4] A communication setting out the details of Cuba's concerns was subsequently circulated in document G/TBT/W/301.

regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create".

The European Communities was requested to take into consideration Article 12.3 of the TBT Agreement, which provided that "Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members". In fact, it was stressed that the adverse effects of the new classifications on the nickel industry were incalculable and would have repercussions on other industries which use nickel and nickel compounds, such as steel, stainless steel, surface treatment, batteries, nanotechnologies, the automotive, aviation and electronics industries. The impact of these classifications would also be felt by other industries which use nickel substances for other industrial or chemical processes as catalysts in oil refining, food processing and hydro cracking.

The representative of Cuba pointed out that the reclassification of these substances would have consequences for their labelling, packaging, transport and handling. At the same time, the reclassification of nickel on one of the largest and most important world nickel markets would affect the access of nickel and nickel products not merely to that market, but also to other major markets, given that it would not be long before a domino effect would see other major markets adopting this classification, as had been the case previously with other standards and classifications. It was his delegation's understanding that such consequences would result in substantial costs for a large group of developing countries, including a number of LDCs and African countries which were amongst the poorest in the world, as well as Latin American and Asian countries. In particular, they would be required to set up special and costly storage and handling facilities to improve worker protection and safety, and to pay higher wages at both the production, storage and transport stages and in the end-use industries. All as a result of purported risks which, in the Cuban delegation's opinion, had not been scientifically proven.

The Cuban representative also stressed that the reclassification of nickel substances was taking place in the context of a financial crisis which was affecting developing countries, and which had led to a global contraction of credit and investment. In this regard, such classification of nickel substances as Category I carcinogen would trigger a contraction in demand and investment in this industry and an increase in production, transport and insurance costs. It was also recalled that the international price of nickel, which climbed to more than US$50,000 per ton had fallen to just above US$8,500 per tonne. Given the speculative nature of the markets for commodities such as nickel and their sensitivity to factors such as new standards, it could not be ruled out that the process related to the 31st ATP was one of the factors that brought about the drop in nickel prices. Again, the representative of Cuba highlighted that these adverse effects would be particularly severe for developing countries which, given their low levels of development and industrialization, relied on a few export products for employment and revenue. The Cuban economy would be significantly affected by this measure given that it possessed one of the world's largest reserves of nickel and that nickel constituted the country's main export product.

The representative of Cuba considered the 31st ATP as an unnecessary obstacle to trade and therefore inconsistent with Article 2.2 of the TBT Agreement. He drew the Committee's attention to the fact that the read-across methodology consisted of predicting adverse effects on environment and health from chemical substances for which no toxicity data existed, by comparing them with other substances with similar structures or properties for which information did exist. In particular, the European Communities was trying to establish a similarity between one hundred nickel compounds and nickel carbonates on the basis of a

comparison of their water solubility. The representative of Cuba pointed out that the same substance being used as a reference was already incorrectly reclassified as dangerous, using the same method without any scientific underpinning.

He further stressed that a number of specialized bodies, such as the Nickel Institute, stated that the comparison methodology used by the European Communities did not follow either the guidelines established by the OECD or the criteria of the US Environmental Protection Agency (US EPA), on the basis of which such methodology was developed. This was due to the fact that the European Communities disregarded three of the eight essential verification steps established by the OECD guidelines, without providing any explanation as to why those steps were omitted. The European Communities asserted that this procedure was justified by "expert criteria", but contrary to the OECD guidelines, US EPA practice and even European Community legislation itself, the data on which the "expert criteria" was based had not been furnished. Moreover, for both the OECD and the US EPA, establishing categories or groups of chemicals for the purpose of this methodology was a complex process involving the review of a number of elements. One of the many physico-chemical properties to be considered when making the comparison was water solubility. Far from taking the entire range of factors established in the OECD guidelines into consideration, the European Communities restricted itself almost exclusively to the least appropriate one, if account was taken of the fact that no data existed on the water solubility for most of the nickel compounds that were classified in the 31st ATP. The representative of Cuba also recalled that it was scientifically demonstrated that water solubility was not a property which determined whether nickel compounds were soluble in biological fluids, given that solubility varies widely from one fluid to another.

Cuba raised five specific questions in respect of the above. First, could the European Communities explain how water solubility was used as the key factor for grouping nickel substances, when there was no available data on the water solubility for most of the nickel compounds which were classified in the 31st ATP? Second, data existed which indicated that the solubility of nickel compounds in water was not the same as solubility in body fluids and that the solubility of nickel substances in human body fluids varied. Could the European Communities provide data or scientific studies which provide evidence to the contrary? Third, could the European Communities provide scientific evidence from published studies which prove that water solubility predict the bioavailability of the nickel ion in the cells of human organs? Fourth, could the European Communities provide a detailed explanation, on the basis of published studies, of the scientific criteria and data supporting the conclusion that because one substance is carcinogenic another, different substance, also had to be? Fifth, could the European Communities make available its evaluation, or documented evidence, of the risks of exposure from normal and expected use of the nickel compounds classified in the 31st ATP?

In addition to the lack of scientific consistency, the representative of Cuba drew the attention of the Committee to the timetable established by the European Communities for the adoption of the 31st ATP. Cuba considered that the European Communities was not allowing enough time for Members to submit comments and for consultations to be held. Nor was this period sufficient for the European Communities to review and take into account these comments, as required under Article 2.9.4. of the TBT Agreement. Moreover the deadline also precluded any possibility of in-depth discussions being held within the Committee, as required under Article 2.9 of the TBT Agreement.

The representative of Cuba was particularly concerned by information according to which the European Communities would organize a vote within the Technical Progress Committee on 19 November, two weeks after the TBT Committee meeting and one day after the deadline of the comment period. Considering that after this vote amendments to the 31st ATP would be virtually impossible, the European Communities was requested to explain how they planned to study, take account of comments and, if necessary, amend the 31st ATP Directive within 24 hours of the end of the notification comment period. Finally, the representative of Cuba

requested the European Communities to take into account the concerns and comments expressed by developed and developing countries, and amend the draft regulation to exclude nickel compounds from the scope of its application. Cuba also requested the extension of the comment period, by at least sixty days, in order to enable Members to submit comments and further bilateral and multilateral consultations be held.

The representative of China shared the comments expressed by the delegations of Cuba and Canada. While China appreciated the sixty day period provided for comments on the notification of the 31st ATP, it was recalled that the proposed regulation was highly technical, covering over six hundred chemicals and more than one hundred nickel compounds. The European Communities was therefore encouraged to extend the deadline for submitting comments, in order to give Members the possibility to carefully evaluate the proposed regulation. In this regard, the representative of China drew the Committee's attention to Article 2.9.4 of the TBT Agreement, which provides that "Members shall without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussion into account". Also, China had been informed that the European Communities had scheduled a meeting of the Technical Progress Committee on 17 November 2008, in which EC member States would be asked to vote on the 31st ATP. In this regard, the representative of China requested the European Communities to clarify how they planned to take into account the comments submitted by trading partners, given that Members were still formulating their comments on this notification. Since his delegation considered this to be inconsistent with Article 2.9.4 of the TBT Agreement, the European Communities was requested not to vote on the notified draft regulation before giving full consideration to Members' comments and concerns.

The representative of China noted that using water solubility as the only scientific information and read-across as the methodology to classify over one hundred nickel compounds was not scientifically correct. In fact, it was his delegation's opinion that classification of substances could not be based on one single factor but other factors, such as structure and physicochemical nature, had to be taken into account. China added that the European Communities did not provide any specific data on the water solubility of most nickel compounds. The Chinese representative also pointed out that the European Communities did not follow all the necessary steps in the OECD read-across methodology for substance classification. The European Communities missed three specific steps: "prepare category test plan", "conduct necessary testing", "perform an external assessment of the category and fill data gaps". It was also highlighted that from existing scientific data and risk assessment reports on some substances, read-across classifications based on water solubility appeared to differ from those based on scientific documents. Therefore, China believed that the read-across methodology based on water solubility was not a scientific method. Finally, China invited the European Communities to explain the justification for the draft regulation according to Article 2.5 of the TBT Agreement, and reconsider the classification and labelling of nickel compounds under the 31st ATP.

The representative of Ecuador, speaking on behalf of GRULAC recalled that, on 12 March 2008, a letter regarding the proposed reclassifications of numerous nickel substances under the 30th and 31st ATP had been sent to the European Commissioners for Enterprise and Industry, Environment and External Trade by some Members of the Group of Latin and Caribbean Countries (GRULAC). In this letter, the European Communities was specifically requested not to proceed with the reclassification of nickel substances under the 30th and 31st ATP and allow sufficient time for scientific information submitted by industry to be properly considered. His delegation regretted that the European Communities had adopted the 30th ATP without taking into account the concerns previously expressed by Members of the TBT Committee, and feared that the 31st ATP would follow the same fate. Ecuador stressed that both the 30th and 31st ATP were of concern to Members that produced nickel, that manufactured goods using nickel compounds or used them in other industrial and chemical processes. It was recalled that the

proposed reclassification of nickel substances would negatively affect the trade, economic growth and development of many GRULAC's members.

The representative of Ecuador pointed out that the 31st ATP was not consistent with the provisions of the TBT Agreement. Furthermore, these Directives created concerns for other mineral and substances producers in the Latin America and the Caribbean region, because the approach followed by the European Communities in the application of the read-across methodology in the 31st ATP would likely set a negative precedent for regulating other substances under REACH. While members of GRULAC recognized the need for authorities to regulate the use of dangerous substances for protecting human health and environment, it was noted that the read-across methodology had to be used in a scientifically sound manner in order to avoid unnecessary barriers to trade.

Ecuador was also concerned that, despite the efforts of some GRULAC members, no clarifications on the science and data used to formulate the 31st ATP had been received from the European Commission. While the 31st ATP relied only on water solubility for defining groups of similar nickel substances, the read-across method was a complex process that involved reviewing a number of inputs, not only a single variable. Concerns remained that there was no data on the water solubility for most of the nickel compounds, that existing data on water solubility for some nickel compounds varied from one substance to the other, and that water solubility was not a predictor of the solubility of nickel compounds in biological fluids. Moreover, there were no scientific information on toxicological effects for most of nickel substances or scientific information that nickel substances with similar water solubility would cause similar toxicological effects.

The European Commission was therefore encouraged to take into consideration the demands of transparent and scientific data as basis for any future reclassification of nickel or any other substances. GRULAC members further requested that any regulatory measure that had a large impact on international trade be no more trade restrictive than necessary. Finally, the European Communities was urged to take into account the concerns and objections raised by WTO Members and remove all nickel classification proposals in the 31st ATP.

The representative of Colombia associated his delegation with comments made by Ecuador.[5] Colombia was particularly concerned that the final date for comments established by the European Communities was restricted to sixty days from the date of notification. This period of time was insufficient for Members to exercise their rights, especially since the issue addressed by the draft amendment was a sensitive one and a cause of considerable concern to many Members. Colombia was therefore surprised that the time limit was not ninety days, as recommended in the Fourth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade.[6] In this regard, the Colombian representative requested the European Communities to remove all nickel classification proposals in the 31st ATP and to explain the EC legislative schedule and the steps to be taken prior to the adoption of the 31st ATP, including voting within the Technical Progress Committee.

Colombia made this request on the basis of the European Communities' own assertion in notification G/TBT/N/EEC/212 that: "the inclusion of the entries for nickel compounds is still under internal review". This indicated that there was uncertainty even within the European Commission itself as to whether clear and scientific justification existed for the reclassification of nickel and related substances as dangerous substances in the 31st ATP.

The representative of the Dominican Republic reiterated concerns on the proposed re-classification of nickel carbonates and other components of nickel, which her delegation

[5] The full statement detailing Colombia's concerns is contained in document G/TBT/W/297.
[6] See G/TBT/1/Rev.9 p.18.

considered to lack sufficient scientific evidence.[7] She also noted that the comments expressed by various delegations at the meetings of the TBT Committee on 20 March 2008 had not been taken into account for the amendment of Directive 67/548/EEC. It was her delegation's view that, having been adopted in these circumstances, the above-mentioned directive did not satisfy the requirements of Article 2.9 of the TBT Agreement.

The Dominican Republic had serious concerns about the timing for adoption of the proposal and the basis for the proposed classification of 117 nickel substances. In particular, the Dominican Republic objected to the manner in which the European Communities applied the read-across methodology. While read-across was based on an assumption that groups of chemicals with certain common characteristics caused similar toxicological effects, in order to apply the methodology properly it was necessary to identify the relevant defining characteristics and then to verify that those characteristics in fact produced similar toxicological effects. Without such verification, the assumptions underlying the substance groupings were scientifically unproven hypotheses. In this regard, the representative of Dominican Republic believed that the European Communities violated Article 2.2 of the TBT Agreement. Moreover, she recalled that nickel exports represented, in 2007, more than 50 per cent of the total exports of the Dominican Republic, and that the proposed directive would have a negative effect on industry and the economy of the country as a whole.

In addition, the representative of the Dominican Republic was concerned that the legislative timetable for the adoption of the 31st ATP failed to provide sufficient time for consultation with other WTO Members. The Dominican Republic believed that, unless rectified, the timetable precluded the possibility of a meaningful discussion by the TBT Committee of the 31st ATP, as it was required by Article 2.9 of the TBT Agreement. In particular, it was noted that the sixty days comment period was not sufficient to allow Members to provide comments, and for the European Communities to review, respond and take into account those comments as required by Article 2.9.4 of the TBT Agreement. Finally, the representative of the Dominican Republic expressed serious concern about some reports that the European Communities could organize a vote of the Technical Progress Committee on 19 November 2008, following which amendments to the 31st ATP would be virtually impossible. Therefore, she reiterated the request that nickel substances be removed from the proposed 31st ATP.

The representative of Venezuela supported the comments made by Ecuador, Cuba, China and Canada, and expressed his concern that the adoption of the 31st ATP would create unnecessary obstacles to the trade of nickel substances. In particular, Venezuela was concerned about the lack of discussion and evaluation of the 31st ATP among Members; the quality of the technical criteria used within the Directive; the read-across methodology; the possibility that a precedent was created. It was also recalled that Venezuela was currently strengthening its sector of nickel extraction and in 2008 invested US$100 million in this area. The representative of Venezuela urged the European Communities to remove all nickel classification proposals in the 31st ATP.

The representative of Japan thanked the European Communities for organizing the information session on the Dangerous Chemical Substances Directive, held on 4 November 2008. Japan remained concerned that the European Communities had proposed the reclassification of nickel compounds under the 31st ATP without giving a satisfactory clarification to the many concerns raised on the 30th ATP, in particular with regard to the inadequate read-across methodology. While the read-across methodology proposed by the OECD required the conduct of an eight steps test for chemical categorization, the European Communities did not fully follow the OECD guidance.

[7] A communication detailing Dominican Republic's concerns was subsequently circulated in document G/TBT/W/302.

The Japanese representative stressed that the 31st ATP proposal also contained nickel hydroxide, and that this substance was widely recognized as a material for manufacturing nickel-hydrogen batteries, which were commonly known to be "clean" from an energy perspective. While at the last Committee meeting and at the bilateral meeting the European Communities had explained that the substances covered by this Directive were only required for proper labelling, Japan was concerned that the EC proposal would have a significant impact both on nickel-hydrogen battery manufacturers and on their users if nickel hydroxide would be inappropriately classified on the bases of an inadequate read-across.

Furthermore, the European Communities declared that the methodology applied for the proposed nickel reclassifications would be a model for future classifications under REACH. In this regard, the decision would have a severe impact on the nickel industry and many other related sectors as well as their global supply chain, and it would be more trade restrictive than necessary. Therefore, the representative of Japan requested the European Communities to postpone the 31st ATP, especially the nickel compounds classification proposal, until Members' concerns were fully addressed.

The representative of Mauritius, speaking on behalf of the ACP group shared the comments made by previous delegations, in particular those of Cuba and Ecuador. He also recalled that on 23 October 2008 the Chairman of the ACP Committee of Ambassadors in Brussels had sent a communication to various European Commission authorities in which serious concerns were expressed about the proposed 31st ATP. The 31st ATP was a matter of concern not only for nickel producers but also for those Members that manufactured goods using nickel compounds in other industrial chemical processes. In this regard, the read-across methodology used for the reclassification of nickel could set a precedent for regulating other substances under REACH thereby amplifying the impact of the methodology across numerous products and economic sectors.

It was recalled that Article 2.9.4 of the TBT Agreement obliged Members to "allow reasonable time for Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussion into account". The European Communities was therefore encouraged to extend the deadline for submitting comments to the notification of the 31st ATP. His delegation also regretted that, despite the many concerns previously expressed by trading partners with regard to the 30th ATP, the European Communities continued to use the same methodology for the proposed 31st ATP. While the 31st ATP relied only on water solubility for defining groups of similar nickel substances, the read-across method was a complex process that involved reviewing a number of inputs, not only a single variable. Finally, the representative of Mauritius stressed that the reclassification of nickel substances without scientific justification would restrict a significant proportion of ACP's trade in nickel substances, and would have an adverse impact on the growth and development of ACP countries. In this regard, the proposed 31st ATP would be inconsistent with Article 12.3 of the TBT Agreement. The European Communities was therefore urged to remove all nickel classification proposals in the 31st ATP so as not to create unnecessary obstacles to the trade of nickel substances.

The representative of Brazil shared the concerns raised by other Members and supported, in particular, the comments made by Ecuador on behalf of GRULAC. He expressed his delegation's concern that the 31st ATP, like the 30th ATP, appeared to be based on a conjunction of wrong assumptions and weak science. It was noted that the proposed 31st ATP classified as hazardous more than one hundred nickel components, treating them as proven human carcinogens and many of them as reproductive toxigens and mutagens.

The representative of Brazil stressed that the 31st ATP would impose unjustifiable restrictions on international trade, especially for developing countries. In particular, Brazil was seriously concerned that the classification of nickel compounds in the 31st ATP had been done by means

of an inadequate use of read across methodology. In fact, water solubility was used as the only criteria to group nickel compounds for which no data existed, and to assign them toxicological properties of some reference substances. It was recalled that such an approach was contrary to the OECD guidance on read-across, which stated that category assessments were often complex and involved reviewing a number of inputs.

Brazil therefore requested the European Communities to explain why some fundamental steps indicated in OECD guidance had been skipped in the process of reclassification of nickel compounds. The representative of Brazil also noted that, while nickel carbonates served as a reference substance of soluble nickel compounds in the 31st ATP, however, the classification of nickel carbonates as hazardous substances in the 30th ATP was also carried out amid a lack of toxicological data and inappropriate use of read-across. Specifically, the classification of nickel carbonates was based on nickel sulphate which had different properties regarding water solubility. In this regard, Brazil encouraged the European Communities to explain why water solubility was disregarded when classifying nickel carbonates in the 30th ATP, and, instead, chosen as the *only* criteria for grouping nickel compounds in the 31st ATP.

It was also noted that, in the notification of the 31st ATP, the European Communities mentioned that the inclusion of nickel compounds was still under internal review and if the draft directive was modified in this respect, a revised draft directive and revise explanatory note would be submitted, if possible within the 60 days commenting period. Given the complexity of this issue, Brazil requested the European Communities to grant another 60 days comment period if the draft Directive would be modified. In this regard, Brazil joined other delegations in asking for an extension of the period for comments on the 31st ATP. Finally, the Brazilian delegation encouraged the European Communities to clarify why the 31st ATP had to be adopted by the end of the year if, as stated, the Globally Harmonised System of classification and labelling of chemicals (GHS) would revoke the Directive the following year.

The representative of Indonesia shared the comments made by previous delegations about the proposed 31st ATP. In particular, Indonesia requested the European Communities to ensure that the Dangerous Substance Directive 67/548/EEC would not create unnecessary obstacles to trade, as set out in Articles 2.2 and 12.3 of the TBT Agreement.

The representative of Philippines joined the concerns raised by other Members on the reclassification of nickel, and stressed that this Directive could unnecessarily restrict international trade in nickel products.

The representative of Australia reiterated her concerns regarding the EC's reclassification of nickel carbonate under the 30th ATP and with the EC proposed reclassification of more than 117 other nickel compounds under the draft 31st ATP. Australian authorities had reviewed the scientific literature available on the issue, including EC and OECD documentation, and had concluded that there was no reliable data on the carcinogenic potential of nickel carbonates, that the use of read-across methodology should be based on groupings of substances which were robust and scientifically valid and that solubility in water alone was an insufficient criterion on which to base read-across methodologies. These conclusions had been presented to the European Communities on 29 September 2008.

While Australia appreciated the opportunity to address the experts' meeting organized by the European Communities, concerns remained that the conclusions reached had been disregarded. In particular, the representative of Australia remained concerned that the EC approach to the nickel group could create a precedent for the manner in which other groups of chemical substances would be classified in future, including under the 31st ATP and REACH. In particular, it was her delegation's understanding that Annex VI of the Proposal for a Regulation of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures and amending Directive 67/548/EEC and Regulation (EC) No

1907/2006 (the CLAP Regulation) would include harmonized classifications, including those of the 30th and 31st ATP, and those coming from REACH, via an ATP procedure. This would create a precedent, and her delegation was concerned about the scientific and procedural grounds of this precedent.

The representative of Australia stressed that the EC proposed reclassification of nickel substances under the 31st ATP would have a significant economic and commercial impact on all nickel producing and exporting countries, including developing countries. She also highlighted that the nickel compounds listed in ATP 31st were used in a large range of processes. In this context, concerns remained that nickel substances and preparations containing such substances would need to be labelled with danger symbols, including the "skull and crossbones", which would potentially contribute to the stigmatisation of nickel and nickel-containing material and could reduce research and investment in important nickel-based technologies and materials; that the reclassification of nickel compounds as Category 1 and 2 carcinogenic and mutagenic compounds would trigger a series of downstream regulatory requirements which would impose addition restrictions and prohibition on the substances; that the reclassified Category 1 or 2 carcinogenic and mutagenic substances would be deemed "substances of very high concern" (SVHC) under REACH and could result in additional restriction, prohibition, or substitution of nickel; and finally that the planned classification would reduce supply of nickel substances to downstream users and damage the competitiveness of manufactures in critical sectors that rely on nickel substances.

Furthermore, Australia recalled that, in accordance with Article 2.2 of the TBT Agreement, technical regulations should not be more trade restrictive than necessary to fulfil a legitimate objective. The European Communities was therefore requested to assess what the trade impacts would be prior to the adoption of the 31st ATP, particularly given the serious concerns expressed by developed and developing countries. Australia also supported the concerns raised by the ACP group that the reclassification of nickel compounds without scientific justification would restrict a significant proportion of the ACP trade in nickel substances, and would have negative impacts on their growth and development. Given the significant commercial implications of the proposed reclassification of nickel compounds under the 31st ATP, it was essential that any restriction imposed by the European Communities on nickel compounds be based on sound and transparent science which did not place unnecessary obstacles to international trade.

The representative of Australia was further concerned by reports that, on 19 November 2008, the EC Technical Progress Committee would vote on the 31st ATP. In this regard, she asked the European Communities to confirm the date of this meeting and explain how they planned to take into account the comments submitted by trading partners in accordance with Article 2.9.4 of the TBT Agreement. She sought assurance that no action would be taken to implement the 31st ATP until the concerns raised by nickel producing and exporting countries were satisfactorily addressed.

In concluding, the representative of Australia encouraged the European Communities to adopt a sound, defensible and transparent science-based approach to the reclassification of nickel compounds, and to refrain from the implementation of the 31st ATP until the concerns expressed by a wide range of affected stakeholder, including members of the TBT Committee, were satisfactorily discussed. Australia recognised the importance of ensuring a high standard of protection for human health and environment, and supported the development of regulatory strategies to achieve such protection. However, in accordance with Article 2.2 of the TBT Agreement, these regulations should not create unnecessary obstacles to international trade. In this context, Australia also noted that Article 2.9.4 of the TBT Agreement stated that if a technical regulation could have a significant effect on trade of other Members, the introducing Member should "allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account".

The representative of Korea supported the objectives of protecting health and the environment. However, taking into account the significant impact of the Dangerous Chemical Substances Directive on industry, Korea encouraged the European Communities to implement the ATP 31st only after careful consideration of scientific evidence, social and economic impact assessments and further technical consultations with WTO Members.

The representative of Botswana joined the statement made by Mauritius on behalf of the ACP group, and raised further concerns about the 31st ATP. It was stressed that Botswana was a small and vulnerable economy, highly dependent on mineral exports, including diamonds, copper, nickel and soda ash. In 2007, nickel contributed to about fifty per cent of all exports. The representative of Botswana also noted that copper and nickel mining sectors had benefited from the SYSMIN programme, a system created by the European Communities to stabilize export earnings from mineral products. However, this system would be undermined by the proposed directive.

The representative of Botswana was concerned that the reclassification of nickel compounds as dangerous substances would have far reaching implications for the mining industry in his country, as well as potentially harming other sectors of the economy. It was recalled that this would negatively affect the trade, economic growth and development of Botswana, particularly at a time of global financial crisis. In particular, concerns remained about the adoption of the water solubility read-across method in the 31st ATP, which Botswana did not believe to be an appropriate indication of toxicity. Botswana recognised the importance of ensuring a high standard of protection for human health and environment and supported the development of regulatory strategies to achieve such protection. However, in accordance with WTO provisions, it was recalled that these regulations needed to take into account the special development, financial and trade needs of developing country Members. The European Communities was therefore encouraged to remove all nickel classification proposals in the 31st ATP and provide technical assistance to developing countries with regard to REACH.

The representative of Zimbabwe supported the statement made by Mauritius on behalf of the ACP group, Cuba and other delegations. She recalled that the proposed reclassification of nickel compounds under the 31st ATP did not take into account the special development, financial and trade needs of developing country Members. Finally, the European Communities was urged to extend the comment period of the draft directive.

The representative of South Africa echoed the concerns already expressed about the adoption of the 31st ATP by various delegations, particularly those of Canada and Cuba. While his delegation supported the protection of human health and environment, the proposal appeared to go far beyond the previously established process for identifying hazardous properties based on scientific data. Furthermore, the 30th and the 31st ATP relied on a questionable read-across methodology, which did not follow the eight steps for read-across described in the OECD guidance documents. Also, South Africa remained concerned about the timing for adoption of the proposal and the scientific basis for the nickel reclassifications. In particular, the South African representative noted that the 31st ATP read across the most severe classifications from four identified substances with scientifically proven hazardous properties to almost all marketed nickel-containing substances.

South Africa was especially concerned that these classifications would not only be applied in Europe but that, through the mechanism of the UN's Globally Harmonised System of classification and labelling of chemicals (GHS), they would be extended world wide. Furthermore, South Africa was deeply concerned that these substances would be deemed "substances of very high concern" (SVHC) under REACH, resulting in additional restriction, prohibition, or substitution of nickel substances. It was his delegation's understanding that many of these substances would meet the criteria for listing in Annex XIV of REACH because of the tonnages used by industry. In that case, a company would not be allowed to place on the

market or use a substance included in Annex XIV of REACH unless the European Commission would grant a use specific and time limited authorisation. The progressive replacement of these materials would in effect prevent the use and production of nickel metal and eliminate nickel substances from use in many thousands of important chemicals applications from batteries, catalysts, electronic components, through to dyes and inks.

In concluding, the representative of South Africa stressed that this would effectively shut down an important industry for South Africa and other developing countries. It was recalled that the EC market accounted for about forty per cent of total world nickel usage, and that South Africa's share of this market was worth some US$4 billion per annum. South Africa believed that the implementation of the 31st ATP would seriously affect the future investment by the industry itself and impact negatively on trade and growth. Therefore, the representative of South Africa urged the European Communities to remove all nickel classification proposals in the 31st ATP and extend the comment period on the notification of the Directive.

The representative of Turkey joined the concerns expressed by other Members on the proposed reclassification of nickel compounds under the Directive 67/548/EEC. With regard to the 30th ATP, the inclusion of a preamble indicating the possibility of re-evaluating the classification of certain substances in the light of new scientific information was not considered to address the scientific shortcomings of the adopted classification. In particular, it was recalled that Members appeared to be unable to agree on a common meaning of the term “scientific”. In this context, the representative of Turkey regretted that the European Communities had adopted the 30th ATP without taking into adequate consideration the comments made by other WTO Members.

The Turkish representative pointed out that the objections to the 30th ATP were also valid for the 31st ATP. Finally, the delegation of Turkey reiterated that the classification decisions in both the 30th and 31st ATP did not have a legitimate objective and had the effect of creating unnecessary obstacles to trade. The EC’s approach to classifying substances also appeared to set an inappropriate and dangerous precedent for other assessments. Therefore, these classifications were considered as infringements of Turkey’s rights under the relevant provisions of the TBT and GATT Agreements.

The representative of India shared the concerns raised by previous speakers about the proposed reclassification of nickel compounds. Indian industry had a significant export interest in industrial products containing nickel compounds. The European Communities was therefore encouraged to resolve this issue on the basis of sound scientific analysis, in order not to cause any unnecessary barrier to trade.

The representative of Chile associated himself with the comments made by the delegation of Ecuador on behalf of GRULAC. While he thanked the European Communities for organizing the information session on the Dangerous Chemical Substances Directive (4 November 2008), he shared the concerns already expressed by other WTO Members. In particular, he encouraged the European Communities to extend the deadline for submitting comments to the notification of the 31st ATP.

The representative of the United States reiterated his delegation's concern regarding both the 30th and 31st ATP. With regard to the 30th ATP, he regretted that the European Communities had finalized the 30th ATP and, as a result, classified borates as a Category 2 substance. In particular, he noted that the European Communities did not appear to have taken into account the normal handling and use of borates-containing products when proposing its classification of borates, and that the European Communities acknowledged that its classification was entirely hazard-based and did not factor in the actual risks of exposure from intended end uses. Additionally, the representative of the United States reiterated his delegation's concerns regarding the "skull-and-crossbones" labelling requirements for certain borates-containing products; the "knock-on" effects under other EC legislation, including a ban on the use of

borates in cosmetics, restrictions under the Marketing and Use Directive, and potential placement on the REACH authorization candidate list of a Category 2 classification; and the potential adverse impacts that this could have on the sale and trade of borates and borate-containing products.

With regard to the EC intention to conduct risk and impact assessments before subjecting borates-containing products to restrictions under the Marketing and Use Directive, he noted that the United States was closely monitoring the process and encouraged the European Communities to clarify the status of those assessments. Were such assessments being conducted for all downstream products containing borates? When could United States expect that those assessments would be completed? Would any products be subjected to restriction under the Marketing and Use Directive before the finalization of the assessments?

With regard to the 31st ATP, it was noted that the US nickel plating industry had recently submitted information indicating its concerns with the proposed Category 1 classification of nickel compounds and its serious impact on trade of nickel-containing products in several key industry sectors. In particular, industry had noted that approximately 1,000 companies in the United States provided electrochemical coating services using nickel compounds for thousands of parts and components in the automotive, aerospace, electronics, industrial machinery, hardware and other sectors. The market value of US nickel electroplating and related finishing services was estimated to be US$3.5 billion annually. Given the potential impact of Category 1 classification, representative of the United States urged the European Communities to undertake a science and risk-based analysis, in which the available scientific and technical information and intended end uses of individual nickel compounds would be evaluated.

In this context, the representative of the United States was understandable concerned with the EC argument in the case of borates that a hazard analysis was enough to classify a substance under Category 2 of the Dangerous Substances Directive. If the European Communities would take the same approach to analyzing the classification of nickel compounds in the 31st ATP, the United States would have similar concerns. In addition, the US representative also noted that in its analysis of the nickel compounds proposed to be classified under Category 1 in the 31st ATP, the Danish Competent Authority appeared to skip certain steps when applying the OECD read-across methodology. These steps involved evaluating available scientific and technical information and intended end uses of the relevant nickel compounds, raising questions as to whether the European Comunities adequately took those into account in its analysis. Therefore, the United States urged the European Communities to delay the classification of nickel compounds under Category 1 of the Dangerous Substances Directive until these issues were resolved. The United States was also monitoring the potential adverse trade impacts of the classification of borates under Category 2 in the 30th ATP, and would continue to analyze the European Communities' classification methodology that had led to these classifications in the context of REACH and other EC measures.

In concluding, the representative of the United States drew the Committee's attention to the ongoing work in ISO on the development of a standard on Social Responsibility, ISO 26000, which included provisions on chemicals and hazardous substances. It was his delegation's opinion that the draft standard could be invoked by Members as a putative legal defence for chemicals-related measures that inhibited trade and that were not risk based, thereby circumventing efforts in the TBT Committee to review these measures. In this regard, all Members were urged to discuss the EC chemicals measures with their ISO representatives, in order to ensure that they understood the potential trade policy consequences of the draft ISO standard.

The representative of the Russian Federation, speaking as an observer, shared the concerns of previous delegations with regard to the nickel classification and stressed that the proposed measure would negatively affect international trade, creating unnecessary obstacles to trade

while not resulting in practical benefit for health and the environment. In this context, attention was drawn to the European Communities improper implementation of the read-across methodology prescribed by the OECD guidelines. Furthermore, while the Russian Federation appreciated the information session on the Dangerous Chemical Substances Directive organized by the European Communities, concerns remained on several issues. The representative of the Russian Federation therefore urged the European Communities to remove all nickel classification proposals in the 31st ATP until WTO Members' concerns were fully addressed.

The representative of the European Communities regretted that at the information session on the Dangerous Chemical Substances Directive, held on 4 November 2008, only six of the twenty-two delegations that intervened on the notification of the 31st ATP took the floor to share their views and concerns with EC experts. However, the European Communities believed that the meeting had been useful to clarify some of the concerns and questions that were raised, as well as to explain in more detail how the grouping approach and read-across methodology were applied. In respect of methodology, the representative of the European Communities informed the Committee that the methodology used in the classification of the 31st ATP was similar to the one used for the 30th ATP, and therefore many of the questions raised on the 31st ATP had already been clarified during the discussions on the 30th ATP proposal. Although the 31st ATP draft was notified to the TBT Committee in September 2008, she noted that the proposal had been available together with all relevant documents from the expert meetings since December 2007, and discussions with nickel industry and stakeholders had been ongoing since 2005. Therefore, the European Communities believed that sufficient time had been granted to Members to examine and comment the aforementioned proposal.

The representative of the European Communities gave a short description of the proposed measure. She recalled that the Dangerous Substance Directive 67/548/EEC had been regularly amended, the latest one being the 30th ATP (adopted in August 2008). She also recalled the objective and extent of the EC proposal: the substances covered by this proposal (over 600) would need to bear a label which aimed at informing those who handled these substances, that they should be handled with care. It was her delegation's understanding that this was the least trade-restrictive measure available to convey such information to the people in contact with the substances at issue, therefore in line with Article 2.2 of the TBT Agreement. The EC representative recalled that the label would provide information on the hazardous properties of the preparations, but this classification would not ban or restrict the use of these substances on consumer end-products.

In this context, the EC representative drew the Committee's attention to the fact that the European Commission was required to examine within six months of the adoption of the classification proposal whether the use of those substances or preparations in final consumer products needed to be restricted, for example by setting a maximum concentration level for a given substance. It was stressed that a risk assessment would need to be carried out before imposing any type of marketing restrictions, or setting maximum exposure levels or bans. In addition, the representative of the European Communities pointed out that, due to nickel's allergen properties, only few consumer products still contained mixtures of nickel compounds. Therefore, she rebutted the comments which suggested that the proposed classification would have a significant impact on the exports of nickel compounds to the European Communities. She further recalled that no substantive information about the economic impact this classification could have under REACH or other EC legislation had been received to date.

With regard to the requests of postponing the implementation of the 31st ATP, the EC representative noted that the vote of EC member States at the Technical Progress Committee (TPC) would take place only after the expiration of the comment period. Moreover, while her delegation regularly met the representatives from nickel industry and expert from third countries, to date the European Communities had not received any scientific information which could contradict the EC assessment. She informed the delegation of the United States that the

impact assessment on the use of borates in cosmetic products was being finalized, and was expected to become available at the end of 2008. She also pointed out that the use of borates in cosmetic products was already restricted and therefore the 30th ATP had not modified the situation.

An expert from the DG Environment of the European Communities informed the Committee that the Globally Harmonised System of classification and labelling of chemicals (GHS) would be implemented by the European Communities. In response to some of the questions raised, he said that the grouping approach had been used in the framework of the Dangerous Substance Directive for years. Three specific examples (lead and lead compounds, chromates, petroleum streams and gases) were used to explain that this approach was not new. Moreover, the harmonized classification and labelling of nickel compounds was not new either: ten nickel compounds were contained into Annex 1 of the Dangerous Substance Directive and had a harmonized classification and labelling since 15 years.

On the issue of compliance with the OECD guideline on grouping approach, the EC representative pointed out that the same comments had already been clarified in the context of the 30th ATP at the Committee Meeting held on 20 March 2008. He reiterated that the OECD guideline on groupings had not been applied, in particular the last two steps (confirmatory testing) so as to avoid unnecessary animal testing. Instead, when such confirmatory testing was required to confirm that a classification was necessary, the European Communities had chosen the approach of not classifying at all.

On the comments that the EC approach to nickel compounds could create a precedent for the manner in which other groups of chemical substances would be classified in future, the EC representative recalled that identical rules applied for industry. In other words, the grouping approaches chosen would also be used by industry for meeting the registration requirements of their substances under REACH. Therefore, if a grouping approach needed a significant amount of information to be applied within a regulatory context for setting labelling and harmonized classification, the same amount of information would be required for the registration dossiers submitted by industry under REACH.

On the question regarding the rationality of the phasing between the 30th ATP, the 31st ATP and the GHS, the representative of the European Communities pointed out that the reasons for a two-step procedure with the ATP and the GHS was that the working procedures were different. In fact, under the GHS the European Agency on Chemicals (ECHA) had a central role, where under the ATP the same role was vested in the European Chemicals Bureau as part of the European Commission.

The main assumption of the approach that had been followed to classify nickel compounds in the 30th and 31st ATP was that a nickel ion was responsible for the toxicological effect of the nickel compounds. The approach used in this case, based on water solubility and other information (e.g., chemical structure of the compounds), appeared to be a widely recognised approach and was not new. For nickel compounds, this approach had been validated by EC experts, independent scientific experts within the European Union and experts from OECD countries. It was stressed that the same approach was also used by some WTO Members to classify insoluble compounds as carcinogen, like Australia. Additionally, the International Agency for Research on Cancer (IARC) also classified nickel compounds as carcinogenic. It was stressed that the European Communities had information, based on expert judgement, that both soluble and insoluble nickel compounds were carcinogen and should be classified as carcinogen Category 1. Also, based on information available (human and animal data), soluble nickel compounds had been classified as toxic for reproduction.

The representative of Cuba remained concerned that no scientific publications had been cited by the European Communities. He regretted that, despite the significant number of WTO Members

that had asked to extend the period for comments on the notified 31st ATP, the European Communities had decided not to reconsider the deadline. With regard to the scientific information which could contradict the EC assessment, the Cuban representative stressed that according to Article 2.2 of the TBT Agreement the burden was not on foreign companies to provide information, but rather on the European Communities to make sure the regulation was clear and not discriminatory.

Furthermore, the representative of Cuba recalled that the EC directive lacked scientific consistency and did not allow enough time for Members to submit comments and for consultations to be held. Nor was this period sufficient for the European Communities to review and take into account these comments, as required under the TBT Agreement. Cuba also sought clarification on the date of the Technical Progress Committee, in which EC member States would be asked to vote on the 31st ATP. With regard to the EC comment that the 31st ATP proposal had been discussed with nickel industry and stakeholders since 2005, the representative of Cuba drew the Committee's attention to the fact that at the last TBT Committee meeting the European Communities representative stated that the list of substances to be classified in the 31st ATP had not been drafted.[8] Therefore, he asked the European Communities how comments could be made when there was no classification of products.

The representative of Australia reiterated that her delegation did not oppose the use of read-across methodology when it was correctly applied in a transparent and scientifically valid manner. In response to the EC comments that no substantive information about the economic impact of this classification had been received, the representative of Australia remarked that her delegation had provided the European Communities with relevant information. However, she stressed that it was difficult to provide concrete examples of trade impacts of a directive that was yet to enter into force. Furthermore, since the EC proposed re-classification of nickel substances would have a significant economic and commercial impact on developed and developing countries, the Australian delegation requested the European Communities to clarify what assessment of the trade impact of the 31st ATP had been done. Finally, Australia requested clarification on the date of the Technical Progress Committee (TPC) and urged the European Communities to extend the comment period on the notification of the directive.

The representative of the Dominican Republic reiterated her delegation's position that the proposed re-classification of nickel compounds lacked sufficient scientific basis. In particular, concerns remained that the European Communities did not provide the scientific data and publications used to formulate its "expert judgement". Also, the representative of the Dominican Republic stressed that the legislative timetable for the adoption of the 31st ATP failed to provide sufficient time for consultation with other WTO Members. She reiterated the request that nickel substances be removed from the proposed 31st ATP.

The representative of United States thanked the European Communities for the responses but noted that numerous concerns remained with the proposed re-classification of nickel compounds.

The representative of the European Communities assured Members that all comments received before the deadline would be responded to before the classification of nickel compounds became law. He stressed that his example about lead was intended to show that even though a classification had been made because of the danger posed by this substance, there had not been any major trade dispute, or disruptions to trade – at least not that had been brought to the attention of the European Communities. On another point he emphasized that there was no direct consequences in terms of a ban from a Category 1 or 2 classification – except in the area of cosmetics. (However, it was pointed out that it was unlikely that as nickel compounds would be used in cosmetics as they were know allergens). Nevertheless, there was indeed an

[8] See G/TBT/M/45, par. 106.

obligation on the Commission to evaluate whether a ban was necessary for consumer uses of Category 1 and 2 substances. This was the case of borates where an assessment was underway. The representative of the European Communities further clarified that in respect of consequences for occupational health and safety (from classification as a Category 1 or 2 carcinogen), these would be limited to within the European Union. He reiterated that the European Communities did not expect, from the classification exercise, major trade implications – if countries did believe that there would be such effects, they were welcome to provide this information to the European Communities so that it could be assessed, and appropriate action be taken.

The representative of Canada reiterated that the European Communities did not provide enough time for consultation with WTO Members regarding the 31st ATP and requested clarification on the date of the Technical Progress Committee.

The representative of the European Communities urged delegations that still had concerns to make comments in writing. On the date of the Technical Progress Committee, he explained that the EC member States would vote on the 31st ATP proposal only after careful consideration of the information provided by WTO Members. In this regard, he emphasized that the 30th ATP had been discussed in four TBT Committee meeting; however, in those meetings no arguments or new information had been presented. The EC representative recalled that any new information would be examined and taken into account, but the adoption of the 31st ATP proposal would not be delayed only on the basis of speculation.

The representative of Cuba noted that various concerns remained and said that his delegation would present its written comments to the European Communities in order to further discuss the issue. In response to the EC comments, it he noted that the Cuban industry had provided significant and detailed information on the proposed re-classification, but this had not been taken into account by the European Communities.

The representative of Australia thanked the European Communities for the responses but noted that numerous concerns remained with the proposed 31st ATP.

The representative of Brazil thanked the European Communities for the responses, but stressed that various concerns remained and more time should be allowed to discuss this issue.

The representative of the European Communities stated that the studies used for the EC assessment and the minutes of the expert meetings would be provided to interested delegations. Finally, with regard to the comment of Cuba that studies provided by industry had not been examined, he explained that they had been discussed in a meeting with the nickel industry. However, the experts recognised that these studies were interesting, but either incomplete or inconclusive; therefore, they did not indicate that the proposed EC classification for those substances was inappropriate.

Japão X UE - Capacity labelling of batteries and accumulators

European Communities - Capacity labelling of batteries and accumulators

The representative of Japan noted that the EC Directive on batteries would mandate the labelling of battery capacities as of 26 September 2009, but the methods for measuring these capacities had not yet been announced. Battery manufacturing companies within the European Communities would be able to comply with the Directive within the six month preparation period, since they were only required to ship the compliant batteries before the deadline. However, in the case of electrical and electronic equipment where batteries were enclosed with the products, or lead storage batteries embedded in automobiles, a certain amount of time would be required to measure the capacities of the individual batteries, for the design and manufacture

of the labels, and for transportation and clearance of distributor inventory. This meant that it was impossible for companies outside the European Communities to comply within the preparatory period of six months.

The short preparatory period in these regulations was unfair on companies outside the region, and was not in line with the principle of national treatment embodied in Article 2.1 of TBT agreement. He believed that the preparatory period should be of at least one year between the announcement of the measuring methods and the time the Directive came into effect.

The representative of the European Communities explained that the European Commission was currently preparing requirements for capacity labelling of all portable and automotive batteries and accumulators in accordance with Article 21 of the Directive on batteries. Such capacity labelling requirements did not exist yet at Community level. She pointed out that a study on the measurement method for batteries capacity label had been finalized and that it would constitute the basis for the Commission and EC member States to develop rules for the implementation of these requirements. She noted that member States would be responsible for ensuring that the capacity of all portable and automotive batteries and accumulators was indicated on them by 12 September 2009 and that the same requirements would be applied to manufacturing companies within and outside the European Communities, without discrimination. Industry would be given enough time to prepare for these new requirements and the measures would be notified to the TBT Committee as appropriate.

Previously raised concerns

UE X China – Compulsory Product Certification (CCC) (G/TBT/N/CHN/399 and Suppl.1)

China – Compulsory Product Certification (CCC) (G/TBT/N/CHN/399 and Suppl.1)

The representative of the European Communities welcomed the notification made by China on 24 June 2008, on which his delegation had made detailed comments, concerning a draft amendment to the regulations on compulsory product certification, and hoped that this was a first step in a process involving a more substantive review of the Chinese Compulsory Product Certification System (the "CCC system"). He sought assurance from the Chinese authorities that interested stakeholders would be closely involved in the implementation of the detailed product category specific rules that would have to be enacted by the Certification and Accreditation Administration of the People's Republic of China (CNCA) following the adoption of the framework regulation. He also sought clarification regarding the timeline for the entry into force of the regulation. His delegation, as noted on previous occasions, believed that the current version of the CCC system was one of the main obstacles companies faced in their trade with China due to the complexity, time consuming nature and cost of the procedure. For SMEs in particular, the burden was heavy and in some instances simply impossible to cope with.

The representative of the European Communities encouraged China to undertake a structural review of the CCC system as part of the implementation of the revised framework regulation. Specifically, his delegation believed that China needed to systematically apply a risk-based approach to conformity assessment, with a view to reducing the number of products within the scope of the CCC. Conformity assessment requirements, in particular those relating to factory inspections, testing and certification needed be modulated according to the level of risk associated with the products to be regulated. He stressed that the European Communities stood ready to assist in the process by sharing experiences with CNCA experts on the management of conformity assessment systems for various products based on the suppliers declaration of conformity (SDoC) and effective market surveillance.

Additionally, the representative of the European Communities invited China to consider providing opportunities for mutual recognition of testing results based on international standards. He also stressed that confidentiality obligations of testing and certification organizations needed be set out with respect to any commercially sensitive information obtained during the testing and certification process. He underlined the importance of publishing and enforcing clear rules to ensure that test laboratories and certification bodies operated in such a way that conflicts of interest were prevented. Clearly defined conditions under which such organizations could engage in additional business activities were also important.

The representative of the European Communities further stressed that a clear reference to the risks associated with the products was needed. His delegation hoped that China could provide that foreign-owned testing and certification organizations legally established in China were eligible for designation by CNCA to perform the testing and certification activities required under the framework regulation on equal terms to Chinese-owned conformity assessment bodies. He believed that inspection requirements in the regulation needed to be simplified, and sought assurance that when applicant companies held certificates of their quality management systems, factory inspections would be limited to verifying only those additional requirements laid down in the CCC regulation that were not already covered by the said certificates. His delegation hoped for wider exemptions with respect to spare parts and components, in order to eliminate the current duplicative certification obligation that concerned spare parts and components which were used for assembling final products, which were themselves subject to CCC certification.

The representative of China noted that a detailed reply to the comments and questions raised by the European Communities had been prepared, including on the implementation timetable, on how to deal with the protection of confidential information, on how to ensure the involvement of certification bodies, on spare parts and components and on exceptions from CCC certification. He pointed out that the objective of the modification of the CCC system was to streamline the compulsory certification design and to improve the effectiveness of the system, based on the experience accumulated in the past six years. With respect to the recognition of foreign certification bodies and their testing results, he stressed that China recognized the test results of the IECEE CB scheme, in accordance with the regulation of the People's Republic of China on certification and accreditation. Foreign certification bodies qualified for CCC certification could only be allowed through inter-government agreement, agreements recognized by the Chinese government or agreements with competent authorities of the Chinese government. So far, China had signed 15 cooperative agreements with agencies or certification bodies from other countries and regions which covered, for example, factory inspection and recognition of certification testing results.

On the issue of SDoC, in accordance with the TBT Committee's discussion in the Second, Third and Fourth Triennial Review of the TBT Agreement, the representative of China pointed out that there was a common view that, in order to ensure that SDoC was implemented effectively, appropriate legislative framework including safeguards against non-compliance of dangerous products such as market surveillance and product liability legislation needed to be established in advance. As a developing country Member, China had difficulties in this regard, therefore SDoC had not yet been adopted as part of conformity assessment procedures. His delegation looked forward to continued cooperation and sharing of experiences with the European Communities and other interested Members.

UE, EUA e China – Excessive packaging (G/TBT/N/CHN/447 and Suppl.1)

China – Excessive packaging (G/TBT/N/CHN/447 and Suppl.1)

The representative of the European Communities noted that the recently notified draft aimed at restricting excessive packaging of certain commodities and that its content was similar to the

one notified previously (G/TBT/CHN/N/321) and on which the European Communities had expressed concerns in the TBT Committee of March 2008, while stressing that it supported the objective of restricting excessive packaging in order to protect the environment. As a reply to the EC concerns, China had confirmed that the provision laying down that for certain products the total cost of packaging should not exceed 15 per cent of the sales price was a recommendatory provision. However, it appeared that in the new notified draft the cost requirement had become a mandatory requirement and the representative of the European Communities sought clarification as to why China had changed the approach previously announced.

The representative of the European Communities also reiterated concerns with regard to such a cost requirement. Her delegation was of the opinion that the fact that packaging was costly did not always and automatically mean that it had the most harmful impact on the environment. Moreover, it would be difficult to respect and to verify this requirement, since the compliance could not be verified with regard to the product itself, but needed the collection, submission and verification of considerable amount of data in order to calculate the packaging cost, the sales price and the relation between both. This data would be especially difficult to provide for imported products.

As a consequence, rendering this provision mandatory was considered as more trade restrictive than necessary to fulfil the pursued legitimate objective of the protection of the environment and therefore not in compliance with Article 2.2. of the TBT Agreement. In addition, even if the provision applied equally to domestic and imported products, it was more difficult to comply with for importers, which was contrary to Article 2.1. of the TBT Agreement. China was invited to reconsider its approach that rendered this requirement mandatory. These concerns had also been expressed (along with the request for further clarifications), in the comments sent by the European Communities to China on 31 October 2008.

The representative of the United States pointed out that his delegation supported China's stated objective of environmental protection and rationalization of resources and welcomed the clarification by China about the method of calculating the inter space ratio for determining maximum packaging size. However, when the excessive packaging requirements had been re-notified, it was indicated that the requirement for calculating the packaging cost was no longer voluntary. He noted that this was a change in position from China's response to comments provided on 5 March 2008. At that time, China had indicated that the provision on packaging cost was merely a reference and compliance with it was not mandatory.

The representative of the United States further noted that industry alleged that the provision limited the total packaging cost to 15 percent of the ex-factory price of the product; this could have an adverse effect on the ability of the distilled spirits industry and other industries to properly deliver a well-packaged product to consumers. His delegation also noted that the calculation methodology did not appear to adjust for the many costs associated with the distribution of internationally traded products, such as shipping costs, which could make it more difficult for imported products to comply with the 15 percent limit than it would be for domestic products. Furthermore, many industries did not manufacture their own packaging or have control over input prices. Thus, the requirements could put many companies in an uncomfortable position, since compliance with the 15 percent limit could not be within their exclusive control, and trade flows could be disrupted as a result. He requested that, before the measure was put in place, China re-evaluated its approach to this technical issue or revert to its earlier position that compliance with the 15 percent limit was voluntary. He also noted industry's request that, when the measure was implemented, an adequate grace period, for example 12 months, needed to be provided to allow for current packaging stocks to be depleted.

The representative of China pointed out that, at the request of the European Communities, the comment period on the notified measure had been extended until 1 December 2008. Comments

received would be analyzed and a reply would be provided. He stressed that the purpose of the draft standard was to protect consumer interests and the environment, which was in line with the legitimate objectives in the TBT Agreement. His delegation welcomed other Members' comments as well as experience-sharing in this regard.

UE X Peru – Labelling of footwear (G/TBT/N/PER/19)

Peru – Labelling of footwear (G/TBT/N/PER/19)

The representative of the European Communities pointed out that, in its notification, Peru maintained the existing requirement to indicate on the label of footwear the fiscal number of the importer. Her delegation was of the opinion that this requirement created significant costs for the producer and exporters, while the information provided was irrelevant for the consumer. It would therefore be more appropriate to require the indication of the fiscal number on the accompanying documentation, and not on the footwear itself. Moreover, the notified text seemed to lay down special testing requirements for labelling of footwear manufactured abroad and did not seem to accept European testing methods. Her delegation considered that these requirements were more trade restrictive than necessary and therefore not in compliance with Article 2.2 and Article 5.1.2 of the TBT Agreement. She invited Peru to take into account the comments sent on 1 October 2008 and looked forward to receiving a written reply.

The representative of Peru noted that the Enquiry Point was coordinating all the comments that had been received and that a reply would soon be provided through the Permanent Mission in Geneva. He took note of the concerns expressed, which would be transmitted to the competent authorities in capital.

Catar, Canadá, Egito, Coréia, Japão e outros X UE - Regulation on the Registration, Evaluation and Authorization of Chemicals (REACH) (G/TBT/N/EEC/52, Adds 1-5 and Add.3/Rev.1)

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

The representative of Qatar, speaking on behalf of the Gulf Cooperation Council (GCC), expressed concern about the adverse impact that REACH could have on trade in chemicals, including petrochemicals. His delegation was particularly concerned about the lack of transparency and clarity arising from the complexity of REACH and the non-notification of a number of guiding documents. The ambiguity of certain provisions made it difficult to establish the precise requirements of REACH. Uncertainty was also caused by inconsistent implementation of REACH across EC members States. Other concerns related to the lack of flexibilities for developing countries, despite the particularly burdensome nature of the requirements for developing countries to ensure compliance (e.g., the obligation to test chemicals in EC laboratories).

The regulation would, no doubt, have a significant impact on developing countries. For the implementation of REACH, technical assistance was needed to contribute to awareness and capacity building at the company level so as to better understand the legislative framework. This would be an appropriate way of increasing transparency. Given the rigorous requirements imposed by REACH, which appeared to be more strict than necessary to achieve the EC's objectives, the representative of Qatar requested the European Communities give due

consideration to the comments of WTO Members to ensure that the Regulation was fully consistent with EC's obligations under the TBT Agreement.

The representative of Canada supported the objectives of protecting health and the environment, but reiterated his delegation's concerns about REACH. With respect to the issue of the Only Representative (OR), he encouraged the European Communities to explain what measures were being taken to protect confidential business information that non-EC firms were expected to provide to their OR. On the subject of test methods regulations, Canada expressed its concern that the test methods which would be adopted by the European Communities had not been approved by the OECD. Therefore, Canada urged the Commission to postpone the adoption of any unique or alternative test methods until their review and acceptance by the OECD. The representative of Canada also requested the European Communities to clarify what the timeline for adoption of the test methods would be.

Furthermore, the Canadian representative asked how the pre-registration procedure was progressing. In particular, she asked if the procedure was on schedule and if the European Commission foresaw the need of an extension. Canadian industry had indicated that the European Chemicals Agency (ECHA) was encouraging companies not to pre-register until the threshold of one ton was meet. Considering that this could increase costs for industry that would not be able to benefit from the savings of engaging an OR to register for them in bulk, Canada requested the European Communities to explain what the conditions were to allow a company to pre-register late. Finally, despite the Canadian efforts to inform industry, concerns remained that companies would not be able to register in time.

The representative of Egypt shared many of the concerns expressed by previous speakers, and noted that more than fifty per cent of her country's chemical exports to the European Communities would be significantly affected by REACH. She pointed out that many Egyptian exporters were still not ready for the registration procedure due to lack of information about the relevant substances. Accordingly, her delegation requested the European Communities to extend the period of pre-registration at least until the end of the first quarter of 2009. Concerns were also expressed with regard to the list of chemical substances to be registered, for instance, whether it should be considered as a component or part of the finished product. It was also unclear if certain products, such as Portland-cement, dyeing and tanning products in leather, needed to be registered under REACH.

With regard to the issue of the Only Representative, Egypt requested the European Communities to provide a recommendation list of accredited ORs, in order to assist the Egyptian companies and minimize the time needed for registration. Moreover, the European Communities was requested to clarify the definitions of Small and Medium Size Enterprises (SMEs) so as to apply more flexible conditions related to their registration and fees. Finally, the Egyptian delegate stressed that Egypt still had several concerns related to the cost, complexity and burdensome requirements of REACH. Therefore, the European Communities was requested to provide further technical assistance to Egypt and other developing countries.

The representative of Korea thanked the European Communities for their prompt response to the concerns expressed at the previous Committee meeting. However, he stressed that the Korean industry was still facing difficulties in complying with the pre-registration procedure. In particular, the Korean representative requested the European Communities to clarify whether it was necessary to pre-register certain items like microcapsules, which could be classified as "preparation in a container" or "articles". Furthermore, he encouraged the European Communities to postpone the implementation of REACH and provide more technical assistance to developing countries, especially to SMEs.

The representative of Japan thanked the European Communities for organizing the information session on REACH, held on 4 November 2008. However, Japan shared the concerns already

expressed by other Members. On the Substance Information Exchange Forum (SIEF), the Japanese representative requested that foreign-based firms in the European Communities be treated without discrimination, and that their opinions be respected when participating in SIEF. In this regard, he recalled that at the previous Committee meeting, the European Commission assured that it would share information on SIEF. On the issue of the uniform application of REACH, the representative of Japan recognised that the European Commission was trying to ensure the consistent application of REACH throughout EC member States. However, his delegation was worried that some EC member States would implement REACH in a different way after the pre-registration period, and encouraged again the Commission to ensure a unified implementation of REACH.

The representative of Japan also noted that, according to the REACH regulation, non-EC companies represented by a Only Representative needed to pay a fee depending on their business size. However, since most non-EC companies did business also on non-EC markets, there was concern about discrimination against non-EC companies. Therefore, the representative of Japan requested the European Communities to modify the fee structure so as to calculate only business related to the EC market. Concerns remained that SMEs lacked the means to find appropriate representatives; the European Communities was therefore requested to establish a support system which would facilitate the work needed to obtain an appropriate OR. Furthermore, the representative of Japan highlighted that, according to Article 33 of REACH "Duty to Communicate Information on Substances in Articles", suppliers of articles were to provide consumers with information concerning Substances of Very High Concern (SVHC) on request by the consumer and within 45 days of receipt of the request. However, depending on the article or substance, suppliers could find themselves needing to inquire from other suppliers in the upper supply chain. In that case, it would be impossible to provide the relevant information at such short notice if adequate information was not provided by the upstream suppliers. He therefore requested the European Communities to postpone the application of Article 33 of REACH until the deadline indicated by Article 7 of REACH, on 1 June 2011.

Finally, it was noted that the European Chemicals Agency (ECHA) had encouraged companies to pre-register monomers in polymers if they were not sure that the monomers concerned would be registered by the end of the pre-registration period, on 1 December 2008. Japan's industry expressed concerns that this would impose an excessive burden on enterprises manufacturing or importing in the European market. The representative of Japan therefore requested the European Communities to clarify whether the meaning of "registered by 1 December 2008" included "pre-registered by 1 December 2008".

The representative of Argentina thanked the European Communities for the comprehensive replies received on 27 June 2008, but stressed that the responses received did not satisfy the concerns expressed and generated further uncertainty for industry seeking to implement REACH. In this regard, he reiterated his delegation's concerns with respect to the limited capacity of the European Communities to provide uniform and adequate technical assistance to industry. This situation was aggravated by the entry into force of the period of pre-registration, and constituted a serious impediment to the continued presence of such companies in the European market. The serious transparency problems of REACH showed that this regulation could become an unnecessary barrier to trade, since it was not complying with the objectives for which it had been created and was instead introducing distortions in the trade of chemicals.

The representative of Botswana associated himself with the comments expressed by previous speakers. While his delegation supported the objectives of the protection of human health and the environment, the complexity of REACH posed enormous challenges to developing countries such as Botswana. Therefore, the European Communities was requested to provide more technical assistance to developing country Members.

The representative of Philippines supported the objectives of the protection of human health and the environment, but also shared concerns raised by other delegations on REACH. In particular, he expressed concerns about the consequences of the OR provision on Small and Medium size Enterprises (SMEs), which represented the majority of Philippine's industry.

The representative of Switzerland expressed support for the objective of REACH to better protect humans and environment against the risks associated with the use of chemicals, while enhancing innovation. It was recalled that REACH would speed up the process of control and evaluation of more than 30,000 substances, and would enhance corporate responsibility in terms of marketing and sale of chemical products. However, the Swiss delegation believed that REACH placed significant burdensome costs, especially on SMEs. In addition, the complexity of the European regulation gave rise to unexpected results during its implementation. For example, ECHA set out the pre-registration rules for re-imported substances, recovered substances or monomers and polymers only on 6 October 2008. To avoid further trade distortions, the representative of Switzerland invited the European Communities to seek solutions to facilitate the implementation of REACH.

The representative of Australia reiterated her delegation's concerns regarding REACH and noted its potential to disrupt and impede global trade in chemicals. While Australia recognised the importance of ensuring a high standard of protection for human health and environment, the complexity of such a policy and enormous challenges faced by non-EC companies remained a concern. Australia was particularly concerned that REACH would have a disproportionate impact on SMEs and that the OR provision could discriminate against non-EC companies, placing higher costs on non-EU producers and manufacturers. In particular, Australian SMEs indicated that the costs associated with appointing an OR to pre-register their chemical substances were prohibitive; as a result, many SMEs would be unable to continue exporting into the EC market after 1 December 2008. Considering the high costs associated with the registration of few chemical substances, it was her delegation's opinion that there were other less trade restrictive measures to achieve the European Communities' health and safety objectives.

In addition, while non-EC companies continued to require further assistance from EC experts to ensure a correct implementation of the European regulation, Australian SMEs indicated that the REACH national Help Desks were not in a position to assist them. The representative of Australia welcomed the development of the REACH guidance documents by the European Communities but noted that they were continuously subjected to change and key issues for non-EC industries were unclear. She also requested that a finalized list of chemical substances exempt from REACH be provided. Finally, Australia urged the European Commission to take into consideration the concerns expressed by Members and adjust REACH implementation deadlines until these concerns were satisfactorily addressed.

The representative of Chile raised four specific concerns. First, there was still lack of clarity on the product coverage of the REACH regulation. While his delegation raised this issue at the information session held on 4 November 2008, the response of the European Commission had not been satisfactory. Second, the European Communities was encouraged to clarify the penalties for non-compliance according to Article 126 of REACH, which had not been notified yet by EC member States. Third, Chile encouraged the European Communities to explain who could appoint an OR and whether it was possible to change the OR without its consent. Finally, the representative of Chile drew the Committee's attention to the limited capacity of the European Communities and ECHA to provide adequate technical assistance regarding the pre-registration procedure.

The representative of China thanked the European Communities for organizing the information session on REACH. However, he shared the concerns expressed by previous Members. With regard to the penalties for non-compliance, he noted that according to Article 126 of REACH,

EC member States should lay down the provisions on penalties applicable for infringement of the provisions of the regulation, and notify those provisions to the Commission no later than 1 December 2008. Since there was no indication that such penalties were being formulated, the European Communities was encouraged to clarify when they would be notified. This would be helpful to reduce uncertainty about REACH and prevent unnecessary obstacles to trade.

On the issue of special and differential treatment, the representative of China requested the European Communities to take into account the special needs of developing country Members according to Article 12 of the TBT Agreement. In particular, it was requested to extend the deadline of pre-registration for developing country Members. China also requested the European Communities to reconsider the criteria of SMEs categories and to make the staff headcount an optional criterion of SMEs under the REACH Regulation. In addition, China emphasized the importance of transparent guideline documents and the importance of good and effective operation of the EC Help Desk services.

The representative of Mexico joined the comments made by previous delegations, and noted that concerns remained with regard to the issue of the OR. In fact, it was his delegation's opinion that the requirement of an OR was contrary to the provisions of the TBT Agreement. In particular, Mexico believed that there were less trade-restrictive alternatives to the OR requirement, such as extra-territorial inspections that would enable exporters to register chemical substances themselves.

The representative of Chinese Taipei shared the concerns expressed by other Members. In order to provide technical assistance to industry, she suggested that the European Communities establish a REACH Help Desk in Chinese Taipei. The purpose of such a Help Desk would be to provide guidance on the classification of substances, preparations and articles. The representative of Chinese Taipei also recalled that, in order to gather information from the Substance Information and Exchange Forum (SIEF), non-EC manufacturers had no alternative but to appoint an OR. In this regard, the costs associated with the appointment of an OR had substantially increased the costs of exporting to the EC market. The European Communities was therefore encouraged to explain how the OR provision did not discriminate between EC and non-EC based companies. Finally, the representative of Chinese Taipei encouraged the European Communities to disclose the non-confidential information of the SIEF to all non-EC based companies.

The representative of Cuba joined other delegations in concerns expressed about REACH. In particular, she was concerned about the complexity and lack of transparency of REACH, its information requirements, the OR provision, the uniformity of the information provided and the overall difficulties faced by SMEs of developing countries in the implementation of the regulation. Also, the Cuban representative drew the Committee's attention to a document (G/TBT/1/Rev.9) which contained all the decisions and recommendations adopted by the TBT Committee. She stressed that in the Committee's Third Triennial Review (in 2006) Members had been encouraged to inform the Committee of special and differential treatment provided to developing country Members, including information on how they have taken into account special and differential treatment provisions in the preparation of technical regulations and conformity assessment procedures. The European Communities was therefore encouraged to make best use of the Committee's recommendations and provide a proper response to the concerns raised by Members. Finally, the delegation of Cuba joined Egypt in requesting the European Communities to extend the period of pre-registration.

The representative of Indonesia associated himself with the comments expressed by other Members. While Indonesia supported the objectives of the protection of human health and the environment, the disproportionate impact of such a policy on SMEs and the fact that the OR provision could place higher costs on non-EC producers and manufacturers remained a concern.

Efforts to provide technical assistance to developing countries needed to continue in order to enable these countries to implement the measures at issue in the best possible way.

The representative of Thailand referred to her delegation's previously expressed position on REACH. While Thailand supported the objectives of the protection of human health and the environment, the complexity of REACH was beyond the capacity of many developing and least developed countries to understand and comply with. Concerns were also expressed with regard to the OR provision, which created unnecessary and unaffordable costs for industry. Such difficulties were particularly evident for SMEs, which represented the majority of Thailand's industry.

The representative of South Africa associated himself with the concerns already expressed by other delegations, particularly on the burden on SMEs and the OR provision. In particular, he highlighted the high costs borne by SMEs to comply with the OR provision and requested the European Communities to provide more technical assistance. Concerns also remained about the possibility of changing from the OR. In fact, it was his delegation's opinion that confidential information provided to the former representative could prevent companies from seeking the assistance of other representatives.

The representative of Brazil shared many of the concerns previously expressed by others, stressing the difficulties and the costs imposed by the registration procedure, testing, and the OR requirement, especially in the case of SMEs.

The representative of the United States noted that his delegation shared the EC's interest in protecting human health and the environment. However, concerns remained that the REACH regulation appeared to be overly broad and to adopt a particularly costly, burdensome, and complex approach that could disrupt and distort global trade. In particular, the representative of the United States noted that the number of concerns raised by industry was growing exponentially as the pre-registration period progressed. Since all of those concerns cantered around the lack of transparency of REACH, he had found disappointing that the European Communities had not responded to a request for bilateral technical talks made by the United States and was attempting to keep REACH off the agenda of the Transatlantic Economic Council discussions.

Many concerns remained both within and outside the European Union, including: are blood and blood derivatives covered by the regulation? Do re-imported substances need to be pre-registered a second time? What substances in articles such as autos are intended for release? Where does the dividing line between a substance and a preparation lie? Other issues were, for example, the justification of registration requirements for reacted monomers in polymers and lack of information on the penalties for non-compliance. It was noted that the failure of the European Communities to clarify and remedy such issues and others would lead to serious trade disruptions and even potential adverse impacts on public health and safety.

With respect to the issue of cosmetics, the representative of the United States recalled that the European Communities had already recognized that REACH could discriminate against foreign cosmetics producers. Therefore, he requested the European Communities to provide legal certainty that non-EC cosmetics producers would be able to pre-register their substances, participate in the SIEFs and continue shipping into the EC market. In particular, the European Communities was invited to clarify when and how the European Commission would provide legal certainty on this issue, whether through an amendment or corrigendum to REACH or through a binding legal opinion. It was also stressed that some US companies had already stopped shipping cosmetics to the European Communities. If this situation remained unresolved, up to US$4 billion worth of cosmetics exports to the European Communities could be negatively impacted.

On the Only Representative provision, the representative of the United States welcomed the fact that the European Communities determined that non-EC manufacturers who did not directly export to the European Union would be able to appoint an OR to register their substance. However, this did not address the fundamental structural problem with the OR requirement. In fact, this provision raised serious concerns for non-EC supply chains, because sensitive commercial information could be compromised depending on who in the supply chain appointed the OR and how the supply chain was set up. It was highlighted that this problem was leading several companies to consider as part of their sourcing policies whether they needed to start purchasing more of their inputs from companies located in the European Union. Foreign chemical distributors were being particularly impacted since they were not permitted to appoint an OR. In this regard, it was also recalled that one of the primary objectives of REACH was to increase the competitiveness of the European chemical industry.

With respect to the "authorization candidate list", the United States delegation was concerned that this list, officially known as the Substances of Very High Concerns (SVHCs) list, was hazard based and would be used as a "black list". To address this problem, the representative of the United States had urged the European Communities to provide guidance on the status and purpose of the candidate list prior to the publication of the candidate list and candidate substance dossiers. Specifically, the European Communities had been encouraged to make clear that: (i) only substances on the final authorization list would be subject to authorization and related restrictions, (ii) that ECHA would evaluate use-based risk assessment information to determine which substances would be subject to authorization; (iii) that producers should not use the inclusion of a substance on the candidate list as a reason not to use that substance, or to use a substitute for it; and (iv) that substitution or reformulation could exacerbate negative environmental, health, or safety concerns as the risks associated with substitutes might not be known.

With respect to the burden on SMEs, the representative of the United States stressed that many SMEs, who were engaged in selling their products domestically, did not have the resources or the ability to discern the data necessary to ensure complete and accurate registration under REACH. It was further highlighted that this was a problem for both developed and developing countries. Unlike large multinationals, SMEs would be less likely to have a European presence and, therefore, would effectively have little choice but to appoint an Only Representative to register their products; or their downstream user would find another supplier who would do it. It was noted that registration and testing fees, even with the reduced registration fees for SMEs, could easily exceed US $50,000 per substance. If a particular company used 400 substances to manufacture a particular fragrance, which was not uncommon, the cost could be prohibitive. The delegate of the United States stressed that many companies would no longer be able to ship all of their products, particularly small, niche products, to the EU market, since they lacked both the manpower and financial resources to register all of the necessary substances. Therefore, it was his delegation's opinion that the regulation would increase the market share of large chemical companies and drive many SMEs out of the EU market. Finally, the representative of the United States stated that his delegation would reflect on the ideas expressed by some delegations for addressing differently the issue of the Only Representative. The European Communities was urged to take into consideration the concerns which had been expressed by its trading partners and other interested parties, and to ensure a meaningful opportunity to reflect the views of other governments and stakeholders in the process.

The representative of the Russian Federation, speaking as an observer, joined other delegations in concerns expressed about REACH. While the Russian Federation supported the objectives of the protection of human health and the environment, REACH was probably more trade restrictive than necessary to fulfil the legitimate objective of ensuring high standards of human health safety and environmental protection. In particular, the representative of the Russian Federation expressed concerns about the possible discrimination between EC and non-EC based companies. While EC based companies could register their substances, non-EC companies had

to rely on different EU importers to register the same substances. This approach resulted in additional burden for non-EC companies, increased costs and disclosure of confidential information. Moreover, non-EC companies could not participate in SIEF and consortia. The Russian Federation believed that such treatment could be seen as less favourable than that accorded to like products of national origin.

Moreover, the representative of the Russian Federation considered that the complexity of REACH could lead to uncertainty for chemical producers and to arbitrary decisions when applied in practice. Considering the previous discussion on nickel compounds, her delegation expressed concerns about the fact that the European Communities would adopt the same simplified approach for the classification of substances also in the framework of REACH. This would result in decisions taken without sufficient scientific data. Finally, concerns remained that the REACH regulation appeared to be overly broad and to adopt a particularly costly, burdensome, and complex approach that could disrupt and distort global trade in chemicals. The European Communities was therefore encouraged to take into consideration the concerns which had been expressed by its trading partners, and to ensure a meaningful opportunity to reflect their views in the process.

The representative of the European Communities thanked the delegations which raised questions about REACH. She pointed out that the pre-registration period under REACH had started on 1 June 2008, and ended on 1 December 2008. She also noted that the European Communities was doing everything to facilitate the pre-registration process. In fact, her delegation had organized an information session on 4 November 2008, where Members could ask specific questions to EC experts. The European Communities would carefully consider the questions and concerns raised by other delegations.

The representative of the European Communities noted that the Only Representative was not an obligation under REACH, but rather a possibility given to non-EC manufacturers. In fact, the OR provision was introduced in REACH to address some of the concerns that had been expressed by trading partners, particularly regarding the protection of confidential business information. It was further stressed that the obligation to register substances manufactured outside the European Union fell only upon the European importers. Therefore, the claims that there were higher costs for non-EC based companies than for EC based companies were not correct. On the proposal of inspections outside the EC territory, the representative of the European Communities stated that such a provision would be in violation of basic principles of international law. With respect to the questions on the possibility of changing the OR, she noted that a transfer of the registration would be possible by submitting an update to the earlier dossier. This had been clarified in the guidance documents on registration. However, the former Only Representative would have to agree with the change, because the registration dossier belonged to the OR that had made the submission. She further clarified that these aspects were to be covered in the private arrangements between the non-EC manufacturers and the Only Representative. In this regard, non-EC based companies could impose conditions that would require the OR to agree to a subsequent change. Moreover, since the appointment of an OR was purely voluntary and the relation between the entity that appoints the OR and the OR itself was not governed by REACH, the European Communities could not provide a list of representatives that were considered to be appropriate or sufficiently knowledgeable. Regarding the concerns about the protection of confidential business information, the EC representative explained that also such aspects could be covered in the private arrangements between the non-EC manufacturers and the Only Representative.

On the issue of pre-registration, the representative of the European Communities noted that over 800,000 pre-registrations had been received so far. With respect to the request whether it was necessary to pre-register substances that were re-imported or recovered, or substances in monomers and in articles, she noted that REACH foresaw exemptions from the obligation to register in these cases, provided certain conditions were met (for example, that the relevant

substance had to be previously registered with ECHA). She explained that the interpretation that pre-registration was required to benefit from the exemption to register was consistent with the explanation provided in the first version of the guidance documents; however, the European Communities would take into account the comments received and would examine them in detail.

On the fees regulation, the EC representative noted that the requests from some delegations that fees and charges be applied equally to EC based and non-EC based companies showed that there could be a misunderstanding about who had to register and who was a member of the Substance Information Exchange Forum (SIEF). It was therefore recalled that registrants (and, consequently, members of SIEF) were only EC based companies, be it manufacturers, importers, or Only Representatives. It was also stressed that ORs were treated in the same way as manufacturers and importers established in the European Union. On the request to share some of the non confidential business information obtained by the SIEFs, the European Communities representative pointed out that one of the objectives of REACH was to increase the level of information available about chemicals and that therefore such information would be freely published on the ECHA website in accordance with Article 119 of the REACH regulation.

On the issue of SMEs, the representative of the European Communities explained that the meaning of the term SME had been clearly defined in the Commission's recommendation on the definition of SMEs. Such uniform interpretation ensured that all companies would be treated equally. The European Communities was ready to provide the full text of this recommendation and extra informative material to all interested parties. With regard to the fees to be applied for SMEs, it had been suggested that the reduction for SMEs should not be based on the entire turnover of the non-EC based company. In this regard, the EC representative noted that, in effect, when a manufacturer established outside the EU decided to appoint an OR, the assessment of the SME status thereof for the purposes of applying the reductions of fees would be done on the basis of the turnover of the company represented (i.e. including also business which was not linked to the exports of chemicals to the EC market). However, she stressed that the same principle applied to EC-based companies as the consideration of their SME status would also have to consider the turnover linked to business outside the EU.

With regard to the questions on the candidate list, it was noted that the European Communities had been requested to provide guidance on the status of the candidate list and to clarify that substances contained in such list were not subject to authorization. In this regard, the EC representative noted that the REACH regulation already indicated, clearly, that an authorization was only required for the substances included in Annex XIV (List of Substances Subject to Authorisation).

On the issue of uniform interpretation across the European Communities, the EC representative recalled that the legal instrument chosen for REACH was a regulation, which was directly applicable in all member States without the need of any national measure for the transposition thereof. Furthermore, it was stressed that EC member States could not depart from the content of the regulation by adopting different national measures.

On the issue of penalties for non-compliance to REACH, the EC representative clarified that sanctions fall under the competence of EC member States and information on sanctions would be published in their national official journals according to each member State's legislative system. It was stressed that sanctions have to be sufficiently serious as they had to dissuade stakeholders from infringing on the rules set by REACH.

An expert from the DG Environment replied to some specific questions raised by delegations. On test method regulation, he said that the European Commission supported the approach of implementing OECD methods wherever possible. However, under exceptional circumstances

the European Commission could have to consider to propose a specific alternative method as there are animal welfare considerations that, in accordance with REACH, the Commission should take into account.

With regard to the question on late pre-registration, the EC representative referred to Article 28.6 of the REACH regulation, which outlined a clear procedure for late pre-registration. It was his delegation's opinion that companies were perhaps not aware of the option in Article 28.6, which allowed any importer who had not imported a substance after 1 June 2008 in volumes above one ton to pre-register after the deadline of 1 December 2008 within six months of his first import.

The EC representative noted that the European Communities fully understood the requirements of the registration process; however, he recalled that under the former EU legislation there were already obligations for the importers to know which substances they were importing. For example, if a new substances not in EINECS was imported in volumes above 10 kilos per year, the importer was required to make a notification (a so-called mini notification). Furthermore, if an importer imported any substance listed in EINECS in volumes above 10 tonnes, there was also a notification requirement; it was therefore necessary to know which chemicals were contained in the preparations being imported. In other words, the obligation to know what was imported in the EU market had existed for many years.

On the specific question about microcapsules raised by Korea, the EC representative pointed out that more information was needed in order to reply to the question. Lack of necessary information was also often the reason why the European Agency on Chemicals (ECHA) was sometimes not able to answer clearly to a specific enquiry. The same applied for the issue of Portland-cement which had been raised by the delegation of Egypt. On the issue of the substances exempted from the obligation to register, the EC representative recalled that Annex IV contained a list of such chemicals, and Annex V contained categories of substances exempted. In this regard, he noted that the REACH Help Desks would answer questions related to these exemptions, provided they were given all relevant information, . For example, it was noted that blood, as a natural substance, was covered by Annex V, but that the question whether it could benefit from the exemption would also depend on whether the blood had undergone processing (as indicated in Annex V).

With regard to the issue of the frequent revision of guidance documents, it was clarified that most of the revisions were made to add information related to specific questions received. Regarding the request to have REACH Help Desks in third-countries, the EC representative took note of the request made. On the issue of grouping approach, it was recalled that under REACH there was an obligation to consider testing only as the very last resort, while first considering all the other possibilities to obtain information with a similar scientific level and quality. Among those possibilities, there were also the grouping approach and "read-across". Finally, the EC representative clarified that the European Commission had understood the issue raised by the US delegation regarding cosmetics, and was working with EC member States to facilitate the registration of the substances concerned. However, he stressed that REACH was not discriminatory, and that US companies had been asked to provide information about the substances concerned in order to give the EC the possibility to assess the scope of the issue raised, but no information had been provided.

With respect to the possibility of inspecting enterprises outside the EC territory, the representative of Mexico drew the EC delegation's attention to Articles 2.7 and 6.4 of the TBT Agreement. In particular, he requested the European Communities to explain how such provisions could not be applied outside the territory of a party. The representative of Mexico also brought to the attention of the Committee the relevant provisions on inspections under the SPS Agreement.

The representative of Australia joined the comments expressed by Mexico and recalled that there was no violation of international law in inspecting enterprises outside the EC territory. Regarding the EC statement that there was no obligation on companies outside the European Union under REACH, it was his delegation's understanding that a non-EC based company had either to establish within the European Union or appoint an Only Representative. In this regard, the Australian representative stressed that the costs faced by SMEs in appointing an OR clearly showed the differential treatment between EC and non-EC based companies. She also emphasized that SMEs had a very limited time to pre register.

The representative of Egypt thanked the European Communities for their response. However, concerns remained with regard to the issue of the Only Representative, the extension of the pre-registration period beyond 1 December 2008 and the need of special and differential treatment to developing countries.

The representative of the United States shared the concerns expressed by previous speakers with regard to the EC statement that there was no obligation on non-EC based companies under REACH. Considering that small non-EC based companies could not afford to open a facility in the European Union, it was his delegation's understanding that the only remaining option was to hire an Only Representative or stop shipping to the European Union. With regard to the issue of cosmetics, the representative of the United States stressed that the burden was not on foreign companies to provide information; rather, it was the European Communities' responsibility to make sure the regulation was clear and not discriminatory.

The representative of Pakistan joined the concerns already raised by Egypt about the need of a special and differential treatment for developing countries, and the comments expressed by the delegation of Mexico about the possibility of having international inspections.

On the issue of inspections outside the EC territory, the representative of the European Communities noted that voluntary agreements for the exchange of inspections already existed. However, the kind of inspections that would be required for the implementation of REACH outside the European Union were different, including unannounced inspections on site in private entities. This was illegal under the law of most of the Members. On the Only Representative provision, the EC representative stressed again that it was not a mandatory requirement and that the obligation to register substances manufactured outside the European Union fell only upon the European importers. Also, she recalled that an extension of the pre-registration period was not foreseen. With respect to the issue of cosmetics, she recalled that REACH was not discriminatory, and that the European Commission was working to facilitate the registration of the substances concerned within the framework of REACH.

Finally, regarding the need of special and differential treatment and technical assistance to developing countries, the EC representative recalled that the primary objective of REACH was the protection of human health and environment; no exceptions for developing countries could therefore be provided for requirements such as the pre-registration/registration obligation. However, by developing the guidelines on the implementation of REACH, the European Communities also gave assistance to developing countries. The representative of the European Communities invited Members having specific needs for technical assistance programs, to direct their requests to the respective delegations of the European Commission in their country. She recalled that certain programmes were already carried out in cooperation with UNIDO.

The representative of Mexico requested further clarification on the issue of international inspections, and highlighted that similar mechanisms of international inspections were already in force. As an example, he drew the Committee's attention to the situation of his pharmaceutical industry, and introduced a document recently submitted to the Committee in this regard (G/TBT/2/Add.14/Suppl.1).

The representative of the United States raised again the issue of the Only Representative and stressed that the EC's statements did not reflect how the relevant supply chains actually operated in practice. The importers tended to be downstream users of chemical substances and, as such, lacked the requisite technical knowledge to register those chemical substances. At the same time, the importers were often the largest players within their supply chains and, thus, had the power within those supply chains to insist that their smaller, upstream suppliers register the substances (or risk losing the business) which, in most cases, would require those suppliers to appoint an Only Representative.

The representative of Egypt raised again the issue of extension of the pre-registration period, and requested the European Communities to clarify the reasons for not granting such extension, especially for developing countries. On the issue of special and differential treatment, he drew the attention of the Committee to Article 12.3 of the TBT Agreement, which requires Members to take into account the special needs of developing country Members in the preparation and application of technical regulations, standards and conformity assessment procedures. The representative of Egypt asked the European Communities to clarify how they intended to apply this provision of the TBT Agreement in the implementation of REACH.

The representative of China joined the comments expressed by the delegations of Cuba, Mexico, Egypt and other developing country Members with respect to the issue of special and differential treatment. He also drew the attention of the Committee to Article 12.3 of the TBT Agreement, and recalled that the delegations of Mexico, Cuba and China had already raised this issue at the previous Committee meeting without obtaining any response from the European Communities. Furthermore, the Chinese representative clarified that special and differential treatment to developing country Members did not mean to exclude products or enterprises from the provisions of REACH. Therefore, concerns remained about the pre-registration period, the criteria for the definition of SMEs and the fees for developing country Members, especially for SMEs.

Canadá e México X EUA - Country of Origin Labelling (COOL) (G/TBT/N/USA/281 and Add. 1)

United States – Country of Origin Labelling (COOL) (G/TBT/N/USA/281 and Add. 1)

The representative of Canada recalled that her delegation had expressed concerns about the US mandatory country of origin labelling (COOL) program, as set out in the 2008 Food Conservation and Energy Act. Concerns had been raised at TBT Committee meetings in June 2002, March and July 2003, March and June 2005, and July 2007. Comments had also been submitted to the formal USDA rulemaking process, requesting that flexibility be applied in implementing the rule so as to minimize any disruptions for Canadian industry.

The representative of Canada noted that the stated intent of the measure was to provide consumers with additional information on which to base their purchase decisions. However, she stressed that the United States had yet to provide evidence that the mandatory COOL program would benefit consumers as a retail labelling program. On the contrary, domestic support for the program did not appear to be consumer-driven, but rather, producer-driven. She stressed that the mandatory country of origin labelling requirements implemented for fish and shellfish in 2005 had created considerable administrative burdens for Canada's fishing industry, especially in small and medium enterprises. It had also created a competitive disadvantage for these protein products. She wondered why the new regulation distinguished between wild and farm seafood products, given that the HS code did not allow for such a distinction, and how this rule would be implemented.

It was further highlighted that although mandatory COOL for beef and pork had only been in place for one month, Canada's industry was already reporting unfavourable treatment, as several

major US processors had indicated that they would no longer be buying Canadian animals as a result of COOL. In Canada's view, the mandatory COOL program imposed an unnecessary technical barrier to trade and could therefore be inconsistent with the US obligations under the TBT Agreement, particularly as voluntary alternatives existed. She requested that the requirements for the current mandatory COOL program be abandoned for all products, including fish and shellfish.

The representative of Mexico supported Canada's views. In comments sent to the United States on 29 September 2008, it was stressed that, in Mexico's view, this system did not appear to have the intention to protect the consumer, but rather, the manufacturer. Additionally, he noted that the US regulation was not based on the relevant international Codex standard on pre-packeged goods and food. His delegation was willing to discuss the matter with US authorities and was expecting that comments be taken into account.

The representative of the United States noted that, further to the 2008 Farm Bill, the amendments to the COOL programme were now law in the United States. The United States Department of Agriculture (USDA) had published an Interim Final Rule (IFR) in the US Federal Register on 1 August 2008 in order to implement those changes. Comments on the IFR were received until 30 September 2008. In accordance with the legislation, the mandatory COOL program had been implemented on that date, with its "interim" status enabling USDA to continue considering the comments received and making revisions to the rule. He pointed out that the Interim Final Rule and related guidance had incorporated additional changes sought by several commenters. For example, the measures simplified the labelling for meat from multiple countries of origin, ensured that meat from animals imported for immediate slaughter was not treated less favourably with respect to labelling than meat from animals of exclusively US origin, and reduced the potential civil penalties by 90 percent.

It was further highlighted that USDA had also provided six months from the date of implementation of the IFR to conduct education and outreach. Three information sessions had been conducted since 30 September 2008, in an effort to assist industry to achieve compliance. The grace period was also intended to allow covered commodities already in the chain of commerce, for which no origin information was known, to have sufficient time to clear the system. USDA had also provided guidance materials and resources to interested parties via the USDA website.

The representative of the United States understood that there continued to be concerns among trading partners, and stressed that his delegation remained committed to implementing COOL in a fair and balanced manner, to continuing meeting with interested parties to discuss comments and take them into account in revising the interim final rule, and to helping ensure that actors in the supply chain could comply with the new requirements. He noted that Canada's comments on fish and shell fish would be transmitted to competent authorities for response.

UE, Japão, Coréia, EUA X China - Proposed Regulations on Information Security (G/TBT/N/CHN/278-290)

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

The representative of the European Communities reiterated his delegation's concerns with respect to the proposed regulations that would mandate compulsory certification of various information technology products in relation to information security requirements. He invited China to clarify whether a decision had been taken to postpone the publication and entry into force of the proposed regulations pending bilateral discussions both at government and at experts level with the WTO Members which had raised concerns at previous meetings. He noted that, according to previous announcements, the proposed entry into force for the new

requirements was 1 May 2009. A confirmation that this date was no longer the target date for entry into force was particularly important and would provide legal certainty.

The representative of the European Communities noted that China had stated that the goal of the proposed regulation was the protection of national security. However, his delegation believed that adopting any technical regulation mandating testing and certification for products intended for commercial or consumer use would be inconsistent with the stated goal of national security. Moreover, the proposed regulations would be unprecedented and unique in view of their wide scope, the depth of the conformity assessment envisaged and the corresponding detailed information that would be required of companies. He encouraged China to pursue dialogue with other WTO Members and stakeholders with a view to exchanging experiences on current government and business practices with regard to information security, as several economies faced similar problems in this field.

It was further stressed that technology in the field of information security progressed at a very fast pace and that limiting the choice of applicable technical specifications to a single set of standard requirements would stifle innovation and foreclose the introduction of new and more advanced technologies in China. Also, the certification process that was envisaged in the proposed regulations would be very long according to the best estimate based on current industry practices, and as a result the latest technologies could not be deployed in the Chinese market. Therefore, there were doubts about whether the proposed regulatory approach would be effective to achieve the goal of improving the level of national information security protection. It was also noted that information that companies would have to disclose under the proposed regulations was sensitive intellectual property protected information, which related to the core of the IPR portfolio of IT companies. Therefore, companies would not be in a position to provide to foreign conformity assessment bodies information that was vital for their business. In this regard China's attention was drawn to the provisions in Article 5.2.4 of the TBT Agreement on the protection of legitimate commercial interests in the framework of conformity assessment procedures.

The representative of Japan shared the concerns raised by the European Communities and stressed that the regulations could have a significant impact on trade of other Members. He pointed out that, in accordance with Article 2.5 of the TBT Agreement, China should explain the justification for these measures in terms of the provisions contained in Articles 2.2 to 2.4 of the TBT Agreement. He added that there was also concern from the viewpoint of the protection of technical information and IPRs, especially because of the characteristic of the products at issue. He invited China to explain the rationale and the purpose of the measures. He agreed with the European Communities that other countries had similar concerns and sought updated information, in particular on the timetable for entry into force of these regulations.

The representative of Korea shared the views expressed by the European Communities and Japan. He noted that Korean industry was concerned about the scope of the measure and the likelihood of information leakage once the regulation was adopted. He requested China to postpone the adoption of the regulation and to reinforce bilateral discussions both at a technical and at a political level.

The representative of the United States stated that his delegation continued to have strong concerns about the 13 proposed technical regulations related to information security, notified by China in August 2007. As previously stated, these regulations went substantially beyond global norms by mandating testing and certification of information security in commercial information technology products. In other countries, mandatory testing and certification for information security was only required for products used in sensitive government and national security applications. He wondered whether China had analyzed the practices followed in other countries with regard to the regulation of information security in the commercial sector and, if so, whether could China explain the results of its analysis.

Despite the concerns, the United States appreciated the willingness of officials from the Certification and Accreditation Administration of the People's Republic of China (CNCA) and China's Ministry of Commerce to maintain an open line of communication with government officials and industry groups from the United States and other countries on this issue. The United States also welcomed the commitment that China's Vice Premier had made in September 2008 that China would delay the publication of final technical regulations while Chinese and foreign experts continued to discuss possible approaches to the regulation of information security.

It was further noted that China had previously indicated that compliance with the 13 proposed technical regulations would become mandatory on 1 May 2009. Subsequently, CNCA officials had indicated that they had envisioned a one-year transition period between the eventual publication date of the 13 technical regulations in final form and the date by which compliance would become mandatory. China was invited to clarify whether it would delay its planned 1 May 2009 certification requirement for the covered products. China was urged to refrain from adopting any measures that mandated information security testing and certification for commercial products and to clarify the status of the 13 proposed technical regulations and China's future plans. This had also been indicated in the submission from the United States for the Transitional Review Mechanism (G/TBT/W/292).

The representative of China explained that the objective of the proposed information security products compulsory certification scheme was in compliance with the legitimate objectives stipulated by the TBT Agreement. He pointed out that many countries had established certification schemes for information security products and that China had been open and transparent in developing the draft by notifying the proposed regulation and soliciting comments from stakeholders, both domestically and abroad. He also noted that fruitful bilateral discussions had been held with interested trading partners, including the European Communities, Japan and the United States and that China was committed to continue to be transparent to ensure that the final regulations would be science-based and reasonable.

The representative of China further stressed that his delegation attached great importance to other trading partners' concerns on the proposed regulations. This is why the regulations had not been adopted on 1 May 2008 as originally scheduled – to leave more time for further technical communication and discussion among regulators and experts both at national and international level. His delegation was aware that a period of transition was needed and therefore a reasonable time would be provided for adaptation. With respect to standards in the proposed certification scheme, he stressed that China had complied with the TBT Agreement by taking ISO IEC 15408 "Guidelines for information technology safety evaluation" as the foundation for the standards involved. More specifically, the common criteria requirements on the products functions and safety assurance had been adopted. The scheme would be applied equally for both domestic and imported products.

UE X China – Wines (G/TBT/N/CHN/197)

China – Wines (G/TBT/N/CHN/197)

The representative of the European Communities reiterated her delegation's concerns about the above-mentioned notified measure, in particular with respect to the maximum levels of sulphur dioxide in wines. She pointed out that these limits were more restrictive than the maximum levels set by the International Organization of Wine and Vine (OIV) and constituted an unnecessary obstacle to trade according to Article 2.2 of the TBT Agreement. The European Communities had been informed by the Chinese authorities that the wine standard concerned was being reviewed and that relevant international standards would be taken into account in the revision process. She sought an update of this revision and invited China to indicate when these new measures would be notified to the TBT Committee.

The representative of China confirmed that the standard on wine was being revised and that a notification would soon be made. Comments by the European Communities on the new draft would be welcome.

UE, EUA 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 Communities reverted to a previously raised concern about India's Order laying down a registration procedure for imported cosmetics products, which had been adopted before being notified. She pointed out that comments had been sent on 22 July 2008, in which it had been highlighted that this measure would introduce long delays before products could be placed on the market, would be unreasonable costly, would discriminate against imported products and would require the disclosure of confidential business information. The requirements seemed unnecessary and unjustified to attain the stated objective of increasing product safety for consumers and of curtailing counterfeiting and parallel trade. Her delegation was also of the opinion that the Order was in certain aspects vague, and could lead to problems in interpretation and enforcement. As no reply to the comments made had been received, the representative of the European Communities invited India to provide a written reply, as well as an update of the state of play.

The representative of the United States reiterated his delegation's concerns on India's "Drugs and Cosmetics (Amendment) Rules of 2007" which amended the Drug and Cosmetics Rules of 1945. His delegation's understanding was that this amendment would introduce a new registration system for cosmetics products that US industry believed to be overly burdensome and unreasonably costly, and that it would cause unnecessary delays to market for companies' products.

The representative of the United States sought confirmation from Indian authorities about whether an equivalent measure existed for domestic products or not. His delegation was also interested in gaining a better understanding of how India foresaw this measure would increase product safety. In particular, what type of analysis had been done before determining to apply these measures to all imported cosmetics? Further, given that cosmetics producers already had to obtain a non-objection certificate from the Ministry of Health, could India explain what value was added by the additional registration requirement?

It was also noted that there did not appear to be any publicly available information concerning: what testing laboratories were, or would be, certified for the examination, testing and analysis of cosmetics; the criteria or procedures by which India would accredit labs; or the procedures that labs had to follow in order to participate in the registration system. Did India plan to publish such information? Given the outstanding concerns, India was urged not to mandate compliance with the amended rules until these issues were addressed.

The representative of India explained that the proposal for amendment in the Drugs and Cosmetics Rules had been considered by the Drugs Consultative Committee, following recommendations by the State Licensing Authority that there was a need to regulate the import of cosmetics and cosmetic products in order to assure their quality and safety. Based on these recommendations, the Government of India had approved the proposed draft rules.

The purpose of the amendment was to streamline import of cosmetic products into India with the objective of ensuring public health and safety. The registration process would ensure that cosmetics coming into India were pre-examined. This would also reduce complications at customs to verify cosmetics after imports. It was noted that cosmetic products manufactured in different countries followed different regulations. While some countries followed rigorous

systems of regulatory control to ensure that cosmetics manufactured for sale in those countries conformed to safety norms, such norms were not uniformly employed by all countries.

It was also noted that certain chemicals which were prohibited in benchmark countries continued to be used in several other countries. It was therefore necessary to regulate the import of cosmetics into India to ensure that these did not contain harmful ingredients and conformed to the standards prescribed for them. Clarification and additional information would be provided to interested Members, including the United States and the European Communities.

UE, EUA e Japão X Índia - Pneumatic Tyres and Tubes for Automotive Vehicles (G/TBT/N/IND/11 and 20)

India - Pneumatic Tyres and Tubes for Automotive Vehicles (G/TBT/N/IND/11 and 20)

The representative of the European Communities recalled that at the last Committee meeting her delegation had stated that there were still concerns with regards to the requirements for tyre manufacturers. In the reply to these concerns, the Indian delegate had said that the comments would be transmitted to capital and responses would be given at the next TBT Committee meeting. She invited India to provide replies to the questions raised before and in particular: (i) if the notified draft was already adopted and, if so, when it would enter into force; (ii) if the license fee for tyres was calculated in a different way for tyres produced in India and for imported tyres; (iii) if tyres could be certified in other laboratories than the only accredited laboratory in India (Central Institute for Road transport); (iv) if tyres complying with UN-ECE Regulations would be recognized.

The representative of the United States sought a better understanding of the objectives and requirements of the Bureau of Indian Standards (BIS) protocol on conformity assessment procedures for tyres, so as to allay industry's concerns that imported tyres could be treated less favourably than domestic tyres. Of particular concern was the fact that differential fee calculation methodologies applied to domestic and imported tyres might discriminate against imported tyres. Industry had estimated that the conformity assessment fee for domestic tyres was 0,5 cents per tyre whereas the fee for imported tyres was 34 cents per tyre. He noted that India had denied that the conformity assessment fees were higher for imported tyres and sought information from India about how industry calculations were incorrect and if India could provide its own calculations supporting its position that the fees were the same.

Additionally, the representative of the United States recalled that a draft amendment had been proposed to the Central Motor Vehicles Rules on 6 May 2008. The draft, which included a provision that appeared to govern conformity assessment procedures for tyres, also appeared to require that tyres meet the applicable requirements as of 1 May 2008, five days prior to the publication of the draft amendment. His delegation was awaiting clarification from India as to how the draft amendment related to the BIS tyre protocol, whether compliance was required as of 1 May 2008 and whether India intended to notify the draft amendment to the WTO. Given that compliance with the BIS protocol would be mandatory once implemented, and in light of the outstanding concerns, he urged India not to require industry compliance with the protocol until these issues were addressed.

The representative of Japan shared the concerns expressed. In his delegation's view, the regulation caused unfair and excessive testing and certification costs as well as time constraints for foreign-based firms. Furthermore, testing and certification capacity within India was insufficient to meet the needs. Japan also believed that there needed to be a longer implementation period: two years might be necessary in order to allow trading firms to get such certifications.

The representative of India recalled that the proposed mandatory requirements for standards with respect to imported tyres had been made to ensure quality and safety and that the same requirements were equally applicable to the domestic producers. The Government of India had proposed to bring pneumatic tyres and tubes for automatic vehicles under mandatory BIS certification as per the following Indian standards: 15627, 15633, 15636, 13098. He stressed that the proposed mandatory certification was in public interest and was not intended to treat imported tyres less favourably than domestic tyres as the same requirements would also be applicable to Indian tyre manufacturers. In response to the European Communities and the United States, he clarified that the measure had not yet been adopted.

With respect to the implementation period, the representative of India noted that the notification was circulated in July 2006, giving 60 days for comments. He considered that over two years of implementation period, after the expiry of the comment period, had already been given and that by no means this period could be considered inadequate. With respect to the questions raised by the European Communities and the United States on the license fee structure and by Japan on the testing facilities in India, they would be referred back to capital and a reply provided in due course.

Relatório da Noruega – Hazardous substances (G/TBT/N/NOR/17)

Norway – Hazardous substances (G/TBT/N/NOR/17)

Following concerns raised by Members at previous meetings of the Committee, the representative of Norway confirmed that Norway intended to introduce measures to restrict the use of some hazardous chemicals in consumer products. The justification for the proposed regulation was the risk of adverse affects to health and environment from hazardous properties of these chemicals combined with their use in consumer products. She recalled that the proposed regulation had been subject to an extensive hearing process at the national and international level. This process had triggered several comments on the proposal from WTO Members, EU industry and other stakeholders.

As a follow-up, a second review of the proposed regulation was conducted. An expert from the Norwegian Pollution Control Authority informed the Committee that as a result of the second review, eight substances had been removed from the list of the regulation: musk ketone, tens ides, phthalate DEHP, tinorganic compounds and the brominated flame retardant TBBPA. Other modifications were being considered for the remaining ten substances, such as limit values or further exemptions. She noted that WTO Members had made comments on about six of these substances.

In particular, on arsenic and arsenic compounds, the representative of Norway explained that the draft regulation was based on the classification in the European Communities in accordance with Directive 67/548/EEC, as well as on monitoring data from Norway documenting widespread occurrence of arsenic in the environment. Arsenic and arsenic compounds were not degradable and could be acute and chronically toxic for many organisms, even in small concentrations. They were very toxic for aquatic organisms, and could cause adverse long-term effects in the aquatic environment. In Annex 1 of the Directive 67/548/EEC there were group entries for all arsenic compounds classified as carcinogenic.

It was noted that, according to Norwegian monitoring reports, arsenic contamination had been found in the air, reindeer, sediments and soil contamination. Arsenic was used in semiconductor production and there were indications that electronics comprised the greatest remaining source in products. The European Chemicals Agency Member State Committee had agreed on the identification of 4 arsenic substances as Substances of Very High Concern (SVHC) that could be subject to authorisation in the context of REACH. ECHA had also added the 4 arsenic substances to the "Candidate List" of Substances of Very High Concern for

authorisation published in a press release from ECHA of 28 October 2008. It was further pointed out that, in the Norwegian draft regulation, arsenic and arsenic compounds were proposed to be regulated when the content of the substance in the product's homogeneous individual parts was greater than or equal to 0.01 percent by weight for consumer products in general with some exemptions and individual limits.

With respect to Bisphenol A, the representative of Norway explained that the hazards of this substance were evidenced by a number of studies showing neurotoxic effects at low level exposure, by the classification in the European Communities according to Directive 67/548/EEC, by the concerns for endocrine disrupting effects in aquatic organisms documented in the EC risk assessment in the framework of Regulation No 793/93/EEC, as well as by the comprehensive monitoring data from the environment in Norway. Bisphenol A was classified as toxic for reproduction with the risk phrase "possible risk of impaired fertility", and was classified with the risk phrase "harmful to aquatic organisms".

The representative of Norway further pointed out that laboratory studies had shown that low level exposure to Bisphenol A during development could cause neurotoxic effects, in particular changes in brain and behaviour. The EC risk assessment for health concluded that there was no risk to humans exposed via the environment. However, studies showing neurotoxic effects at low exposure levels had not been taken into account. Norway, Sweden and Denmark had concluded that the studies showing neurotoxic effects at low level exposure could not be ignored. The National Toxicology Program Centre for the Evaluation of Risks to Human Reproduction Expert Panel had also concluded that there continued to be concerns connected with possible neurotoxic effects of Bisphenol A and that further tests ought to be carried out. This was supported in a recently published monograph from National Toxicology Program and was in line with the assessment of Norway.

It was also highlighted that the EC risk assessment for environment reported that Bisphenol A had endocrine-disrupting effects in fish. Moreover, there continued to be a concern for possible affects on snails at even lower concentrations than the predicted no effect concentration for aquatic organisms that was used in the risk characterisation. Further work in order to clarify this was being conducted by the UK Government. The risk assessment would be re-evaluated in the context of REACH when the final results of the testing would be made available. Monitoring data showed a substantial spreading of Bisphenol A in the environment in Norway, such as freshwater and fish along the Norwegian coast and sediments in the Barents Sea. The Norwegian Pollution Control Authority had undertaken a study which showed that individual consumer products were identified with some very high quantities of free (residual) Bisphenol A.

The representative of Norway stressed that in the estimates of children's combined exposure for Bisphenol A from consumer products, food and the environment, the margin of safety based on the no adverse effect level (NOAEL) carried out by the European Food Safety Authority was too low. The NOAEL concluded by EFSA had not taken into account the studies reporting neurotoxic effects at low exposure levels. She pointed out that the Canadian authorities had published the final screening assessment report and proposed risk management approach of Bisphenol A in October 2008 and that regulations were expected to come into effect in 2009. This supported the Norwegian proposal. Additionally, she noted that the draft regulation only set a limit for the content of residual monomers. It was proposed to regulate free Bisphenol A when the content of residual (free) Bisphenol A in the product's homogeneous individual parts was greater than or equal 0.005 per cent by weight. Some exemptions were also suggested.

As for cadmium and cadmium compounds, the representative of Norway explained that the proposals were based on the classification in EC Directive 67/548/EEC as well as on monitoring data from Norway which documented widespread occurrence of both cadmium and lead in the environment. Cadmium was acutely and chronically toxic to humans and animals even in very

small concentrations. Cadmium was very toxic for aquatic organisms, particularly in freshwater and acutely toxic for mammals. Most cadmium compounds were carcinogenic and cadmium bioaccumulated in fish and mammals and had a long biological half-life in mammals. According to the Norwegian monitoring, cadmium had been shown in vegetation, surface soil and animals, fjords and watercourses.

It was further stressed that the EC Risk Assessment Report (RAR) had concluded that, for both cadmium and cadmium oxide, there were scenarios that needed specific measures to limit the risk for humans exposed via the environment. Moreover, it was recognised that cadmium toxicity in water was dependent on water hardness (mg CaC03/L). In Norway, there were many very soft waters (hardness < 40 mg CaC03/L) and a cadmium exposure in Nordic waters would therefore have a higher possibility to cause negative environmental effects than in waters with higher hardness. Cadmium and cadmium compounds would be regulated when the content of the substance in the product's homogeneous individual parts was greater than or equal to 0.01 per cent by weight. Also in this case, some exemptions were proposed.

Turning to lead and lead compounds, the representative of Norway pointed out that lead was not degradable and was toxic in low concentrations, having both acute and chronic health and environmental effects. Lead was acutely toxic to humans and chronic lead poisoning could have neurotoxic and immunological effects. Lead was also harmful to reproduction and could result in brain injuries. Children were more exposed than adults. The lead compounds were also very toxic for aquatic organisms, and could cause long-term adverse effects in the aquatic environment. According to the Norwegian monitoring, lead had been shown in humus layers, sediments in lakes and fjords, soil and organisms.

It was also noted that Denmark had a national regulation in force on the use of lead and lead compounds for selected application areas. The Norwegian proposal was to a great extent based on the Danish regulation in force and proposed to regulate lead and lead compounds when the content of lead compounds in the product's homogeneous individual parts was greater than or equal to 0.01 per cent by weight. The proposed regulation on metallic lead only applied for specified areas. In particular, some exemptions were provided for both metallic lead and lead compounds.

With regards to Hexabromocyclododecane (HBCDD), the representative of Norway pointed out that the risk assessment was based on comprehensive work done in the EC risk assessment (framework of Regulation 793/93/EEC) and proposal for classification according to Directive 67/548/EEC. HBCDD was considered as extremely toxic to aquatic organisms. Moreover, it was persistent and could cause long-term adverse effects on the environment. In the EC working group on classification and labelling of dangerous substances, no resolutions had been adopted concerning health classification of HBCDD. However, a proposal did exist concerning classification with the risk phrase "may cause harm to breast-fed babies". She highlighted that, in June 2003, it had been agreed that the substance should be classified as dangerous to the environment and that lower specific concentration limits would be set to 0.025 per cent.

It was stressed that HBCDD had been found in remote areas, far from potential sources: in fish from Northern Norway and Spitsbergen, in Polar bears from Greenland and Spitsbergen and also in animals high in the food chain. These findings suggested that HBCDD was transported long-range via the atmosphere, and this was supported by recent studies. Since the highest concentration had been measured in marine mammals, this indicated that HBCDD was biomagnified. More recent data indicated that the levels in marine mammals were increasing. The European Chemicals Agency Member State Committee had also agreed that HBCDD was a PBT substance, which meant that it was accumulating and toxic. It identified HBCDD as a Substance of Very High Concern (SVHC) that may become subject to Authorisation in the context of the REACH Regulation. ECHA had added HBCDD to the "Candidate List" of

Substances of Very High Concern for Authorisation. In the draft regulation, HBCDD was proposed to be regulated in consumer products with a limit value of 0.1 per cent by weight.

Finally, concerning Perfluorooctanic acid (PFOA), the representative of Norway explained that the draft regulation was based on the classification in Directive 67/548/EEC as well as on monitoring data documenting widespread occurrence of PFOA in the environment. For example, in studies on mammals, the substances were shown to be chronically toxic and harmful to reproduction. PFOA was also suspected of being carcinogenic and studies had shown that PFOA was toxic for aquatic organisms. PFOA was classified as cancinogenic Category 3 and harmful to Reproduction Category 2.

It was also noted that several studies had shown that PFOA did not degrade in the environment. PFOA had been found everywhere in the environment and PFOS and PFOA had been shown as the most common perfluorinated compounds in sediments from Spitsbergen, a location where there had been no human activity for 40 years, which demonstrated that the substance was transported in the air. Monitoring data confirmed that the substances had been widely spread in the environment in the Nordic countries, including Norway. The substances had been found in relatively high levels in human blood and in animals, including in the Arctic. A new Norwegian study of human blood samples from Northern Norway and Siberia showed PFOS and PFOA in all the samples. The draft regulation included PFOA in consumer products with a limit value of 0.005 per cent by weight (for the products homogenous individual parts). Exemptions and individual cut off values for textiles and coated products were under consideration. Finally, the representative of Norway noted that additional substances, medium chain chlorinated parafins, musk saline, pentaclorofino and triklosane had also been included in the proposal and that fact sheets on all ten substances were available on request.

The representative of Jordan appreciated the update from Norway. With respect to the substances of interest to his delegation, TBBA and HCBBD, he was pleased that TBBA was exempted from the scope of the regulation. His delegation would seek bilateral consultations with Norway with respect to HCBBD, for which many other Members had also called for an exemption.

The representative of the United States appreciated the detailed report from Norway, and noted that it would be shared with experts in capital.

Israel, Jordânia, UE, EUA e Japão X Suécia - Restrictions on the use of Deca-bromo diphenylether (deca-BDE) (G/TBT/N/SWE/59) and European Communities – Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) (G/TBT/Notif.00/310, Corr.1)

Sweden – Restrictions on the use of Deca-bromo diphenylether (deca-BDE) (G/TBT/N/SWE/59) and European Communities – Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) (G/TBT/Notif.00/310, Corr.1)

The representative of Israel recalled that deca-BDE had been exempted from the RoHS Directive following a risk assessment which had concluded that deca-BDE did not represent any significant risk to health or environment. However, on April 2008, the European Court of Justice had ruled that the exemption given for deca-BDE should be annulled by 1 July 2008, based on procedural flaws in the exemption process. As a result, deca-BDE was not be exempted from the ban within the RoHs Directive, and as of 1 July 2008 was restricted from use in electronic and electrical equipment. She noted that the RoHS Directive was being reviewed and urged the European Communties to exclude decaBDE from its scope, thus amending the unjustified distortion to trade.

The representative of Israel further recalled that, on 26 May 2004, the European Union competent authorities had closed, after 10 years of research, the scientific assessment of commercial deca-BDE. The assessment had concluded that there was no significant risk for the environment or human health and that therefore there was no scientific justification for the inclusion of deca-BDE in the RoHS Directive. Her delegation considered this restriction as an unnecessary obstacle to international trade, within the meaning of Article 2.2 of the TBT Agreement and urged the European Communties to follow its own scientific results and exclude deca-BDE from the RoHS Directive scope in the current review.

The representative of Jordan shared the concerns expressed by Israel. He pointed out that the EC risk assessment had concluded that was no significant environmental or health risks posed by the use of deca-BDE. On that basis, deca-BDE had been excluded from RoHS Directive. However, the Court decision of April 2008 had ruled out the exemption of deca-BDE from the scope of the Directive. His delegation considered this as an unnecessary obstacle to international trade and therefore not in compliance with Article 2.2 of the TBT Agreement. He urged the European Communities to exclude deca-BDE from the scope of the Directive as there was no scientific justification. He sought an update from the European communities on this matter.

The representative of the European Communities explained that the Communities were bound to respect decisions the European Court of Justice and confirmed that, due to procedural flaws, the exemptions covered in the RoHS Directive had to be withdrawn. The European Communities were in the process of revising and recasting the Directive and deca-BDE was among the issues which were currently being examined in the context of the revision. She informed the Committee that an impact assessment on the revision of the RoHS Directive had been completed and a proposal was being finalized on the basis of that impact assessment. Both the proposal and the impact assessment would be published in early December. The revised proposal would be notified to the TBT Committee at the draft stage and sufficient time would be provided to submit comments.

The representative of the United States noted that his delegation continued to monitor closely the ongoing recast of the RoHS Directive concerning restrictions on hazardous substances. Concerns remained about the potential magnitude of the cost of compliance - in particular for small and medium sized enterprises - that could result from an expansion of the Directive. He emphasized the need for EC regulators to ensure a risk and science-based approach to the RoHS review, including in evaluating whether to add substances to the list, set maximum concentration levels for specific products, or grant exemptions.

The representative of the United States further encouraged the European Communities to provide clarity in a timely manner on how RoHS and REACH would fit together. There was the potential that this could be a problem as there were several substances that were slated for priority assessment under the draft RoHS recast which were also listed on the authorization candidate list for REACH. Could the EC clarify which measure governed in such a situation? Was the RoHS Directive going to be phased out in order to ensure that similar conflicts would not develop in the future? He pointed out that such potential overlap highlighted the importance of receiving published legal guidance from the European Communities as to the significance of a substance being placed on the REACH authorization candidate list, and that it would be premature to substitute for any substances until analysis of particular end-uses had been completed.

In concluding, the representative of the United States stressed that, as the European Communities proceeded with its review of the Directive, a transparent process should be conducted that allowed meaningful opportunity for comment by all interested stakeholders. The European Communities was also requested to provide a reasonable period of time for suppliers to implement any changes made to the Directive, as this had not necessarily occurred in the past.

The representative of Japan shared the concerns expressed by the United States and sought an update on the scenario being considered by European Communities which would minimize the negative impact on trade.

The representative of the European Communities referred to the comments made earlier about the finalization of the impact assessment. She stressed that one of the objectives was to clarify links between the RoHS Directive and other EC legislation, including REACH and the Marketing and Use Directive.

Noruega, Canadá, UE X Alemanha - Ban on Seal Products (G/TBT/N/DEU/5 and Add.1)

Germany – Ban on Seal Products (G/TBT/N/DEU/5 and Add.1)

The representative of Norway reiterated concerns on the banning of imports of seal products by several EC member States, the most recent of which had been notified by Germany. Her delegation believed that the ban on seal products was not an animal welfare issue, it was not a conservation issue and it was not a management issue. Rather, it was a public opinion issue which was considered as unsubstantiated and unjustified. Banning the imports of seals in member States of the European Communities set a dangerous precedent for trade in animal products that were harvested in a sustainable and humane manner.

It was Norway's expectation that the European Communities would notify any draft on future regulations concerning trade in seal products to the TBT Committee within the times limit of the TBT Agreement. It was noted that the European Commission had not notified its proposed regulation concerning trade in seal products to the TBT Committee, whereas the in-part restrictions of certain individual EC member States had been notified. The European Communities was requested to clarify their plans with respect to the notification to the TBT Committee or other WTO bodies and how they would ensure that WTO Members' views would be taken into account. Norway continued to reserve its right to take any appropriate action necessary to defend its interests under the TBT Agreement and other relevant WTO agreements.

The representative of Canada fully supported Norway's views.

The representative of the European Communities pointed out that, as had been noted in previous meetings of the Committee, the draft proposal had been notified to the European Commission under internal procedures and discussions with the German authorities were underway. She took note of the comments made by Norway with respect to the EC notification.

EUA, Nova Zelândia, Suíça, Austrália e UE X Canadá – Compositional Requirements for Cheese (G/TBT/N/CAN/203)

Canada – Compositional Requirements for Cheese (G/TBT/N/CAN/203)

The representative of the United States recalled that his delegation had raised concerns in previous meetings of the Committee regarding the market access impact and potential cost burden of Canada's new compositional requirements for cheese. As these issues were of great concern to US industry, his delegation would continue to review developments - including the new litigation in Canadian domestic court, and would be monitoring the measure's impact on trade flows.

The most immediate concern of the US delegation was that Canada would require compliance with the compositional requirements on 14 December 2008. The United States and other Members had raised this issue at the previous meeting of the Committee and Canada had indicated that an “import-licensing scheme” would be published later in the summer. However,

thus far the United States had not seen any such publication. A copy of the general implementation approach had been received by the United States, but there seemed to be additional details to follow and there were less than six weeks to go before the requirements became mandatory.

The representative of the United States further stressed that the TBT Agreement required Members to provide a reasonable interval between the publication of conformity assessment requirements and their entry into force. He urged Canada to consider delaying enforcement of the measure beyond 14 December, until the complete implementation approach had been put in place following a process of stakeholder review and comment.

The representative of New Zealand echoed the US views. His delegation had also raised concerns at previous meetings, in particular about the restrictive nature of the regulations. He noted that his delegation had engaged bilaterally with Canada to express concerns, and acknowledged the information on the implementation approach. However, like the United States, his delegation was concerned that there were only six weeks before the measure was to be implemented, and a lack of clarity remained. He was also concerned that the regulations deviated substantially from the Codex Alimentarius' standards for cheese and was unclear about what was Canada's legitimate objective in pursuing these standards.

The representative of Switzerland recalled that her delegation had raised concerns on this issue at previous meetings of the Committee. The new requirements on cheese composition were of particular interest to Switzerland in light of the significance of cheese exports. She stressed that it was essential for exporters to receive further relevant information on the new regime for import licenses, particularly in light of the fact that the new system would be entering into force in one month's time.

The representative of Australia joined the previous speakers in expressing concern about Canada's compositional standards for cheese and reiterated the views expressed by her delegation at previous meetings. She noted that Canada had recently provided additional information, which would be analyzed in capital, and expected the opportunity for further dialogue on this issue prior to the introduction of the new standards.

The representative of the European Communities joined concerns expressed by other delegations and reiterated her delegation's view that these standards would have a negative impact on exports to Canada of certain cheeses, as well as basic products such as milk protein concentrates. Also, the new licensing requirements could create unnecessary obstacles to trade. She noted that Canada had recently published measures which implemented the new requirements. While her delegation welcomed this publication, it regretted that the requirements would come into effect on 14 December 2008. This short deadline was not sufficient for WTO Members and exporters to get acquainted with the new rules and did not give Member sufficient time to discuss any concerns with the Canadian authorities

The representative of the European Communities also shared the concerns raised by other Members regarding the lack of information on the import licensing regime and urged Canada to delay the entry into force of the new compositional standards while third countries and exporters examined the implementing measures. She also asked that these were notified to the TBT Committee, so as to allow WTO Members opportunity to submit comments.

The representative of Canada noted that, on the import licensing regime, more information had been released on 31 October 2008 and this would be notified to the TBT Committee. Her delegation believed that this regime would minimize the impact on importers and foreign cheese suppliers. She explained that in Canada the food industry was responsible for having measures in place to verify that all products met the appropriate regulations and the Canadian food inspection agency would then assess compliance. The licensing regime would continue to

require the import declaration, whereby the importer attested that the product met all Canadian requirements. To obtain this cheese import license, importers of cheese would need to submit an application to the Canadian Food Inspection Agency, along with a recall programme, a list of cheeses expected to be imported and additional information. She stressed that her delegation was willing to meet with trading partners to discuss this further.

With respect to the implementation approach, the representative of Canada pointed out that the new requirements applied to both imported and domestic cheese, as well as food imported and domestic that declared cheese as an ingredient. Records for imported cheese and cheese produced for federally registered establishments would be monitored and would be consistent with other consumer protection activities. Instances of non-compliance would be assessed on a case by case basis and actions taken would be proportionate to the gravity of non-compliance.

It was further noted that there were no plans to allow for an extension in the implementation date. However, Canadian Food Inspection Agency inspectors would require training prior to implementation of the inspection. Interested Members were invited to provide more details on the additional information they required, so that this could be provided as quickly as possible. With respect to the concerns raised about the impact on trade, it was stressed that assertions that the new requirements would result in a reduction on imports of milk ingredients, including milk protein concentrates remained to be substantiated. The use of milk ingredients in cheese manufacturing varied from one cheese processor to another and there was no evidence that that minimum quantity of casein required by the regulation would serve as an effective constraint on the existing use of milk ingredients such as milk protein concentrate.

Colômbia, Chile e Paraguai X Argentina - Measures affecting Market Access for Pharmaceutical Products

Argentina – Measures affecting Market Access for Pharmaceutical Products

The representative of Colombia recalled that his delegation had raised concerns on previous occasions about pharmaceutical products market access in Argentina, specifically with regards to the country classification and the application of conformity assessment procedures as well as issues related to classification and application of quotas or tariffs for undertaking verification in manufacturing facilities located in the originating country. This issue was originally raised in document G/TBT/W/280 dated 29 October 2007 and reiterated at the March and July 2008 meetings of the TBT Committee. The issue had also been discussed bilaterally with the Argentinean authorities. In particular, Colombia's requests had been that the country should be included in Annex 2 of the Decrees 150 of 1992 and 177 of 1993 and that Argentina submit the country risk studies and criteria used for the classification of countries. However, no information had been received from Argentina. The representative of Colombia stressed that his delegation's concern was not related to problems with laboratory inspections, but rather with Annexes 1 and 2 of the above-mentioned Decrees.

The representatives of Chile and Paraguay supported the statement made by Colombia.

The representative of Argentina took note of the views expressed and stated that these would be conveyed to the capital. He stressed that, although a solution had not yet been reached, several meetings had been held with Colombia with a view to addressing the concerns expressed.

Japão, UE X China - Draft Standards on Lithium Batteries for Mobile Phones

China – Draft Standards on Lithium Batteries for Mobile Phones

The representative of Japan recalled concerns expressed by his delegation on the above-mentioned measures and sought an update from China on the state of play. He requested that

the standards be limited to safety issues, since the measures currently under consideration stipulated requirements related to the environment, to performance and were related to battery chargers as well, despite the characteristic of safety standards. Also, the representative of Japan expressed concern related to the protection of intellectual property, since the standards contained requirements about the kind of materials and the methods of manufacturing. He stressed that harmonization with international standards and a cooperative relationship with firms were very important. He also asked when the second Working Group meeting on the lithium-ion battery safety standards would be held.

The representative of the European Communities supported Japan's statement and requested an update on the state of play of these standards.

The representative of China said that standards on lithium batteries were still under discussion and had not been finalized, and that therefore they could not be discussed in the TBT Committee. He noted that some more time was needed until the drafts would be finalized as either a technical regulation or a voluntary recommendation. He stressed that the process of developing standards on lithium batteries was open to all stakeholders and encouraged stakeholders to submit comments to relevant Chinese agencies.

EUA, África do Sul, Nova Zelândia, Argentina e outros X UE - Regulation on Certain Wine Sector Products (G/TBT/N/EEC/15, Corr.1-2 and G/TBT/N/EEC/57)

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

The representative of the United States noted that his delegation continued to have concerns regarding the EC efforts to severely restrict the ability of non-EC wine to use common or descriptive and commercially valuable terms, on the grounds that those terms were traditional to European wines. He pointed out that these were common or descriptive terms, many of them adjectives, used on wine labels all over the world. He was concerned that the European Communities appeared to be trying to claim exclusive rights in such common terms, except under certain limited circumstances where the third country regulated the terms to the satisfaction of the European Communities. He noted that some of these terms did not have a common definition across all member States.

The representative of the United States further pointed out that the EC apparent justification for exclusive rights in these terms was that such measures were necessary in order to prevent consumer deception and stressed that, despite repeated requests from third countries, EC officials had never presented any evidence of consumer confusion or deception with the current use of such terms by foreign wines on the EC market. Consumer protection, if needed, could be achieved through the use of existing IPR protection, which could accomplish many of the same results. Examples were bottle shape protection, or use of a generic term in a trademark with other terms that make it protectable. He urged the European Communities to consider these concerns with the current regulation as it published implementing regulations on traditional terms.

The representative of South Africa recalled that the representative from the European Communities had clarified that the use of certain traditional expressions was protected under EU law as they related to a given language and to a specific category of wine.[9] Third countries could therefore, freely use these expressions for all the other remaining wines. The European Communities had stated that "it was, imperative that a request was made by that third country, according to Article 24 of Regulation 753/2002. The application is made in terms of the

[9] G/TBT/M/45, paragraph 75.

regulation". It had also been pointed out that South Africa had filed an application and was exporting wines to the European Communities labelled with the Spanish expression "Vino Fino" meaning "Fine Wine", being a traditional expression which was protected in the European Communities for three types of Spanish wines.

The representative of South Africa stressed that his delegation had remained opposed to the EC system of protection of traditional expressions and that South Africa had requested that it be added to the relevant Annex as per the requirements of EC Regulations 753/2002 as amended by EC regulation 316/2004, thereby making provision for the use of the words "ruby, tawny and vintage" and other expressions by South African wine exporters to the European Communities. He confirmed that the terms "ruby, tawny and vintage" would be utilised in conjunction with the word "Cape" on South African wine exports to the European Communities. He further noted this request was made without prejudice to South Africa's rights and obligations with regard to the TBT Agreement, the TRIPS Agreement and the South Africa-European Union Wine Agreement, which was part of a bilateral agreement between South Africa and the European Communities.

In concluding, the representative of South Africa stressed that his delegation's concerns were related to the nature, scope and applicability of the system for protection of certain terms by the European Communities. South Africa therefore supported the views expressed by the United States with respect to the restrictions on the use of traditional expressions on wine labels in the European Communities, as some of these expressions had been introduced in South Africa with European settlements since 1652.

The representative of New Zealand reiterated his delegation's interest in EC regulation for wine trade and recalled that concerns had been expressed and comments sent to the European Commission in April 2008, to which a reply had been provided. However, additional clarification was needed and his delegation would follow up with the EC TBT Enquiry Point. His delegation would also await the EC notification of the draft implementing regulation and was looking forward to discussing them with the European Communities. He shared the concerns expressed by the US and South Africa with respect to the restrictions on the use of traditional expression on wine labels in the European Communities.

The representative of Argentina reiterated the concerns which were set out in G/TBT/W/290 and expressed at the previous meeting of the TBT Committee relating to the application of the EC Regulation 753/02 and its amendments No. 316/04 concerning the exclusive use of a series of traditional expressions by various EC member States in each of their respective languages. He supported the concerns voiced by the United States, New Zealand and South Africa in relation to the restrictions of the use of traditional expressions on wine labels and recalled that this had led to the rejection of labels bearing additional quality terms of wine of Argentinean origin within the EC territory. He stressed that additional quality terms were mainly adjectives and referred to particular production methods or quality features that were not eligible for protection as intellectual property rights under the TRIPS Agreement, so that their use was governed by the TBT Agreement.

As acknowledged by the European Commission in its own communication to the national TBT Enquiry Point, Argentina considered that the use of traditional expressions was inconsistent with Article 2 of the TBT Agreement and for that reason it called for the immediate revision of the regulations to ensure consistency with the TBT Agreement.

The representative of Canada supported the comments made by previous speakers, in particular the US, and noted that Canada agreed that existing legislation to protect consumers from misleading labelling claims could accomplish many of the same results as the current EC 753/2002 Regulations. Her delegation would continue to follow developments in this area with interest.

The representative of Mexico associated his delegation with the comments made by previous speakers and recalled that his delegation had raised concerns on this issue various times since 2002. He believed that the regulation on traditional expression was inconsistent with the TBT Agreement. His delegation was also ready to engage in discussions and submit the necessary documentation to the European Communities as required.

The representative of the European Communities noted that the EC rules concerning the common market for wine had been recently reviewed. This new regulation provided new rules on the labelling of products that had to be further developed by implementing rules. The implementing rules were currently being discussed in Council by member States working groups. The implementing rules would be notified to the TBT Committee and her delegation looked forward then to having an exchange of views on these rules. She invited those delegations who had comments on the replies provided by the European Communities to send them to the EC TBT Enquiry Point.

EUA X Israel – Infant Formula

Israel – Infant Formula

The representative of the United States reiterated his delegation's concerns about the fact that a draft regulation on measures related to infant formula had not yet been published by Israel, nor had it been notified to the WTO. US industry continued to have concerns that Israel's unpublished requirements for infant formula were discriminatory against imports and unduly costly, burdensome, and unpredictable. Israel denied these allegations, yet refused to publish the measures. He stressed that the issue could not be resolved until Israel published draft measures governing infant formula for comment.

The lack of published requirements governing the quality and safety of infant formula, as well as related conformity assessment procedures and labelling provisions, was of particular concern given the 2003 Remedia incident. It was a difficult position to maintain that infant health in Israel was more protected by keeping the Ministry of Health infant formula requirements secret, rather than by publishing them for the public to review and comment, which was perhaps the most basic of all TBT and good regulatory practice principles. A promising resolution of this issue had appeared to be near this summer, and Israeli authorities were urged to resume working with industry to resolve this issue in the near term.

The representative of Israel pointed out that, due to grave health problems caused by deficient imported infant formula, the Ministry of Health had been forced to reconsider the import system in order to ensure the health and safety of infant foods. She highlighted that the issue was sensitive and important to Israel and renewed her delegation's invitation to the United States to engage with Israel at bilateral expert level in order to find an agreed solution to the issue.

Japão X China - Energy Efficiency and Energy Efficiency Grades for Copy Machines (G/TBT/N/CHN/331 and Rev.1 and Suppl.1)

China - Energy Efficiency and Energy Efficiency Grades for Copy Machines (G/TBT/N/CHN/331 and Rev.1 and Suppl.1)

The representative of Japan was grateful for the reply sent by China to the comments made by his delegation on the above mentioned notified measure, as well as for the bilateral discussions held. However, his delegation still had concerns on two issues. First, there was no international example of standards in the same field which were compulsory. For example, the international Energy Star Program was a voluntary standard. The Chinese standard might therefore be an obstacle to international trade. Second, it would not be possible to measure energy efficiency accurately, because energy efficiency was measured by copy mode in the proposed standard,

even if copy-based machines had the function of a printer. He noted that it was difficult to establish whether machines were copy machines or printers and inquired what the criteria for this determination had been used by China. Finally, he inquired whether China had plans to develop the same standards for printers and fax machines and, if so, when a notification would be made. He stressed that such standards should be harmonized with international standards.

The representative of China stressed that the objective of this standard was to save energy and protect the environment, which was in line with the legitimate objectives in the TBT Agreement. He explained that the standard divided energy efficiency into three grades. It was only the lowest grade (grade three) which was a compulsory requirement. Both grades one and two were voluntary, and grade two was equivalent to the requirements of the Energy Star Programme. Therefore, his delegation believed that this standard would not cause unnecessary obstacles to international trade.

The representative of China further pointed out that the scope of the standard was clear: it was applicable to copying machines as well as to multiple functional machine with a copier as a basic function. If the machine was a printer with a copier as secondary function, it would not be subject to the standards. Similar energy efficiency standards on printers and faxing machines were being planned and notification obligations would be fulfilled in due time.

EUA X Tailândia - Labelling Requirement for Snack Food (G/TBT/N/THA/215 and Add.1)

Thailand – Labelling Requirement for Snack Food (G/TBT/N/THA/215 and Add.1)

The representative of the United States appreciated Thailand's efforts on the revised labelling regulation and supported Thailand's goal of promoting healthier citizens. However, industry groups from Thailand and the United States, as well as from other trading partners, had continued to raise questions as to whether the measure was necessary in light of potential alternatives. He recalled that, at the last Committee meeting, the United States had requested a status report on the measure, particularly in light of the Thai FDA's statement earlier this year that nutrition labelling should be directed at all food categories, and that mandatory labelling requirements for snack foods and other foods "deemed necessary" would eventually be put in place "at appropriate stages." He sought an update on the status of this measure from Thai authorities. He also noted ongoing work in Codex to review strategies regarding diet and health, and encouraged Thailand to actively participate in the Codex work and to consider approaches that could have the benefit of both encouraging better health and facilitating trade.

The representative of Thailand pointed out that the Thai FDA was willing to enter into discussion and work on the issue with the United States. Concerns raised would again be conveyed to the authorities in capital.

EUA e Coréia X Arábia Saudita - Saudi Arabia - International Conformity Certification Programme (ICCP)

Saudi Arabia - International Conformity Certification Programme (ICCP)

The representative of the United States reiterated his delegation's concerns about Saudi Arabia's apparent failure to abide by its accession commitments to publicize in English its Conformity Certificate requirements. He stressed that Saudi Arabia had committed to remove the burdensome requirements of its former International Conformity Certificate Program (lCCP) administered by the Saudi Arabian Standards Organization (SASO), and replace it with a "Conformity Certificate" program to be administered by the Ministry of Commerce and Industry. Saudi Arabia had also committed to provide detailed public guidance on how to

comply with the new conformity assessment requirements post-ICCP. These commitments did not appear to have been fulfilled.

The representative of the United States stressed that the lack of publicly available information on the requirements had created confusion and had allowed the company previously contracted to provide services for Saudi Arabia's previous certification program to falsely advertise on the internet that its services were a mandatory requirement for access to the Saudi market. Saudi Arabia should take steps to dissolve the "ICCP.com" website. Furthermore, he urged Saudi Arabia to publish the current requirements for product testing and certification. Specifically, Saudi Arabia should publish the list of entities that it believed were qualified to complete testing and certification work for the country, in order to be clear about which service providers met Saudi requirements.

Moreover, it was noted that Saudi Arabia should also provide: (i) the criteria that Saudi Arabia was using to recognize approved test laboratories and certification bodies to provide services to the Saudi market; (ii) a formal notification process for accrediting or approving such bodies; (iii) clear procedures for approved bodies to follow when issuing conformity certificates or marks to convey that a product complies with the relevant requirements; (iv) whether the procedures would change or be superseded once the GCC conformity assessment scheme was put in place; and, (v) whether products that were covered by a Conformity Certificate would be grandfathered or would enjoy a transition period once the GCC system was finalized. Publication of this information would provide the necessary clarity that companies needed to trade their goods in the Saudi market.

The representative of Korea shared the concerns expressed and noted that Korean industry had difficulties in exporting to Saudi Arabia.