SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/43)

New Concerns

Colômbia e Chile x Argentina - Measures affecting market access for pharmaceutical products

Argentina – Measures affecting market access for pharmaceutical products (G/TBT/W/280)

The representative of Colombia introduced his delegation's concerns relating to the system applied by Argentina for the entry of pharmaceuticals into its market, specifically with regard to the classification of countries and the resulting application of conformity assessment procedures. He was also concerned about the classification and application of tariffs or fees for undertaking verification visits to plants located in the countries of origin of the pharmaceuticals. Colombia was of the view that some of the measures could be considered contrary to the rights and obligations under the TBT Agreement, particularly those regarding the principle of national treatment and transparency.

The representative of Chile noted that her delegation had had similar difficulties with respect to market access for pharmaceuticals in Argentina and this despite the fact that Chile was included in Annex 1 contained in the Decree 177 (listing those countries whose sanitary system and pharmaceuticals are reliable). For three years Chile had been asking for a review of its request with respect to the regulation at issue, yet nothing appeared to have been done. Although she hoped that the issue could be dealt with within the relevant MERCOSUR bilateral group, to date there had been a lack of response there as well. Argentina was encouraged to review the situation and provide a response.

The representative of Argentina took note of the statements made.

UE x Moldávia - quality and control measures for bottled, non-alcoholic beverages including mineral, natural water and soft drinks

Moldova – quality and control measures for bottled, non-alcoholic beverages including mineral, natural water and soft drinks

The representative of the European Communities was concerned about a measure adopted by Moldova on 15 August 2007 (Government Decision 934) which introduced new quality and control requirements for bottled, non-alcoholic beverages including mineral, natural water and soft drinks. This decision introduced a state registry for bottled non-alcoholic beverages, which required that, as of January 2008, all such products had to be labelled with a special state commercial stamp or mark. She pointed out that the European Communities was a major exporter of these products to the Moldovan market and would be adversely affected by this measure, if adopted. The European Communities considered that the entry into force of this measure needed to be delayed until third countries had had opportunity to get acquainted with it and submit formal comments.

The European Communities requested Moldova to notify the decision to the TBT Committee and to fulfil the transparency obligations set out in Article 2.9.2 of the TBT Agreement. In addition, there were a number of implementing measures, including how the stamp had to be affixed and the size of the bottle, which had not yet been adopted. The European Communities hoped that these

measures would be notified at a draft stage to the TBT Committee and that they would not be more trade-restrictive than necessary. Any further information that Moldova could provide would be welcome.

The Chairman noted that the concerns expressed by the European Communities would be conveyed to the appropriate Moldovan authorities.

EUA (Israel, Japão e Jordânia) x Noruega - Proposed regulation concerning specific hazardous substances in consumer products

Norway – Proposed regulation concerning specific hazardous substances in consumer products (G/TBT/N/NOR/17)

The representative of the United States noted that the above-mentioned regulation would prohibit the use of 18 substances in a wide range of consumer products. Several WTO Members and industry stakeholders had submitted comments to Norway's Enquiry Point. These comments questioned the technical justification, raised concerns that compliance would be overly burdensome and costly and noted the lack of viable alternative substances in many instances. In certain respects the proposed regulation appeared to be premature; the United States understood that risk assessments were underway and close to completion on at least two of the substances contained in the proposal (*tetrabromobisphenol A* (TBBPA), when used as an additive and *hexabromocyclododecane* (HBCDD)). The United States hoped that Norway would reconsider any further action until the science-based assessments were complete. She noted that Norway's notification indicated a proposed date of adoption of 15 December 2007 and that the measure would enter into force on 1 January 2008. The United States was of the view that such a short implementation period would not give industry sufficient time to comply either with existing drafts or any future revision.

The representative of Israel echoed the concerns of the United States. Israel was particularly concerned about two flame retardants affected by the proposed measure, known as TBBPA, when used as an additive, and HBCD – both of which were produced in Israel. Although Israel was aware of Norway's legitimate concerns regarding the protection of human health and the environment, his delegation was of the view that the proposed restrictions could not be justified based on available scientific information. Detailed comments concerning this matter had been sent to Oslo and, in brief, the following points had been made.

Israel considered that the proposed measure was an unnecessary obstacle to international trade in the sense of Article 2.2 of the TBT Agreement. Available scientific information within the context of an EU risk assessment process had established that there was no risk to human health and that the environmental risk was limited and controllable. Moreover, the risk assessment process had not yet been concluded and risk reduction actions would be incorporated within the REACH regulation. Therefore the proposed restriction could not be justified with reference to the available scientific and technical information as required by Article 2.2 of the TBT Agreement. As the proposed measure was more trade-restrictive than necessary, Norway had to consider the adoption of less restrictive measures concerning the use of the two substances. In addition, the prohibition could not be justified under Article 2.10 because the nature of the proposed ban did not concern any urgent problem.

Finally, Israel was of the view that Norway's decision to implement measures differing from those established in the European Union derogated from the principle of harmonisation of technical regulations referred to in Articles 2.6 and 2.7 of the TBT Agreement. As a member of the EEA, Norway participated in the risk assessment processes in accordance with EU rules and had therefore to afford mutual recognition to the conclusions reached by those assessments. In light of this, Israel objected to the implementation of the proposed restriction by Norway and urged Norway's authorities to consider its comments and proposed to further discuss the issue on a bilateral basis.

The representative of Japan, like other delegations, recognized the importance of the protection of human health and environment in considering regulations. However, Japan was concerned about the potential negative effects on international trade of the above-mentioned measure. Japan had also submitted its comments to Norway (on 6 and 10 August 2007) outlining their concerns. In essence, Japan was of the view that a risk assessment of the European Communities had concluded that *tetrabromobisphenol A* (TBBPA), *hexabromocyclododecane* (HBCDD) (*diethylhexylphtalate* (DEHP) and BPA (*Bisphenol A*) did not pose serious risk. Furthermore, the Japanese Government had also undertaken studies regarding the hazards of DEHA and BPA which had concluded that the endocrine-disrupter effect was not present. Norway was therefore requested to take into account pre-existing research and explain why its interpretation of the risk differed substantially from those arrived at by other WTO Members.

The representative of Jordan noted that his country was one of the major producers in the world of *tetrabromobisphenol A* (TBBPA) and elemental bromine which was an input material for *hexabromocyclododecane* (HBCDD). Hence, Jordan – as well as other producers – would suffer direct negative consequences through the reduction in TBBPA sales and indirectly through reductions in elemental bromine sales to other TBBPA and HBCDD producers worldwide. Jordan had also sent official comments to the Norwegian authorities requesting Norway to exempt TBBPA and HBCDD from the above-mentioned ban and to further examine the health and environmental risk of these products. In Jordan's view, available risk assessments did not offer sufficient basis to impose a ban. Therefore, Jordan considered that the proposed restriction was an unnecessary obstacle to international trade.

The representative of Norway noted that in May 2007, Norway had sent the proposed regulation for a public hearing and the deadline for comments had been 1 September 2007. The comments received in the public hearing were being evaluated by the Norwegian Pollution Control Authority. The Ministry of the Environment would subsequently assess the recommendation from the Pollution Control Authority as well as the comments received in the international hearing before a final decision on the prohibition was made. She informed the Committee that Norway had a goal to reduce emissions of several hazardous substances substantially by 2010 and to eliminate use and emissions before 2020. These targets were stated in a White Paper from 2006 and in this document on Norway's Chemical Policy, Norway had devoted special attention to consumer affairs and, *inter alia,* the need to reduce the use of hazardous chemicals in consumer products. In respect of the process, Norway had received 80 comments. Due to the substantial amount of work involved in scrutinizing these, the Norwegian Pollution Control Authority would not finish this work as early as had been anticipated. Hence, the regulation would not be implemented on 1 January 2008. A decision would take place at a later stage. Naturally, the proposed regulation would be evaluated in light of the WTO rules as well as the EEA.

Argentina x EUA - Proposed Rule on Labelling and Advertising of Wines, Distilled Spirits and Malt Beverages

United States – Proposed Rule on Labelling and Advertising of Wines, Distilled Spirits and Malt Beverages (G/TBT/N/USA/290 and Add.1)

The representative of Argentina raised a concern regarding the above-mentioned measure affecting alcohol products. In his view, the inclusion of mandatory information on labels stating alcohol content as percentage of alcohol by volume, as well as statements on calories, carbohydrates, fat and protein and other nutritional information was contrary to Article 2.2 of the TBT Agreement in that it could restrict trade more than what was necessary to achieve the legitimate objective sought. There were other ways to minimize risk that had not been considered and that could be efficient and appropriate to achieve the legitimate objective. The United States had mentioned chronic diseases that were common to the population and excessive consumption of alcohol; however, there were no new aggravating circumstances that could justify the new measure or that could show that the information currently provided to the consumer was insufficient. To provide the additional information to the consumer would imply higher costs for the adaptation of the printing equipment of the labels, re-design of labels and the costs for equipping laboratories to enable them to undertake necessary tests. All this would have negative consequences on market access. The United States needed also to consider relevant international organisations, especially in the wine sector. None of these organisations contemplated this type of nutritional labelling for wines. In fact, no other Member of the WTO had a similar requirement in place.

The representative of the United States took note of Argentina's statement and indicated that his delegation would review it and provide a response.

UE x China - Amended Hygiene Standards for Alcohol Products

Chinese Taipei – Amended Hygiene Standards for Alcohol Products (G/SPS/N/TPKM/64 and Add.1)

The representative of the European Communities drew the Committee's attention to a measure notified by Chinese Taipei to the SPS Committee in G/SPS/N/TPKM/64. In the view of the European Communities, the measure needed also to be notified to the TBT Committee as important elements of the standard fell under the scope of the TBT Agreement, in particular those relating to labelling and additives. The European Communities was concerned that the proposed standard would cause serious problems for exporters of alcohol and spirits due to the fact that certain additives which were allowed in the European Communities – as well as under the relevant Codex standards – had not been included in the proposal. The European Communities was not aware of any scientific justification that would support the exclusion of such food additives from the proposed authorised list. She urged the delegation of Chinese Taipei to notify the measure to the TBT Committee and to provide an exhaustive list of the approved additives together with an explanation, where relevant, for exclusions.

The representative of Chinese Taipei took note of the statement made.

Previously raised concerns

Argentina (EUA, Coréia do Sul, Japão, Canadá e Outros) x UE - Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH)

European Communities - Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) (G/TBT/N/EEC/52, Add. 1-4 and Add.3/Rev.1)

The representative of Argentina reviewed the process of the development of the REACH regulation and noted that, despite all the notifications made by the European Communities (addenda and revisions) the information was not complete: in particular some annexes and guidelines were incomplete and the determination of certain deadlines had not been done. Hence, although the REACH regulation had entered into force in June 2007, there was significant uncertainty about how it would work in practice. In particular, it was stressed that REACH constituted a *restriction* on trade in chemicals; it was not only about registration and authorization. This could be seen as an unnecessary barrier to trade.

The representative of Argentina was concerned that although the regulation originally notified to the Committee had been subject to many successive changes to clarify and to define certain aspects, expressions such as "adequate justification" or "equivalent concern" remained and these were open to subjective interpretation. The intrinsic complexity of the regulation with its 17 annexes made it very difficult for those concerned to understand it. Ambiguous concepts could lead to arbitrary decisions when applying the regulation in practice; this situation was aggravated by the number of bureaucratic requirements and the need to meet various deadlines that – in some cases – had yet to be set.

For the Argentinean industry this caused many serious problems. In particular, REACH established a mandatory registration system the cost of which was very high and would have to be borne by all the producers and users of these products, whether or not from the European Communities. This meant that products which were not registered could not be produced within or imported into the European Communities. Argentina was of the view that the costs would disproportionably affect producers in developing countries exporting to the European Union, putting them at a disadvantage over their competitors, especially in developed countries. REACH required that a product be registered after various tests that had to be carried out exclusively in EC laboratories and thus the costs were listed in Euros; this was clearly disadvantageous for third country producers. Moreover, the producer or importer into the European Union had to go through an Agency that had been created in the European Union. Thus, the exporter was subordinated to a EC client unless he decided to designate his own representative for that purpose, which, in turn, would add to the costs of registration. The representative noted that the exports from Argentina to the European Communities were relatively limited in terms of size and value and absorbing the cost of the registration made Argentina's presence on the European market unviable. Other countries with a greater level of production and investment would continue to export to the European Union leading to a distortion of conditions for competition.

Argentina was of the view that the situation was even more difficult for Small and Medium Sized Enterprises (SMEs), which in Argentina generally produced a large variety of chemical products at low volumes. Since REACH required individual registrations per product and on a case-by-case basis, the cost would be outside the possibilities of SMEs in Argentina which had very low profit margins and difficulties in accessing new technologies. There was little capacity to carry out the sophisticated studies that were necessary in this regard. It was difficult to estimate the actual value that had to be added to the product to absorb the additional costs and this introduced more

uncertainty which affected competitiveness. The investment and development of products in Argentina for export solely to the European Communities would therefore be seriously affected by this drastic change in the conditions of market access.

The representative of Argentina concluded by stressing that the regulation not only lead to uncertainties with respect to procedure but also with respect to costs. These costs would have severe consequences both for EC producers and for exporters, particularly exporters from developing countries. The structure of REACH was so complex and difficult to understand that it worried not only the chemical industry but also users of chemicals and preparations containing such chemicals. While Argentina was not of the view that registration needed to eliminated, it needed to be done in a way that did not create unnecessary obstacles to trade: REACH needed to become much less trade restrictive. The European Communities was requested to clarify the regulation and provide technical assistance to developing countries as current clarifications and guidance provided on the webpage was not sufficient.

The representative of the United States noted that while his delegation supported the EC objective to protect human health and the environment, concerns remained that the REACH regulation appeared to be overly expansive, potentially discriminatory and trade restrictive. The United States as well as other WTO Members and a large number of other stakeholders continued to raise questions and concerns with regard to the REACH regulation and its implementation, including about: the potential for differential enforcement across the member States; continued uncertainty regarding the scope and applicability of the provisions relating to articles; potential differential treatment with respect to phase-in substances; the issue of monomers and polymers; the chilling effect of having a substance placed on the authorisation candidate list; transparency issues in the development of the REACH implementation projects; the protection of business proprietary information; the new registration fee schedule and the potential trade ramifications caused by the shortage in existing capacity of laboratory facilities and "only representatives".

The representative of the United States noted that many of these issues had been discussed at a recent meeting between members of the APEC Chemical Dialogue and EC officials in Brussels, an event which had been attended by representatives from business and governments from nine WTO Members and held at the Embassy of Malaysia. At that meeting, the APEC delegation had noted the substantial trade effects that REACH was having on global supply chains and that there were several areas where additional information on the REACH implementation would need to be provided. Regrettably, the EC response was that the REACH process had been transparent and that current efforts to explain the implementation process had been largely sufficient. The United States hoped that the European Communities would reconsider its position and give sincere consideration to the broad expressions of concern which had been registered by its trading partners and other interested parties and ensure a meaningful opportunity to reflect views of non-EU governments and stakeholders in the process. The United States would continue to study the REACH regulation and to closely monitor the implementation process.

The representative of Korea emphasized two points in respect of REACH. First, SMEs continued to express that there was a lack of information regarding REACH and a need for clarification. Second, on the guidelines, it was noted that the Korean Government was willing to join the process of establishing new guidelines; participation in this process was seen as an important and useful way for industry to become more familiarised with REACH.

The representative of Japan reiterated his delegation's hope that there would be adequate opportunities for firms from outside the European Communities to have their views taken into account in a transparent manner – with respect to the development of guidance documents on the

actual implementation of REACH. Also, although Japan hoped that the "only representatives" provided for in Article 8 of the Regulation would become a useful mechanism for firms established outside the European Communities, on behalf of the Japanese industry, Japan asked the European Communities to ensure that there would be sufficient number of adequately qualified "only representatives" to meet the needs of these foreign firms. Japan also asked the European Communities to explain its understanding of Article 33, Clause 2 of the Regulation, and, in particular, the meaning of "available to the supplier" – a point which had led to some confusion and where clarification could help better prepare the Japanese industry for compliance.

The representative of Canada concurred with the points already raised and wished to stress one in particular. Canada was interested in hearing from the European Communities whether more technical guidance documents were being developed and whether or not these would be notified. In the spirit of transparency and considering the unprecedented level of interest among WTO Members on REACH, the representative of Canada reiterated her delegation's earlier request that all technical guidance documents in support of REACH implementation be notified while at the draft stage with an opportunity for Members to provide comments as they were being developed.

The representative of Chinese Taipei joined other speakers in their concerns about REACH, particularly with respect to implications for SMEs. He asked if the European Communities had developed any plan or mechanism to assist SME's in resolving problems resulting from implementation of REACH and how such assistance could be accessed. The representative also noted that the definition of "only representative" in the REACH regulation was now limited to legal entities or natural persons located *within* the European Union and asked that this be changed to allow for such legal entities or natural persons in other Members to become the "only representative". This would be particularly important to SME's outside the European Union and especially in the chemicals industry. In addition, it was noted that the European Communities had set up several Help Desks within member States. From a technical assistance point of view, and based on the principle of national treatment, Chinese Taipei requested that the Commission provide similar arrangements to other WTO Members so as to enable these Members to respond to problems in a timely and efficient manner.

The representative of Chile reiterated her delegation's concern about the impact the Regulation would have on exports from Chile and developing countries in general. Chile's export sector had voiced increasing concerns and confusion regarding the REACH regulation and Chile therefore underlined the need for clarification. Moreover, regarding the actual application of REACH, Chile still considered it difficult to follow the discussion on the Internet regarding the REACH guidance documents. Also, Chile remained concerned about possible differences in the application of REACH in different member States of the European Union. In addition, Chile did not have a complete list of substances that needed authorisation as set forth in the Annex 14. Similarly to the point raised by others, Chile wished to benefit from technical assistance so as to better understand the application of REACH. It would be particularly useful if an expert from the European Commission could travel to Chile and provide some training in this area.

The representative of China noted that his delegation had raised concerns both at the WTO and in bilateral consultations. He urged the European Commission to pay attention to the impact of REACH on international trade, especially the impact on chemicals trade of developing countries. Developing countries' level of technological development in the chemicals industry was low and the data needed for registration of chemicals was held mostly by companies in the developed world. Therefore, firms in developing countries would have to pay high fees for such data for registration leading to increases in costs in chemical production and trade. Moreover, the cost of importing chemicals from the European Communities would also rise. REACH also impacted on exports

from SME's differently compared to bigger companies; SMEs had a severe lack of technical capacity to deal with REACH. The representative of China reiterated the need for the European Communities to take these concerns into account in the process of the Regulation's implementation.

The representative of Mexico reiterated the importance of expert advice and information on the details about REACH. She informed the Committee that the European Union had sent an expert who had clarified and addressed concerns voiced by the Mexican industry. Hence, the chemical industry was, to a certain extent, better informed regarding the way in which the system was to be applied. Mexico welcomed this technical cooperation as extended by the European Union.

The representatives of Australia, Brazil and Thailand shared concerns expressed by other delegations on REACH.

The representative of the European Communities stressed the efforts made by the Commission to ensure the utmost transparency in the development of the REACH regulation. Part of the legislative process had led to changes in the proposed regulation – the one notified in 2003 was, naturally, not the final one. In this process comments of trading partners had been taken into account. He stressed that there had been, throughout the process, bilateral and multilateral meetings between the experts, the most recent one for APEC countries as had been mentioned by the US delegation.

Regarding guidance documents and the point raised by Canada, the European Communities was of the view that these documents were *technical guidance* documents and, as such, were neither technical regulations nor conformity assessment procedures. Therefore, they had not been notified. Nevertheless, they were available for public consultation and to interested stakeholders on the Internet. In addition, third parties were involved in the REACH implementation project which notably included the drafting of these guidance documents. There was, moreover, a possibility for third countries to be involved in the "stakeholder expert groups" for the REACH implementation projects if they had specific expertise.

Regarding testing and costs for manufacturers, especially SME's, the representative of the European Communities pointed out that their importers located in the European Union or their "only representatives" which they had appointed within the European Communities would become part of the so-called "substance information exchange fora" after the pre-registration of all chemicals. This meant that the toxicological and eco-toxicological tests need not be carried out by each and every company; instead they could participate in the information-sharing procedure which would reduce the over-all costs of the required testing. The "substance information exchange fora" would take stock of all existing data, identify gaps and propose a testing strategy to the European Chemicals Agency. This entailed that the costs for the required testing would be shared and this would be of particular benefit to SMEs, including SMEs outside the European Communities. On laboratories, it was noted that REACH required that toxicological and eco-toxicological tests be carried out in compliance with the Good Laboratory Practices as set out in Directive 2004/10/EC which was based on OECD guidelines. Therefore, any such tests had to come from laboratories – also outside the EU – that had obtained a certificate indicating that they applied Good Laboratory Practices.

Regarding Japan's questions on third party participation in the implementation of REACH, it was – as had been mentioned – possible for third parties to take part in the stakeholders expert groups. On the issue of the choice of "only representatives", this was a contractual relationship between the manufacturer from outside the European Communities and the company it chose within the European Communities. Under the current chemicals legislation, the "only representative" was called "sole representative" so this was not a new concept; it was the continuation of the current system as applied under REACH. The Commission could not interfere – or ensure – the number of

"only representatives" because this was left to the market forces. Regarding the uncertainties Japan had mentioned on Clause 33, Paragraph 2 ("... on request by consumer, any supplier of an article containing a substance meeting the criteria of Article 57 [registration] shall provide the consumer with sufficient information available to the consumer to allow safe use of the article, including *as a minimum the name of the substance*..."), the last part of the sentence (in italics) made it sufficiently clear what ultimately would be required from the supplier.

Regarding equal enforcement throughout the European Union, the representative of the European Communities pointed out that REACH was adopted in the form of a regulation which was directly applicable in the whole Union. The European Commission as "guardian of the EC Treaty" was responsible to ensure coherent application of EU law by the Member States.

The representative of the European Communities reiterated that, according to its own assessment, REACH was not discriminatory since it treated both EC manufacturers and importers and third country manufacturers in the same way. Also, the European Communities was of the view that REACH was not overly restrictive, especially as it took into account the objectives which were pursued by REACH: a high protection of the consumer, of human health and life, and of the environment. He encouraged stakeholders to make use of the REACH Help Desks which were operational at the European Chemicals Agency in Helsinki and in member States. Questions could be forwarded by e-mail to these Help Desks and they would be responded to.

Noruega x Bélgica e Holanda - Seal products

Belgium and The Netherlands – Seal products (G/TBT/N/BEL/39 and G/TBT/N/NLD/68)

The representative of Norway reiterated her delegation's concerns about restrictions implemented in Belgium and the Netherlands to ban imports on seal products. As had been previously stated in the Committee, Norway regarded these measures, as well as possible plans to impose measures by other EU member States, to be inconsistent with obligations under the WTO TBT Agreement and the GATT 1994. Norway noted with interest that Canada on 25 September 2007 had requested consultations under Dispute Settlement Understanding (DSU) and stated her delegation's intention to follow the development of those discussions closely.

Norway was deeply concerned by declarations made by the European Parliament calling on legislation to ban trade in seal products across the board in the European Communities. Any such legislation would be reviewed with regard to WTO consistency. The representative reiterated that her delegation could not see how, and to what extent, the appropriate assessments regarding available scientific and technical evidence had been made by Belgium and the Netherlands in the case at issue. Norway had provided factual information on seal hunting to Belgian and Dutch authorities as well as to the European Commission pointing out that the Norwegian seal hunt was strictly regulated and was both sustainable and humane.

It was noted that the European Commission had given the European Food Safety Authority (the EFSA) the task of reviewing the methods used in seal hunts. Norway was confidant that EFSA would have the best information available before submitting the report to the Commission; the deadline had been set to 15 December 2007. The Norwegian Scientific Committee for Food Safety had been asked to contribute to EFSA's work and the best qualified experts in this field had been selected.

Norway considered that the measures implemented by Belgium and the Netherlands as being premature and regretted that the European Commission had not taken action to discourage EC member States from proceeding with the ban. The representative of Norway reiterated that seal quotas were set on the basis of scientific advice and the state of seal populations was well within the boundaries of sustainable management. Moreover, the seal populations in question were currently not endangered and were therefore not listed on the Convention on International Trade in Endangered Species (CITES). In addition, Norway had demonstrated that humane harvesting methods used in Norwegian seal hunting compared favourably to those used on domestic livestock.

In conclusion, the ban on seal products was not an animal welfare issue, it was not a conservation issue and it was not a management issue. It was a public opinion issue and from the Norwegian point of view, this was unsubstantiated and unjustified and set a dangerous precedent for trade in animal products that were harvested in a sustainable and humane manner. Norway continued to reserve its right to take any appropriate action to defend its interest under the TBT Agreement and other relevant WTO Agreements.

The representative of the European Communities took note of the comments raised. Given the fact that the Belgian and Dutch measures would be examined under the context of the Dispute Settlement Understanding, her delegation did not consider it appropriate to discuss the issue any further in the TBT Committee. The European Communities was nevertheless open to continue bilateral discussions with Norway and provide any information that it considered appropriate.

Nova Zelândia e UE x Coréia do Sul - Fish Heads

Korea – Fish Heads

The representative of New Zealand, supported by Norway and the European Communities, noted that edible hake heads which were caught in New Zealand waters and processed by New Zealand boats were prohibited from entering the Republic of Korea while hake heads caught in New Zealand waters and processed by Korean boats were allowed entry. Thus New Zealand was again raising the matter in the TBT Committee. The representative was pleased that some progress on this issue had been signalled by Korea with the announcement of their intention to add hake heads to their national Food Code and that this had been notified to the SPS Committee and that this issue had been considered by the Korea Food and Drug Administration Food Sanitation Council. However, further unexpected delays meant that changes to the Korean Food Code were unlikely to happen in 2007 as had been previously stated. Therefore, New Zealand asked Korea to ensure that the required changes to the Korean Food Code were made swiftly so that the matter could finally be resolved.

In addition, the representative of the European Communities expressed her delegation's disappointment that, since the last meeting of the Committee, no progress had been made on the signature of a Memorandum of Understanding.

The representative of Korea was of the view that considerable progress had been made on a bilateral basis. He noted that specific legislation had been notified to the SPS Committee and that Korea was now in the process of establishing the specific regulation. Because this was a sensitive issue, dealing with human health, Korea needed to consult with experts. After the domestic processes had been completed, Korea would take due and appropriate action to conclude consultations with New Zealand. Regarding the signing of the MoU with the European Communities, probably both parties

were ready to conclude on this matter. Nevertheless, Korea would convey the concern expressed by the European Communities to the relevant ministry to expedite to process. Also, regarding the concern which was raised by Norway, the representative urged Norway to make bilateral contacts with relevant persons and contact points within the Korean government.

Nova Zelândia e Canadá x EUA - Country of Origin Labelling (COOL)

United States – Country of Origin Labelling (COOL) (G/TBT/N/USA/25, G/TBT/N/USA/83 and Corr.1, G/TBT/N/USA/281)

The representative of New Zealand recalled that her delegation had outlined New Zealand's concerns at the last meeting of the Committee, in July 2007 and a formal submission on the issue had been made in August. She hoped that the US domestic process would take its submissions into account in the final outcome. New Zealand continued to oppose the imposition of mandatory COOL on the basis of its likely trade-restrictive effect, its irrelevance to food safety requirements and the high implementation costs involved. She stressed that a policy allowing for voluntary COOL would be far less trade restrictive and would not impose the same potential barrier to international trade. In New Zealand's view it was preferable to leave country of origin labelling to be implemented on a voluntary basis by industry and not to impose it by way of prescriptive regulation.

The representative of Canada also expressed concern with the US mandatory country of origin labelling, as prescribed in the 2002 Farm Security and Rural Investment Act. As had been stated at the last meeting of the Committee (July 2007), Canada remained of the view that current requirements for fish and shellfish needed to be repealed and that plans for mandatory country of origin labelling for remaining commodities should be abandoned.

The representative of the United States noted that there was currently legislation in the US Congress that would amend the COOL Law which had been in place since 2002, including adding a new provision that would address the labelling of products with multiple countries of origin. As the timing and outcome of the legislative process was uncertain, the United States was unable to provide additional information at the current time. An update would be provided at the next meeting of the Committee if there was a change in status.

Nova Zelândia (EUA, Austrália e UE) x Canadá - Compositional requirements for cheese

Canada – Compositional requirements for cheese (G/TBT/N/CAN/203)

The representative of New Zealand reiterated her delegation's concerns about Canada's draft regulations governing compositional standards for cheese. In August 2007, New Zealand had provided a formal submission to the Canadian Food Inspection Agency outlining its concerns with the proposed new standards. New Zealand was interested to know more about the results of Canada's domestic process.

The representative of the United States underscored her delegation's concerns also raised at the last meeting of the Committee regarding the prescriptive nature of Canada's proposed amendment to its compositional standards for cheese, as well as the potential adverse market access impact on milk

protein concentrates. In response to Canada's notification, the United States, along with numerous other Members and interested parties, had provided comments. The representative of the United States asked Canada when it intended to provide responses.

The representative of Australia joined in the concerns expressed by New Zealand and the United States noting that its delegation too had made comments on the proposed regulation and was looking forwards to a response.

The representative of the European Communities reiterated his delegation's concerns. It was noted that detailed comments had also been submitted to the Canadian enquiry point in the end of August 2007. In particular, the European Communities was concerned that the proposal, if adopted, would effectively reduce EC exports to Canada of both cheeses and basic products such as milk protein concentrate. The European Communities failed to understand the nature of the legitimate objective that was being pursued in the amendment and why Canada considered it necessary to deviate from the relevant international standard set out by the Codex Alimentarius Commission. The European Communities was also concerned that there would be a breach of the national treatment principle by allowing domestic producers to produce light cheese using skimmed milk powder but that this exception would not be extended to imported products. The European Communities also remained concerned about the proposed licensing scheme which appeared to be more restrictive than necessary and thus potentially inconsistent with Article 5.1.2 of the TBT Agreement. Finally, the representative asked Canada about the current state of play of the proposal and whether its implementation would be delayed to take into account the numerous and serious concerns which had been voiced by third countries and industry.

The representative of Canada noted that the Canadian Food and Inspection Agency was currently reviewing the numerous comments received and would take them into account. At the current meeting, she did not have any new information – if such information was available by the next meeting this would be shared with the Committee.

Israel (Jordânia, Japão e EUA) x Suécia - Restrictions on the use of Deca-bromo diphenylether (deca-BDE)

Sweden – Restrictions on the use of Deca-bromo diphenylether (deca-BDE) (G/TBT/N/SWE/59)

The representative of Israel reiterated his delegation's concerns about the above-mentioned measure. The measure, which had entered into force on 1 January 2007, had already affected negatively Israeli exports to Sweden. Israel was of the view that the Swedish prohibition was an unnecessary obstacle to trade in breach of Article 2.2 of the TBT Agreement. Although Sweden invoked the protection of human health and the protection of the environment, the existence of a risk had not been demonstrated. Moreover, since, under the TBT Agreement, there was no recourse to the precautionary principle, it was Israel's view that Sweden could not claim that the substance posed a potential risk to the environment and human health. In accordance with Article 2.2 of the TBT Agreement, available scientific information and technical information needed to be considered in order to take account of the risks. However, in this case there was no scientific basis for the imposition of such a measure. In fact the European Union had itself undertaken a comprehensive risk assessment and concluded that there was no need for risk reduction measures to be imposed on the substance decaBDE or products containing that substance, beyond those that were already in place. Israel urged Sweden to consider the adoption of less trade restrictive measures concerning the use of decaBDE, similar to those adopted in the European Union, for example: an emissions

reduction programme and bio- and environmental monitoring. Sweden, being a member State of the European Union, participated in risk assessments in accordance with EU rules and had to afford mutual recognition to the conclusion reached by such assessments. The representative urged the European Commission and Sweden to provide an update.

The representatives of Jordan and Japan echoed the concerns raised by Israel and recalled that, at the last meeting, the EC representative had informed the Committee that consultations between Swedish authorities and the European Communities were ongoing. They asked for an update on the results of these discussions.

The representative of the United States noted that her delegation had also submitted comments on Sweden's draft regulation regarding decaBDE and continued to have serious concerns with the measure. She stressed the importance accorded to the use of available scientific and technical information in assessing risk under the TBT Agreement and was concerned that Sweden's partial ban ignored the results of a comprehensive EU risk assessment of decaBDE which did not identify any risk to health or the environment. In fact, Sweden's draft regulation could encourage the use of alternatives on which there was *less* scientific information on the potential health and environmental risks. Also the United States placed great importance on the protection of human health and the environment and continued to believe that the good regulatory practices embedded in the WTO TBT obligations were the best way to achieve those objectives. The US Environmental Protection Agency had conducted its own risk assessment on decaBDE and remained willing to discuss its findings with appropriate officials of the Government of Sweden.

The representative of the European Communities noted that the Commission had initiated formal discussions with Sweden in respect of the adopted measure. As the bilateral discussions were ongoing, she was not in a position to disclose any further information. Nevertheless, it was pointed out that the European Communities was giving serious consideration to the comments that had been made by third countries and she hoped that a solution would be found in the near future.

Japão (Israel, Jordânia e EUA) x Noruega - Restrictions on the use of Deca-bromo diphenylether (deca-BDE)

Norway - Restrictions on the use of Deca-bromo diphenylether (deca-BDE) (G/TBT/N/NOR/6, Corr.1 and Add.1)

The representative of Japan, supported by Israel, Jordan and the United States, reiterated his delegation's view regarding the proposed prohibition on decaBDE by Norway. Although Japan was grateful for having received a written response to comments on a bilateral basis from Norway, his delegation was of a view that there remained a wide discrepancy on both sides' interpretations of the available scientific evidence. The Japanese industry remained, therefore, deeply concerned about the draft regulation.

The representative of Norway informed the Committee that the proposed regulation had not yet entered into force and the Norwegian Ministry of the Environment was considering comments from Members as well as from other stakeholders with regard to the possible ban on decaBDE. Developments in the European Union would also be taken into account. She noted that Norway had set a target to substantially reduce emissions from a number of environmentally hazardous chemicals, including with respect to brominated flame retardants.

EUA x Turquia - Product-tracking system for tobacco products and alcoholic beverages

Turkey - Product-tracking system for tobacco products and alcoholic beverages

The representative of the United States recalled that at the last meeting, his delegation had raised the issue of Turkey's strip stamp regime. Follow-up discussions had been held with Turkish authorities in September 2007. The United States understood, from discussions with the Government of Turkey, the purpose of the strip stamp regime and welcomed the commitment made by Turkey to clarify the strip stamp system so as to ensure no less favourable treatment for imported products. Specifically, Turkey had indicated that importers were now able to apply the strip stamps at their tax warehouses inside Turkey and that the price for those stamps was the same for like domestic products. These changes could potentially benefit other WTO Members seeking to export distilled spirits and other covered products to Turkey. The United States understood that a circular describing those changes had been published in Turkey's official gazette and indicted its intent to review it. Nevertheless, the United States remained concerned about certain aspects of the strip stamp system, including potential changes to the strip stamps that Turkey appeared to be considering. The representative of the United States noted that his authorities would continue to monitor the situation closely and urged Turkey to notify any further revisions to its strip stamp system to the WTO.

The representative of Turkey stressed that the purpose of the system was to stop tax evasion by ensuring that the products were produced and/or imported legally in to Turkey. Following some postponements requested by the industry, the system had become operational on 24 July 2007. Since then, Turkey had neither received any complaints on the implementation of the system nor requests for further consultation from interested parties. As of 5 November 2007, the system had become fully operational with the beginning of the mandatory application of the strip stamps for products produced or imported before 24 July 2007.

In respect of the notification, Turkey recalled that the general communiqué for the product tracking system did not lay down any product characteristics or their related processes and production methods. Moreover, the strip stamps did not provide information to consumers on particular aspects of the product. Accordingly, Turkey neither considered the communiqué as a technical regulation nor the strip stamps as a label within the meaning of the TBT Agreement. Therefore, although Turkey was willing to continue working with interested parties in order to ensure the smooth functioning of the system and eliminate any possible concerns they might have, Turkey reiterated its position that its product tracking system for tobacco products and alcoholic beverages did not fall under the scope of either the TBT Agreement, nor the work of the TBT Committee. If this system were to evolve to include additional quotes with the strip stamps that would contain specific features of the products, depending on the characteristics of the new system, Turkey would consider its notification obligation under the TBT Agreement.

Canadá x Nova Zelândia - Ban on the Importation of Trout

New Zealand – Ban on the Importation of Trout

The representative of Canada recalled that her delegation had raised concerns over New Zealand's ban on the commercial importation of trout on numerous occasions at the TBT Committee. The ban had been put in place in December 1998 as an interim conservation measure under an order entitled "Customs and Import Prohibition Trout Order 1998". In June 2005, New Zealand had informed the

TBT Committee that its officials had been tasked with finding alternative measures to extending the ban prior to its expiry – which was, in fact, a repetition of the statement New Zealand had made during the TBT Committee meeting of November the year before. Despite this, and a number of years later, New Zealand had informed Canada on 6 November 2007 that the ban would be extended for a sixth time, until 8 November 2010. Canada expressed its disappointment with this decision. As had been stated in the past, Canada did not believe that the ban was scientifically justified, nor had Canada received any evidence from New Zealand demonstrating otherwise. Additionally, Canada was of the view that the ban might not be consistent with New Zealand's obligations under the TBT Agreement. The representative of Canada asked New Zealand for information about the measures that its officials had identified and that could be considered as alternatives to the ban, and that it inform the Committee why an extension of the ban had been chosen over these alternative measures.

The representative of New Zealand confirmed that on 8 November 2007, New Zealand's Customs Import Prohibition Order had been extended for a further three years, until November 2010. In reconsidering the issue, including the various options available, the New Zealand Cabinet had decided that extending the custom order for a further three years would be the most effective mechanism to achieve the legitimate policy objective behind the order. The order did not prohibit the importation of trout into New Zealand as imports of trout in non-commercial quantities for personal consumption were allowed and this ensured that both domestic and imported trout were subject to the same treatment. It was emphasized that there was no commercial production of trout allowed in New Zealand. Hence, the Customs Import Prohibition Order was neither discriminatory nor protectionist, it addressed legitimate objectives consistent with New Zealand's international obligations.

The representative of Canada noted that her delegation did not consider allowing commercial imports for personal use as adequate; Canada was seeking full commercial access.

EUA x Israel - Infant Formula

Israel – Infant Formula

The representative of the United States noted that since the July 2007 meeting of the TBT Committee, when the United States had first raised the issue, the United States had held two meetings with Israeli officials to discuss Israel's infant formula requirements and its failure to provide copies of its regulations. The United States understood the sensitivity of the issue in Israel and welcomed Israel's recent effort to provide the written guidance document used by the Israeli Ministry of Health to regulate imported infant formula and to clarify that there were no regulations currently in place. Regrettably, the information provided by Israel had served to confirm the problems the US industry was facing in the Israeli market.

Principally, this was about a lack of transparency and differential treatment. There was no published information on nutrient composition standards or Ministry of Health requirements for issuing import approvals or licences for infant formula. Moreover, the United States was of the understanding that these requirements often changed. In addition, Israel maintained discriminatory testing requirements, fees, and labelling rules for infant formula in favour of domestic producers. For instance, it was the US understanding that each batch of imported infant formula had to undergo 12 different laboratory tests in an Israeli government laboratory whereas domestic producers could perform their own tests, only needed to do so once each quarter, and could self declare the test

results to the Ministry of Health. Furthermore, while Israeli authorities had to approve all labels with nutritional claims on imported products, no pre-marketing approval was required for domestic products and there was no real post-market surveillance in place. US infant formula manufacturers were willing to comply with regulations that were published, treated all producers in the same way, were clear and consistent and based on sound science. The representative of the United States urged Israel to continue and expand its dialogue with interested parties as it developed its regulations on infant formula, and to notify any proposal to the WTO.

The representative of Israel informed WTO Members that up until two years ago there had been no particular treatment of imported infant food and the authorities relied on quality certificates issued by the exporting countries. Due to specific and grave health problems caused by deficient imported infant formula, the Israeli Ministry of Health had been forced to rethink the import system in order to ensure the health and safety of infant food. The regulation which the US delegation was referring to was being finalized by Israeli health authorities. Following the concern expressed by the United States, Israel had provided the United States on 16 October 2007 with a document containing guidelines for importers so as to make the import process predictable and transparent.

EUA (Austrália, Canadá e UE) x Tailândia - Labelling Requirement for Snack Foods

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

The representative of the United States recalled that his delegation had expressed concerns regarding Thailand's proposed labelling requirements for selected food categories. The United States welcomed the actions from Thai authorities in response to these concerns since the last meeting of the Committee, including the postponement of the implementation and the issuance of a revised regulation which had been notified in an addendum. Although the United States appreciated Thailand's efforts, the key US concern had still not been addressed. While Thailand had withdrawn the "traffic light" scheme, the regulation required suppliers to affix a special label on the same items covered by the initial proposal. The label would urge consumers to consume less of those items and to exercise.

Assuming that the objective of the revised regulation was to promote a healthy lifestyle, it did not appear that this labelling scheme would be an effective means to do so and in fact it could create additional consumer confusion. As with the initial regulation, no explanation was provided as to why the labelling requirement was only limited to certain product categories. The United States would appreciate if Thailand could explain the scientific and/or technical criteria it used for determining which products required warning labels and which did not, as well as the criteria the Public Health Minister would use in adding other food categories to the list. The labelling requirement also appeared to apply equally to all items in these categories irrespective of their nutritional profiles. For example, in the case of popcorn, in the revised proposal no-sodium, butter-free popcorn had to bear the same warning label as buttered-salted popcorn. The proposed label also provided no information on portion size. In sum, the revised regulation did not appear to provide consumers with information that would help them make informed decisions for developing a healthy and balanced diet. Instead, it appeared to demonise certain products that might have a more healthy nutritional profile than other products that were not subject to labelling requirements.

The United States was of the view that there were more effective and less trade restrictive ways to promote a healthy lifestyle than singling out certain food categories to bear warning labels. For example, Thailand could focus its regulations on guideline daily amounts which provided tools for

consumers to determine their consumption of food products in the context of their daily needs. The United States urged Thailand to discuss the labelling issue with the many stakeholders that had expressed concerns with both the initial and revised regulations.

The representative of Australia was concerned that the warning message to be included on all packages to consume less and exercise for health might be misunderstood by consumers. Australia was of the view that there could be alternative, non-mandatory schemes that informed consumers about nutritional choices, such as contribution to daily intakes.

The representative of Canada noted that her country, like Thailand, was also concerned about the growing problem of obesity and shared Thailand's goal of promoting healthy eating habits among its citizens. Nevertheless, the Canadian industry had expressed concern over the labelling requirements proposed for the five snack foods identified. In a letter dated 1 November 2007, the Canadian industry had questioned the scientific merit of the proposed regulation and argued that it discriminated against snack foods. The representative of Canada asked Thailand to provide information on alternative regulatory and non-regulatory instruments it had considered when designing the proposed labelling requirements, as well as on the analysis that had led Thailand to focus only on five snack foods.

The representative of the European Communities joined the concerns expressed by the previous delegations regarding the Thai measure. While her delegation also shared the objectives of the measure (improving consumer information on nutritional facts so as to promote a healthy and balanced diet) the European Communities failed to understand on what basis the five product categories which were subject to mandatory labelling requirements had been chosen and how limiting the scope of this measure to certain products would be sufficient to fulfil the objective that was being sought. The European Commission encouraged Thailand to review the proposal to take into account the comments made and in particular to ensure that the measure was scientifically based, proportional and not arbitrary.

The representative of Thailand took note of the comments made.

T**urquia (EUA, Malásia, Canadá, Austrália e Outros) x UE - Dangerous Chemical Substances - Draft Commission Directive amending Council Directive 67/548/EEC**

European Communities - Dangerous Chemical Substances - Draft Commission Directive amending Council Directive 67/548/EEC (G/TBT/N/EEC/151)

The representative of Turkey expressed his delegation's concern with the above-mentioned EC measure affecting borates. His authorities had studied the draft and provided the European Communities with detailed comments in July 2007. Unfortunately, the recent reply was not to Turkey's satisfaction. In particular, the representative of Turkey was concerned about the proposed amendment's classification of borates as toxic to human health. In the view of Turkey, all decisions on classifications needed to based on normal handling and use criteria which had not, in this case, been applied properly. The classification was not based on available scientific and technical data; it did not consider intended end-users of borates and had the effect of creating unnecessary obstacles to trade and a disguised restriction on international trade. The results had been obtained from high-dose feeding of laboratory animals although normal human exposure to these substances was through inhalation or dermal exposure. The eating of borates by humans could only be considered abnormal. Moreover, oral intake would induce vomiting via an auto-reflex action long before the

toxic effect arose. Therefore, the use of data obtained from oral administration was neither relevant for humans nor related to normal handling and use of borates. Turkey considered the argument used by the European Communities as a misinterpretation of the science criteria in Article 2.2 of the TBT Agreement. Moreover, his delegation failed to see how the European Communities had taken his delegation's comments into account as required by article 2.9.4 of the TBT Agreement. It was noted that the European Communities had stated their intention to delay the implementation of the 30th Adaptation to Technical Progress (ATP) and to respond to the concerns raised.

The representative of the United States noted that his delegation had just received the European Communities' replies to comments submitted. Since his delegation had not yet had the opportunity to thoroughly review them, the present remarks were of a preliminary nature; written reactions would be provided after the meeting. He asked the European Communities to confirm that issuance of the 30th and the 31st ATP would be delayed until at least late December 2007. The US representative associated his delegation with many of the concerns that had been raised by other Members at the last meeting of the TBT Committee and at the current one regarding the proposed classification of nickel carbonates as a Category 2 substance under the dangerous substances directive.

In September 2007, US and EU officials had met in Brussels to discuss the proposed EC classification of borates as a Category 2 reprotoxin under the Dangerous Substances Directive (DSD). Despite that meeting and the document recently submitted by the European Communities, the United States continued to have serious concerns with both the rationale for the classification itself as well as the downstream effects of such a classification. To support its findings about exposure under normal handling and use, the European Communities, in its explanatory memorandum (lines 201 through 202), asserted that a study regarding occupational exposure in borate mines provided sufficient evidence that borates had severe health effects under normal handling and use. However, neither the explanatory memorandum nor the EC reply explained how exposure in a mine related to normal handling and use of borates or borate-containing products. Furthermore, it was the US understanding that the mine study cited by the European Communities had not found any reprotoxic effect from inhalation.

In addition, the representative of the United States pointed out that the explanatory memorandum had referred to studies of rats that were force-fed large quantities of borates. However, human end-users would not and in fact could not consume such large amounts of borates. Moreover, the European Communities maintained that the objective of the measure was to provide information to borate users enabling them to use the substances safely. But the European Communities failed to consider alternative less burdensome ways to provide such information; the United States had offered to discuss possible alternatives.

The European Communities appeared to dismiss the commercial impact of the labelling itself. The skull and crossbones label would deter the production and use of products containing borates and encourage substitution. No producer would want a product it manufactured or used in its manufacturing process to bear that label or carry the stigma of a Category 2 classification. Instead, producers would seek out alternatives if such existed. In fact, some companies had policies against using products that were classified as Category 2. The European Communities had not done a full cost benefit analysis that balanced the risks with the burden on trade the regulation would impose.

The representative of the United States noted that the European Communities mischaracterized the downstream consequences of the classification. For instance, under the Cosmetics Directive, there would be a total ban on the use of borates in cosmetics irrespective of concentration level. The European Communities response had been that there was some room for manoeuvre but the

Directive appeared clear on this point. Under the Marketing and Use Directive, the use of Category 2 substances was restricted. The EC response that such restrictions were not automatic was misleading since such restrictions were standard practice. The United States had asked the European Communities to provide examples where such restrictions were not triggered by the Marketing and Use Directive.

Finally, a Category 2 classification also carried implications under REACH as Category 2 substances were put on a candidate list for authorization. The European Communities had noted that authorisation was not automatic but in effect it was a blacklist for all substances contained therein. Moreover, the European Communities had acknowledged that it could take decades to evaluate all of the substances on the candidate list. Producers would have a strong incentive to stop using substances contained in the candidate list, including borates. Research and development activities on new borates applications would also be deterred.

The representative of the United States noted that several WTO Members had raised concerns with the proposed Category 2 classifications for both borates and nickel, as had representatives of producers and users. He urged the European Communities to consider carefully the comments and questions that had been raised by its trading partners and other stakeholders and consider less trade-restrictive alternatives than a Category 2 classification under the Dangerous Substances Directive.

The representative of Malaysia, having carefully considered the EC response of 7 November 2007, strongly urged the European Communities to confirm its postponement of the 30th Draft Commission Directive amending, for the purpose of its Adaptation to Technical Progress (ATP) for the following reasons. First, Malaysia – like the United States – was not convinced that the European Communities' late response had afforded sufficient opportunity to be informed of the justifications and grounds for the Category 2 classification of borates in particular. In addition, in the response and the contents therein, the European Communities appeared to contradict itself. The EC response did not afford sufficiently robust scientific evidence to justify the grounds for pursuing a Category 2 listing of borates. In Malaysia's view this was contrary to Article 2.2 of the TBT Agreement. Moreover, Malaysia was also concerned that the classification of borates under Category 2 appeared to be based on the precautionary principle; this would mean that the measure was more trade-restrictive than necessary.

The representative of Malaysia urged the European Communities to further consider the inter-relation between the Category 2 classification of borates under Directive 67/548/EEC and other EC legislation, specifically REACH and in particular EC Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the member States relating to restrictions on marketing and use of certain dangerous substances and preparations. Malaysia, again, was not convinced that downstream effects of these measures was as limited as contended by the European Communities. She also reminded the Committee that the European Communities had acknowledged its deviation from the original grounds it cited to justify the Category 2 listing of borates.

In light of the above, the representative of Malaysia contended that the European Communities had not succeeded in providing sufficient clarity to address the concerns raised by several delegations. Due to unresolved legal issues and uncertainties, Malaysia supported all other delegations who had spoken in urging the European Communities to postpone its adoption of the 30th ATP and to reconsider its approach.

The representative of Canada concurred with the concerns raised by other Members regarding the proposed classification of borates under the above-mentioned measure. Canada had a systemic

interest in ensuring that the assessment of substances was scientifically based and conducted in an appropriate manner. Canada's prime concern regarding the 30th ATP Directive, was with the classification of nickel carbonates. Canada had raised this matter at the previous meeting of the Committee and had submitted comments and detailed questions to the European Communities on 11 July 2007. Canada would need more time to determine whether her delegation's questions had been fully addressed.

Regarding nickel, Canada remained concerned that the European Communities' proposed classification was not based on sound scientific analysis and might set an inappropriate precedent. Canada was also concerned by reports from industry stakeholders that their offer to provide detailed data to assist in a scientific assessment of these substances had not yet been accepted by the European Communities. Canada was not taking a position on the toxicity or carcinogenicity of particular nickel-based substances, rather, it was the process by which the European Commission had reached its conclusion that was of concern. Her delegation was concerned that inappropriate approaches could set a dangerous precedent for the large number of assessments to be performed under REACH. As the world's second largest producer and exporter of nickel and related substances, Canada had a major trade interest in ensuring that this measure did not represent an unnecessary barrier to trade. Canada also insisted that such assessments had to be scientifically based and conducted in an appropriate manner.

Thus, Canada strongly encouraged the European Commission to accept any industry offer to provide scientific data that would permit a more solid scientific basis for the assessment and classification of nickel carbonates and joined other delegations in requesting a delay of the implementation of the 30th ATP until such time as it became clear that the numerous questions and concerns of WTO Members had been resolved. In addition, it was Canada's understanding that the 31st ATP directive would contain further nickel classifications proposals based in part on the nickel carbonates classification. Canada hoped that the European Communities would notify the draft 31st ATP directive to the TBT Committee and allow sufficient time for Members to review and comment.

The representative of Australia shared the concerns expressed, in particular with relation to nickel carbonates as Australia was a major producer thereof. She questioned the non-testing methodology that had been used in the EC process and the scientific validity of the classification of nickel carbonates. Australia too was concerned that the classification in the draft 30th ATP Directive would be used as a reference for classifying additional nickel substances and that the "red cross" approach could be used as a model for further assessments under REACH. Like Canada, the Australian delegation had received advice from its industry stakeholders concerning the science involved in the process. Although Australia was not taking a position on the toxicity of the particular nickel-based substances, her delegation was concerned with the need for opportunity to ensuring a sound science-based approach. The European Communities was requested to defer consideration of the 30th ATP until such time as Member's concerns had been addressed.

The representative of China shared the concerns of previous speakers. While her delegation appreciated the efforts made by the European Communities for protection of the human safety and the environment, it was necessary to ensure that the consequent regulations did not create unnecessary obstacles to trade. Bearing this in mind, China had submitted comments on the EC notification G/TBT/N/EEC/151 on 19 September 2007 where her delegation had emphasized, in particular, the issue of the classification and labelling of chemicals with nickel and borates. China acknowledged receipt of the EC response on 7 November 2007 and would now proceed to analyze these. Her delegation expected that the 31st ATP would be notified to the WTO as soon as possible so as to allow Members a reasonable period of time for comments.

The representative of Chile also shared the concerns raised by other Members. She recalled that during the last meeting of the Committee, her delegation had raised the issue of trade impact. Despite the fact that the European Communities did have the right to protect health and the environment, this could not be done in a way that was more restrictive than necessary – as was the case with the classification provided for in the regulation at issue. Like other delegations, Chile had not yet had the time to consider the written response received from the Commission and would follow-up within the framework of bilateral agreements.

The representative of Brazil reiterated the points made by others and stressed the need for a scientific basis for the classification of nickel compounds. Like other delegations, Brazil was concerned that the classification could be extended to other nickel compounds with possible impacts on the REACH system. He sought confirmation that the 30th ATP would be suspended.

The representatives of Argentina and Japan supported the points made by previous delegations.

The representative of the European Communities noted that an expert (DG Environment) from her delegation had intended to make a presentation on borates at the current meeting but due to circumstances beyond control the European Communities was not in a position to do so. She assured Members of the importance the European Communities attributed to the Committee process and noted that the adoption, which had been scheduled to take place in September, had been delayed because of the numerous concerns received. She invited delegations to consider the response that had been provided and to submit any further comments in writing if that was considered necessary. It was noted that the opening statement of the DG Environment official was available on the Internet.

Japão x UE - Fire Performance of Construction Products

European Communities - Fire Performance of Construction Products (G/TBT/N/EEC/92 and Add.1)

The representative of Japan raised his delegation's concern about the European Commission's decision regarding fire performance of construction products. He acknowledged receipt of a written response on 27 October 2007 regarding his authority's comments on Commission Decision 2006/751/EC. The response was being reviewed in detail and Japan expected to provide comments regarding the interpretation of scientific data.

The representative of the European Communities noted the very technical nature of the matter (regarding security criteria) and stressed that further comments from the Japanese authorities would need to be discussed among experts.

UE e EUA x Índia - Pneumatic tyres and tubes for automotive vehicles

India - Pneumatic tyres and tubes for automotive vehicles (G/TBT/N/IND/20)

The representative of the European Communities recalled an issue regarding pneumatic tyres that it had raised on several occasions in the TBT Committee. The European Communities remained concerned that the mandatory application of the standard would result in an unnecessary barrier to trade for manufacturers from outside India. The European Communities was also concerned that

the calculation of license fees discriminated against foreign producers. The European Communities encouraged Indian authorities to engage in further bilateral consultations to provide clarification.

The representative of the United States echoed the concerns raised by the European Communities and reiterated his delegation's previous intervention encouraging continued participation by India in the UNECE WP29 discussions on a global standard for tyres. With respect to the new Bureau of Indian Standards (BIS) protocol for tyres, the United States asked for clarification on several issues, including the objective of the new protocol, the issue of whether the protocol was voluntary or mandatory, whether compliance testing at the central institute for road transport applied to both imported and domestic tyres, whether foreign and domestic tyres were subject to the same performance criteria for tyre specifications, and, lastly, why licensing fees were calculated differently for foreign and domestic companies. It was the US understanding that the fees for foreign companies were based on sales invoiced to dealers in India, whereas fees for domestic companies were based on units per tyres sold in India. The US industry was raising this issue because the different fee calculation methodologies were resulting in much higher licensing fees for foreign tyre companies.

The Chairman noted that the EC and US concerns would be conveyed to authorities in India and that a more comprehensive response would be forthcoming at the latest by the next meeting of the Committee.

EUA x Índia - Drugs and Cosmetic Rules 2007

India – Drugs and Cosmetic Rules 2007

The representative of the United States, supported by the European Communities reiterated his delegation's concern that India had not notified the above-mentioned amendment to the Drug and Cosmetic Rule 2007 to the WTO. The United States had serious concerns over the amendment's potential negative impact on trade as the procedures it appeared to introduce were unnecessarily burdensome and included a costly registration system that appeared to discriminate against imported products. The United States had been unable to ascertain how these procedures would increase product safety for consumers and wanted to have a better understanding of the objectives and rationale of the new rules. Therefore, the United States requested India to consider delaying enforcement of the amendment to allow a reasonable time for interested parties to provide comments and to afford suppliers a reasonable interval to comply with the new requirements.

The Chairman noted that the US concern would be conveyed to authorities in India and that a more comprehensive response would be forthcoming at the latest by the next meeting of the Committee.

China x EUA - Volatile Organic Compound (VOC) Emissions

United States - Volatile Organic Compound (VOC) Emissions (G/TBT/N/USA/249)

The representative of the United States reverted to an issue raised by China at the last meeting of the Committee regarding a proposed regulation from the Massachusetts Department of Environmental Protection. The measure set out requirements for the control of volatile organic compound emissions from the use of consumer and commercial products. The Regulation had gone

into effect on 19 October 2007 in the State of Massachusetts and China's comments had been considered in the Department's decision making process.

It was the US delegation's understanding from the comments submitted by China, and China's intervention at the last meeting, that China's primary concern was that the Massachusetts measure should be eliminated since it was more restrictive than current regulations of the US Environmental Protection Agency. In this regard, it was pointed out that the TBT Agreement made provision for Members' ability to take into account fundamental climatic or geographical factors in the development of technical regulations. In this case, the US Clean Air Act required state-specific plans which were stringent enough to reduce the severity of air pollution in each US State. Areas with more severe ozone pollution such as in the North Eastern United States where Massachusetts was located would probably adopt stricter requirements than states where the ground level ozone problem was not as severe. Many states, such as California, had done so already. The United States also noted that the city of Beijing had recently adopted compositional standards for fuel that were stricter than those used in the rest of China.

The representative of China looked forward to receiving a copy of the Massachusetts regulation.