SPECIFIC TRADE CONCERNS (Retirado do documento G/TBT/M/34)

New Concerns

UE x México - Pre-packaged products

Mexico: Pre-packaged products(G/TBT/N/MEX/95)

The representative of the European Communities reminded Mexico that, on 14 September 2004, it had submitted comments concerning G/TBT/N/MEX/95 on pre-packaged products. Concerns had been expressed on the fact that the Mexican law differed from the revised version of the international standard OIML R 87, which had been approved in November 2003. She stressed that according to Article 2.4 of the TBT Agreement, when international standards existed, Members should use them, or the relevant parts of them, as a basis for their technical regulations.

The representative of Mexico pointed out that the comments received from the European Communities were being considered and that a written reply would be provided. He stressed that the technical regulation was at a draft stage and that all the comments, not only those of the European Communities, were being discussed in a working party; the results would be made public on completion of work.

EUA x UE - Hip, knee and shoulder joint replacements

European Communities: Hip, knee and shoulder joint replacements(G/TBT/N/EEC/70)

The representative of the United States raised concerns on G/TBT/N/EEC/70, in which the European Communities had announced its intention to reclassify or up-classify hip, knee and shoulder joint replacements from Class II b to Class III, under Directive 93/42/EEC on Medical Devices. The US and European medical device industry had expressed strong concerns about the lack of a comprehensive scientific review of total joint replacements to substantiate the EC's planned up-classification. She also noted that the EC's proposed action diverged from regulatory treatment of these medical devices in the United States, where the US Food and Drug Administration (US FDA) had down-classified many joint replacement products. She urged the European Communities to carefully consider comments from all interested parties and to consult with the US FDA and other regulatory authorities. She explained that under the US FDA's classification system, devices with different characteristics but in a single category could be in different classes, depending on the degree of regulatory oversight necessary to achieve safety and effectiveness. This flexibility had enabled FDA to maintain the Class III classification for some joint replacement devices that posed a higher risk, while down-classifying other joint replacement devices that presented a lesser risk.

The representative of the European Communities stated that the comments received by the United States were being reviewed and a written reply would be provided shortly.

UE x Peru - Labelling of footwear

Peru: Labelling of footwear (G/TBT/N/PER/4)

The representative of the European Communities reminded the Peruvian delegation that, on 25 February 2004, her delegation had submitted comments on G/TBT/N/PER/4, concerning the labelling of footwear. She welcomed the fact that the notified text took into consideration previous comments made (G/TBT/N/PER/1). However, it still required the label to contain information on the country of origin of the good, and the corporate tax number of the manufacturer or importer. The European Communities reiterated the concerns that these mandatory requirements might impose significant costs on producers and exporters. She believed that the same objective might be achieved by a less trade restrictive measure, in accordance with Article 2.2 of the TBT Agreement; the country of origin labelling could be made voluntary, for example. Moreover, she considered that the requirement to indicate the tax number was irrelevant for the purpose of consumer information.

The representative of Peru recalled that the regulation on labelling of footwear had been notified twice, in G/TBT/N/PER/1 and G/TBT/N/PER/4. It had been adopted six months after the last notification, and the competent authority in Peru had taken into account the comments received when the first regulation had been notified. On the issue of the tax number, her understanding was that this information could be obtained at a later stage from the importers.

Canada x Bélgica - Ban on the Importation and Commercialization of Seal Skins and Seal Derived Products

Belgium: Ban on the Importation and Commercialization of Seal Skins and Seal Derived Products

The representative of Canada drew the Committee's attention to a Belgian draft legislation, which banned the importation and commercialization of seal skins and seal derived products. She was disappointed that Belgium had not notified the draft bill under the TBT Agreement, thus preventing Members from submitting comments. In her view, this draft bill would have the effect of creating an unnecessary barrier to trade, as the prohibition of all imports of seal skins and seal derived products was more trade restrictive than necessary to fulfil the draft bill's objective of the protection and of the seal population. Pursuant to the UN Convention on the Law of the Sea, seals were a living marine mammal resource under Canada's jurisdiction. She explained that Canada managed this resource on a sustainable basis, in accordance with its rights and obligations under international law. Its practices were based on scientifically proven and sound conservation principles, as determined by internationally accepted standards and guidelines. Canada also acted to ensure that sealing was humane by implementing strict regulations in this regard. She requested, under Article 2.5 of the TBT Agreement, that Belgium explain its justification for the draft bill, including any risk methodology used as a basis. She also asked Belgium to reconsider its proposed ban on the import and commercialization of seal skins and seal derived products, taking into account all relevant facts.

The representative of the European Communities took note of the concerns raised, and informed Canada that the draft bill in question was being examined at the European level, to asses its compatibility with both Community and international law. In light of this internal discussion, his delegation was not yet in a position to respond substantively to the comments of Canada.

EUA x Jordânia - International Product Conformity Certification Program

Jordan: International Product Conformity Certification Program - DAMAN (G/TBT/W/241)

The representative of the United States raised concerns on Jordan's International Product Conformity Certification Program, known more commonly as DAMAN, a system which included testing, certification and accreditation. She recalled that Jordan had issued a document on its conformity assessment program (G/TBT/W/241). Bilateral discussions had been held with Jordan on this program. In particular, the United States had sought fairer treatment in fulfilment of Jordan's legitimate objectives and had asked to look at alternatives and at truly risk-based post inspection systems. Several suggestions had been proposed, but no changes had been made to the program.

The representative of Jordan took note of the concerns expressed by the United States.

Concerns Previously Raised

Malásia (EUA,Japão, México, Colômbia 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/W/208 and G/TBT/N/EEC/52 and Add.1.)

The representative of the European Communities made a presentation in response to comments submitted by Members under G/TBT/N/EEC/52. The European Commission had made the REACH proposal because it had found that, over the years, the current European legislation on chemicals was not effective. It had been difficult both to properly identify the risks arising from the use of chemicals and to manage them. This was largely because, for many chemical substances on the market, there was a relative lack of information.

Under the current EU law, there was no obligation on industry to provide information about the properties of the vast majority of chemicals. Existing legislation put the burden of proof on public authorities to demonstrate the safety of the use of a substance. In addition, there was no efficient instrument to deal with the most problematic substances. In the current system, so-called new substances, i.e. substances which had been on the market since 1981, were subject to much stricter testing and notification requirements than all of the other substances that had been on the market before 1981. This discouraged the development of new, potentially "greener" substances, thus entailing a lack of incentives for innovation.

The purpose of the REACH proposal was the creation of *one* system that covered all chemical substances. Its most significant element was the requirement for substances that were produced or imported into the European Union in quantities above one tonne per manufacturer or per importer per year, to be registered at a Central Agency. This obligation, spread over a period of 11 years, to provide data for about 30 chemical substances, was placed on EC manufacturers and importers alike. This information was also required to be passed down to users of chemicals in the European Union. This would allow downstream users of chemicals to manage and control the risks from exposure to those substances more easily. An evaluation stage whereby a certain number of substances would be examined in more detail by the member States' authorities, was also proposed.

A White Paper, which set out the overall aims and plans for REACH had been published in February 2001. Two years later, a first draft of the Regulation had been published on the Internet. The summer of 2003 had been given for comments to be provided. Over 6000 comments, many of which were from WTO Members, were received at that stage. Following this, some significant changes were made to the first draft proposal and the current proposal had been adopted on 29 October 2003 and notified to the TBT Committee in January 2004 (G/TBT/N/EEC/52). An extended period for comments, until June 2004, had been allowed. It was stressed that at the present time, the legislation was not finalized and that the European Parliament and the Council of Ministers were discussing the proposal in detail, under the co-decision procedure. The European Parliament expected the first reading of the proposal to be completed in Autumn 2005. Any major changes made resulting from the decision-making processes would be notified to the TBT Committee.

The representative of the European Communities recalled that one of the key goals for REACH was to improve the level of health and environmental protection within the European Union associated with exposure from the use of chemicals. The vast majority of WTO Members had recognized the legitimacy of such an aim, and most WTO Members had implemented national legislation to achieve similar objectives.

Written replies to the comments received had been sent out recently, accompanied by a substantive document which delved into the details of the proposal. Information was also regularly posted on the EC website. Specifically, the main concerns raised by WTO Members were related to: (i) alleged discrimination between EU and non-EU manufacturers, focusing in particular on Article 6 of REACH, which dealt with requirements for substances in articles; (ii) the principle of least trade restrictiveness; and, (iii) other concerns, including concerns related to inconsistent application by EU member States, compatibility with international efforts, effects on innovation, protection of confidential information, and technical assistance and capacity building for developing countries.

Starting with Article 6 of REACH, dealing with substances in articles, it was explained that the word "articles" included almost anything that was not a chemical substance or a mixture of chemicals. Although the main purpose of REACH was to focus on chemical substances, and the main obligations of REACH fell on the manufacturers and the importers of chemical substances in the EU, risks could also arise from exposure to substances that were *released from* articles. Article 6 of REACH imposed various obligations on the manufacturers or importers of articles. First, these substances had to meet the EU classification as dangerous. Second, they had to be present in quantities above one tonne per article type per manufacturer or importer per year. Action would only be required if the substance in that article had not been registered for that use further up the supply chain. If those first conditions applied, and the substance was intended to be released (for instance like ink is released from a pen), there would be an obligation to register it.

It could also happen that there was no intention for the chemical to be released, but it was known to be released anyway, for example into the environment or in contact with the skin. In such cases, a decision would have to be taken by the producer or importer of the article as to whether the quantity released could adversely affect human health or the environment. There would be an obligation to notify the Central Agency, which might then require registration. This obligation would only come into force 11 years and 3 months after entry into force of REACH, which would be in 2017 or later.

On the issue of alleged discrimination against non-EU producers of articles, it was stressed that the obligations in Article 6 applied both to EU producers of articles and importers of articles. A proposal had been made by some WTO Members to limit this requirement further by listing the substances to which the provision in Article 6 would apply. However, this was not possible because

the purpose of REACH was to help to identify the hazards of substances, and it would be difficult to identify the substances in advance. In addition, this would be inconsistent with the principle of industry responsibility.

Another concern that had been raised was that REACH was more difficult for non-EU manufacturers to comply with than for EU manufacturers. In this regard, it was stressed that REACH applied throughout equally to EU and non-EU producers. Other concerns were related to confidentiality requirements. In this regard, Article 6(a) of REACH allowed non-EU manufacturers to appoint an single representative, who could, therefore, keep that information confidential, and only pass it on to the Agency (and not to its customers within the EU). In order to make the proposal easy to operate, the European Commission was preparing extensive guidance material, aimed equally at importers and EU manufacturers which would be finished towards the end of 2005. It was the view of the EC representative that REACH was fully compatible with Article 2.1 of the TBT Agreement.

On the principle of least-restrictiveness, the EC representative noted that some of the concerns raised included the potential for duplication of testing and risk assessment, the authorization procedure, and more general concerns about workability and the burden that REACH would have on industry. The European Communities was of the view that individual registrations were necessary and that, as designed, the authorization procedures were limited in scope, workable, and that the decision were taken based on risk. An extensive impact assessment on the proposal had been conducted, which had demonstrated that the benefits from the proposal outweighed the costs.[1] It was concluded that REACH was fully compatible with Article 2.2 of the TBT Agreement.

On the issue of registration, it was explained that its aim was for each EU manufacturer and importer to take responsibility for the substances they produced or imported. This could be done in a number of ways. First, by obtaining information to assess the intrinsic hazards of a substance. In this regard, animal testing should only be undertaken as a last resort. The use of existing data, sharing of data, and other techniques should be considered by the manufacturer or importer before any new testing was carried out. The second main task for the manufacturer or the importer was to assess the risks arising from identified uses of the substance, and to put in place or to recommend risk management controls for that substance. Producers or importers had to demonstrate that this had been done by sending all the information necessary to the new European Chemicals Agency in the form of a registration dossier. REACH encouraged manufacturers and importers to come together in voluntary consortia to provide joint registrations. The European Commission had considered the suggestion made by some EU member States of having a "one substance, one registration" system (OSOR) when the proposal was being designed, but a number of concerns had been raised about its workability in practice, particularly on the compulsory requirement to agree on core data, and about confidentiality.

It was reiterated that the authorization component of the REACH proposal applied only to substances of very high concern, and that its aim was to ensure that these substances were properly controlled, or substituted. These substances, about two and a half thousand, had certain properties, such as being carcinogens, mutagens, or toxic to reproduction (the so-called CMRs), or persistent, bio-accumulative and toxic (PBTs) or very persistent and very bio-accumulative (vpVbs). There was a safety-net in REACH known as the "restriction" part of the process, which enabled the EC authorities to place use or marketing restrictions on certain substances where this was scientifically justified, based on risk.

To ensure workability of the system, the substances of very high concern would be prioritised, and progressively authorized as EC resources allowed. Each substance would be given an individual deadline for the authorization process, but its continued use would be allowed until any decision was made. Decisions on authorization would be taken by the Commission and would be based on expert opinions. Any down-stream user could use an authorization gained by their supplier if the specific use is covered, and for transparency, the applicant and other interested parties could comment during the process. The system was designed to be risk-based, and authorizations would be granted if an applicant could adequately control the risk and may be granted if it was demonstrated that social and economic benefits outweighed that risk.

Another issue that had been raised was the possible inconsistent application by EC member States, which could lead to uncertainty and trade barriers. They believed that this would not happen, since the legal instrument chosen – a Regulation – would be directly applicable in Members States. Furthermore, the European Chemicals Agency ("the Agency") had been given the power to take decisions in certain cases, and to ensure consistency, particularly in the registration and evaluation elements of REACH. The Agency would also have a forum for exchange of information on enforcement where Members States could discuss these issues. In order to promote consistent interpretation of REACH, guidance for authorities would be provided and an appeal would be possible both within the Agency and to the European Court of Justice. They believed that REACH would improve consistency of enforcement within the European Union and facilitate trade flows.

A concern had been raised that REACH was incompatible with international initiatives, such as the ICCA HPV programme and the UN's globally harmonized system for classification and labelling (GHS). The European Communities believed that REACH was complementary to such programmes. For example, information generated under the HPV programme could be used for REACH under certain conditions. Information generated under other programmes could also be used if appropriate. They noted that the European Commission was also planning to implement GHS.

Other issues raised included that REACH was bad for innovation. While this was not a WTO issue, it was stressed that, on the contrary, a number of elements would encourage innovation, including greater exemptions for research and development. Concerns had also been raised about protection of confidential information. REACH tried to achieve a balance between giving information on chemicals on one hand, but making sure that confidential information was not disseminated on the other. Some key information would be made available on the Agency's webpage once it was established, but some information would always be treated as confidential. All other information could be made available by the Agency upon request, but only after consultation with the owner of the information.

One of the other concerns expressed was that REACH was very difficult for developing countries to apply. The European Communities recognized that it had obligations under Article 11.3 of the TBT Agreement. In this respect, extensive guidance material would be provided and technical assistance and capacity building was planned, for example through the Agency.

The European Communities concluded that REACH was WTO compatible and expressed their willingness to continue efforts to explain REACH to WTO Members, to develop good quality guidance and to pursue bilateral and multilateral dialogues.

The representative of Malaysia, in relation to the issue of registration, sought clarification on the approach that was used for the privatization of substances for restriction. He understood that production volume was the criteria for approximation for exposure. However, the approach

preferred by industry was a risk-based one, where intrinsic hazard of the substances, and level of exposure to humans and the environment were taken into account. On the issue of data sharing and confidentiality, he noted that the proposal encouraged companies to form consortia for registration of the same substances which were manufactured or imported. He believed that this might have implications on intellectual property rights, because companies, as part of a consortium, needed to reveal proprietary details such as the manufacturing process that might not have been patented. His country's industry was particularly concerned that the information submitted should not compromise confidential data. In relation to the evaluation process, he believed that there could be inconsistencies from one member State to another, since member States needed to carry out their own evaluation. On the issue of authorization, he noted that some of the terms used, such as "adequate control", and "socio-economic benefits" that determined authorization to be granted were difficult to define. This could result in disagreements since two similar substances undergoing the same evaluation might have different outcomes or results. There was concern that it could happen that substances were withdrawn from the market for economic, rather than safety reasons, since the companies or manufacturers could feel that the costs outweighed the profits. He further wondered how and to what extent information was made available to Members and to the public. Data could be available on the internet, where they could be assessed by anyone. Although there was a need to have access to as much information as possible, the information classified as non-confidential should be restricted to essential items only. He noted that the European Chemical Agency would be funded from the income from REACH fees. He believed that the role of ECA should be one of ensuring the harmonized enforcement of REACH across the European Union and that the fee structure should not be an additional burden to the chemical industry.

The representative of the United States thanked the European Communities for the written responses to the comments submitted, and believed that additional time was needed to evaluate the information received. She noted that extensive discussion on the issue had also taken place at the recent review of the EC's trade policy regime. It was her hope that the European Communities would take into account the questions and concerns raised in that context as well. Her delegations had further questions, on a number of the EC's assertions, notably their prioritization and the estimate of the impact of the proposed regulations. She believed that since the discussions continued with Parliament and member States, it was still too early to make assertions or draw conclusions on the WTO compatibility. She wondered if an additional communication to WTO Members would be made after the conclusion of the first reading, in Autumn of 2005, and if, at that point, there would still be an opportunity for additional comments to be taken into account.

The representative of Japan noted that his delegation was studying the replies received and might later raise some points for clarification. He thought that REACH raised some issues of trade restrictiveness from the perspective of the TBT Agreement.

With regard to substances in articles, he noted that in a previous EC response to Japan, it had been stated that obligations with regard to substances in imported articles were slightly easier than in the case of articles produced in the EU and left ample time for manufacturers and importers to get acquainted with the system. This reply, however, did not directly respond to the concern raised by Japan about Article 6.5 of the proposed regulation, for which the registration of substances in articles should not apply to substances that had already been registered for that use by an actor up the supply chain. This could be disadvantageous for non-EU article producers. He believed that there would be many cases where importers of articles containing chemical substances from non-EU manufactures might have to register the substances because the upstream suppliers had not registered the substance in question. He stressed that this situation might not be consistent with the principle of National Treatment stipulated by Article III.4 of the GATT 1994 and Article 2.1 of the TBT Agreement.

Regarding the creation of a list of named substances, he recalled that the EC representative had explained that this would be inconsistent with the principle of industry responsibility and that it would be difficult to identify the substances in advance. However, the representative of Japan noted that if the provision for the scope of substances was too obscure, industries might not be able to identify substances that they had to register and this could entail an excessive burden. He reiterated that it was preferable to enhance effectiveness and transparency of the regulation through making a positive list of substances or products subject to the registration. With regard to the requirement for every manufacturer and importer to register a substance, he suggested that duplication of registration should be avoided for hazard data and data of risk assessment for the same use of the same substances.

The representative of Japan understood the importance of the objectives of REACH, namely, safeguarding human health and environment and recognized that the regulation could not work effectively without the cooperation of third countries and their industries. He hoped that the European Communities would continue to take into consideration the concerns of their trade partners and, in this sense, welcomed the EC's proposal to have bilateral dialogues with the countries concerned for further detailed discussions.

The representative of Mexico recalled that his delegation had made comments in the context of the EC trade policy review and in the consultations in May 2003. He regretted that Mexico had not received any response to these comments made in May 2003 and noted that, while the Communities had replied to other Members, the Mexican questions had still not been answered. He thought that the presentation was useful, but that it was not a replacement for the consultations at the bilateral level between the European Communities and Mexico on the matters previously raised. He stressed that it was fundamental to be able to determine whether the REACH initiative had really been the object of an evaluation from the regulatory side beforehand, and which elements had been taken into account. He sought clarification on how the European Communities were considering granting special and differential treatment to the developing countries. He believed that the guidelines on how to use the system which were under preparation would not be enough for industries and firms to comply with REACH.

The representative of Colombia thanked the European Communities for the information provided. He noted that developing countries had just started to assimilate this regulation, and hoped that there could be greater communication of information, technical assistance and capacity building. He shared the concerns raised by Malaysia on the handling of confidentiality and intellectual property aspects of products which were to be registered, evaluated and authorized. This involved the designation of an agent for the handling of this information. He believed that this represented an additional cost because a special agent had to be designated only to handle this specific matter. He supported the comments made by Mexico to study the possibility of implementing the TBT Agreement as it referred to special and differential treatment for developing countries. He also sought clarification on granting authorization on the basis of socio-economic considerations, if the risk involved in the product could not be adequately managed.

The representative of Egypt noted that the comments made in the TBT Committee had come from either developed or advanced developing country Members. He feared that developing countries might not have understood nor evaluated the impact that the regulation might have on them. He asked whether the European Communities had made an evaluation of the impact of REACH on the market in general, and on developing countries in particular. He wondered if information on the sharing of developing countries' exports to the European Communities of substances, either in quantity or in value, was available on the EC website. He suggested that this information should be made available to help assess the impact of REACH on developing countries. He feared that the

capacity of developing countries to make an evaluation of some substances would not be considered adequate by the European Communities, and asked what kind of recognition and assistance was being considered on the specific issue of evaluation.

The representative of China appreciated the transparency that the European Communities had provided on the REACH proposal, and the responses made to the Chinese enquiry point. He welcomed the fact that Members would be informed on major amendments to the proposal as commented in the EC response. He appreciated the expressed readiness to continue efforts to explain the REACH proposal to WTO Members and to continue to pursue bi-lateral and multilateral dialogue with their trading partners. His country was studying the response received and further concerns on REACH had arisen. Therefore, he reserved the right to provide further comments to the European Communities.

The representative of Australia shared a number of the questions raised by previous speakers. Her delegation had submitted comments both directly and through the Trade Policy Review process and she thanked the European Communities for the replies received. However, her delegation remained concerned about the WTO implications of the proposal.

The representative of Thailand thanked the European Communities for their responses to the comments and noted that more time was needed to study them. She was not sure whether her country's concerns and comments had been answered and taken into account, in particular with reference to the proposal made by Thailand to examine the registration of the substance in articles. She noted that the European Communities had stated that the proposal had given rise to a number of misunderstandings and wondered whether the European Communities could point out all of the misunderstandings wherever possible.

The representative of Chinese Taipei shared the concerns expressed by the previous speakers. His delegation also needed more time to discuss the response provided by the European Commission with the local industry. She noted that in the EC's presentation, it was mentioned that the requirements for the registration of substances and articles would come into force only 11 years and 3 months after the entry into force of the REACH Regulation. She wondered whether it could be presumed that until that time most of the substances would have been registered, and if it would be possible for manufacturers to get information on what substances were being registered and for what uses, instead of asking for this information to be provided from the supply chain.

The representative of Chile thanked the European Communities for the replies to the comments received, which were being reviewed. She sought clarification about whether the study on environmental impact was available, so that the variables which were used to calculate the cost of the system could be analysed. She was doubtful whether the REACH system was a risk-based one, since it was an obligation for the producer to demonstrate whether there was a risk, in order for a substance to be authorized. She thought it was still unclear which substances would reach that stage, and what the costs to demonstrate the existence of a risk would be. She was worried that until a guide would be made available, which could be by the end of 2005, it would not be possible to evaluate the impact of the cost and how the system would affect the exports of different countries. With respect to the obligation under Article 11.3 of the TBT Agreement to provide technical assistance, she noted that funding was not always available and the needs were different for different countries. Her delegation would continue bilateral discussions in order to have a better understanding, especially about the costs associated with the application of the regulation.

The representative of Korea noted that more time was needed to study in depth the information provided by the European Communities. As a general point, he raised a concern regarding the fact

that importers of chemical substances would be likely to request from exporters the data necessary for registration. The exporters' proper understanding of the regulations was then critical for its successful implementation. He noted that according to the current draft of the regulation, exporters were not able to register. However, Korea was of the view that exporters should also be permitted to register, either directly or through importers. He sought clarification about the non-GLP data mentioned in the EC presentation. He noted that following 1.3 SAL (Structure Activity Relationship) over QSAL in Annex 4 of the REACH draft, SAL data could be accepted. However, it had not been mentioned how SAL programs having different systems or logic would be verified and accepted. This problem needed to be clarified.

The representative of Cuba raised four specific questions. First, on the compatibility of the REACH system with other international efforts to control chemical products, such as GHS and ICA, he asked whether compatibility with other international treaties and conventions such as the Basel Convention would be valid too. Second, he asked whether the requirements of REACH for specific substances, and the consequences and risks for human health associated with some of these requirements, were in all cases demonstrated scientifically. Third, he noted that, with respect to the difficulties of implementing REACH for developing countries, the European Communities had argued that on the basis of Article 11.3 of the TBT Agreement, capacity building and technical assistance would be provided and that this could be done through the Agency. He asked how the European Communities intended to implement this action. Fourth, he wondered if there was any substantive reason that had led the European Communities to set the specific limit of 11 years and 3 months with respect to Article 6 of REACH.

The representative of El Salvador reiterated the concerns that her delegation had expressed in the trade policy review of the European Communities. She stressed that the measures applied by the European Communities should not be more stringent than those applied in other international agencies.

The representative of the Dominican Republic recognized the right of all WTO Members to implement measures based on legitimate objectives, such as the objectives of REACH to provide a high level of protection for the environment, and human health. However, she stressed that the REACH system constituted a complex and costly initiative which might have a negative impact on the EC's trading partners. She urged the European Communities to incorporate special and differential treatment measures in their draft regulation and to establish a structured system of technical co-operation and assistance for developing countries and their small and medium-sized enterprises.

The representative of Canada shared the goals of REACH to protect human health and the environment, to promote competiveness of the chemical industry, and to increase transparency and integration within international efforts. She believed that international co-operation was essential to achieve these goals and wished to continue the on-going dialogue on chemical policy with the European Communities, including through regulatory co-operation. She recalled that her delegation had submitted comments in writing at each step in the process and had a number of additional questions to pose to the EC experts. She sought clarification on the following issues: (i) if forest products such as pulp, cellulose, and recovered paper were exempt from the proposed legislation; (ii) if waste would be included under the registration process of REACH, except in the case of unintentional release, and what was the definition of the phrase "unintentional release"; (iii) if the European Communities intended to allow an applicant to use pre-existing animal test data in its registration package, even though it might not be the first to register the substance. She believed that the proposed phase-in process in REACH would require much duplicative and repetitive testing and sought information on the steps that the European

Communities were taking to encourage the submission of all available data regardless of the volume threshold reached by potential registrants when the substance was first registered; (iv) if criteria had been set out for the recognition of foreign testing bodies; and (v) if the European Communities intended to provide procedures for the recognition of data which were already available. She raised concerns on the process to be put in place to ensure the consistent application of REACH across the member States and asked if the data recognized by one member State would automatically be recognized by all member States.

The representative of Uruguay stated that it would be important to have access to the study about the impact of this regulatory initiative carried out by the European Communities. She raised concerns about the impact on market access for developing countries, in view of the complexity and cost of the system and encouraged the European Commission to provide concrete shape to any form of assistance which would help to clarify and to implement the REACH system before it came into effect.

The representative of Brazil supported the comments made by Mexico and by the Dominican Republic on the special and differential treatment for developing countries. She noted that the REACH system foresaw that the required tests would be undertaken by laboratories accredited according to OECD standards. Brazil, as other developing countries, had based its accreditation system on ISO standards. She noted that some kind of communicability between those systems should be ensured and asked the EC representative to address this issue.

The representative of the European Communities, in relation to the concern raised by Mexico on the non-response to comments made in May 2003, explained that the European Communities had not replied formally to any of the 6000 comments that had been made in response to its internet consultation. The response to these comments was the change to the proposal that had been made. The way in which those comments had been taken into account was set out in the explanatory memorandum accompanying the proposal. Nevertheless, the European Communities was willing to continue the dialogue in case there were outstanding questions from Mexico, or from other Members.

It was noted that a number of questions referred to the issue of the impact assessment and the extent to which REACH had been subject to an evaluation beforehand. It was explained that an impact assessment had been completed, and it was available on the EC website above. It had taken into account both the direct costs to manufacturers and importers of complying with REACH as well as indirect costs to other industries. However, in relation to the question raised by Egypt, the impact assessment had not been carried out country by country. It had been conducted as an overall impact, bearing in mind that the overall phasing in of the substances to be registered was spread over an 11 year period.

On the question raised by Malaysia concerning problems that might be associated with intellectual property rights in connection with the formation of consortia, it was noted that the purpose of the creation of these consortia was for companies to benefit from the sharing of information and expertise. This was particularly important for small companies and companies from developing countries, which would be able to share and pool expertise when putting together a registration. However, the concern raised by Malaysia was a valid one, and this was why REACH proposed that consortia formation should be voluntary. If, in the development of a joint submission, concerns would arise about sharing information which an individual company would prefer to keep confidential, the proposal did not force that sharing of information, unless it was animal test data. In contrast, the “one substance one registration” proposal would force companies to form consortia,

and this was one of the reasons the European Commission does not think such a proposal would work.

On the definition of "adequate control", it was recalled that, for the substances that had to be authorized for use, an authorization would be granted if the company, or the group of companies could demonstrate that the risks from exposure to those substances could be adequately controlled. The term "adequate control" meant that the company had identified a DNEL (derived no effect limit) below which there was no risk, and risk management measures were in place in order to ensure that exposures were kept below that level. On the authorization granted for socio-economic reasons, guidance might be needed in order to improve the understanding of these principles and provisions.

It was explained that some non-confidential information (e.g. on the hazardous properties of the substance) would be made available to the public via the Agency's website. The particular type of information was set out in Article 116 of the proposal. This was limited to information that was required for health, safety and environmental reasons.

The Agency would ensure a harmonized enforcement among the EC member States, particularly in the evaluation stage, and would ensure the decisions taken as a result of an evaluation in one member State were consistent with those that had been taken in another member State.

On the timing of the next notification to the TBT Committee, it was stated that the first major amendment to the proposal would be made following the first reading of the European Parliament, whose completion was tentatively expected in the Autumn of 2005. The Commission would then need some additional time to finalize an amendment, and it would at that point update the current notification to the TBT Committee.

It was stressed that it was difficult to draw up a list of substances to be subject to controls on the basis of existing knowledge. Only by requiring information on the properties of the substances which were not fully known, or on uses which were not fully known, would it be possible to understand whether the substances could pose any problem. The risk of drawing a list on the basis of the existing knowledge might be that the substances for which more information was available might be penalized, whereas substances for which less information was available could be considered safer. One purpose of the project was rather to raise the level of information on all substances.

In reply to several comments on the possibility to grant special and differential treatment to developing countries, it was stated that it was not yet possible for the European Communities to be specific about exactly how this would be done, since the legislation was still at a discussion stage. The agency, which would play a major role in the management of the legislation and a major role in capacity building exercises, had not been established yet, and it would not be established until some months after the entry into force of the legislation. They stressed that the European Communities would fully abide with all of the obligations under the TBT Agreement, would take all possible measures in order to be able to ensure sufficient technical assistance, capacity building and training.

On the issue of prioritization in registration and on why the proposal had not been formulated on a more risk-based approach, it was explained that the proposal was based on volume, which was an approximation of exposure, and hazard. Nevertheless, a lot of other prioritization was foreseen in the proposal: it included the lower requirements for intermediates, the exemption of polymers and the requirements for substances in articles not coming into force until 11 years and 3 months after the entry of force of REACH. An advantage of a volume based system was that it provided legal

certainty for companies to know when they had to register their substance. The period of 11 years and 3 months for the provisions on substances in articles had been chosen on the basis of the need to have these requirements come in after the last registration date for substances themselves, so that the information that was gained during the registration of those substances could be used, and allowing 3 additional months for importers and manufacturers to assess that information.

Some Members had been concerned about the nomination by third country exporters of a single representative who would take over the duties of registration, and about the additional costs that this might imply. In this respect it was noted that this was a voluntary requirement and was offered in order to help third country manufacturers, who could chose to appoint a single representative, in order to avoid giving confidential information to importers. The choice was theirs.

On the questions raised by Canada as to whether pulp cellulose and paper or waste paper were covered by REACH, it was stated that cellulose fiber would be a chemical substance, and as such would be covered, except in the cases foreseen in Annex III whereby they would be taken out if they were not chemically modified. This meant that cellulose would not normally be required to be registered, unless it had been chemically modified. Paper would be considered to be an article. As far as waste was concerned, it was neither a substance, a preparation nor an article, so it would not have to be registered and was outside the scope of REACH. However, in the assessment that was done of chemical substances, the consequences for the waste stage of their life-cycle would need to be taken into account.

In response to Canada's questions about recognition of existing test data and accreditation of foreign test bodies, the representative of the European Communities noted that all existing data and other information that was not necessarily test data should be used to provide the information requirements and only as a last resort should new test data be generated. Such test data could be generated anywhere in the world, so there was no need for any accreditation of any foreign test bodies. To be used, data had to be fit for purpose, and that all available data should be registered along with the precise requirement.

It was stated that REACH was designed in such a way to be compatible with international conventions, such as the Stockholm Convention on Persistent Organic Pollutants (POPs). Finally, on the evaluation stage of REACH, it was stressed that the proposal made sure that certain parts of the evaluation were subject to strict deadlines. This was also valid in cases when member States were evaluating individual dossiers: they would be requested to notify the start and the finish of their evaluation process to the Agency.

Argentina: MERCOSUR Regulation on Definitions Relating to Alcoholic Beverages Other than Fermented (G/TBT/N/ARG/159)

The representative of Mexico raised concerns on the MERCOSUR technical regulation on definitions relating to alcoholic beverages, that had been notified by Argentina in G/TBT/N/ARG/159, dated 16 April 2004. His delegation had sent comments to the Argentina enquiry point, but he was unaware of whether these comments had been taken up in the MERCOSUR Technical Sub-group 3, which was the body competent to analyze them. Mexico wished to continue the dialogue with Argentina and the other MERCOSUR members. It was noted that being MERCOSUR Members as well as WTO Members, the measure should have been notified also by Brazil, Paraguay and Uruguay.

The representative of the Dominican Republic, speaking also on behalf of Barbados, Trinidad and Tobago and Jamaica, was concerned by the negative impact which this draft technical regulation of

MERCOSUR could have on trade in wine and spirits of Caribbean countries. Her concerns were related, in particular, to the characterization of sugar cane based alcohols as well as simple alcohols, and to the reference in the regulation to rum as a totally or partially fermented beverage. Comments had been submitted to Argentina both through the Permanent Mission in Geneva, and to capital officials. Her authorities would continue studying the issue and she hoped that MERCOSUR would address the concerns raised.

The representative of the European Communities reiterated comments submitted to Argentina on 18 June 2004. He considered that the reply provided by Argentina, on 29 June 2004, had not been satisfactory and invited the Argentinian delegation to take the concerns into account and to provide a full written response.

The representative of Barbados endorsed the intervention made by the representative of the Dominican Republic. She recalled that at the previous TBT meeting, on 1 July 2004 the delegations of the Dominican Republic, Jamaica, Trinidad and Tobago and Barbados had elaborated their concerns, relating, *inter alia,* to the definition of alcoholic beverages as contained in the technical regulation notified by Argentina. These had also been submitted in writing. She reiterated her delegation's willingness to continue the dialogue between the respective technical experts.

The representative of Argentina recalled that at the last meeting of the Committee, his delegation had stated that the competent authorities were open to consider any comments and concerns expressed. On that occasion, it had also been pointed out that these comments were going to be addressed at the MERCOSUR level, in the Technical Sub-group 3. He highlighted that this was a *draft* regulation, and that any comments would be taken into account. His country notified MERCOSUR regulations once they were incorporated in the national legislation. He asked the EC representative to clarify what they had meant when stating that the responses received were not satisfactory.

The representative of Brazil, in reply to the concern expressed by Mexico, explained that Brazil had not notified the MERCOSUR draft resolution because it had not yet been incorporated into its national legislation. It was necessary to amend the Brazilian Decree 4851 before this could be done. Both the MERCOSUR draft regulation and the Brazilian Decree 4851 were being reviewed, and a notification would be submitted to the TBT Committee at the end of this process.

The representative of Paraguay, as a Member of MERCOSUR, had taken due note of all the concerns raised, which would be conveyed to national authorities. He pointed out that all WTO Members had the right to adopt regulations or measures to protect health, security, safety and environment, and supported the statement made by the representative of Argentina.

The representative of Guatemala stated that his authorities were studying the draft regulation and might make comments in the future.

UE x Argentina - Legal Appellation System for Wine Products

Argentina: Legal Appellation System for Wine Products (G/TBT/N/ARG/107)

The representative of the European Communities reminded the Argentinean delegation of the comments sent on 27 August 2004 on the legal designation system for wine notified by Argentina in G/TBT/N/ARG/107. He raised concerns on the labelling requirements, which would create

unnecessary barriers to trade, and on the misuse by Argentina of the geographical indications for Champagne and Cognac. He invited Argentina to provide written answers to these concerns.

The representative of Argentina recalled that a preliminary response to some of the comments made had been provided to the European Communities; a copy of the replies sent on 4 October 2004 had been given to the EC delegation. His delegation remained open to discuss the issue further and to provide additional information.

EUA (Nova Zelândia, México, Austrália, Uruguai e Outros) x UE - Regulation on Certain Wine Sector Products

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 recalled that the Committee had been discussing the issue of the EC wine labelling regulations for some years. On 23 August 2003, the United States had submitted extensive comments and questions to which the European Commission had promised a written response, which had yet to be fulfilled. Some plurilateral meetings, hosted by relevant Commission officials, had been held in October 2002 and in July 2003, prior to the submission of her country's written comments. She expressed frustration with the Commission's continued assertion that questions and concerns had been addressed at those meetings. Her delegation was given the same response for the 24 questions that it had raised in the recent EC trade policy review. If that was the case, why could the European Communities not provide an explanation in writing? Outstanding questions and ambiguities remained, which made it difficult for suppliers to know how to comply. She believed that an explanation would seem to be in the Commission's interest if, as it had been stated, the purpose of the regulation was "to ensure that quality wine sector products are truthfully labelled".

It was the understanding of the United States that two wine industry associations in two EC member States had developed publications in an attempt to give guidance to their industries on how to comply with the regulations, and that the information contained in these publications was conflicting. It seemed that even European wine industries were experiencing difficulties with compliance. She also understood that additional amendments to the regulations might have been made, but that these had not been notified. She urged the European Commission to provide a clarification and written explanation in response to the questions and concerns raised.

The representative of New Zealand joined the United States in raising concerns about the Wine Labelling Regulations 753/2002 and 316/2004. She recalled that these concerns, both of a substantive and procedural nature, had been raised on a number of occasions. On substance, she considered that the limitation on the use of terms relating to vine varieties, production methods, and vintage to wines carrying a GI seemed to disregard fundamental TBT requirements as they could prevent accurate information from being conveyed to consumers. On procedure, she recalled that her delegation had raised concerns that the notification and consultations (of 753/2002) had to be in line with TBT requirements. New Zealand had welcomed the delays in implementation of the Regulation. However, she was surprised at the short time period between the publication and the notification of the amending Regulation (316/2004), on 24 February 2004, and its implementation on 15 March 2004. This had not provided sufficient time for Members to make comments and for those comments to be taken into account, as per the obligation in Article 2.9 of the TBT Agreement. The representative of New Zealand remained disappointed that the amendments by the

Regulation 316/2004 had not adequately addressed all the concerns expressed. Nevertheless, she commended the European Communities for providing written responses to recent questions raised in relation to the REACH Regulation and reiterated her request that a written response in relation to the Wine Labelling Regulations be provided to help to understand justification for the Regulations.

The representative of Mexico supported the comments made by previous speakers. He believed that the Wine Regulations should be treated by the European Communities with the same open attitude shown in relation to the REACH Regulation. Written responses to comments made, and detailed explanation of these Regulations would be useful to be able to understand what the objective pursued was, and to determine that the Regulations did not create unnecessary barriers to international trade.

The representative of Australia associated herself with the comments made by previous speakers. She noticed the difference in approach between the explanation that the European Communities had provided on REACH and the lack of responses with regard to the wine regulation. She sought written responses to questions posed by her delegation.

The representative of Uruguay shared the concerns stated by previous speakers and stated that the amendment made to Regulation 753/2002 did not cover all the concerns expressed by his delegation. He remained concerned about the impact that this regulation might have on trade.

The representative of Argentina was disappointed that the scope and coverage of Regulation 753/2002 had not been clarified.

The representative of the European Communities noted that legislation pursued a number of legitimate objectives, *inter alia*, the promotion of quality wines, and the protection of consumers' interests. He pointed out that, where appropriate, the European Communities had demonstrated, through amendments to wine labelling legislation adopted earlier in the year, its willingness to respond substantively to third countries' concerns. A number of informal consultations had also been held with interested Members to clarify the legislation in question. His delegation had taken note of the comments made, and would continue to reflect on these points.

Nova Zelândia (UE e Noruega) x Coréia do Sul - Import of Fish Heads

Korea: Import of Fish Heads

The representative of New Zealand once again raised concerns on the issue of edible fish head imports by Korea. She was concerned that during recent bilateral discussions, Korea had informed New Zealand of its intention to continue to prohibit imports of fish heads from New Zealand, but that it would allow imports of fish heads from certain other exporting countries. She understood from discussions with the Korean authorities that they were concerned that opening the market to New Zealand hake heads would lead to requests from other hake-exporting nations for market access, which would in turn impact on Korea's domestic industry. Her delegation did not regard these concerns as a legitimate justification for the ban on hake head imports, whether considered in terms of GATT Article XI or under the relevant provisions of the TBT Agreement. While Korea allowed the importation of fish heads from certain species, it argued that these products and New Zealand hake head were not like-products, because the two species were biologically different. New Zealand did not accept that this was a legitimate distinction, particularly as a variety of edible

fish heads, including hake heads, sourced from Korean fishing boats or from imported whole fish were consumed in Korean restaurants and homes on a daily basis.

The representative of New Zealand recalled that Korea had previously stated that it did not allow the importation of hake heads for human consumption because it regarded it as a waste product, and this despite the popularity of the product as a food item in Korea's domestic market. She reiterated her assurance that hake heads for export to Korea could be prepared to an edible standard, and that her government could provide the appropriate sanitary assurances. Her country considered that, provided the product was accompanied by official certification giving assurance that the product was fit for human consumption, Korea ought to allow the importation of edible fish heads. This was the practice with most other seafood products exported to Korea and would seem to be the least-trade restrictive measure available to address all legitimate concerns. She encouraged Korea to move quickly to meet its WTO obligations in this regard.

The representative of the European Communities shared the concerns expressed by New Zealand and thanked Korea for the bilateral discussions underway. He hoped that market access would be granted soon for these products.

The representative of Norway shared the concerns expressed by New Zealand, and recalled that his delegation had also raised the same issue at previous meetings. His country was holding a constructive dialogue with the Korean authorities and was of the view that a solution should be based on the MFN principle, in line with the provisions of the WTO Agreements.

The representative of Korea was fully aware of New Zealand's concerns and remained open to seeking a possible solution through bilateral consultations. It was his understanding that the two parties had undertaken several consultations on this matter since the last meeting of the TBT Committee, and that there was still a different point of view on how to solve this issue in a mutually satisfactory manner. He noted that this issue would also be dealt with at the meeting between Korea and the Joint Committee on Economic Co-operation, which would be held on 10 November. He appreciated New Zealand's willingness to provide appropriate sanitary assurance for Hake head. In this regard, his country was hoping that New Zealand would provide relevant information and data to the Korean authorities as soon as possible, as it would facilitate the bi-lateral discussion. He believed that the issue could be resolved in a mutually satisfactory manner through consultations, and noted that fruitful consultation were also taking place with the European Communities and Norway.

UE x Suíça - Ordinance on the Emission Level of Passenger Cars with Compression Ignition Engines

Switzerland: Ordinance on the Emission Level of Passenger Cars with Compression Ignition Engines (G/TBT/N/CHE/39)

The representative of the European Communities recalled that on 3 June 2004 it had submitted comments on G/TBT/N/CHE/39 regarding the determination of the particle number emission level of passenger cars with compression ignition engines. She reiterated the request to Switzerland to provide an answer to the comments sent.

The representative of Switzerland noted that her delegation had been hoping to be in a position to reply to comments made by the European Communities and the United States for the current

meeting. However, the process of internal decision concerning this draft was complicated, as it was the fruit of the work of an environmental group in the Parliament. She explained that the proposal was being re-discussed on the basis of comments received and that a decision would probably not be taken before the spring of 2005; she would inform the Committee of the result.

China x EUA - Measure on Refillable Lighters

United States: Measure on Refillable Lighters

The representative of the People's Republic of China reiterated her concerns regarding the US safety standard on lighters. She recalled that the concerns expressed were related to the rationale for maintaining a relationship between product, price and safety. China had requested the United States to make a notification to the WTO in accordance with Article 1.6 and 2.9 of the TBT Agreement. Her delegation had also questioned why the international standard ISO 9994 for lighters could not meet the objectives of the United States. She stressed that Article 2.4 of the TBT Agreement requested Members to use the relevant international standard as a basis for technical regulations and recalled that in the *EC-Trade Description of Sardines*[2], the Appellate Body had upheld the Panel's finding to the effect that Article 2.4 of the TBT Agreement applied to measures that had been adopted before 1 January 1995, but which had not ceased to exist, and that Article 2.4 of the TBT Agreement applied to existing technical regulations. She considered that, although bilateral discussion had taken place, China's concern had not been adequately addressed and therefore sought further clarification from the US delegation regarding the link between price and safety for lighters. She also reiterated the request to the United States that it notify the measure to the WTO, providing a comment period for Members.

The representative of the United States believed that the record from the discussions at the last meeting was clear on her delegation's views on whether this proposal should have been notified. She recalled that it had been published for comments some time ago, and that there had not been a change to the regulation. Substantial information had been provided to China in this regard. She was not yet in a position to respond to the question of whether the regulation could change in light of the recent adoption of an international standard and would come back to that in due course.

Canadá x Nova Zelândia - Ban on the Importation of Trout

New Zealand: Ban on the Importation of Trout

The representative of Canada reverted to the issue of New Zealand's ban on trout imports. She recalled that, on 7 December 1998, New Zealand had passed an order in Council entitled *Customs and Import Prohibition (Trout) Order 1998*, which had passed a temporary ban on the commercial importation of trout. In the meantime Canada had raised concerns on the trout ban with the New Zealand authorities, including at the Ministerial level, and also at previous meetings of the TBT Committee, including at the October 2001, March 2002 and July 2004 meetings. Her country did not consider the ban to be scientifically justified and had never received, nor had been made aware, of any science-based evidence from New Zealand. As such, she considered the ban to place New Zealand in a position of being inconsistent with its trade obligations under the TBT Agreement. Her delegation was disappointed to learn that New Zealand had recently extended the ban for the

fifth time, for another three years, until November 2007. The representative of Canada urged New Zealand to immediately restore trade in trout.

The representative of New Zealand reminded the Canadian delegation of the background of this measure. Trout fishing was an important recreational sport in New Zealand, and the conservation of trout continued to be a subject of particular concern. For this reason, the Conservation Act of 1997, prohibited the purchase or sale of trout in New Zealand. To ensure the effectiveness of the domestic sales ban, imports of trout in commercial quantities had been prohibited by successive customs orders. The New Zealand Government had decided to extend the import ban through a new order in Council to ensure that the integrity of the domestic sale prohibition was not undermined. Moreover, the new order did not prohibit the importation of all trout into New Zealand, but specifically provided for the importation of non-commercial quantities for personal consumption. In this way, it ensured that both domestic and imported trout were subject to the same treatment.

The representative of New Zealand further stated that in extending the customs order, the Government had tasked officials to report back on alternative measures to retain the unique status of trout well before the expiry of the temporary measure in 2007. This approach had been adopted as an indication of willingness to work together with trading partners to address this issue of mutual concern. Her delegation did not agree with Canada's suggestion that the measure raised questions in relation to New Zealand's obligations under the TBT Agreement. The order was not discriminatory, nor protectionist; it addressed legitimate objectives and was fully in accordance with trade obligations. There were significant concerns that the sale of trout, whether domestic or imported, would foster the poaching of the stock in New Zealand. This would undermine conservation of the stock and frustrate the legitimate objective that underpinned New Zealand's domestic conservation regime for trout.

EUA x Holanda - "Vos" Bill on Wood Products

Netherlands: "Vos" Bill on Wood Products (G/TBT/N/NLD/62)

The representative of the United States appreciated the Netherlands's early notification of the Vos Bill on the sustainable production of wood products (G/TBT/N/NLD/62). She noted that this proposal addressed a number of the US concerns, which had been raised in response to a previously notified amendment to the Environment Management Act, in 1998.[3] However, she believed that additional changes might still be warranted to eliminate certain ambiguities and elements that could inappropriately restrict trade. She recalled that, in response to the concerns raised at the last Committee meeting by Canada, the European Communities had informed the Committee that the Dutch notification was under examination to assess its compatibility with Community law, and at that time no comments had been received from third countries. She noted that both the US Government and industry comments had since been submitted and looked forward to the European Communities' written response.

The representative of the European Communities informed the Committee that the draft Dutch regulation was still under examination by the European Commission and the member States to assess its compatibility with Community law. The need to avoid the creation of unnecessary

obstacles to trade was taken into account and, once this evaluation was concluded, the European Communities would reply to the comments.

EUA x Emirados Árabes - Conformity Assessment System and Halal Certification

United Arab Emirates: Conformity Assessment System and Halal Certification

The representative of the United States recalled that, at the previous meeting of the Committee, she had raised concerns on the functioning of the United Arab Emirates enquiry point and notification authority, and on the lack of notifications. At the time, her delegation had been seeking information about a proposed conformity assessment programme known as the Emirates Conformity Assessment System (ECAS), whose status was not known, nor the reasons why it had not been notified. She informed the Committee that her delegation had since held bilateral discussions and that it was her understanding that the programme would be a voluntary one, and as such there would be no reason to make a notification.

UE x México - Standard for Glazed Pottery Ware, Glazed Ceramic Ware and Porcelain Ware

Mexico: Standard for Glazed Pottery Ware, Glazed Ceramic Ware and Porcelain Ware (G/TBT/N/MEX/69)

The representative of the European Communities reminded the Mexican delegation that on 10 November 2003 comments had been submitted on G/TBT/N/MEX/69 regarding glazed pottery ware, glazed ceramic ware and porcelain ware. She reiterated the request to Mexico to provide answers. The concerns expressed were related, in particular, to the lead and cadmium limits introduced by the notified draft measure regarding flat ware, which were more stringent than those laid down in relevant ISO international standards. She sought clarification on whether the Mexican authorities would accept the result of conformity assessment procedures of ceramic table wear produced in the European Communities in compliance with ISO standards.

The representative of Mexico recalled that the European Communities had informed his delegation of their comments regarding the official draft standard PROY-NOM-231-SSA1-2002. When the comments had been submitted, the comment period had already expired by one month. The Health Secretariat had received these comments and analysed them carefully. However, since they had not been presented within the deadline for public consultation under the Mexican legislation, there was no obligation to publish the responses in the Official Gazette. The draft standard in question had taken into account, with some deviations, the international standard to which the European delegation had referred. These deviations had been based on the special circumstances of Mexico, as allowed under the TBT Agreement. He invited the European Communities to consult the statement of regulatory impact, available on the website of the Economy Secretariat, to analyze the reasons for which Mexico required a greater level of protection than those offered by the international standards. He highlighted that, with regard to the possibility of accepting the conformity assessment results for ceramic produces in the European Union, Article 6 of the TBT Agreement promoted the recognition of conformity assessment by central government bodies and set out the procedure for such recognition. He invited the European Communities to follow this procedure to obtain such recognition.

Canadá e EUA x UE - Traceability and Labelling of Biotech Food and Feed Products

European Communities: Traceability and Labelling of Biotech Food and Feed Products (G/TBT/N/EEC/6-7 and Add.1-3; G/TBT/N/EEC/53 and Add.1)

The representative of Canada recalled that at the July 2004 meeting, Canada had raised concerns regarding the European Communities traceability and labelling of biotech food and feed products (G/TBT/N/EEC/6-7 and Add.1-3; G/TBT/N/EEC/53 and Add.1). With respect to the GMO moratorium and authorizations, she remained sceptical that the authorization process was functioning as intended. In fact, despite positive scientific assessment, the decision to approve had not been made at the regulatory committee level, nor at the level of Council of Ministers, thereby forcing the Commission to authorize a product after 30 days. Canada continued to monitor the pending canola applications, which were currently at various stages in the authorization process. Canada considered that one authorization did not afford sufficient evidence to imply that the European Communities was acting in full compliance with its obligations under the WTO Agreements.

The representative of Canada believed that the adopted regulations dealing with traceability and labelling were burdensome, and might create unnecessary barriers to trade. Canada would continue to monitor their implementation, with the objective that exported goods did not experience undue delays when imported into the European Communities. She pointed out that the labelling and traceability measures were creating uncertainty for Canadian exporters, since the European Communities had failed to clarify how the regulations would be applied. She wondered how it could be possible for foreign suppliers, especially smaller manufacturers of value added products, to know when they were in compliance with the measures in the absence of clear guidance. Canada noted the notifications of the Commission's recommendation regarding sampling and detection (G/TBT/N/EEC/53 and Add.1). However, it remained unclear how the traceability and labelling requirements could be implemented effectively in the absence of segregation systems and of internationally accepted testing methodologies to validate the presence of GMOs.

The representative of the United States supported the comments made by Canada.

The representative of the European Communities recalled that the measures on traceability and labelling of GMOs were notified in G/TBT/N/EEC/6 and 7. Addenda to these notifications had been provided in order to keep Members fully briefed. In addition, the European Commission had recently adopted a non-binding recommendation providing guidance on sampling and detection of GMOs that would be published shortly. The Commission's proposal for this recommendation had been notified in G/TBT/N/EEC/53 and Add.1. He stressed that the European Communities had, at every stage in the process, followed the highly transparent approach in-line with its international obligations. The legitimate objectives of the measures, as explained on other occasions, were related, *inter alia* to the protection of human, animal and plant health or safety, and environmental and consumer protection. These objectives had been pursued in the least trade restrictive manner. He informed the Committee that, while the traceability and labelling regulation had been in force for over six months, no reports of major difficulties concerning the imports of GMOs and derived products had been brought to the EC's attention.